

NEWS FROM THE NETWORK

NHS

*National Institute for
Health Research*

Clinical Research Network



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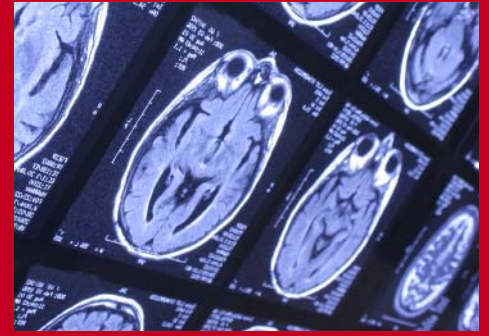
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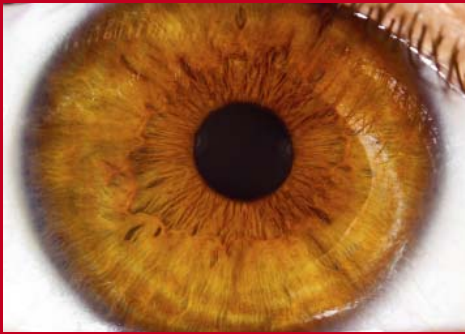
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The next level

October 2010 saw the appointment of a new Chief Executive for the Clinical Research Network. News from the Network talks to Dr Jonathan Sheffield about the current state-of-play in the research field, and his priorities for the Clinical Research Network for the future.

So, now that you've had chance to get to know the Clinical Research Network, how are you finding it?

Over these first months I've spent a lot of time just going out to different parts of the Network and talking to the people working in the Coordinating Centres or within the NHS itself, and that's been a really positive experience. I've been hugely impressed by the enthusiasm and commitment that's evident right across the organisation. We're facing a time of significant change for the NHS – and that will present challenges for everyone involved in delivering research – but we've got great people, and a strong platform to build on.

You referred to changes in the NHS – and presumably you mean the Health and Social Care Bill. What do you think this will mean for the Clinical Research Network?

The new Bill has attracted a lot of comment, and the situation is still fairly fluid, but it does seem inevitable that there will be major changes to the architecture of the NHS, and we will have to adapt to them. One of the key aspects of the Bill is the

idea that the provision of healthcare services will be opened up to 'any willing provider', so we're going to have to be very flexible in the way that we work, to ensure that new providers understand the importance of clinical research, so we can

continue to give patients every opportunity to take part in a study, no matter who carries out the treatment. I don't say it will be easy, but in some ways it does present some new and interesting opportunities.



Patient benefit. Jonathan Sheffield is motivated by the opportunity to help patients

“I genuinely believe that the Clinical Research Network represents a unique achievement in world healthcare”

“We want to see participation in a clinical research study become a standard treatment option for all patients across England”

But with so much focus on changes to commissioning, is there not a danger that clinical research is slipping off the political radar?

Obviously it is important that we keep working with all of our stakeholders to make sure we keep a high profile for clinical research, but I totally disagree there's a loss of political focus – it's actually quite the opposite. Last autumn's Comprehensive Spending Review put more money into the National Institute for Health Research, and you only have to look at the Government's recent Plan for Growth report to see how much attention is being placed on supporting the Life-sciences Industry. You could argue that recognition of the importance of clinical research is at an all-time high, and a lot of the credit for that must go to the Chief Medical Officer, Professor Dame Sally Davies, and her team.

So would you say that supporting the commercial Life-sciences Industry is becoming more of a priority for the Clinical Research Network?

Supporting Industry-sponsored research has always been important, but initiatives such as our Exemplar Programme – which we're now rolling out as business-as-usual – has sharpened our appetite for increasing the portfolio of commercial Life-sciences studies. We're also working towards achieving some stretching objectives around study set-up times and patient recruitment for commercial

studies, so the Life-sciences Industry is very much at the front of our minds, yes.

You mentioned objectives. What is the Clinical Research Network trying to achieve over the next few years?

We have three priority themes. The first is NHS engagement. We want to see participation in a clinical research study become a standard treatment option for all patients across England, and for that to happen, we need to form partnerships with the NHS at all levels, to make sure research really is seen as core business. One issue that we face is that the infrastructure for clinical research can seem complex, so we're going to be looking at how Networks collaborate with one another – and with NHS Trusts – to provide an easy-to-access, seamless service.

Our second theme is managing performance. The whole Clinical Research Network is now directing its effort towards a common set of objectives, based around speed of study set-up and achieving study targets for patient recruitment. NHS Trust R&D departments are our close partners in this, and we need to provide them with the right support, in the right way. Achieving the objectives is going to be tough, but we are funded by the public purse, so it's right that we should have to prove our worth. I would say we're now more focused on performance management than ever before.

“the real motivating factor for me is the chance to help patients....
...I've seen the positive difference that introducing clinical studies can make to patient care and patient lives”

The third priority is working smarter. Many NHS Trusts have transformed performance and productivity using 'lean' techniques to identify blockages and streamline systems, and there's much we can learn from that. We need to give our people the tools to hone performance, and take the Clinical Research Network to the next level.

You've talked a lot about the performance challenges ahead. What motivates you to take on these issues?

I genuinely believe that the Clinical Research Network represents a unique achievement in world healthcare. Yes, we all want the clinical research system to



All time high. Jonathan Sheffield believes clinical research remains high on the health agenda despite pending changes to the NHS
View a video of Jonathan Sheffield in our e-magazine online at www.crncc.nihr.ac.uk/resources/newsletters



grow and improve, but what we have is the envy of many other countries. But the real motivating factor for me is the chance to help patients. In my previous role as an NHS Medical Director I've seen the positive difference that introducing clinical studies can make to patient care and patient lives. The work we do is for patients, and we must never forget that responsibility.

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“we need to form partnerships with the NHS at all levels, to make sure research really is seen as core business”

Study addresses key question

Premature babies are born with under-developed immune systems and one of the major dangers they face is infection. MABN007 is a neonatal clinical research study exploring the effectiveness of an experimental antibody drug designed to strengthen premature babies' immune systems, thereby preventing them from getting infection. If this drug proves successful, it will boost premature babies' chances of survival, shorten their stay in neonatal intensive care and improve their overall health.

Dr Mark Turner, an Associate Director for the Medicines for Children Research Network and chair of the Network's AMR (Action Medical Research) Neonatal Clinical Studies Group, acknowledges the significance of the study:

"It recognises one of the most important problems for premature babies, which is infection due to the germs on our skin. We work hard to stop germs getting to baby, but we do feel insecure, because no matter what we do, infections can still take place."

Over 1550 premature babies took part in MABN007 in 93 sites across the world. The study was sponsored by the American biopharmaceutical company Biosynexus and closed to recruitment on the 1 December 2010. Eight sites in England recruited a total of 53 patients. Leading UK recruitment with 14 babies was Dr Paul Clarke, the study's national chief investigator based at Norfolk and Norwich University Hospitals NHS Foundation Trust, who was performing the role for the first time.

Dr Clarke embraced the opportunity, engaging patients and clinicians alike in the relevance and merit of the trial. Dr Jimmy Mond, Chief Scientific Officer and Executive Vice President at Biosynexus, was fulsome in his praise:

"There are almost no words to describe Paul's commitment and energy. He is remarkable."

In driving the study forward, Dr Clarke benefitted from close and supportive relationships from within Biosynexus, the Medicines for Children Research Network and the Comprehensive Clinical Research

"It's crucial that the Comprehensive Local Research Network funded dedicated time for me and my research nurse"



Triplets. Othniel, Sinead and Shivonne were born 13 weeks premature

Network. This was first demonstrated in August 2009 when initial problems in obtaining ethics approval led to a great deal of frustration, but equally a collaborative culture that produced an influx of support:

"I can't over state how helpful Dr Mark Turner was throughout," explains Dr Clarke. "His advice proved invaluable towards achieving ethics approval and although much of Mark's significant behind-the-scenes work and assistance is unrecorded, the expertise, knowledge and contacts he provided were vital."

