Welcome to our Cardiac Surgery Research PPI Newsletter.

In the Department of Cardiovascular Sciences at the University of Leicester we have a specialised team involved in the trials we are currently undertaking and we would like to share with the public how funding from the British Heart Foundation and other funding bodies is used.

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Charitable donations:
Please contact Sue Page on 0116 2583021

Members of our team

Professor Gavin J Murphy, British Heart Foundation Professor of Cardiac Surgery, University of Leicester/Honorary Consultant Cardiac Surgeon, University Hospitals of Leicester NHS Trust

Giovanni Mariscalco
Senior Lecturer / Honorary Consultant Cardiac Surgeon

Sue Page
Team Administrator

Tracy Kumar
Research Manager

Nikol Sullo
Research Associate

Lathishia Joel-David
Research Nurse

Marcin Wozniak
Research Fellow

Sue Cockburn
Research Nurse

Paolo Pais
Hon Visiting Research Fellow

Alan Dawson
NIHR Academic Clinical Fellow

Filiberto Serraino
Hon Visiting Research Fellow

Alan Dawson
NIHR Academic Clinical Fellow

Filiberto Serraino
Hon Visiting Research Fellow

National Institute for Health Research
**Our Clinical Trials**

**Ongoing Studies**

**REVAKI-001: How Using a Drug Called Sildenafil Might Prevent Kidney Damage After Cardiac Surgery**

A known medicine, Sildenafil (Revatio®), is now being studied as a potential preventive treatment for serious kidney complications after cardiac surgery. Sildenafil is already available in the United Kingdom to treat erectile dysfunction (impotence) and a lung condition called pulmonary arterial hypertension. In this study, the amount of Sildenafil in your blood stream, and the way your body removes it during and after heart surgery will be investigated. Other aims of this research study are to find out how safe this medicine is in patient’s receiving heart surgery and which side effects, if any, it causes. Recruitment to this study is now complete and data will be published in the near future.

**Redwash: Investigating the Damaging Side-Effects of Blood Transfusion After Cardiac Surgery**

Blood transfusion may have unwanted side-effects that increase the risk of complications after cardiac surgery. We believe that this may be due to the microscopic particles released by the blood cells into the blood bag during storage. Currently these microscopic particles are transfused to the patient along with the donor blood. We want to establish whether removing these particles by washing blood cells immediately prior to transfusion can reduce the side-effects attributed to blood transfusion in cardiac surgery patients. Recruitment to this study is now complete and data will be published in the near future.

**New Studies**

**REVAKI-002: The Effect of Sildenafil (Revatio®) on Post-Cardiac Surgery Acute Kidney Injury: a Randomised, Placebo-Controlled Phase IIB Clinical Trial**

The aim of the study is to establish whether a known medicine, Sildenafil (Revatio®), can prevent damage to the kidneys during cardiac surgery. Kidney damage is a common complication of cardiac surgery and there is no current treatment. Sildenafil is already available in the United Kingdom to treat erectile dysfunction (impotence) and a lung condition called pulmonary arterial hypertension. In a previous trial (the REVAKI-1 trial) we identified a dose of Sildenafil that was safe and resulted in blood levels that are known to be effective for the treatment of these other conditions. In the REVAKI-2 trial we now want to compare the level of kidney damage in patients receiving the dose of Sildenafil identified in the REVAKI-1 trial compared to those receiving a placebo (a test substance).

**Mi-ECMO Study: A Feasibility Study to Consider the Relationship Between Markers of Red Cell Damage, Inflammation and the Recovery Process of Newborns Requiring Extracorporeal Membrane Oxygenation (ECMO) for Persistent Pulmonary Hypertension of the Newborn (PPHN)**

*What is ECMO (Extracorporeal Membrane Oxygenation) and what is the purpose of the study?*

Children are admitted to the Glenfield Hospital because they have respiratory failure that needs urgent care with Extracorporeal Membrane Oxygenation (ECMO). ECMO is the use of an artificial lung located outside the body, which adds oxygen to the blood and removes waste gases. ECMO can replace the function of the child’s heart and/or lungs for a limited time until the child recovers from the initial cause of the failure.

