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Case study: The BASICS trial

The British Antibiotic and Silver Impregnated Catheters for ventriculoperitoneal Shunts multi-centre randomised controlled trial (The BASICS trial) led by Mr. Conor Laurence Mallucci, Consultant Neurosurgeon, Alder Hey Children's Hospital, received Health Technology Assessment (HTA) funding in excess of £2 million with support from the Research Design Service North West (RDS NW).

Hydrocephalus (commonly known as "water on the brain") is a condition that can affect all age groups from babies to the elderly. In hydrocephalus, there is an accumulation of the normal brain fluid within the fluid cavities (ventricles) of the brain. Untreated, hydrocephalus can be life-threatening. The commonest treatment involves an operation to insert a tube into the swollen ventricles to drain off the excess fluid. This is called a ventriculoperitoneal shunt (VPS). In the UK, 3000-3500 shunt operations are performed each year. One of the main risks of a shunt operation is infection (surgical meningitis), which results in the need for further surgery, antibiotic treatment and prolonged hospitalisation. It can have lifelong consequences, affect intellectual function and can be life-threatening.

Two new devices have been introduced to try to reduce shunt infection; antibiotic-impregnated (Bactiseal) and silver-impregnated (Silverline) shunts. This study will compare these new shunts to standard shunts in a study called a randomised multi-centre controlled trial. There has never been a similar trial to compare these shunts on such a scale. This will be a national trial recruiting 1200 participants from specialist neurosurgical units. The goal is to establish which VPS provides most protection against infection and the long term goal thereafter is to inform NHS policy and to ensure standardisation of care and infection rates across the country.

In addition, the research team will be exploring the impact that infection could have on participants in terms of hospital stay, post-operative complications and the potential cost to participants and the NHS. This team is well placed to carry out this research and already has experience of projects in similar settings.

A change of colour

You will notice the original red colour of the RDS NW being replaced by green. This includes this newsletter, our e-bulletins and our website. This change is due to the Research Design Service moving to the research programmes work strand within the National Institute for Health Research (NIHR).

RDS NW e-mail list sign-up

Why not sign up to our e-mail list to receive the latest in-



The project team received advice from the RDS NW in a number of areas including trial design and sample size calculations from frontline adviser Dr Steven Lane.

Health economics advice was provided by Prof. Dyfrig Hughes, senior adviser for RDS NW. The project team also asked for help in finding a collaborator and as a result Dyfrig agreed to be a co-applicant on the bid.

The nature of the advice given covered all aspects of the economics and an overview of the proposal. This included which costs should be included in the analysis, in this case it was an NHS perspective so these will be secondary care costs only, and include catheters, duration of intensive care stay and hospital admission, antibiotic treatment, and contact with health professionals. Resource use data will be based on entries in the hospital records, and analysis of Hospital Episode Statistics. Given that the economic question under consideration is one of technical efficiency, the advice was to approach this as a cost-effectiveness analysis, based on the incremental cost per shunt failure averted. Secondary economic outcomes will include: (i) incremental cost per shunt infection avoided; and (ii) incremental cost per Quality-adjusted Life-year (QALY) gained. Stratified cost-effectiveness analyses will be conducted on important, pre-specified patient subgroups (including neonates, patients under 1 year old).

News in brief

formation from the Research Design Service and health and social care, including events, funding news, our monthly e-bulletin and other relevant information. Sign up on our website home page at www.rds-nw.nihr.ac.uk.

RDS NW Patient and Public Involvement bursaries

If you are in receipt of RDS NW advice then you may be eligible for one of our Patient and Public Involvement (PPI) bursaries. These provide a small sum of money to help you incorporate PPI into your research design. For more information please visit www.rds-nw.nihr.ac.uk/public-involvement/ppi-bursary.



Patient and Public Involvement update

The Patient and Public Involvement (PPI) team

Prof. Soo Downe (strategic lead), Dr Sara Morris (Cumbria and Lancashire), Dr Paula Byrne (Mersey and Cheshire), Dr Tracey Williamson (Greater Manchester) are the PPI team for the NIHR RDS NW.

Soo has now settled in to the role as lead PPI strategic lead and the team has been meeting regularly. We are currently seeking to identify any gaps or areas for improvement around our PPI delivery. We will be looking at recent RDS NW satisfaction survey results and also will be seeking feedback or observations from advisers relating to their experience of clients' PPI needs. All our advisers possess PPI knowledge and are supported by the PPI team.