Dr Mond jetted in from America solely to join Dr Clarke in attending the second ethics committee meeting. Following full ethics approval the study was soon up and running in the UK. The flying visit of the

Biosynexus Vice President set the tone for a study in which he provided an open line of communication to Dr Clarke:

"Close collaboration energises investigators, ensures data is of high quality and arouses enthusiasm in colleagues" explains Dr Mond, "This provides good PR for the job and gives us all a better understanding of how the study can be improved. It's also an exercise in good manners."

Additionally, Biosynexus operated on the very front-line of the study, monitoring and assuring delivery. The supervisory role was delegated to a Contract Research Organisation (CRO) enlisted by Biosynexus to oversee the study set-up and its day-to-day execution. One of the challenges facing Sarie Gilooly, a Senior Clinical Research

in neonatal care

“I was on the verge of throwing in the towel when I received a call from the Medicines for Children Research Network”

Associate for the CRO, was making contact with the right physicians. Sarie is grateful for the focus and direction the Clinical Research Network brought to the search:

“There seemed to be no route through which I could target neonatal specialists who were interested in the study”, she explains. “I was on the verge of throwing in the towel when I received a call from the Medicines for Children Research Network. From that point forth the study gained momentum and within a week they had provided me with 10 to 12 expressions of interest from enthusiastic sites.”

Sarie had no Network experience, so she needed guidance during set-up. The Medicines for Children Research Network provided support with NHS Permissions, ethics approvals and costing templates. She also received support from Comprehensive Local Research Networks who helped her adapt the study to achieve set-up in England.

When a pharmaceutical company seeks to expand a global trial into a new country it often needs adaptation. Dr Fiona Maxton, Senior Research Nurse Manager for West Anglia Comprehensive Local Research Network, explains how her team supported this process:

“UK and US instrumentation are not necessarily the same and we had to offer the funder guidance on the equipment they

were permitted to use in the UK. So, this meant we had to find equivalents and justify them.”

While MABN007 received administrative guidance from the Clinical Research Network, it also benefitted from staff support. When Dr Clarke’s neonatal research nurse went on maternity leave, the Norfolk and Suffolk Comprehensive Local Research Network helped maintain study continuity. Natalie Barber, Network Industry Manager for Norfolk and Suffolk, explains how:

“Paul simply did not have the time to support the study without a research nurse. Fortunately, a nurse within his team, Karen Few, stepped into the breach and our experienced Senior Nurse Research Manager, Clare Darrah, gave her the training she needed to perform the role. Karen has been well nurtured by Clare and remains in position as a full-time research nurse funded by the Network.”

Dr Clarke is clear that without the involvement of the Clinical Research Network, he would have struggled to carry out his role:

“It’s crucial that the Comprehensive Local Research Network funded dedicated time for me and my research nurse, because this provided us with the protected time necessary to carry out our research activities and achieve our recruitment targets. Their investment also supported our hospital with a research pharmacist and laboratory personnel, vital to local running of the study. The positive news for Norfolk and Norwich patients is that the neonatal team delivered. As a result, we’re able to invest in our research infrastructure and plan involvement in further high quality studies. This will give more patients the opportunity to take part in studies at our hospital.”

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Baby benefit

When Hope and Lydia Deih’s triplets were born 13 weeks prematurely at Norfolk and Norwich University Hospitals NHS Foundation Trust, their thoughts were focused on the well-being of their babies. Lydia explains how Dr Clarke addressed the subject of MABN007:

“I remember very little from that time, it’s all a bit of a blur, but one thing I do remember is that Dr Clarke had a nice approach from day one. So when he came to talk about the study we felt we could trust him.”

After giving it some consideration, Hope and Lydia decided their babies’ best option was to take part in MABN007:

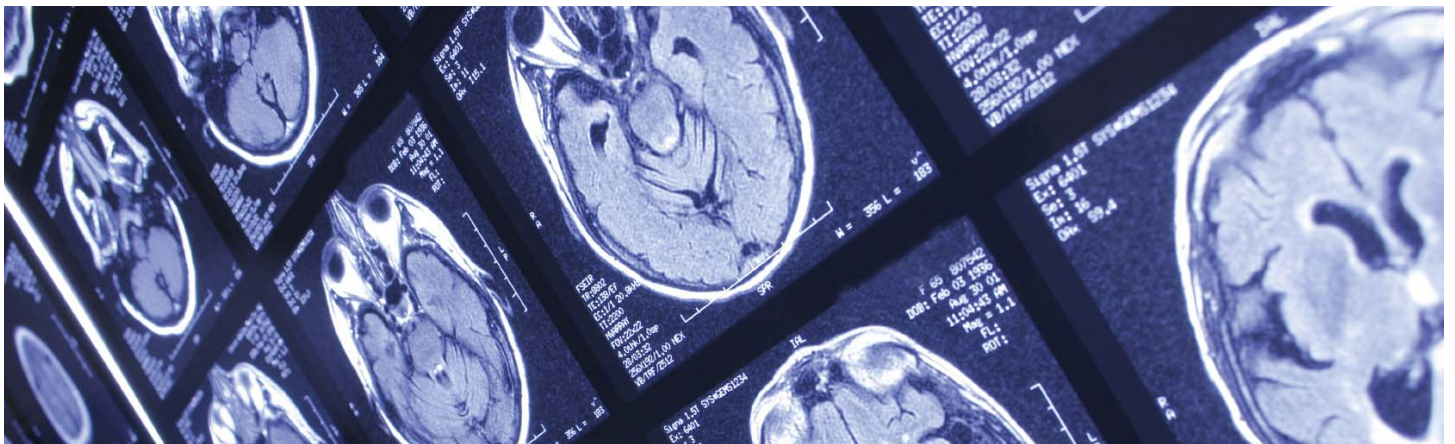
“The information Dr Clarke gave us was convincing and reasonable,” says Hope. “We thought it may help our children and would benefit premature babies in the future. With God’s grace, Sinead, Othniel and Shivonne are just over a year old now and doing well.”



Healthy. The triplets are over a year old now and doing well

Not just hype

Last June the Stroke Research Network launched eight Hyper-acute Stroke Research Centres across England providing patients with round-the-clock access to clinical research into breakthrough stroke treatments. One year on – and the future looks bright for hyper-acute stroke research.



Assessing the damage. Brain scanning technology is used to assess the severity of a stroke

When a stroke strikes the first few hours are critical. Early access to specialist treatment - known as 'hyper-acute' stroke treatment - can improve a patient's chances of recovery. Over recent years a number of NHS Trusts have developed dedicated 'fast response' stroke units capable of providing specialist 'clot busting' therapies within hours of stroke onset. This has had a major impact on stroke treatment, but until now there has been limited means to undertake research in this vital area.

Hyper-acute Stroke Research Centres are changing that by increasing research capability and capacity. The centres are staffed by multidisciplinary research teams - including clinical stroke specialists, research nurses, radiographers and interventional neuroradiologists - who provide out-of-hours cover in evenings and at weekends to ensure that any patient suffering a stroke can take

part in pioneering research at any time of day.

Manchester Hyper-acute Stroke Research Centre is based at the stroke unit in Salford Royal Hospital - an area covered by the North West Stroke Research Network which is managed by Judy Ford. She explains how research capacity has increased and the impact it's had so far:

"For example, before the centre was launched we had three part-time research nurses covering Monday to Friday, 9am to 5pm. Since then we've recruited more nurses - specifically with out-of-hours responsibilities. By November last year we'd achieved 7am to 7pm cover. Now we have 7am to 9pm cover and we've introduced an on-call rota until 11pm seven days a week. So if a Doctor identifies a patient for a study and gives them a patient information leaflet - they know that a research nurse will follow it up.

"It's already had an impact on the confidence of the clinical staff who are beginning to feel that research is embedded into care, rather than something extra. In terms of recruitment the figures speak for themselves. In the seven months before our out-of-hours service was in place we were recruiting on average just three patients per month to all hyper-acute, acute and sub-acute studies. Since November last year, when we began out-of-hours cover, that number has almost quadrupled to 11.2 patients per month."