Even if this technology has been used for many years, the reaction of newborns’ body to the ECMO support is still poorly understood. Moreover, during ECMO up to 64% of children have kidney damage and they are at risk of additional complications. Unfortunately, we still don’t have effective techniques or treatments that can prevent kidney or lung injury in children undergoing ECMO.

Our research has identified specific particles in the blood of adult patients undergoing cardiac surgery that may be related to early diagnostic markers of kidney damage. These are small particles called microvesicles and microRNAs that are released within hours of injury, and before kidney damage is established. Our research is now considering whether these microvesicles could work as good diagnostic markers or even as potential targets for future treatments in children who are at risk of kidney damage. Professor Gavin Murphy and Mr Attilio Lotto are leading this “feasibility study” which means that it is a small study that will help the researchers in the design of a larger one with many other patients. Recruitment to this study is complete and data analysis is ongoing.

**p-MiVAKI Study: Preventing Kidney Damage in Children After Cardiac Surgery**

Cardiac surgery can lead to damage to the kidneys in more than 50% of children, especially newborns or very ill children. If they develop a kidney injury, they are at risk of additional complications such as the need for dialysis. Our research has identified specific particles in the blood of adult patients undergoing cardiac surgery that may serve as early diagnostic markers of kidney damage. These are small particles called microvesicles and microRNAs that are released within hours of injury, and before kidney damage is established. Our research is now considering whether these microvesicles could work as good diagnostic markers or even as potential targets for future treatments in children who are at risk of kidney damage. Professor Gavin Murphy and Mr Attilio Lotto are leading this “feasibility study” which means that it is a small study that will help the researchers in the design of a larger one with many other patients.
Volunteer Services

One of our main projects is how to get members of the public involved in research. We see the role of a volunteer as being similar to the existing patient volunteer but more “research” orientated. After a period of negotiation with both the UoL and UHL, we succeeded in finding a member of the public, Alan Phillips, who already had patient volunteer experience. Alan undertook a very successful 6 month pilot phase and following this, we have been given approval to make this role permanent within cardiac surgery research. It has been suggested that in the future this could be extended out across the whole UHL Trust.

Alan’s role involves:

• Talking to and supporting research participants - some patients do not feel at ease talking to Doctors or the research team but would talk to a volunteer.
• Helping to explain clinical terminology in layman’s terms
• Reporting any issues or concerns to the research team
• Offering support to participants
• Help to present a positive image of research participation

Patient & Public Involvement (PPI) in Cardiac Surgery Research

To help raise public awareness that Glenfield Hospital is a “Centre of Excellence” for research and to encourage members of the public to be involved in our research, we have formed a Patient & Public Involvement (PPI) Group. This group is made up of members of the public who have volunteered their services to assist us in our research. Within this group we have members helping us with: Consultation – reviewing applications for new studies and Dissemination responsible for local publicity and social networking.

Who we are

We are a group of volunteers of different ages, from different backgrounds and walks of life who all, for one reason or another, have an interest in being part of the ground-breaking research work in cardiac surgery which is being carried out by Professor Gavin Murphy and his team at the University of Leicester/University Hospitals of Leicester NHS Trust. Some of us have experienced cardiac interventions at some stage of our own lives. Some of us have friends and relatives who have undergone and had their lives dramatically improved by cardiac surgery, and some of us simply have a technical interest in the type of research that is going on. However, all of us share one common goal – to help drive forward the life-enhancing and often life-saving research work going on at these centres of research excellence, our local hospitals here in Leicester.

What we do

Our cardiac surgery PPI group meets regularly to receive updates directly from the research teams on the latest developments in cardiac surgery. Often we are asked to review research projects (sometimes even to suggest projects), and comment on how relevant we feel the work is. We give the patient and public perspective - including making sure that any letters or documentation which are designed to go out to patients are written in a way that everyone can understand.

Most research projects need volunteers, so part of our work involves spreading the word about the great research work that is going on in Leicester. We are always on the lookout for fresh opportunities for the research team to get out and about into the community to talk about their exciting work, often with PPI members at their side.

Professor Gavin Murphy commenting on the part played by his PPI group, says: ‘By making public and patient participation part of our research strategy we will ensure that our research best reflects the needs and concerns of the community which it aims to help. We would be unable to deliver our current research strategy without the commitment and time kindly given by the previous patients and members of the public who make up our PPI, which is directly making a difference to both patient experience and research success to an unprecedented extent.’

