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# Liver F.O.C.U.S

*Factual, Open, Current, Useful, Straightforward*

*Highlighting research whilst cutting through the medical jargon! Liver Focus is produced by the Centre for Liver Research, Birmingham*

## **Chronic disease diagnosis inspired clinical trial participation**

In 2006 Katharine Francis received some news that would change her life forever. She was only 10 years old when she was diagnosed with the chronic liver disease Primary Sclerosing Cholangitis (PSC).

PSC is a disease of the bile ducts in and around the liver. They become inflamed and obstructed which in turn causes scarring and hardening of the bile ducts (fibrosis).



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It is a chronic progressive disease commonly found alongside Inflammatory Bowel Disease (IBD), which Katharine also has.

The cause and cure for PSC is unknown. As it is progressive, it can sometimes lead to liver failure which means a liver transplant could be required.

Despite the disease being in its early stages, Katharine was experiencing symptoms which impacted on her daily life including fatigue and discomfort around the liver area.

Many different medications were tried but unfortunately they had a negative effect on her IBD.

So, in early 2013 she was invited to participate in a clinical trial involving a new drug to hopefully ease the symptoms of PSC.

The drug concerned was also being tested to see if it could help with fibrosis of the lungs, as well as the liver. Katharine's grandfather had been diagnosed with lung fibrosis so the dual-purpose of this drug encouraged her to apply in the hope it could be revolutionary for them both, as well as many others.

Before being accepted on a trial there is a screening process that takes place to ensure a participant is suitable. As a young adult, Katharine also had concerns how the trial would impact on her life at university and any possible side effects, so wanted to have these questions answered beforehand.

*"At first I was dubious - the trial was two years long, did I really want to commit to something for that length of time?"*

A consultant reassured her that life would hardly be affected during the trial and virtually no side effects were expected. The only problem was a weekly self-injection; something she dreaded but knew she could overcome.

After going through the screening process Katharine was accepted on to the trial. The first appointment was a daunting experience but Katharine recalls *"I met my trial nurse who was lovely and very reassuring"*.



*"I had never injected myself, so had to be taught. I was so worried and my nurse had to do it for me. Now, I never thought I'd be doing it so quickly and easily - I can do it on my own with no trouble at all"*.

Katharine is now 19 years old and is still participating in the trial. *"I'm really proud of myself for sticking it out! I've learned I can do something important, even if it does involve needles"*.

Being diagnosed with a chronic condition is never easy, especially at such a young age, and clinical trials are not suitable for everyone. For those who are suitable, it is an empowering and motivating way to take part in revolutionary research that could benefit so many. Or as Katharine states,

*"I'm not just taking part in this for myself; I'm doing it for everyone with my condition, their families and the people close to them"*.

**Could you be a 'Katharine'?** Speak to your consultant to find out what clinical trials are taking place, or email [liverresearch@contacts.bham.ac.uk](mailto:liverresearch@contacts.bham.ac.uk)

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## **QUICK LIVER FACTS:**

Your liver acts like a chemical processing factory; it sorts out what your body needs, and what is toxic. It performs over 500 functions every day. Your liver is the only organ that can repair itself - but only to a certain point so don't take advantage of its remarkable talents!

# Should organ donation be mandatory?

Since 2008 enormous progress has been made in improving the rates of organ donation in the UK. However, according to [www.organdonation.NHS.UK](http://www.organdonation.NHS.UK) about 1,300 people still die every year while waiting for an organ transplant, or are removed from the list because they have become so ill whilst waiting, that they would not survive an operation.

Currently, anyone in England who wishes to donate their organs must 'opt in' to the system. This means that unless they have actively signed up to the organ donor register, their organs will not be considered for transplant.

Countries such as Spain and Austria have an 'opt out' system which means that unless individuals have specifically stated they do not want their organs transplanted, it is assumed they automatically consent to donate.

Although figures vary, research available does seem to indicate that countries where presumed consent is in operation tend to have up to 30%<sup>1</sup> higher donation rates than those where explicit consent is required.

Perhaps more contentious is the issue of authorisation from relatives. In England, even if a person has signed up to the donor register, relatives can prevent organs from being used.