The study that has benefitted most from the new arrangements in Salford is the SOS study. The average monthly recruitment at Salford was previously one patient per month. That figure rose to six per month once the centre was up and running. The Salford team even managed to recruit patients on both Christmas and New Year's Day. Sarah Pountain manages the SOS study. She reports that the study recruitment pattern has changed, not just in Salford, but across the country:

"The Hyper-acute Stroke Research Centres have opened up an area of research that couldn't easily be addressed before"

“our aim is for the UK to become a world-leader in hyper-acute stroke research and for more effective treatments to be available to UK stroke patients”

“We have definitely noticed an impact on out-of-hours recruitment. Before the Hyper-acute Centres were in place recruitment largely took place Monday to Friday, but since then patients have been recruited every weekend. This puts us in good stead to meet our 6600 recruitment target. But there are other studies that will also benefit; I think the research centres are having a positive impact across the board.”

This would certainly seem to be the case at the Nottingham Hyper-acute Stroke Research Centre where 2010/11 overall recruitment levels have increased by 34 per cent compared to the year before. Diana Havard, Senior Research Nurse for Trent Stroke Research Network, describes the changes to the research infrastructure in her region:

“It took until late autumn last year to get our full out-of-hours service in place but our nurses are now available to screen and recruit patients from 8am to 8pm during the week, and 8am to 4pm on weekends.”

Similar arrangements have been put in place at all the centres, which is great news for stroke patients. Brian Ward underwent out-of-hours ‘clot busting’ treatment before agreeing to participate in a study at Addenbrookes Hospital where the Cambridge Hyper-acute Stroke Research Centre has been established. He says:

“Having a stroke was a petrifying experience. I was so grateful for the speed of treatment and care that I received. The research that I took part in looked at how the brain heals and re-wires itself round the damaged parts after a stroke. It’s only by doing research like this that we can hope to improve treatments for other stroke patients in the future.”

Hyper-acute Stroke Research Centres have also been set up in Stoke-on-Trent, Newcastle and at Kings College, University College and St Georges’ Hospitals in London. Although the centres are relatively well spread across England, it’s important to make sure that the benefits are available to all patients - and the Network is uniquely placed to do just that. Jo McCormack is West Midlands Stroke Research Network Deputy Manager and Lead Nurse for hyper-acute stroke research. She explains how:

“Our Network area has three large Trusts; Birmingham, Coventry and Stoke-on-Trent. All three are able to deliver hyper-acute studies, but the Hyper-acute Stroke Research Centre is based at the stroke unit in Stoke-

on-Trent. Despite that, we consider the region as a whole where access to hyper-acute studies is open to all patients for equality of opportunity and continuity across the region. So we’re putting ‘hub and spoke’ models in place – firstly around Stoke, then Birmingham and Coventry. This means that smaller sites can refer patients to take part in hyper-acute studies – who can then be repatriated to their local hospital. Secondly and equally as importantly, we’ll make sure that the knowledge, learning and experience gained at the Stoke centre is disseminated to improve stroke care across the region.”

Dr David Sandler is a Consultant Physician in Elderly and General Medicine in Birmingham. He recognises that the Network has an important role to play:

“In Birmingham we don’t have the additional funding to become a Hyper-acute Stroke Research Centre and there has been concern about funded centres becoming isolated pockets of research activity. But being affiliated with the Stroke Research Network has already improved patient access to research no end in our region, which is important for stroke patients as individuals and stroke services on the whole. The Network has completely changed the way research takes place and I have no doubt that it will be key in ensuring equality of access to hyper-acute research for all

patients and also in distributing the learning from the Stoke centre.”

Since it was set-up in 2006 the Stroke Research Network has already doubled the number of patients taking part in stroke research. So what further developments should we expect? Professor Philip Bath is the Network’s Associate Director for Industry and the Clinical Lead for the Nottingham Hyper-acute Stroke Research Centre. He looks to the future:

“The Hyper-acute Stroke Research Centres have opened up an area of research that couldn’t easily be addressed before. We now have the required research capacity and capability and the early signs seem to show that it’s working. This puts the UK in a unique position to deliver this type of research to target and on time. That’s fantastic news for commercial companies – in fact the centres are already generating interest – so that’s even better news for patients. With the development of these centres our aim is for the UK to become a world-leader in hyper-acute stroke research and for more effective treatments to be available to UK stroke patients.”

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Keen to get involved. A stroke patient and SOS study participant with two nurses at Salford Hyper-acute Stroke Research Centre

Network GUIDANCE helps study meet recruitment targets

A major benefit of working with the Clinical Research Network is the support infrastructure you can gain access to. When the South East Midlands Diabetes Research Network set about supporting the delivery of GUIDANCE (UK) (Guideline Adherence to Enhanced Care), the primary care recruitment programme was largely structured around the movements of a mobile retinopathy screening clinic. When this clinic became temporarily unavailable, close collaboration between the study team and the Clinical Research Network meant the trial remained in a strong position to recruit to time and target.

GUIDANCE was an international study based in eight European countries that assessed the quality of care for type-2 diabetes and compared this to existing guidelines for treatment of the condition. Patients completed a questionnaire which provided an insight into their care and gave permission for the study to gather some basic information from their health records such as their height, weight and blood test results.

The study took place across Leicestershire, Lincolnshire, Northamptonshire and Rutland, in both primary and secondary care. It had a challenging recruitment target of 1000 patients, which was achieved as a direct result of a shift in recruitment planning and close collaboration between the study team and the Clinical Research Network.

Stephen Bosel-Doyle is a Research Nurse for the South East Midlands Diabetes Local



Preventable. Retinopathy is a complication of diabetes and can cause blindness

Research Network and is responsible for recruiting patients in primary care within Lincolnshire. He explains the importance of the screening clinic to GUIDANCE (UK):

“People with diabetes need to have their retinas checked as part of their annual health review, so a mobile retinal screening programme travelling around our region provided a fantastic recruitment opportunity. We approached practices on the route of the clinic to see if they were happy to support the study, and three expressed an interest. But when we were about to begin recruitment, the clinic was taken off the road.”

Without the mobile screening programme, Stephen needed to identify practices with their own diabetes clinics, and since only one of the sites taking part in the study had the service in place, the study team asked the Primary Care Research Network for support.

The involvement of the East Midlands and South Yorkshire Primary Care Local Research Network gave the study team access to a broader range of GP practices. In Lincolnshire, Stephen benefitted from the work carried out by Trent-based Locality Manager Nathalie Bailey-Flitter and Clinical Studies Development Officer Janice Wiseman to improve GP engagement in their area. They were able to recommend a number of sites for GUIDANCE (UK), two of which had diabetes clinics and could support the study.

In Leicester, Northamptonshire and Rutland, Locality Manager Janice Strand and Clinical Studies Development Officer Jane Robertson were engaged in a similar development project. As in Lincolnshire, this enabled the Primary Care Research Network to identify interested GP practices, which provided a broader range of recruitment opportunities.

“through our collaboration with PCRN we have gained access to more practices”

Jane Robertson feels the relationships that the Primary Care Research Network has with GPs, plays an important role in helping studies such as GUIDANCE (UK) recruit on time and to target:

“Part of my role involves providing a link between study teams and practice sites. I know who the study teams need to speak to, which saves them work, and I know the research areas practices are interested in, which makes the approach of the study team more likely to succeed. By providing a ready and trustworthy resource, practices come to rely on our service.”

The retinopathy screening clinic in Lincolnshire remained off the road for a year, during which time Stephen recruited from three GP diabetes clinics and the study team continued to recruit patients in secondary care. This meant that when the screening clinic did return, it remained possible for the study to meet its recruitment target.