Alan Phillips (Volunteer)

I am Chairman of Take Heart Leicester (THL), the Adult Cardiac Charity covering the 3 Leicester Hospitals. THL runs an Adult Cardiac Support Group, with many events to meet the needs of patients, ex patients and carers. This includes Social events from a walking group to lunches, dinners, skittles nights, boat trips and many more. Money raised through donations is used to provide a Bursary fund and much needed equipment for the Cardiac wards at the hospitals.

Personally I am a volunteer with University Hospitals Leicester and visit patients on the Cardiac wards, AICU and CDU at Glenfield. I am a Lay member of the Cardiovascular Surgery Research Programme Steering Committee. I am also the cardiac surgery research volunteer, in which role I visit the in-patients who have volunteered for one of the research programmes, to see how they are progressing and to answer any non-medical queries they may have.

PPI Members

David Mayes, Phil Caldwell, Ballu Patel, Anthony Locke, Paul Haywood, Jagruti Lalseta, Terry Finnigan, Gajendra Chhatrisha

Cardiovascular Surgery Research Programme Steering Committee.
The PPI members help to locate public events where Professor Murphy, who leads all current cardiac surgery trials at the UoL, can attend and speak about how funding from the British Heart Foundation and other funding bodies is used within his trials. Each year Professor Murphy undertakes a series of public lectures and for 2016 the title of these lectures is “Can Obesity Be Good For You?”. Further details of these can be found by following the public lecture links.

### Events 2016

**24 May Public Lecture at Loughborough University Brockington Building**

Professor Murphy to give public lecture on “Can Obesity be good for you?” to be held in Theatre U0005, Brockington Building, Loughborough University LE11 3TU at 6.20pm. Refreshments available from 6.00pm. To book a place please email: a.stanley@lboro.ac.uk www.ll.dlpa.bru.nihr.ac.uk

**13 June Public Lecture at Café Scientifique, The Exchange, Rutland Street, Leicester**

Professor Murphy to give public lecture on “Can Obesity be good for you?” at the latest round of Café Scientifique events to be held at The Exchange, 50 Rutland Street, Leicester LE1 1RD at 6.00pm. www.exchangeleicester.com

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### Comments from our PPI Members

**Phil Caldwell**

I got involved in PPI five years ago, and my first ‘project’ was helping the Cardiac Rehab team to re-develop a website called ‘Activate Your Heart’ which provides a self-management option for people who are getting themselves back on track after a heart attack or other cardiac event.

The work I am currently involved in is all about spreading the word about how much amazing research work is going on in our Leicester hospitals in the world of cardiac surgery, to which Professor Murphy’s research is making a major and lasting contribution. It is a way I can play a small part in what is undoubtedly a brighter future for people facing heart operations.

**David Mayes**

My father had plastic valves put into his heart 40 years ago and he lived until he was 88. I heard Professor Murphy talk at our Rotary Club and heart surgery has advanced significantly in that time but the unexpected still happens and if I can help in any way to reduce this then I would like to.

**Paul Haywood**

I would say that the PPI keeps us up to date on the cutting edge of cardiac research.

**Anthony Locke**

I am committed to the vital role of patient and public involvement in research. I have been a volunteer for a number of research projects in respiratory and cardiovascular functions. I am a member of the East Midlands Clinical Research Network and for four years a member of the NIHR Committee for Research for Patient Benefit. I am a PPI member of the Cardiovascular BRU of Leicester University and the Cardiovascular BRC at St. Thomas’ Hospital and a Visiting Research Fellow at University of York.

**Terry Finnigan**

For over 13 years I’ve been a UHL volunteer and a member of Take Heart Leicester, the Adult Cardiac Patient Support Group which supports the cardiac wards in all three hospitals, though primarily at Glenfield where I visit the cardiac wards. I talk to patients about my own experiences in relation to cardiac surgery and subsequently this led me to become a member of the PPI group.

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**For more information**

Sue Page, Administrator

Phil Caldwell, PPI Member

Terry Finnigan, PPI Member

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