Our PPI bursary which provides a small amount of funds to support our clients in the PPI aspects of developing their proposals has recently had its guidelines revised to allow for more detail of what we are looking to be given in order to ensure enough information is provided for us to review applications. It is also intended to help researchers to think about best practice in PPI in research.

The PPI team is involved in the North West People in Research Forum - on the Executive committee, the Training working group and now on the newly formed Events working group. The first meeting of this group was in September 2012 and it aims to develop a programme of patient and public involvement and engagement events to be held across the North West.

A report of the role and value of patient and public

involvement and engagement in research event, which was held on 31 May 2012 in Manchester is now available. Around 100 people attended and Simon Denegri, Chair of INVOLVE and the NIHR's National Director for Public Participation and Engagement in Research gave the keynote speech. www.northwestpeopleinresearchforum.org/wp-content/uploads/2012/07/31-May-Forum-Event-Report-FINAL.pdf.

Selected news from INVOLVE

Developing Training and Support

www.invo.org.uk/resource-centre/training-resource.

This resource is for people who are planning training and support for public involvement in research. It offers advice and guidance to help develop training and support packages specific to your context – whether that's for members of the public, researchers or both.

INVOLVE's National Conference

www.profbriefings.co.uk/involve2012/index.html.

This conference takes place every two years and this year it is on 13/14 November 2012. The themes this time centre around how people are involved in research; learning and support for involvement; researching impact; and future directions. Tracey Williamson will be giving a paper entitled "Involving older people in inclusive design: Approach and learning from an ESRC New Dynamics of Ageing Research Study (Design for Ageing Well)."

North West People in Research Forum update

Events working group and INVOLVE conference

The Forum recently expanded its Events Working Group, inviting eight new members (four public members and four health care professionals) to join the existing membership. The Working Group's remit is to develop a programme of involvement and engagement events to take place over the next 18 months. They will meet every six weeks and will start by reviewing the results of the events survey that went out to the Forum membership earlier this year.

Next month the Forum will be presenting with two other regional patient and public involvement groups, People and Research South West and the South Yorkshire PPI Joint Strategy Group, at the bi-annual INVOLVE conference. Attendees will hear an update on the Forum's progress and reflections on the challenges, successes and the future of regional working in the area of patient and public involvement and engagement.

Call for new executive committee members

The North West People in Research Forum is currently looking for new Executive Committee members. This is a great opportunity to get involved in the work of the Forum and interested people who live and / or work in the North West are invited to apply.

The role description for Executive Committee members is:

1. To act as ambassadors for the Forum and for a collaborative approach to patient and public involvement (PPI) and public engagement (PE) in health and social care research across the North West of England. This might include giving talks, taking part in meetings or workshops.
2. To attend and take an active part in Executive Committee meetings. Meetings take place quarterly during normal working hours.
3. To be available for consultation (by phone or email) for matters arising between Executive Group meetings.
4. To read any background papers before meetings take place and to comment on papers and reports between meetings.
5. To oversee the development and implementation of annual work plans for the Forum, and to monitor whether the Forum is meeting its aims and objectives.
6. To take part in (and where appropriate to chair) working groups set up by the Executive Committee to take forward the aims of the Forum, and to report back on progress of the working group at Executive Committee meetings.

For more information, and to apply, see www.northwestpeopleinresearchforum.org/the-forum-is-looking-for-new-executive-committee-members.

Adviser spotlight: trials

I was fortunate enough to be given the opportunity to work for the National Institute for Health Research's Research Design Service North West (RDS NW) in January this year. For me, this is a part-time post, with a particular focus on research in dentistry and oral health.

The best part of the job is getting to meet new and interesting people. Being able to advise on research projects that have the potential to significantly change people's lives for the better is very rewarding. The cases I have managed to date have been in many different clinical areas, but the methodological advice I provide is widely applicable. I have advised on Research for Patient Benefit (RfPB), Programme Development Grant (PDG), Service Delivery and Organisation (SDO) and Health Technology Assessment (HTA) applications.

The most successful cases I have advised on have been with applicants who have a clearly identified research question; it's difficult to advise on an application that doesn't have clearly defined aims and objectives. The best methodology cannot make up for poorly defined research ideas.

For the remainder of my working week, I am employed as a Senior Lecturer in the School of Dentistry at the University of Manchester. I specialise in evidence synthesis and clinical trials, working towards improving clinical practice for patient benefit.

As statistical editor for the Cochrane Oral Health Group I have been heavily involved in a number of systematic reviews, with contributions to protocol development, analysis of studies, development of methodologies and write-up of reports. This covers both intervention and more recently diagnostic test accuracy reviews.