The principal investigator for GUIDANCE (UK), Professor Kamlesh Khunti, who is also the Co-Director of the South East Midlands Diabetes Research Network, feels his ability to recruit from across the region reflects well on the development of the Network:

“We had our own contacts in Leicester, simply because we’ve been based in the community for some time, but Stephen is

“When I use a drug, I want to say ‘this works’ and I am in a better position to do that if I have been involved in its development”

the first Diabetes Research Nurse situated in Primary Care within Lincolnshire. It’s a new territory for us and through our collaboration with PCRN we have gained access to more practices, which means we can target the area for recruitment opportunities in the future.”

A scheme that is integral to the development of primary care research infrastructure in England is the Research Sites Initiative (RSI). The scheme is funded by Comprehensive Local Research Networks and supports practices that agree to contribute to Clinical Research Network Portfolio studies on a regular basis.

Practices are invited to apply for membership and, if successful, they receive funding to cover infrastructure costs. In return for this support they need to meet specific criteria, with a scale of payments allowing them to sign up to different levels of commitment. In East Midlands and South Yorkshire, the criteria for a practice at level 1 include delivering at least two Clinical Research Network Portfolio studies and at least one member of staff attending GCP training. Higher levels of the scheme include a requirement for the site to undertake more studies.

The Ibstock Surgery in Leicestershire is a level 1 site that took part in GUIDANCE (UK). GP and Research Lead at Ibstock, Dr Houghton, explains why she decided to engage with the Network:

“When I use a drug, I want to say ‘this works’ and I am in a better position to do that if I have been involved in its development. Initially, there was some reluctance on behalf of my senior partner to engage with research. He thought the studies would be driven by the needs of sponsors and not patients. But he sees the relevance of the studies that PCRN are

submitting to us and has seen the impact this has had on care and treatment.”

Since the surgery began supporting Clinical Research Network Portfolio studies, patients have responded enthusiastically. In fact, their reaction to GUIDANCE (UK) prompted an extension to the site’s involvement and an offer of extra staff support from the Primary Care Research Network:

“We were originally asked to support GUIDANCE (UK) for two weeks”, explains Ibstock Practice Manager Caroline Botham. “But midway through recruitment the study team asked if they could stay on for seven more days. Although we were happy to help, we didn’t have administrative support in place. Fortunately, the Primary Care Research Network provided a research assistant to facilitate the work and we were able to extend our involvement.”

This experience has ensured the Ibstock team will continue with their commitment to research, and look to progress to level 2 of the RSI scheme at some point in the future:

“Without research, we’ll never move forward”, continues Caroline. “By supporting research in our own practice we have developed a better understanding of our patients, and ultimately this benefits our community as it’s enabled us to treat people more effectively.”

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GUIDANCE. Network support ensures the study goes in the right direction

Singing the praises of breakthrough in bladder cancer treatment

More than 10,000 people are diagnosed with bladder cancer each year in the UK. Many of these suffer a recurrence of the disease if standard treatments fail and can often be left facing major surgery as their only option. But the Cancer Research Network is now supporting a study which is trialling a pioneering new treatment that could give patients an alternative.

Bladder cancer is one of the most common cancers in the UK and patients suffering with this high risk disease have limited therapy options. Despite this, there are few trials in this area because they are complex and difficult to run. The standard treatment is to put BCG (the vaccine for tuberculosis) into the bladder using a catheter - but it is only 50 per cent effective. If this fails, patients face a major operation to remove the bladder - often when they have other medical problems making them unfit for surgery. Plus, it usually means living with a urostomy bag for the rest of their life.

But with the help of the Clinical Research Network, a new treatment called thermo-chemotherapy is already providing patients in Middlesbrough with options they didn't previously have. The HYMN study, developed through the National Cancer Research Institute and funded by Cancer Research UK, is trialling this innovative treatment. It is available to patients with an aggressive form of the cancer that has a high risk of invading deeper into the body and spreading beyond.

Jo Cresswell is one of the principal investigators for the HYMN study and a Consultant Urological Surgeon at The James Cook University Hospital, part of South Tees Hospitals NHS Foundation Trust. She explains how thermo-chemotherapy works:

"We put a chemical wash into the bladder and then heat the bladder to 42°C using a special catheter with small

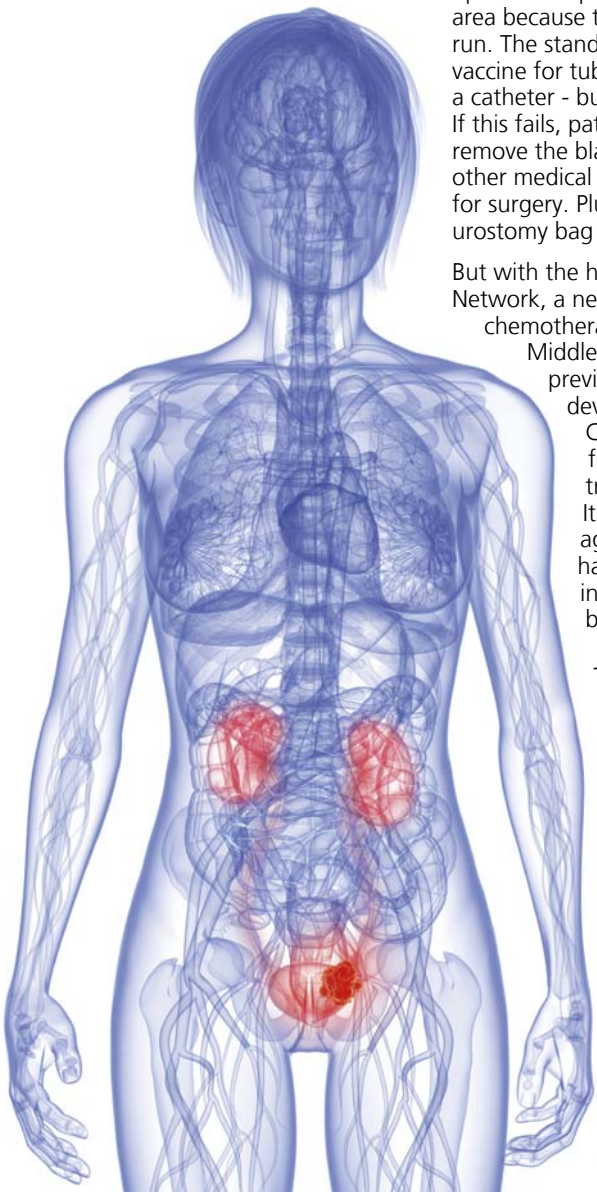
electrodes; this catheter has three channels which are inserted into the bladder. One puts the chemotherapy drug mitomycin C in, another removes it, and the final one heats the bladder via radio frequency to increase the take up of the drug."

This promising new treatment appears to improve the absorption of the chemotherapy - killing the cancerous cells. It has already been trialled in Europe where studies show over half of those treated in this way remain disease free after two years.

"it would have been impossible to run the study without Network support"

Patients who do not respond to the standard NHS treatment are invited to take part in the trial. They agree up front to be randomised to either continue with the BCG washes or begin thermo-chemotherapy. The HYMN study has reached its target to get 10 sites out of 20 open for recruitment in its first year and so far 30 patients have joined the trial. Eight of these have been recruited at the Middlesbrough site and four of those have received thermo-chemotherapy treatment.

Improving the odds. The HYMN study is providing bladder cancer patients with an alternative treatment option



This is good news for Jo Cresswell and her team who are motivated by the welfare of their patients. Their enthusiasm and commitment to the study meant that the first patient was recruited within a day of it opening. She points out how valuable this trial is to patients:

“This trial has been needed for a while and it has been frustrating not to be able to help some patients. Despite the fact that it’s a randomised controlled trial and patients may or may not receive the new treatment, they are still keen to participate because they don’t have many other choices if the standard treatment fails. They would rather a 50 per cent chance of getting the new treatment”.

But trials like this one are difficult to set up. Jo Cresswell explains:

“Surgical trials are infrequent because they are difficult to deliver as they are labour intensive and require expensive equipment. The Synergo system© had to be installed at Middlesbrough on loan as this provides the key heat-generating system essential to the treatment.

