



news February 2011

ISSUE 2

Andrew Lansley Opens the Leicester Cardiovascular Biomedical Research Unit

Issued by University of
Leicester Press Office on
04 November 2010

Health Minister Andrew Lansley opened the new Cardiovascular Biomedical Research Unit in Leicester – part of a multi-million pound scheme to prevent, diagnose and treat ill-health.

It is expected to benefit thousands of people in the region by using ground-breaking research developed at the University of Leicester to provide life-saving treatments at the Glenfield Hospital.

For the first time in the UK, the new centre will house a dedicated research database linked to a collection of blood samples from patient volunteers who have made their medical records available to researchers.

This will lead to faster research and therefore faster results; better information on genetics and heart disease; new, more accurate tests to detect heart conditions and



Staff and dignitaries present at the unveiling of the plaque.

enhanced clinical decision-making at the patients' bedside.

Key research will include the genetics and inheritance of heart disease, genetics of cardiovascular disease, studies of blood pressure and vascular diseases and the development of novel treatments for heart disease, stroke, cardiac rhythm

diseases and the cardiovascular complications of diabetes.

More than 100 doctors and scientists are involved in the new Leicester Cardiovascular Biomedical Research Unit (BRU), located at Glenfield Hospital. It is a partnership between the University of Leicester and University Hospitals of Leicester NHS Trust and funded by the National Institute of

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Health Research (NIHR), part of the Department of Health.

Andrew Lansley said: "Research is fundamental to our future health - it underpins the advances in diagnosis, prevention and treatment of disease that are essential for a 21st century NHS. We simply cannot expect health outcomes to improve without investing in research and the brilliance of our doctors and scientists.

"I'm pleased to be here to open this pioneering centre, which will lead to faster research and more accurate tests to detect cardiovascular conditions, ultimately leading to better results for patients."

Leicester is internationally renowned for its cardiovascular research. The Director of the BRU, consultant cardiologist Professor Nilesh Samani, British Heart Foundation Professor of Cardiology and Head of the University's Department of Cardiovascular Sciences, is one of the foremost researchers in cardiovascular genetics in the world.

He commented: "The centre cements Glenfield's reputation as a leading international heart hospital.

High quality research and better patient care go hand in hand. Heart disease takes life prematurely. We will bring together the best minds and technologies from all our local universities and industry so that we can achieve a better understanding of the disease and how we tackle it."

Professor Bryan Williams, Deputy Director of the BRU and lead for the Translational Medicine Facility which was formally opened by the Secretary of State said: "This is a wonderful new state-of-the-art facility, embedded in the heart of the hospital which has provided a step change in our ability to bring exciting and novel research innovations directly to the patients."

Malcolm Lowe-Lauri, chief executive of Leicester's Hospitals, said: "Research and development is extremely important for university hospitals like Leicester and so we are delighted to house the Leicester Biomedical Research Unit. This really is wonderful news for the people of Leicester and Leicestershire. Glenfield Hospital is already a world renowned heart centre and this extra facility really



Professor Bryan Williams

does put us at the forefront of medical advances. We have the best team in Professor Samani and his colleagues and I am sure it won't be long before we start hearing a lot more about breakthrough work from this team."

Vice-Chancellor of the University of Leicester Professor Sir Bob Burgess said:

"I am delighted that the University has been able to develop this Cardiovascular Biomedical Research Unit at the Glenfield Hospital site. It provides excellent facilities for high profile scientists who are working on many important areas of research including genetics and heart disease. This facility will result in improved patient care and will benefit the whole community in Leicester, Leicestershire and Rutland. It is another example of the University's long-standing relationship with the University Hospitals of Leicester NHS Trust in providing high quality health care."