My research includes evaluating the prevalence and management of dental disease, clinical trials



Dr Tanya Walsh

into improving oral health in children, and cost and effectiveness evaluations of dental services. I teach biostatistics and research methods to postgraduate students at the University as part of the MSc in Dental Specialities programme. I am delighted to be able to use my experience to assist others with their research through the Research Design Service.

So if you think that your application could benefit from advice in any of these areas then I would be happy to help. Good luck with your application.

For advice on trial design please contact rds-nw@lancaster.ac.uk

The RDS NW self-help resources

The RDS NW website (www.rds-nw.nihr.ac.uk) is providing home to an increasing number of self-help resources. The resources aim to provide you with basic information on research design which complements our advice service.

Resources range from links to externally produced material to internally produced material in a variety of formats. They cover particular topics such as Patient and Public Involvement (PPI), provide case studies and links to useful tools. Examples of resources that we have to offer are shown below.

Interactive PPI how-to guide

LINK	DESCRIPTION	DATE
About the NIHR Research Design Service North West	These slides provide an overview of the NIHR Research Design Service and provide details about the North West region of this service.	September 07 2012
ECR's Successful applications: the methodologist perspective	This multimedia presentation is presented by a successful Programme Grant for Applied Research applicant (on numerous grants). It provides advice on areas including building the team and hints for the PI.	August 14 2012
From Programme Development Grant to Programme Grant	This multimedia presentation provides an example of a project that started with a Programme Development Grant application and then went on to develop into a Programme Grant for Applied Research application.	August 14 2012
PPI in Research Practice		

Link library

Multimedia presentations

To view a list of all of our self-help resources please visit, www.rds-nw.nihr.ac.uk/news-training-events/nihr-rds-nw-self-help-resources.

Funding deadlines

[Department of Health \(DH\) Policy Research Programme \(PRP\)](#)

Chronic Hepatitis 13th November 2012

[NIHR Research for Patient Benefit \(RfPB\)](#)

Competition 20 23rd January 2013

[NIHR Clinical Lectureships 2012 recruitment for medics and dentists](#)

Closing date 31st March 2013

[NIHR 2012 Dental Academic Clinical Fellowships Recruitment](#)

Closing date 31st March 2013

[NIHR Health Technology Assessment \(HTA\)](#)

Clinical Evaluation & Trials - stage 1 7th January 2013

www.netscc.ac.uk/funding/funding_timetable.xml

nihrcfcalls.tumblr.com/rss

Events

[Mental Health Network annual conference and exhibition](#)

London 8th November 2012

[INVOLVE Conference](#)

Nottingham 13th & 14th November 2012

[The NIHR Research for Patient Benefit \(RfPB\) research programme seminar](#)

Leyland 23rd November 2012

[Change by design: systems modelling and simulation in health care](#)

Exeter 26th & 27th November 2012

[iLINKS Innovations Annual Conference and Exhibition](#)

TBC 22nd May 2013

For further events in the North West and Nationally please visit the NIHR RDS NW website at: www.rds-nw.nihr.ac.uk.

Please always check the event or funder website for the latest information and dates.

Useful links and resources

Database of Instruments for Resource Use Measurement

www.dirum.org

Being a good research partner: the virtues and rewards

www.nhsconfed.org/Publications/Documents/HSRN_briefing_270.pdf

The National Research Register (NRR) Archive

www.nihr.ac.uk/Pages/NRRArchiveSearch.aspx

National Research Ethics Service (NRES)

www.nres.nhs.uk

The Cochrane Library - The reliable source of evidence in health care

www.cochrane.org

UK Clinical Research Collaboration (UKCRC)

www.ukcrc.org/patientsandpublic

Opportunities available within the Programme Grants for Applied Research programme

The NIHR is seeking to appoint new members, including Chairs, to serve on Programme Grants for Applied Research sub-panels.

They would welcome applications from clinicians and methodologists with a strong track record in applied health research and from members of the public who wish to contribute to the assessment of research proposals from a service user perspective.

Deadline for receipt of applications is 5pm on 5 November 2012

For further information visit the [announcement here](#).

Research for Patient Benefit Update

From Competition 19, the funding available for an individual RfPB research project will increase from up to £250k to up to £350k. Project duration can be up to 36 months. More information at www.rfpb.nihr.ac.uk.

For advice on any aspect of your research proposal please contact the RDS NW at rds-nw@lancaster.ac.uk.

Further contact details are available on our website at www.rds-nw.nihr.ac.uk.