“Plus a study like this takes up a lot of clinical time, as each patient requires one treatment per week for six weeks, taking one hour of a clinical nurse and doctor’s time – that’s six hours per patient. And if the treatment is effective, booster treatments are given thereafter.”

Consequently, the Network support for this trial has been crucial. Jo Cresswell continues:

“We can’t deliver treatments in the context of normal clinics so it would have been impossible to run without Network support. Our Comprehensive Local Research Network covered the cost of the medical and nursing sessions, that is, a nurse and doctor to deliver the treatment. And the Cancer Research Network was a massive support in recruiting and counselling new patients.”



HYMN study team. Lynn Mudd, Lorna Braim and Tracey Whittingham with the thermotherapy machine

Jo Cresswell is emphatic that not only would it have been impossible to run the study in Middlesbrough without the Network, but also without the very motivated study team.

Paul Caster who is taking part in the trial was diagnosed with cancer in October 2009. After failing to respond to standard treatments, he was facing the decision to remove his bladder when he was told about the HYMN trial. He talks about his experience:

“I didn’t want to take the next step, so when I was told about this trial I was keen to be involved to avoid having my bladder removed. My illness is very embarrassing and a lot of people find it difficult to talk about, but the study team, in particular Sister Lynn Mudd, have made me feel totally relaxed throughout the treatment. I have now had the full course and I’m awaiting the results of my biopsies – I’m hoping for good results!”

He goes on to explain why this form of cancer is so devastating to patients and why the study is so important:

“The cancer and treatment is a huge imposition on my life. My company have

been very understanding but it is still difficult to manage, and it affects my partner too. If the cancer spreads we will deal with the consequences together but I don’t know how I’m going to feel; my life will change forever. This new treatment has given me hope and if it’s successful it will be better than winning the lottery. Put simply, I will get my life back.”

It is hoped that if this multicentre trial proves that thermo-chemotherapy works it will eventually be taken up as a standard treatment within the NHS - to the benefit of all patients.

Jo Cresswell reflects on the Network impact on the HYMN study;

“The Network was supportive, flexible and receptive to new ideas, they helped me work through the regulatory steps and necessary paperwork.” She adds, “the study wouldn’t have run without the Network”.

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“This new treatment has given me hope and if it’s successful it will be better than winning the lottery”

Harnessing enthusiasm and

The Clinical Research Network supports research across the whole spectrum of disease and healthcare. Areas such as cancer, stroke and diabetes remain high on the research agenda. But what about other medical specialties such as surgery, critical care and hepatology? These and other areas are also packed with research enthusiasm and expertise, which until recently has not been harnessed. The Comprehensive Clinical Research Network Specialty Groups are changing all that - and with impressive results.



Making research happen. Critical care is a challenging area for researchers

Specialty Groups operate on local and national levels and provide a forum for likeminded individuals to come together with the common aim of supporting and advancing research within their specialty. When Specialty Groups were introduced two years ago, many of the 26 groups started out with small research portfolios which, in most cases, was due to a lack of resources rather than a lack of interest. But in some cases it was simply because the research was difficult to do. Since then Specialty Groups have rapidly evolved and now offer leadership and clinical expertise coupled with the resources needed to make research happen.

Critical care is a fitting example. In 2008/9 just under 6,500 patients took part in 14 critical care studies across the entire NIHR Clinical Research Network Portfolio. Whereas the data collected so far for 2010/11 shows an increase to over 33,000 patients participating in 32 studies. West Midlands (South) Comprehensive Local Research

Network experienced a similar rise at a local level. Julie Norris, Lead RM&G Manager, explains:

“The number of patients in critical care studies in West Midlands (South) has rocketed from 48 in 2007/8 to over 2000 in 2010/11. Our Specialty Group work has provided the focus necessary to drive the research forward, but perhaps the most significant results can be seen in our work with West Midlands Ambulance Service where there was previously no research infrastructure or activity at all.

“There is a lot of scepticism around pre-hospital research mainly because it is so new - and getting paramedics research savvy can be challenging. But we’ve shown it can be done and we’re now the lead Network for the PARAMEDIC study which is a major NIHR funded trial and the largest pre-hospital

care study in the UK. With our support the Ambulance Trust has gone from zero to 180 patients recruited in 12 months.”

Professor Gavin Perkins is one of the study’s co-investigators and the local Critical Care Specialty Group lead. He puts the success down to the Network:

“Specialist areas often require specialist support. Investment from the Network via the appointment of a research paramedic working within the Ambulance Service has had a huge impact. It means they can get their colleagues on board as well as identify patients. That engagement with the Ambulance Service is crucial and would not have happened if there had been no resource centrally. It’s that combined with the leadership, coordination and communication that Specialty Groups bring that makes these complex trials possible.”

“with the correct level of support from the Network, we can accomplish a lot”

expertise

Surgery is another complex area for researchers. It spans all areas of healthcare so surgical studies often come under the heading of other medical specialties. Consequently it's a difficult research community to bring together, but by providing specialist support Kent and Medway Comprehensive Local Research Network have made significant headway. Lee Tomlinson joined the Network as a Specialist Researcher to help build and support the surgery research portfolio in the region. She explains how:

"We trawled the national Portfolio database for studies that we could contribute to. We also held two events; one last summer and one in February 2011. Around 25 people attended the first event, but that figure tripled for the second event - so we knew the message was getting through. We showcased research and generated a lot of interest. Surprisingly, many attendees were not aware of their colleagues' involvement in research. Next we had to keep the momentum going and my surgical nurse know-how really helped - knowing how to reach surgeons and anticipating the kind of support they would need. Sometimes I'd find myself hanging around outside operating theatres waiting for the surgeons so that I could speak with them face to face!

"The hard work is paying off now", continues Lee. "Two and a half years ago this Network was only participating in one surgically orientated cancer study. We now have six surgical studies open and two more in the pipeline at two new sites with two new principal investigators. Plus we have a further four at feasibility stage involving three more new investigators. So that's five new consultants on board at four new sites. And what's more, all four NHS Trusts in Kent and Medway are now involved in surgical



Overcoming obstacles. Surgery spans all areas of healthcare which makes it a difficult research community to bring together

research – that certainly wasn't the case before."

Gastrointestinal and General Surgeon, Haythem Ali, is also the Surgery Specialty Group lead for Kent and Medway Comprehensive Local Research Network. He works closely with Lee and contextualizes the achievement:

"It's often hard to put a surgery research question through the research process, and the outcomes are not easily tangible. Plus the Kent and Medway region is unusual because we have no university back-up; there's no professor of surgery to help grow the research base. We just have seven district general hospitals across 50 square miles. Despite that, the Specialty Group mechanism has helped channel our enthusiasm and we've shown that, with the correct level of support from the Network, we can accomplish a lot and build a substantial research portfolio from nothing."

The impact of Specialty Groups is not just felt locally. Lorraine Underwood is a Research Associate for Peninsula Comprehensive Local Research Network. Last year her Network supported a large observational musculoskeletal study which Lorraine showcased at the national Musculoskeletal Specialty Group meeting in September 2010. Six months later, at the subsequent meeting in March 2011, study recruitment figures had soared by over 1000 patients as a result of highlighting the study to the national group members - many of whom had contributed locally.

Lorraine continues to work across a number of Specialty Groups providing support where ever it is needed. When a recent hepatology study presented specific challenges, Lorraine had to call on all available resources:

"The STOPAH study was tricky. The patients involved were seriously ill so it was important that I worked with the Specialty Group lead to make sure the principal investigators knew exactly what they were taking on. Pharmacy was also a big issue and speaking to the director of pharmacy directly was key to unblocking the study. Then we

"the development of Specialty Groups over the last two years has been both successful and rapid"

had to use a 'hub and spoke' system to distribute the drugs from Plymouth to the other sites across Peninsula within a 48 hour window of a patient being recruited. Further complications included storage, temperature control, and organising the courier service to make sure the drugs arrived at the bedside on time."