One of the key strengths of the new unit is how it allows latest research advances to feed into advancing knowledge. Dr Will Nicolson, a Research Fellow investigating the prevention of



BRU Physiologist Dr March demonstrates state of the art technology in the Translational Medicine Facility

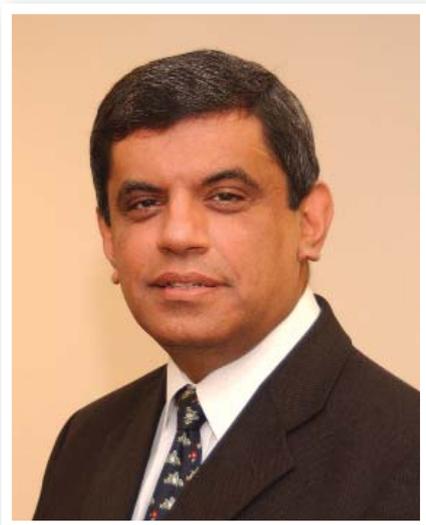
sudden cardiac death, said: "The Leicester Cardiovascular Biomedical Research Unit has provided essential funding and facilities for my work and created a platform for multidisciplinary collaboration."

Dr Nicolson's research fellowship is translating basic science in electrophysiology research into a patient specific electrical map of sudden cardiac death risk and combining it with a cardiac MRI anatomical map of arrhythmia risk. Early results are promising; a patent application is pending. Combining this electrical map of the heart with state of the art cardiac imaging has the potential to transform treatment and risk stratification of sudden cardiac death.

The focus of the new centre is to translate world-class research for patient benefit:

Mike Price, 77, from Anstey, is supporting the research work of the unit. He said: "I had a heart attack some years ago and all of my problems stemmed from there. I lost nine tenths of my heart muscle and can get quite out of breath. It recently got worse so I went into Glenfield for a procedure to correct an irregular heart rhythm.

"I was asked to take part in this project and I immediately said yes.



Professor Nilesh Samani



Andrew Lansley with Professor Bryan Williams and a patient.

To me, anything which helps other people and maybe prevents them suffering like I have can only be a good thing."

Research participant, Mr Bernard Croft, 66, from Market Harborough says:

"I was very pleased to be asked to participate in this research programme, as I felt it would be a beneficial extension of the excellent care I have received from my doctors and the health service in general."

"Participating in the research programme, has given me a chance to put something back into the system, as, hopefully, the results will promote improved treatment of hypertension and a reduction in heart problems in future generations."

"Personally, it has provided me with the close personal attention of several health professionals, for an hour or two every 6 weeks, when, not only have I been thoroughly checked out, but I have been able to learn much more about the effect of my life-style on my general health and hypertension in particular, which

has encouraged me to commence a programme of weight loss and dietary changes which should benefit the prognosis for my condition and thereby reduce the burden I place on the health service in future."

The BRU was opened on November 4 by Health Minister Andrew Lansley in the presence of Professor Dame Sally Davies, Director General of Research and Development and Chief Scientific Adviser for the Department of Health and NHS.

Influencing Research: The Role of a Patient Advisor

What are Patient Advisors?

written by Patient Advisor Roy Dick

The University Hospitals of Leicester Trust started recruiting Patient Advisors in 2002 in accordance with Section 11 of the NHS and Social Care Act 2001. The first group of four were in post from May 2002 and I have been in post since October 2002. We participate as members of specific corporate directorate committees to provide a lay perspective on issues relating to increasing patient and public involvement in the Trust. Patient Advisors are members of the general public and are not full time employees of the Trust (it only feels as if we are). We are attached, as the title suggests, in a purely advisory capacity.

The Patient Advisors are from various backgrounds. Among our members, we have a retired police Chief Superintendent, a retired librarian/book publisher, a retired teacher, a semi retired businessman and a Doctor of Sociology. My own background is that of retired professional engineer. The mix is now more eclectic with 14 in post. We are required to attend a meeting every 6



weeks but in reality, we all attend more meetings than the basic requirement. My own commitment in July this year was 7 meetings and some of my colleagues may have done more.

Patient Advisors are individual members of the public and are not affiliated to, nor are we representatives of, any particular community or organisation. We do not actively seek the views of NHS users although we may assist UHL staff to do this. We are not available to be contacted directly by patients or members of the public, that is the remit of the Patient Information and Liaison Service. There is no contact with the patients unless specifically asked to do so by the medical or clinical staff. It should be emphasised, however, that we have all received instruction in the ramifications of Staff and Patient confidentiality.