Sadly, despite the wishes of the deceased person, according to [www.NHSBT.nhs.uk](http://www.NHSBT.nhs.uk) only 57% of their families agree to donation.

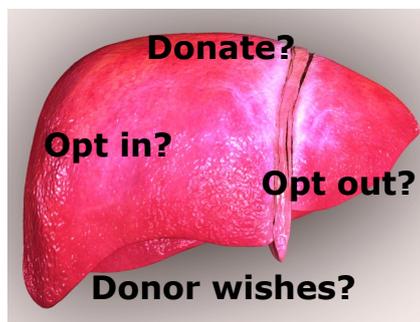
## Should England change to presumed consent?

Changing to a presumed consent system (with an 'opt out' choice) and the removal of family rights to block donation against a deceased's wishes, may increase the number of organs available and reduce the number of deaths caused by the shortage of donors. However, there are many ethical, religious and personal views which complicate matters.

Needless to say, England is closely watching Wales and other countries who have introduced an opt-out system so see if this idea could be feasible here.

References: <sup>1</sup> Abadie & Gay, 2006; Neto et al, 2007, Bilgel, 2012

**Did you know:** A unit of alcohol is not the same as a measure of alcohol! Be very wary of this if you decide to have 'just one drink'. Visit [www.drinkaware.co.uk](http://www.drinkaware.co.uk) for the full facts on how many units are in your alcohol. Don't forget that alcohol also has calories in it! A pint of lager has around 250 calories and could contain up to 3 units (depending on type and strength). **Be savvy, be safe.**



*A donated liver could save two lives*

# My PSC support group & me

By Kevin McCabe, PSC Sufferer

I was diagnosed with the autoimmune liver illness Primary Sclerosing Cholangitis (PSC) in 2003.

Living with a chronic illness raises many questions and medical professionals are well placed to answer many of them, but there is no substitute for the experience of others.

The first time I was inspired by another PSC sufferer was a few days after my diagnosis.

The doctor who gave me the life-changing news explained that I may one day need a liver transplant. I had never heard of PSC before so after several failed internet searches (misspelling the disease!) I finally found some information. It wasn't good and predicted a gloomy future.

However, amongst it all was a blog from a man who also had PSC. He cycled a lot and had been diagnosed over twenty years ago. I cycled too so thought *"if he can just get on with life, so can I"*.

Following diagnosis I discovered 'PSC Support', which has a growing number of experienced members and an active online forum for questions and debate.



A support group is a great resource of experiences and guidance on dealing with everyday challenges of life such as: How do I tell my employer? Where do I get travel insurance?

Being able to discuss issues with people who have actual experience is priceless. Medical experts are great at explaining the intricacies of the disease, but can never truly understand life as a sufferer.

The inspiring effect of others has continued right up to my recent transplant where a 'thumbs up' from a fellow patient as I was wheeled into the operating theatre really gave me strength. I'm so proud how PSC Support has helped my life, I even bought their sweater!

Martine Walmsley, Chair of PSC Support says: *"The exchange of information and personal support between patients face-to-face at PSC Support meetings and in our online forums is inspiring."* Visit [www.pscsupport.org.uk](http://www.pscsupport.org.uk).

For liver related groups visit the British Liver Trust Website [www.britishlivertrust.org.uk](http://www.britishlivertrust.org.uk). The University of Birmingham also run an annual PSC Support group meeting hosted by clinical scientists. Details can be found at [www.birmingham.ac.uk/clr-ppi](http://www.birmingham.ac.uk/clr-ppi).

# FOCUS ON:

## Dr Gideon Hirschfield

Gideon is a Senior Clinical Lecturer at the University of Birmingham and Queen Elizabeth Hospital Birmingham. He specialises in autoimmune liver diseases such as PSC, PBC and AIH. Alongside his clinical responsibilities and treating patients, Gideon works with a team of research scientists at the University of Birmingham who are looking into the causes of liver disease and possible new drugs or treatments.

### **Why did you decide to become a doctor?**

Because it is an interesting job; it is one of those few jobs where even on your last day at work before retirement you may encounter a new challenge.

