Welcome

...to the third edition of the Sheffield Clinical Research Facility (CRF) newsletter.

This month:
- ♦ read about the role of the Research Nurse—see page 2 for a real-life example
- ♦ CRF study results in development of new care pathway for patients— full story on page 3
- ♦ the CRF opened its doors for International Clinical Trials Day on 20 May 2013 – read more about the ‘OK to ask’ campaign on page 4.

Sheffield to Host 2014 UKCRF Conference

The Sheffield CRF is pleased to announce it has won its bid to host the UK Clinical Research Facility Network Conference in 2014.

This will be the 10th year of the annual conference and is an opportunity for the CRF to demonstrate the research expertise in Sheffield. The audience is expected to be between 250-300, comprising members of the CRF teams from across UK and Ireland, senior clinical investigators and representatives from NIHR, Department of Health and research funding bodies.

The theme of the event is “Excellence, Innovation & Integration. The conference will be held at the University of Sheffield Endcliffe Village on the 3rd and 4th July 2014.

Karen French, CRF Manager, said: “We are delighted to be hosting the 10th Anniversary National Conference. This is a fantastic opportunity to showcase Sheffield, its researchers and its research achievements through this prestigious event”.

Get in touch
For more information about how the CRF could help you in your research, contact Karen French, CRF Manager ☏ RHH: 0114 271 3339 ☏ NGH: 0114 271 5779 ✉️: karen.french@sth.nhs.uk

Sheffield to Host 2014 UKCRF Conference

Congratulations

Congratulations to the CRF Director!

The CRF team extends its congratulations to the CRF Director, Professor Chris Newman, who has been awarded a Personal Chair in the University of Sheffield. Chris is now Professor of Clinical Cardiology.

Chris has provided the CRF with strategic leadership since the CRF opened in 2006.
Roles in Research: CRF Research Nurse

The role of the CRF Research Nurse is pivotal to the success of a research project. The Research Nurse works alongside the investigator team to recruit and retain subjects, supporting participants throughout study visits in addition to performing protocol-specific procedures.

Sister Nicola Bennett, Research Nurse in the CRF, was the lead nurse working on the ePAQ-PO study (see page 3 for further details) working alongside Senior Sister Jo Kadziola and Sister Jane Collins.

Nicola project-managed the study, assisting with a wide range of activities including:

♦ setting up a study site file and working file
♦ pre-screening medical notes
♦ compiling source data worksheets
♦ liaising with Information Governance regarding data safety and developing an SOP to outline the agreed data transfer methods
♦ organising and attending meetings with the study team
♦ recruitment of participants to both phases
♦ conducting all 1:1 interviews
♦ transcription of qualitative interviews, giving feedback on these and contributing to the analysis
♦ contribution to study strategy meetings, including production of additional patient documentation to increase recruitment
♦ link forging with the clinical teams
♦ recording predicted and actual expenditure to track against the grant budget.

Nicola said: “This was a great study to work on. There was a high volume of patients to recruit, so the most important factor of the studies success was building a good working relationship with the pre-op nurses. Due to theatre operating times the study often required very early study visits, but these could be accommodated within the CRF by working as a team.”

The CRF is currently working with a total of 169 different investigators

Abstract highlight

Goodhart I, Andrzejowski J, Berthoud M, Jones GL, Wrench I, Bennett N, Turnbull I, Radley SC

Electronic Personal Assessment Questionnaire PreOperative: patient experience and face validity of an interactive, electronic questionnaire for the preoperative assessment of patients due to undergo general anaesthesia.

British Journal of Anaesthesia
2012; 109 (4): 655P-668P
doi:10.1093/bja/aes232

"1 Department of Critical Care and Anaesthesia, Sheffield Teaching Hospitals NHS Foundation Trust
"2 ScHARR, The University of Sheffield
"3 NIHR Sheffield Clinical Research Facility
"4 Directorate of Obstetrics, Gynaecology and Neonatology, Sheffield Teaching Hospitals NHS Foundation Trust

CRF Study Success

A commercial renal study supported by the CRF has achieved 180% of the original target and recruitment is ongoing.

The portfolio-adopted study is looking at patients with Autosomal Dominant Polycystic Kidney Disease (ADPKD) to establish the rate, characteristics and determinants of disease progression.

CRF User Feedback Continues to Improve

All CRF investigators are invited to complete a web-based feedback survey on completion of their study. Staff scores are consistently high, with year-on-year trends showing an overall improvement between 2007-2010 and 2010-2013 in all staff groups.

One investigator commented: “The CRF and nurses have been invaluable in getting my study completed. The nurses were very dedicated and I am grateful for your support.”

If you would like to share your experiences of the CRF, please contact Debby Hawkins, at debby.hawkins@sth.nhs.uk

Would you consider using the CRF again?