Despite these obstacles the study is now open to recruitment. Jennifer Black, is a STOPAH Clinical Trial Coordinator at the University of Southampton Clinical Trials Unit:

"Lorraine has been fantastic in coordinating and communicating with the hub and spokes and maintaining the speed of set-up and motivation of those involved. Having that single point of contact is invaluable. Plymouth was the first of 12 hubs to be set up nationally. It was also the first region to get spoke sites open and recruiting."

So are Specialty Groups making a difference?

Although this national initiative is relatively new, the above examples clearly demonstrate that Specialty Groups are having an impact. A recent review panel comprising external input, stakeholder representation and Comprehensive Clinical Research Network representation, concluded that 'in overall terms, the development of Specialty Groups over the last two years has been both successful and rapid.' So whilst there is still much to do, the ongoing enthusiasm, expertise and commitment of the 450 members nation-wide means that we can expect further successes in the future.

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Primary challenge for diabetes research

In the last five years, a great deal of diabetes treatment has moved from secondary to primary care. This shift in environment has brought a new challenge for researchers: how do they recruit patients in GP surgeries when the majority of their contacts are based elsewhere? A global study supported by the North West Diabetes Research Network and Greater Manchester Comprehensive Local Research Network demonstrates how GP engagement, collaboration and effective study support can help to meet this challenge.

Study X, which recently closed to recruitment, took place in 11 countries, with six sites in the UK. Three of the sites were based in the North West of England where the North West Diabetes Local Research Network worked with the Greater Manchester Comprehensive Local Research Network to support set-up and delivery.

In 2007 the North West team addressed the movement of diabetes treatment from secondary care into the local community by recruiting Jane Davies as their Senior Research Nurse in Primary Care. One of the key aspects of the role was to engage frontline services with diabetes research:

“We needed to develop relationships with GPs interested in diabetes studies,” explains Jane. “The most effective way we had of doing this was collaborating with Primary Care Local Research Networks and Comprehensive Local Research Networks throughout the North West. Both have developed links with practices that we’ve used to better deliver diabetes research within the region.”

Study X came to the attention of the North West team at an interesting stage in their development. Having just recruited a research nurse with experience in primary care, they were keen to explore the impact an experienced diabetes research nurse could have on the delivery of a trial.

In this respect, close collaboration within the Network proved central to study success. The North West team and Greater Manchester Comprehensive Local Research Network have a close relationship and often discuss the development of research in the region. When Greater Manchester mentioned they were in need of a diabetes research nurse to support study X, it presented the North West team with the opportunity they had been looking for:

“The difference with a Network-supported study is that I get the help I need”

“It enabled us to show we could support diabetes studies in primary care,” continues Jane. “This was an important step in the development of our team and demonstrated the role experienced diabetes research nurses can play in the delivery of studies.”

Study X was a significant opportunity for the Greater Manchester team too. They had increased the number of GP practices supporting Network research in the region from 13 to 35 in three years. Led by their Industry Manager, Paul Hedgeland, they had achieved this rate of development by identifying ‘partner sites’ that were most likely to get involved and targeting high-profile GPs with the experience and contacts needed to help embed research within the community.

The Greater Manchester team offered practices two choices: they could become Patient Identification Centres (PICs), or hub sites. PIC sites agree to identify patients for a minimum of four studies a year, who then visit either primary or secondary care hub sites to take part in the research. Primary care hub sites have to host a minimum of four studies per year and, where appropriate, act as a PIC too. Together, the two types of site form a hub and spoke structure that has helped Greater Manchester provide more patients in the region with access to clinical research in primary care.

Health of the nation. Diabetes is one of the biggest health challenges facing the UK



“Giving patients access to studies in primary care is important for both GPs and patients. It helps us develop a better understanding of our patients and it gives them a better understanding of their own health”

When the sponsor approached Paul Hedgeland regarding study X, he recommended Dr See Kwok as a principal investigator. Dr Kwok had been a GP in Manchester for nearly thirty years and was a recent addition to Greater Manchester’s Network of sites:

“We really wanted Dr Kwok to support Network studies in primary care.” Paul explains. “She is an eminent GP with a vast amount of experience in delivering commercial studies in secondary care and has an array of local contacts.”

Not only did Dr Kwok have the ideal profile, she was based at the Barlow Medical Centre, which had patients keen to take part and research-ready rooms. But Dr Kwok did not have the staff to deliver the study and without the support of the North West Diabetes Local Research Network, she would not have been involved. Dr Kwok explains how the Network made a difference:

“I ran a study within primary care a few years ago, but that was independent of the Network and was difficult to support due to the amount of work involved.

“The difference with a Network-supported study is that I get the help I need. We now have a research nurse funded by the Network who assists me with study procedures.”

“Giving patients access to studies in primary care is important for both GPs and patients. It helps us develop a better understanding of our patients and it gives them a better understanding of their own health. Over the eleven years I’ve been involved in research I feel that my patients have become an extended family and I know from the conversations I have with them that they feel the same way.”

Study X was Dr Kwok’s first Network-supported diabetes trial in primary care, yet she managed to exceed her recruitment target of four patients. By enrolling ten people and randomising seven of them, the Barlow Medical Centre became the leading site for patient recruitment in the UK.

In total, Dr Kwok identified three of her seven patients through neighbouring practices. In doing so she introduced a new group of GPs to the Clinical Research Network and Paul Hedgeland is grateful for the exposure:

“By involving local practices, Dr Kwok has given more people in her region access to leading-edge techniques and treatments. It has also provided the practices with a valuable insight into research and given us an opportunity to explain the extra support and funding that they can access as a partner site.”

While the Network benefitted from Dr Kwok’s local knowledge, she gained more than purely staff support. Engaging with the Diabetes Research Network ensured everyone involved in delivery was trained in Good Clinical Practice. Jane Davies sees the relationship as an “interchange of knowledge that benefits us all, including patients.”

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Changing trends. Diabetes is increasingly managed in primary care

Making outcomes matter

Questionnaires are routinely used by researchers to give an insight into a person's mental health and to gauge the success of mental health treatments, services and packages of care. But sometimes patients have a different view to that of the clinician or researcher about which outcomes matter most. The Mental Health Research Network recently joined that debate by asking service users if, in their opinion, questionnaires do the job they're supposed to.



Standard practice. Researchers frequently use questionnaires to assess people's mental health

Service user involvement is intrinsic in mental health research because it's really all about the person's experience and, more often than not, the only way to find out if there has been an improvement or deterioration is to ask them. As a result, questionnaires - which are often referred to as 'outcome measures' or 'scales' - are widely used. But the Mental Health Research Network's service user community fed back that they were not happy about some of the questionnaires that were being used to assess their mental health, especially since the same ones were being used again and again. The Network responded by commissioning a piece of work to look at a range of outcome measures that are commonly used by both researchers and health professionals.

Mike Crawford, Clinical Psychiatrist and Researcher, led the project. He explains why this is such a important area:

"There is a lot of emphasis at the moment on finding out what mental health services achieve. So measuring outcomes is critical - to evaluate the quality of existing services, and also in research that is looking at the effectiveness of new treatments and interventions. But the very nature of mental health problems means that improvements can be difficult to gauge. They affect the way that a person sees the world, so someone who has mania may believe they have excellent health at a time when others would disagree. And a person who has been unwell for a long time may come to accept that this is how they usually feel and rate their health better than other people would. Plus, staff and patients may use different

criteria to judge whether a treatment has helped.

"Part of the problem is that the outcome measures are often developed by researchers, with little or no input from patients. Some projects rely entirely on ratings of patient outcomes that are made by staff. And while staff ratings can be very helpful, it is wrong to wholly rely on staff reports. This approach also undermines efforts to develop services that are centred on the needs and experiences of the people who use them."

The project focussed on two specific areas of mental health and invited 25 people to attend two expert panel meetings. The first panel examined measures of depression and social functioning and the second looked at scales used to assess people experiencing psychosis and measures of quality of life.