### **Why did you specialise in liver?**

I was very lucky to do my clinical training as a student in Cambridge. My first medical attachment at the start of the clinical course was with the academic medicine team which included liver medicine, and then with the academic surgical team. It seemed pretty obvious to me at that point that I should do Transplant Hepatology as a career.

### **What is most gratifying about your job?**

I am most satisfied after seeing patients with complex autoimmune liver disease, spending time answering their questions and educating them about their disease and the best treatments for them.

### **What upsets you about your job?**

Admin ... i'm not very good at filing or filling in forms. Seems such a waste of time!

### **What is the best piece of advice anyone has ever given you?**

Try and finish what you start.

### **Why do you think medical research is important?**

Whether you look after patients with common or rare diseases, patients need new treatments and we'll deliver those new treatments only if we continue to do basic and applied medical research.

### **If you were 16 years old, what alternative career might you have chosen?**

Tricky but probably a Lawyer.

### **What single advancement in liver treatments or research would you like to see in your lifetime?**

Rational and effective treatment for autoimmune liver disease, preferably as a result of research conducted in Birmingham!



You can see Gideon and his colleagues talk about their scientific research and their work with patients in a new video which has been made by the National Institute for Health Research (NIHR) Birmingham Liver Biomedical Research Unit (BRU).

**Visit [www.birmingham.ac.uk/clr-ppi](http://www.birmingham.ac.uk/clr-ppi)**

Go to 'clinical trials and research videos'

# Keeping YOU informed about research

We aim to ensure you are kept up to date about current clinical trials, what research we are undertaking, and free events you can attend.

You can also join our volunteer group who work with us in a range of ways from preparing items for this newsletter, to advising on patient information sheets used in clinical trials. You don't need any experience or special skills to volunteer, just an interest in liver disease. For more information on joining this group, please email [liverresearch@contacts.bham.ac.uk](mailto:liverresearch@contacts.bham.ac.uk). You can also visit [www.birmingham.ac.uk/clr-ppi](http://www.birmingham.ac.uk/clr-ppi). The time commitment is about 20 hours per year, half of which is done from your own home via email.

## Some of our 2014 events

A Commonwealth athlete providing health advice ensured our public engagement team won 'best stand' at the Queen Elizabeth Hospital Research Showcase Day in May. There were a range of free activities from body mass indicators to alcohol unit games. Doctors were also on hand to give advice.

*Right: Dr Stuart Curbishley with visitor*



The British Science Festival was an amazing week of science for all ages held at the University of Birmingham in September 2014. Our liver surgeons, scientists and clinical doctors presented a fantastic talk entitled 'Your Astonishing Liver: disease investigation to transplant innovation'.

**Details of all past and future events can be found on our website: [www.birmingham.ac.uk/clr-ppi](http://www.birmingham.ac.uk/clr-ppi)**

## FREE videos and courses

What does your liver do? Why is it so important? We have made a 3 minute video introducing you to this remarkable organ. It is suitable for all ages and found at: <http://bit.ly/1voMc44> (or visit [www.birmingham.ac.uk/clr-ppi](http://www.birmingham.ac.uk/clr-ppi)).

Dr Patricia Lalor and Dr Zania Stamatakis produced an online course which went live in October 2014. This 3 week completely free course was presented by scientists and clinicians from the University of Birmingham and Queen Elizabeth Hospital Birmingham. It allowed people to learn all about the liver at their own pace, and at a time convenient to them. It is likely to be run again in 2015. For further details please visit the learning website [www.futurelearn.com/courses/liver-disease](http://www.futurelearn.com/courses/liver-disease).



*Online course presenters Dr Lalor & Dr Stamatakis*

# Haemochromatosis – a mixed up disease

Haemochromatosis is caused when the body collects too much iron, which over time can damage various organs and parts of the body.

In isolation, or in combination, it can cause arthritis, diabetes, chronic pain, loss of libido, liver disease, mood swings, heart disease, skin bronzing, chronic fatigue, muscle and joint pain, and abdominal pain.