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Improving healthcare for the benefit of patients

www.sheffield.crf.nihr.ac.uk
ePAQ-PO (electronic Personal Assessment Questionnaire – Pre Op) is an interactive computerised questionnaire that has been developed and tested in Sheffield, where it is now being introduced into clinical practice.

Supported by the CRF, the questionnaire was validated in 330 patients in a 15 month, 2-phase study. ePAQ-PO uses a scoring system to assess how fit a patient is for surgery and anaesthesia. There are now over 25 Trusts nationally are interested in using the system”.

Dr John Andrzejowski, Consultant Anaesthetist and Principal Investigator, spoke to us about the project:

What is ePAQ-PO?
A tool to help assess a patient’s fitness for surgery.

How was the questionnaire developed?
We first started protocol development in 2008 – it has been a long road! We secured a Sheffield Hospitals Charity grant award in 2010 and the study began with the CRF in the same year. The questionnaire was initially compiled with input from a team of clinicians and nurses. This was then reviewed by 30 patients during one-to-one interviews and changes were made to the questionnaire based on their feedback and comments. Phase 2 then assessed the validity and reliability of data gathered in a larger group of patients (n=300), establishing the domain structure and scoring system (factor analysis), construct and criterion validity, internal reliability and test-retest reliability.

Did patients have an input into the design of the questionnaire?
Yes, at several stages. In addition to the qualitative data from phase 1, selected patients were asked to complete a 10-item questionnaire (QQ-10) on their experience of using the system. Before finalising the questionnaire, a PPI meeting was held to get further feedback as we felt it was important to get patient input into the patient interface.

What is the potential benefit and impact on patient care?
ePAQ-PO enhances the pre-op assessment process as the questionnaire can be done at home, in the patient’s own time, hopefully decreasing admission times. Eventually we hope that the score from ePAQ-PO will be used to determine what type of appointment patients receive – currently all patients get the same appointment. With the support of ePAQ-PO, some patients may be suitable for phone consultations so they wouldn’t need to come to hospital at all for their pre-op appointment; resulting in reduced burden for the patient and efficacy savings to the hospital. The system meets national NHS initiatives: preoperative screening is a government priority in the ‘Digital by Default’ programme launched in 2012 and Connecting for Health has highlighted ePAQ-PO as one of its QIPP solutions.

Who is already using the system?
Currently the system is being piloted in gynaecological surgery within STH. This pilot is ironing out the operational glitches and testing both the clinician and patient experience, to determine how the system actually affects the patient pathway. We already have a very good pre-op assessment service in Sheffield, which made it a good place to develop ePAQ-PO, but it is also hard to improve what we already have. There is a potentially bigger impact at other Trusts and several other NHS Trusts nationally, in both primary and secondary care, have expressed interest in the system.

What are the plans for the future?
We would anticipate that other Trusts may start using the system in summer 2013. A £40k grant from the Yorkshire and Humber Strategic Health Authority has been secured to develop an implementation toolkit in other Trusts. We also hope to expand the questionnaire to include PROMs (patient reported outcome measures) and are applying for a grant in conjunction with ScHARR at The University of Sheffield to take this forward.

For further information about the system visit: [http://www.epaq.co.uk/](http://www.epaq.co.uk/)
CRF Open Day for International Clinical Trials Day

This year the Sheffield CRF opened its doors at both sides of the city from 2.30pm till 6.00pm on Monday 20th May, as part of a national initiative to promote clinical research.

The NIHR is encouraging patients and their carers to ask about clinical research as part of its new “OK to ask” patient empowerment campaign, launched on International Clinical Trials Day (20 May).

The open afternoon was an opportunity for local researchers and members of the public to have a look at the facilities available at both the Northern General and Royal Hallamshire Hospital sites.

Talks, demonstrations and hands on activities were available throughout the afternoon, including simulation of equipment such as bone scanners, laboratory demonstrations by the Cardiovascular research team and interactive sessions by Infection Control.

Clinicians are already doing a great job of making research happen within NHS as proved by the fact that annual patient recruitment figures into studies have doubled in the past five years. However the NIHR wants this growth to continue, by encouraging more patient interaction and empowering patients to initiate a conversation about taking part in clinical research.

The total number of trial visits since the CRF opened is nearly 30,000 – 2,077 of which occurred during 2012/13

Sheffield Installs CRFManager® System

In order to streamline and improve internal systems, the CRF has purchased the CRFManager® system. Developed by the Edinburgh CRF, CRFManager® is a web-based data management system, purpose built for Clinical Research Facilities.

CRFManager® is a single system to manage study activity including approvals, the project team, patient recruitment and management of patient bookings, supporting administration and scheduling of CRF research projects. Resource usage and reporting are integrated into the system, enabling efficient recruitment and visit tracking.