The key roles of Patient Advisors are:

1. To be available to attend meetings at the request of the Trust, occasionally at short notice, and to be able to travel across all three sites.
2. To participate in discussions with health care professionals.
3. To play a constructive role in the outcomes of meetings.
4. To proof read patient information leaflets produced by the Trust and to provide a lay perspective as to content and readability.
5. To raise concerns and issues arising from group meetings with the UHL lead for public and patient involvement.

I am currently attached to the Surgery directorate of the Planned Care Unit of the Trust and, of course, the Biomedical Research Unit. In the Surgery Directorate I am involved with Clinical Governance, the Board for Infection Prevention and Control, the Complaints Committee, the Public and Patient Involvement Group and staff interviews on an ad hoc basis. I also do Environmental Audits, Observation Audits and "Walkabouts" with senior managers from time to time on the wards. Prior to being attached to Surgery, I was attached to the Imaging Directorate, the Pain Management and Anaesthetics Directorate and the Clinical Services Directorate. I was instrumental in setting up the Patient Advisor and Public and Patient Involvement service for the School of Nursing and Midwifery at Charles Frear Campus, De Montfort University. Under the new set up at UHL Trust, although we are allocated to a specific department, we can be seconded to where ever, as and when we are needed.

From a personal point of view, it has been interesting and rewarding. I have always been made to feel welcome. The learning curve has been steep to say the least, especially in learning a new language and acquiring a new vocabulary.



The National Institute for Health Research is providing help to researchers developing grant applications to do with '**people-focussed**' health research

If your team includes (or will include) NHS collaborators, you may be able to get free advice and support from us at the Research Design Service (RDS) for the East Midlands. The RDS is part of the National Institute for Health Research (NIHR) and is a national service, regionally delivered. We are funded to help local researchers develop and design high quality research proposals for submission to national, peer-reviewed funding competitions for applied health or social care research. We focus on NIHR funding streams, but can help with other proposals whenever capacity allows. Because we focus on the application stage, our support usually stops at the point when the bid is submitted. However there

is potential for RDS staff to be costed in to help with the work after funding is secured.

The NIHR RDS for the East Midlands (RDS-EM) has its main bases in Leicester and Nottingham. There is a wide skill-mix of staff who can discuss your project with you, including statisticians, qualitative researchers, epidemiologists, health economists, patient and public involvement experts and information specialists. RDS-EM staff are research-active and have considerable expertise in developing and designing high quality research proposals.

For more information, please see our website: <http://www.rds-eastmidlands.org.uk/>, where you can sign up to our newsletter, and read our charter: <http://www.rds-eastmidlands.org.uk/charter.html>. If you have a research proposal you would like to discuss, please contact us as early in the process as possible: you may use this link to send an enquiry (or follow the links to 'support enquiry form' on our website): <http://www.rds-eastmidlands.org.uk/support-enquiry-form.html>

We look forward to hearing from you!

You Have **Spoken!**

Our first anonymous survey of patients and the public about research has been completed. We asked patients and the public on our mailing list, and through links on our webpages and facebook page what types of research they wanted to see. 49 people have so far responded to this opinion poll.

They told us that the areas they most wanted to see research in are cardiovascular health, mental health and cancer. The majority of people (79%) thought that cardiovascular research was very important, 21% thought it was important and no-one thought it was not important. Whilst everyone agreed that cardiovascular research is important most also recognised that there is a shortage of money at the moment and that this would mean a shortage of resources for research. All respondents recognised that healthcare is dependent on research.

In terms of participating in research, respondents thought that patients were only sometimes keen to participate. Most people

would be willing to take part in research that involved completing a questionnaire or survey (96%), giving a sample of blood or urine (70%), or undertaking some form of education (81%) or exercise (72%). About half of respondents would take part in research about a medical device like a pacemaker (45%) or in a project requiring them to make changes in their lifestyle (55%). Respondents were much more cautious about participating in drug studies with just 19% saying they would take part in research about a new (unlicensed) drug and 38% saying they would participate in research about a licensed drug.