"the ways in which we gather that information need to be much more flexible and agile"

“We all have different points of view so it’s important to come together to make sure the research is worthwhile for those who need it most – the service users”

The panel members examined 24 different outcome measures in total and each was given a score out of ten.

Jenny Trite is a Service User Consultant for the North London Mental Health Research Network Hub and sat on the panel reviewing psychosis and quality of life scales. She agrees that the professional’s view can differ greatly from that of the service user:

“One of the questionnaires measuring medication asked ‘do you feel calmer’. The options were ‘yes’ or ‘no’, but often neither of these answers are correct. ‘Yes, I feel calmer’ might be a positive outcome for a researcher, but what if it’s detrimental to the service user’s quality of life? What is the point in being calmer, but feeling too tired to get out of bed in a morning? A yes/no answer doesn’t take into account the quality of life aspect. It should really include space for added comments.”

This was just one among a number of interesting findings. Some of the most widely used outcome measures were scored the lowest by the panel and the highest scores were given to scales designed to assess the side-effects of medication. Overall, only seven of the 24 scales scored seven points or more – the highest being just 7.5. Mike Crawford describes some of the points raised by the panel:

“A lot of measures focus on the negative. This is really common when a person is experiencing depression - they are subjected to question after question about how bad they are feeling. This can be very difficult for the patient and was reflected with low scores. In contrast, the Warwick-Edinburgh Wellbeing scale focuses on how good the person is feeling and how able they feel to contribute to normal life. Not surprisingly, this questionnaire was rated highly.

“Another misconception held by researchers is that people experiencing mental health problems don’t want to be asked to complete long questionnaires. But the panel reported that they are not impressed with very short measures and questioned how accurately they could assess difficult and complex mental health problems. Other

important points were also raised about questions being unnecessarily intrusive, and ensuring that the staff using the measures are properly trained.”

So do the results provide food for thought? Professor Shôn Lewis is an experienced mental health researcher, he says:

“It’s a valuable piece of work but there are some factors that have not been taken into account. For example, I would never use the Global Assessment of Functioning scale in isolation and the European Quality of Life scale might mistakenly be considered to measure ‘quality of life’ - but this is not the case, it’s a health economist scale. So it really depends on the context. Plus there are regulatory constraints which limit the choice of scales and measures available to us.

“That said, I think it’s the first step in an important debate. Our research relies on how the participant is feeling and the ways in which we gather that information need to be much more flexible and agile. If we’re trying to pick up change in a participant then we need to be moving away from paper-based scales. For a start they are open to recall bias – so you’re asking someone to remember how they felt as opposed to how they feel. We need to be more forward thinking and begin utilising sleep sensors, motion sensors and mobile technology such as smart phone, SMS and online applications that can provide real time responses and revolutionise research. Not just in mental health research – but across the board.”

There may still be some way to go but Mike Crawford hopes the findings will encourage researchers to take service user views into consideration when deciding what outcome measures to use:

“It’s important when we are planning the evaluations and studies that we speak to service users and

use their comments and recommendations to help guide us to use appropriate outcome measures. It’s only by doing this that we can expect to improve patient recruitment, retention and the quality of research.”

Jenny Trite agrees:

“Service users and patients don’t know it all, but neither do the clinicians. We all have different points of view so it’s important to come together to make sure the research is worthwhile for those who need it most – the service users. It’s essential to have this input in the beginning when the research is being designed to make sure the research is for the benefit of patients.”

A full report is now available now on the Mental Health Research Network website at www.mhrn.info/pages/publications and is due for publication in the Mental Health Journal later in the year.

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Inadequate. A ‘yes/no’ answer doesn’t take quality of life into account

Network support helps new relationships blossom

The Clinical Research Network is expanding, with the number of research sites in the NHS continuing to grow. This is positive news for society, with more patients getting the opportunity to access leading-edge techniques and treatments, and it's also of huge benefit to the Life-science Industry. With a broader range of locations to recruit from, Industry can reduce its reliance on established partners and use the Network's match-making skills to couple them with new sites that can set-up on time and recruit the patients they need.

A fantastic example of the work being done by the Clinical Research Network to support research can be found in Blackburn. In summer 2009 a project called the North West Exemplar Programme was initiated to demonstrate that the NHS could compete with the best countries in Europe in the performance of commercial clinical research.

One of the studies that took part in the Exemplar Programme was a Phase II trial for patients with mild-to-moderate Alzheimer's disease, with a site based at the Hillview Clinical Trials Unit (Lancashire Care NHS Foundation Trust) in Blackburn. Only two years previously Hillview had no track record for clinical research yet, remarkably, the site succeeded in delivering the study's first patient globally and met its recruitment target ahead of schedule.

Angela Parker, Assistant Manager for North West Dementias and Neurodegenerative Diseases Research Network (DeNDRoN) believes a number of factors put Hillview in a position to compete with the rest of the world in study set-up:

"Firstly, Hillview had an enthusiastic and driven research lead. Dr Iracema Leroi is the Consultant Psychiatrist in Old Age at Lancashire Care NHS Foundation Trust and has dedicated research time within her job plan to work on clinical trials and research. Additionally, the clinic teams at Hillview have been very supportive of our endeavours to embed research within their service and we have had excellent provision of support services, including imaging, pharmacy and cardiology, from East Lancashire Hospitals NHS Trust."

The study was the fifth commercial trial to be placed at Hillview and Dr Leroi is in no doubt that DeNDRoN has been key to the development of the unit:

Front-loading. A full Network research team supported Hillview Clinical Trials Unit during study start-up. Front row: Kerry Ward, Marianne Hare, Jenny Smith. Back row: Janice Birt, Nichola Verstraelen and Sarah Anderson



"I have a single research assistant, but other than that all admin work is carried out by DeNDRoN Clinical Studies Officers (CSOs) who are based in our offices and have a full-time presence in our work. Because the Network have a mobile team of researchers and CSOs, we also benefit from the fact that if someone is ill, they can ask another member of their team to step in and provide support.

"Another benefit is that Network nurses operate throughout Lancashire and as a result we can cast our net wide and recruit from across the region. If we were independent of the Network we would simply not be able to do this and I would not be in a position to recruit patients as I would not have the staff to carry out study set-up."

As with any commercial trial on the Clinical Research Network Portfolio, the study was supported by a lead Comprehensive Local Research Network, in this case Cumbria and Lancashire. Jill Martin, Research Management and Governance Manager for Cumbria and Lancashire, led the successful completion of global governance checks:

"It's my role to provide a central point of contact for everyone involved in the set-up of the study" explains Jill. "I maintain an overview of the process, synchronise activity and help study partners overcome problems should they arise."

Identifying problems early and solving them quickly is much easier if the Network, site and sponsor maintain open lines of communication. Jill feels a set of strong

"Network nurses operate throughout Lancashire and as a result we can cast our net wide and recruit from across the region"



Nurturing new sites. Research community benefits from Network match-making

relationships between the study partners supported this dynamic:

"No set-up is seamless, but the study was a prime example of partners addressing issues as they arose, which led to speedy resolutions. This made set-up simpler and paved the way for the study's recruitment successes."

With Dr Leroi providing leadership for research at Hillview, combined with the support of clinic teams, the Clinical Research Network and a collaborative sponsor, the study had every chance to succeed. But a crucial factor in its performance, explains Network Manager Lynne Owen, was the decision of North West DeNDRoN to change the way they supported set-up and delivery:

"Although our Network was stronger, we found the way we supported studies was staying the same. For this study we made a decision to take advantage of our increased capacity and top-load our resources. Essentially this meant supplementing our team at Hillview to create momentum during set-up, screening and recruitment. Hillview already had a lead research nurse, a research nurse and a CSO from the Network, but we provided two more research nurses to support their work and Angie Parker to oversee the project."

As we know, this change in approach was a resounding success, with study performance outstripping expectations. Not only did Hillview secure its target of 12 patients ahead of schedule, but when recruitment closed before the rest of the UK on 12 July 2010, the site had recruited 17 patients.