Knowledge of this disease is not widespread, therefore sadly it is not understood by everyone. For most people, your diagnosis will be the first time they have heard of the illness.

As this is such a complex disease which can link to many areas of medical specialisms, its treatment can be difficult. A good GP is a huge asset so don't be afraid to ask your GP what they know about Haemochromatosis.

A diagnosis of Haemochromatosis can lead to feelings of isolation. Knowledge is your best friend so try to learn as much as possible about this disease in order to fully understand its complexity, and which areas of medicine it may be linked to.

Through experience, fellow sufferers are well equipped to help increase your knowledge about this condition, they are also a good source of support in other ways.

To contact the Haemochromatosis West Midlands Support Group, email [info@haemochromatosiswm.org.uk](mailto:info@haemochromatosiswm.org.uk), telephone 0121 457 8986 or visit [www.haemochromatosiswm.org.uk](http://www.haemochromatosiswm.org.uk).



*FE is the chemical symbol for Iron, a fitting logo for the West Midlands Support Group*

## Successful clinical trial leads to a promising Hepatitis C treatment and a generous industry donation

The success of the largest Phase III clinical trial of an oral therapy for the treatment of Hepatitis C (Genotype 1), has led to a generous gift by Abbvie, the company who sponsored the trial. Patients at the Queen Elizabeth Hospital Birmingham and other NHS Trusts are being given early access to their drugs prior to licensing early next year.

Abbvie is a Biopharmaceutical company which aims to develop medicines to provide measurable patient benefit in patients with significant need.

In 2013/2014 the research team at the Queen Elizabeth Hospital Birmingham participated in two clinical trials involving over 2300 patients worldwide, using Abbvie combination antivirals. These antivirals are inhibitors designed to specifically target different proteins of the Hepatitis C virus making it harder for the virus to keep making copies of itself and damaging the liver.

*Continued overleaf...*

The Queen Elizabeth Hospital Birmingham recruited 11 patients into the first trial (called 'Turquoise' trial) and 6 patients into the second trial (called 'Sapphire').

All patients had Genotype 1, the commonest strain of Hepatitis C, and were either cirrhotic or non-cirrhotic. All patients had either 12 or 24 weeks of treatment and all patients were **cured!**

Results published by Abbvie revealed cure rates of 92% in the 12 week part, and 96% in the 24 week part in the Turquoise study.

In the Sapphire study, 96% were cured and tolerability was better than current standards of care, and there were lower rates of discontinuation of treatment due to side effects.

In summer 2014 Professor David Mutimer, Consultant Hepatologist, had approval to treat 15 pre and post transplant patients in Hepatitis C treatment clinics at the Queen Elizabeth Hospital Birmingham. This is a fantastic opportunity to treat patients earlier than anticipated following the huge success of the phase III trial.

Abbvie has also made a generous commitment by supplying free drugs with an estimated value of £40,000 for 12 weeks treatment, and £80,000 for 24 weeks treatment. This is a considerable saving for the NHS. Patient treatment using these free drugs commenced in Autumn 2014, lasting for either 12 or 24 weeks.

**Our grateful thanks to Katharine Francis, Ian Soady, Kevin McCabe, Gideon Hirschfield, Kieran Lynch and Emma Burke for their contributions to this issue.**



Centre for Liver Research

This booklet was produced by the NIHR Birmingham Liver BRU, Centre for Liver Research, University of Birmingham and Queen Elizabeth Hospital Birmingham. If you have any queries please email [Liverresearch@contacts.bham.ac.uk](mailto:Liverresearch@contacts.bham.ac.uk) or visit [www.birmingham.ac.uk/liver](http://www.birmingham.ac.uk/liver)

### **Useful Contacts**

Queen Elizabeth Hospital Liver Transplant Support Group: Tel 01902 679 333, or visit [www.uhblsg.org.uk](http://www.uhblsg.org.uk).

British Liver Trust website: [www.britishlivertrust.org.uk](http://www.britishlivertrust.org.uk)

PSC Support Groups: [www.pscsupport.org.uk/support-groups-transplant-units](http://www.pscsupport.org.uk/support-groups-transplant-units)

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