Respondents identified that certain types of research were considered more important than others. They thought that identifying disease mechanisms, working out which treatments are effective and assessing the impact of treatments on quality of life were the most important areas of research. Prevention research, exploring the effects of diet, exercise, and lifestyle were considered important or very important by most respondents. Research exploring the cost effectiveness of treatment and surveying patient experiences was considered important by most respondents. Very few

respondents identified any research as a waste of money, but a small number expressed this opinion in respect of surveying patient experiences (2%), assessing the cost effectiveness of treatment options (2%) and prevention research (8%).

Only 6% of people said they would be put off research if it involved genetic testing, with 70% of people saying it would definitely not discourage them. This is quite surprising as a lot of researcher think genetics does put patients off taking part.

Most people responded to the survey because they are interested in cardiovascular health generally, but a third of people were interested because cardiovascular ill health had affected a family member. 39% said they had taken part in medical research in the past.

If you want to influence local research strategy by responding to our polls and surveys then email rp237@le.ac.uk to join the mailing list, join our facebook page <http://goo.gl/cefUh>

or check our webpages <http://www2.le.ac.uk/projects/bru>.

What happens to your **blood**?

In the last issue of the newsletter we discussed how patients and healthy volunteers are donating a sample of their blood and urine to a collection linked to their anonymous clinical information through the BRICCS system. In this article we find out how the Scientific Officers in the laboratory process your blood and urine.

When a patient consents to the BRICCS project, we draw 5 tubes of blood and a sample of urine. From the blood we extract plasma, serum and white blood cells, and a small sample of the blood is run through a haematology analyser.

Plasma is the fluid and proteins in blood when it is separated from the blood cells. It's a yellow liquid. As it still contains the proteins that cause blood to clot, tubes containing an anti-coagulant are used.

Serum is the fluid in blood separated from blood cells and proteins associated with clotting.

Within 90 minutes of your blood being taken, it will arrive at the lab in the Translational Medicine Facility of the Leicester Cardiovascular Biomedical Research Unit. The blood for plasma will be on ice, while the blood for serum is not, to allow it to clot. The arrival of the samples is logged because it is very important to be able to check



that samples were processed properly and any data from them can be trusted.

Each tube has a barcode on it, and the Scientific Officer in the lab scans this into a piece of software called caTissue. This registers the samples existence in the collection of samples donated by patients for research. Later each sample will be divided up into smaller samples so that a single sample can be used in more than one research project.

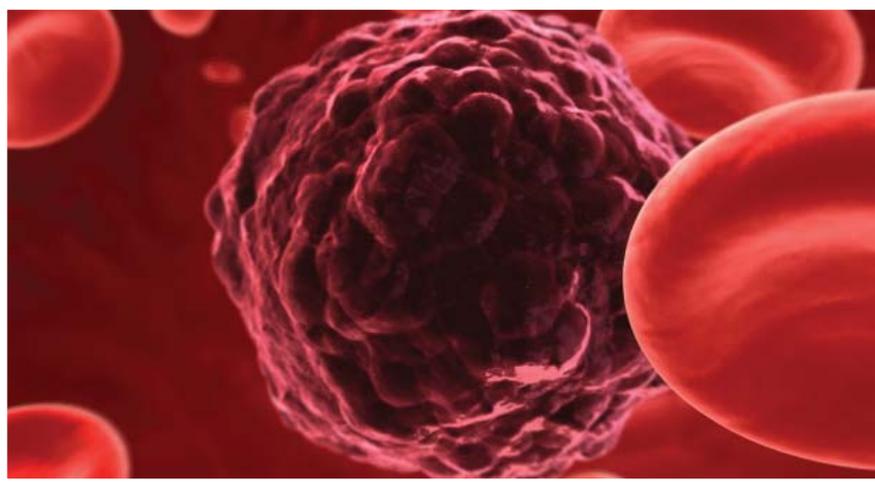
The serum sample needs to start to clot so it has to sit in the lab for an hour.