The study demonstrated that the growth of the Clinical Research Network is helping to improve the performance of clinical research

within the NHS. By placing a full Network research team at Hillview at study start-up, North West DeNDRoN established early momentum and put the site in a position to succeed. In the short-term, this was of benefit to the sponsor and the Alzheimer's patients at Hillview, but in the future Lynne Owen believes it offers further development opportunities for the Network:

"The benefit of this technique is that someone like Dr Leroi will be able to start recruiting her own team. She's planning to employ a clinical trials manager soon, which will make her more independent. We will work with the manager to make sure they have access to the same knowledge and understanding as ourselves, but in the long term, Dr Leroi will develop an independent unit and we can move on to another centre and fully engage them in the Network and its processes.

"Ultimately, even though we're talking about this process in terms of a business model, it is all about the patients. We want people who work with patients to care about them. Sometimes in our drive to meet deadlines, we lose sight of this, but patients are the focus of the Dementias and Neurodegenerative Diseases Research Network and remain at the heart of our work."

For more information about the Exemplar Programme go online and visit supportmystudy.nihr.ac.uk

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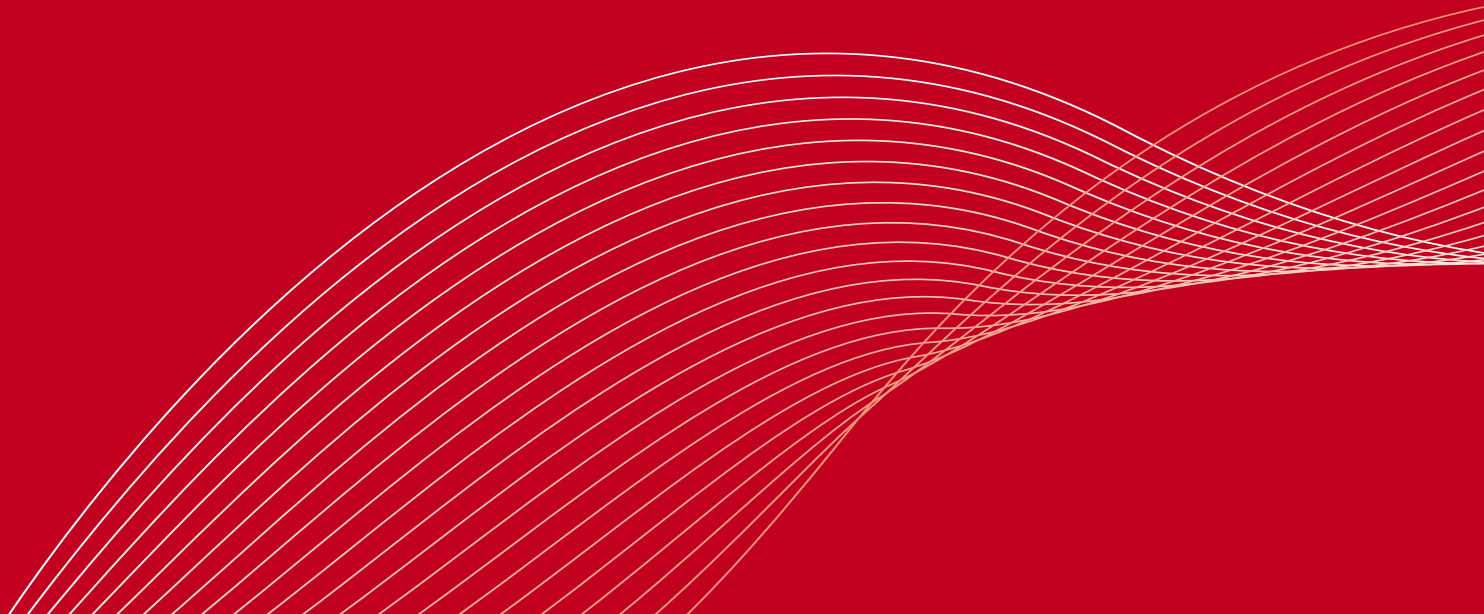
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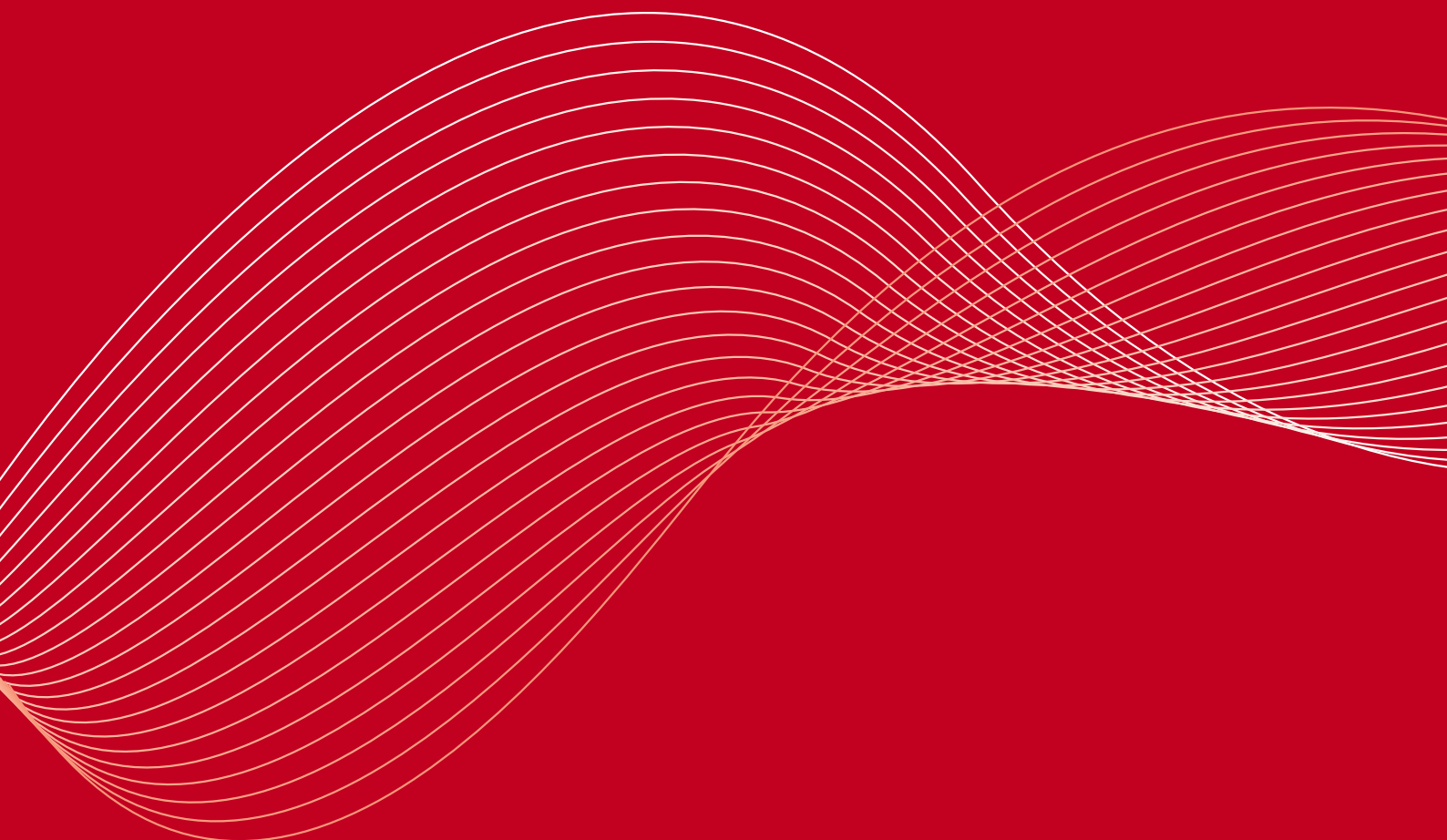
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The Clinical Research Network is part of the National Institute for Health Research. We provide researchers with the practical support they need to make clinical studies happen in the NHS, so that more research takes place across England, and more patients can take part.

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