Growth of CRF Team

The CRF welcomes new starters Cheryl Bailey, Chris Wragg and Alexandra Spooner to the CRF Data Co-ordinator team. New receptionist Jenna Gladding has joined the clerical team and will primarily be based at the Royal Hallamshire Hospital CRF. Profiles of all CRF staff can be found on the CRF website:

www.sheffield.crf.nihr.ac.uk

The Obstetrics, Gynaecology and Neonatology Research Nursing/Midwifery team, based at the Jessop Wing, have recently become affiliated to the CRF. It is hoped this new partnership will provide operational support to the growing portfolio of research in the Directorate.

CRF Education and Development Programme

The CRF Education and Development sessions are available to all researchers within STH. Upcoming sessions include:

- **The Future of the Research Nurse**, 14th June at 2.00pm (CRF, O Floor, RHH)
- **How to Access the CRF; the Feasibility and SAB Process**, 9th August at 2.00pm (CRF, O Floor, RHH)
- **Role of the SYCLRN**, 16th August at 2.00pm (Seminar Room 1, Medical Education Centre, NGH)
- **Experience of a Researcher in a District General Hospital**, 13th September at 2.00pm (Seminar Room 1, Medical Education Centre, NGH)

For more details about these and other training sessions please contact Philippa Ledger:

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Improving healthcare for the benefit of patients

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A nursery worker who found her dad propped up on the garage floor after experiencing dangerously low blood sugar levels is calling on anyone whose relatives suffer from Type 1 diabetes to help prevent the disease.

Gemma Morton of Wincobank decided to take part in the new diabetes study after witnessing her dad endure hypoglycaemia, where blood sugar levels can drop extremely low.

The South Yorkshire TrialNet study – which involves relatives of people with Type 1 diabetes having a blood test and providing some family history – could protect future generations from the disease years before symptoms appear by letting them know if they are at risk because of a family link. The is part of an international research programme originating from the United States, and is a partnership between Sheffield Teaching Hospital NHS Foundation Trust, South East Midlands Diabetes Research Network and the South Yorkshire Comprehensive Local Research Network. The research has been supported by the CRF at the Northern General Hospital.

According to Diabetes UK, 3 million people in the UK have been diagnosed with diabetes, and an estimated 850,000 people have the condition but don’t know. About one in 10 of these people have Type 1 diabetes, which can develop at any age, but usually affects people before the age of 40 and most commonly during childhood.

Gemma said: “Diabetes can be pretty scary, and it’s only through my own knowledge of my dad’s condition that I’ve been able to pull him through some life-threatening situations. Once I found him propped up on the garage floor because of low sugars in the blood. But there’s usually his ‘giveaways’ signs when he’s experiencing an episode – he gets hot and sweaty and starts chewing his lips so I know that I need to act fast.”

Each time Ian, who was first diagnosed with the disease when he was 22 and recently celebrated his 53rd birthday, quickly recovered after his daughter’s intervention. “Taking part in clinical research is not something I’ve ever done before, but it’s really gratifying to know I’ve done something to help doctors find out more about links between Type 1 diabetes and family genes.”

Professor Simon Heller, honorary consultant physician at Sheffield Teaching Hospitals NHS Foundation Trust, said: “Type 1 diabetes is a potentially serious disease, which can be life-threatening if left untreated. Patients learn to manage the condition themselves but this involves a huge amount of effort throughout their lives and continued support from their families. This study will help answer some vital questions about the role genes play in the development of the disease, which could be of benefit to future generations. It may also lead to the development of therapy which prevents the onset of Type 1 diabetes.”

♦ To find out more email sht-tr.TrialNet@nhs.net.
♦ Read the full article online here: http://www.thestar.co.uk/news/health/research-hope-for-diabetics-1-5612580

Did you know…?
The CRF is involved in the biggest investigator led carotid intervention study in the world.

The Asymptomatic Carotid Surgery Trial (ACST-2) is a global multicentre portfolio study comparing stenting to surgery as an intervention for asymptomatic narrowing of the carotid artery. The study is looking at stroke rates over the 5-10 years post procedure. Recruitment is ongoing until 2014.

Finance Update
The CRF is cost neutral to both partner organisations, the University of Sheffield and Sheffield Teaching Hospitals NHS Foundation Trust and continues to develop a self-sustaining model of research support, whilst still insentivising clinical research for both researchers and Directorates.

If you have any feedback on the newsletter or would like to contribute to the next issue, we’d be delighted to hear from you.

Please contact CRF Senior Research Co-ordinator, Samantha Maher:
☎: 0114 271 5114
✉: samantha.maher@sth.nhs.uk

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