Meanwhile, a Scientific Officer gets to work extracting plasma, placing the blood in the centrifuge which spins them at 2000 times the force of gravity for 20 minutes to separate out the plasma and the red & white blood cells. Once the centrifuge is finished the samples are put back on ice. The

plasma (that's the yellow stuff in the small tubes) is now separate and this is put into small aliquots which are then frozen at -80°C . For comparison, your domestic freezer at home would be at about -18°C . The white blood cells form a concentrated layer, floating on top of the red blood cells, which can be sucked off with a Pasteur pipette.

Now the Scientific Officer can turn her attention to extracting serum. The blood which has been sat clotting is centrifuged, along with the urine. As before, the blood centrifugation separates the fluid (serum in this case) from the clotted cells, which can be pipetted, aliquoted and frozen.

Whilst all this is undertaken by one of the Scientific Officers, the other will run a sample of blood on the haematology analyser. She starts by checking the machine is working by doing a quality control check on a small container of synthetic bloodlike product. This should produce 'average' readings which she checks on a series of measures. Then she places the blood sample in the device and it generates the haematology data (things like your white blood cell count). Stored serum, plasma, DNA and urine can then be accessed by researchers at the Biomedical Research Unit investigating the effects of genetics on cardiovascular health or the mechanisms underpinning cardiovascular diseases.



Inside **Research** Part 2

Lots of different types of research take place in health and social care to develop the best interventions and healthcare possible. Lots of medical conditions are treated with drugs or medical devices like pacemakers. Research involving drugs or devices is supervised by a competent authority called the Medicines and Healthcare Regulatory Agency (or MHRA for short). Every member of the European Union has their own competent authority which supervises drug and device research.

The MHRA is a government agency and its role is to ensure that drugs and devices used in healthcare in the UK work and are safe to use. Part of this involves licensing new drugs and devices. Research is a key stage in demonstrating that a drug or device works and is safe so that it can be licensed. The licence will specify in what manner the drug or device can be used.

If a researcher wants to explore the use of a new drug or device, he or she must apply for permission to the MHRA, and also to the hospital they want to do the research in and to an ethics committee (see Part 1 of Inside Research in the July 2010 newsletter). To get permission from the MHRA the researcher must report on the risks likely to be involved in using the new drug or device based on earlier research, provide evidence that other doctors or scientists have reviewed and agree with their proposed

research and explain in detail what the research will involve.

The MHRA will scrutinise the scientific method employed by the researcher to be confident that the research will yield meaningful results which can be applied to healthcare in the future. They will also look at the existing safety information on the drug or device to decide if it is safe to research its use in patients.

The MHRA require the researcher to report everything untoward that happens to a patient taking an experimental drug or using an experimental device, even if it is not related to the patients' use of the drug or device. They collate all this information to detect trends in the use of new drugs or devices. They also require annual reports and a very comprehensive final report which informs their decision about whether or not to licence the new drug or device.

The MHRA also inspect research to make sure it is being conducted as they agreed with the researcher, and in accordance with the law and a set of guidelines called Good Clinical Practice for Research.



News from the Leicester Cardiovascular Biomedical Research Unit

Three hundred and three patients have given permission for researchers to access their clinical data (anonymously), completed a patient interview and provided a sample of blood and urine to the Leicester Cardiovascular sample and data collection (BRICCS). In the near future researchers will begin using the data and samples to further our understanding of cardiovascular disease.

Members of the public had the opportunity to meet staff from the Biomedical Research Unit at Highcross Leicester when the BRU Roadshow visited in September. Members of the public found out all about the new research unit and what it means for them. A number of people also volunteered to help steer future research.

The Biomedical Research Unit is now supporting 86 cardiovascular research projects, many of whom are using the new facilities in the Translational Medicine Facility at Glenfield Hospital including dedicated lab, consulting rooms, exercise testing room and echo-suite.

The Mayor of Leicester has visited the BRU and was particularly interested in the Units approach to communicating with and involving members of the public and patients in influencing research strategy and research activity.

Want to receive the newsletter regularly and express your views on cardiovascular research?

Join our mailing list by emailing rp237@le.ac.uk.

Join our facebook page
<http://www.facebook.com/group.php?gid=124013907609617>

Volunteer to join our research review panel.

Contact Rebecca on rp237@le.ac.uk for more information.

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