

NEWS FROM THE NETWORK



IN THIS ISSUE:

Supporting a gear change
in Motor Neurone Disease
research

A fresh approach to
involving patients and the
public in research

The best prescription for a
heathy study

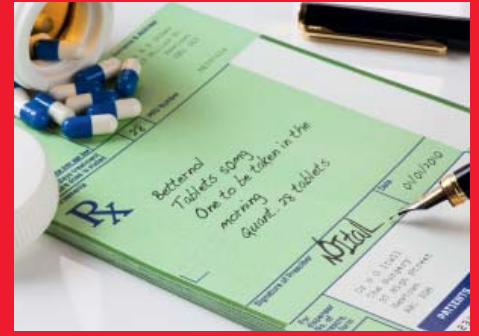
Contents



03 A fresh approach to involving patients and the public in research across the Clinical Research Network



06 Cancer Research Network collaboration is vital to study success



08 Primary Care Research Network is the best prescription for a healthy study



10 Medicines for Children Research Network helps children to benefit from broader protection from infectious diseases



12 Comprehensive Clinical Research Network gives study the Specialty treatment



14 Clinicians and researchers receive a helping hand from the Mental Health Research Network



16 Diabetes and Primary Care Research Networks take recruitment to new heights



18 Dementias and Neurodegenerative Diseases Research Network supports a gear change in Motor Neurone Disease research



21 Using the Stroke Research Network to get stroke rehab research on the right 'TRACS'

'Big society' is underway

The Government's 'Big Society' flagship policy aims to empower and encourage people to take a more active role in their communities. In terms of the patient and research communities, the NIHR has always placed the patient at its core and consequently the views of patients and the public have been intrinsic in the work of the Clinical Research Network from its inception. But in recent years the cultural shift towards involvement of patients, carers and the public in NHS activities, including research, has gathered momentum. So, as the drive for a patient-centred NHS intensifies, how is the Clinical Research Network preparing to step up to the mark?

Derek Stewart is the Clinical Research Network's Associate Director for Patient and Public Involvement (PPI). He explains what the term 'PPI' means in relation to the Network:

"It's about developing collaborative partnerships with researchers to improve research. It's about making sure research is relevant to the patient. It's about making a real difference to the patient experience. Ultimately it's about making sure that the research is applied in the NHS. It's not just about patients sitting on boards."

This is a far cry from the historical view of patients purely as subjects of studies and although the argument about involving patients has mainly been won, the benefits remain difficult to measure. This is especially true if done on an ad-hoc basis. To really determine the impact of patient involvement it needs to be done systematically. Based on its excellent track record of involving patients, the Clinical Research Network is developing a new 'Way Forward' to achieve exactly that.

The Way Forward was initiated following the review of the Topic-specific Clinical Research Networks towards the end of 2009. Although it was clear that some world-class work involving patients was taking place, it was also evident that each Network took a very different approach. The Department of Health asked for more coherence, coordination and collaboration. Consequently the Clinical Research Network PPI team has been tasked with developing a new approach to involving patients in



Derek Stewart discusses PPI issues during workshops in Leeds

research within the scope of the Network. Derek Stewart summarises the aims of *The Way Forward*:

"This is not a review of the quality or quantity of the work involving patients. It's about refocusing and realigning the work that's already happening. We want to show how it's done and what level it should be done to. But to do that we need to provide a structure to work within – so it can be better measured, monitored, evaluated and shared."

Work to develop *The Way Forward* comprises three stages. A period of consultation, now complete, was used to shape a set of recommendations. The recommendations form the basis of a business plan being prepared for the Department of Health. The business plan will then be implemented

across all eight Clinical Research Networks. The process so far has been incredibly successful. A multitude of people from both inside and outside the Network have been keen to contribute. Consultation mechanisms have included dialogue with a panel of people with broad expertise and knowledge of PPI issues, open workshops, plus an online survey which alone solicited 193 responses.

The workshops in particular have demonstrated an impressive range of perspectives from across the research environment. Ade Adebajo is a researcher, a consultant rheumatologist at Barnsley Hospital NHS Foundation Trust, and an honorary senior lecturer at the University of Sheffield. He describes how he has benefitted from taking on board patients' views:

"It's about making a real difference to the patient experience"



Ade Adebajo (left), researcher, describes how his work has benefitted from patients' input

"Involving patients has made a tremendous difference to my work. As a result of involvement I have identified studies, where I had assumed that the design was great, but patients point out little things that can make a big difference. So for example, that asking patients not to drink any alcohol might cause difficulties with recruitment. Or sometimes it might be more complex and requires changes to the study design to ensure we get the outcome that we want. I cannot speak too highly of their contribution."

As one would expect, there was also a strong patient and carer voice present in the workshops. Richard Stephens is a heart and cancer patient and a carer for his brother who has had a stroke. He's participated in three studies and has become an active patient representative. As such he's well qualified to give his views on why it's important not only to participate in research, but also to become actively involved:

"There are different ways to be involved in research. As one participant on one trial you might feel that you are not making a lot of difference, but the trials that I have taken part in have finished, reported and the treatments have been embedded as the standard treatment in the NHS. Even if the study looks at a treatment that turns out not to be effective, it has still answered a question, and others will benefit because they'll get a different treatment."

"More and more patients and public are becoming involved in the design and

approval of research, but also in the strategic decisions about healthcare. My message to patients would be to do the trials and get more involved with research. The skills that you need are an open mind, the ability to listen and the courage to say when you don't understand something and to ask; how does this help patients?"

Direct participation is one way of getting involved in research, but the patient's perspective is equally important.

"Patients are experts in their own illnesses," says Derek Stewart. "They provide a personal insight into a disease or condition and bring additional knowledge that only they have. They challenge assumptions that medical professionals may make and identify problems that researchers might not have anticipated. But not only that, they sometimes come up with solutions that researchers would not expect. Again and again we see evidence of this throughout the Networks."

The Way Forward has indeed highlighted some excellent yet very diverse examples of involving patients in research and, whilst aiming to achieve a coherent, coordinated, collaborative approach, *The Way Forward* also recognises the diversity of approaches that are necessary across the disparate Networks. Consequently many exemplars of successful work involving patients have been used to inform the process. Here are just a few:

Boosting Recruitment

Of the 2.8 million people with diabetes in the UK, one in 10 has Type 1 diabetes and requires daily insulin infusions for life. An opportunity recently arose for patients to inform and shape the early stage development of a new type of 'artificial pancreas', which could herald an end to insulin injections. The research team was keen to get input from those affected by Type 1 diabetes so they designed a survey to gather views and attitudes towards insulin delivery. But the study survey struggled over its first six months, recruiting less than half of the required 800 responses. The study team turned to the Diabetes Research Network (DRN) for help. DRN used their network of patient advocates to more than double recruitment to the survey in less than four weeks, adding more than 500 new respondents. Martin Lodemore is DRN's patient and public involvement officer. He explains why DRN's network of patient advocates is so important:

"A large part of the patient and public involvement role in our Network is about raising awareness of diabetes. That's why we developed a network of contacts. DRN patient advocates are people that we come into contact with at events, exhibitions, patient support group meetings and the like. They register their interest and select the level of involvement that suits them. So that might be to complete surveys and questionnaires, or to be a representative on a panel, or to take part in research, or any combination of the above. We keep their information secure so that when an opportunity like this one comes along we are able to circulate information to those wishing to take part, in this case in a survey. This could be an important study and the responses to the survey will inform the direction the study takes. The research team was keen to get the views of people affected by Type 1 diabetes, and those people were keen to take part, we just needed to bring them together. This is patient involvement in its truest form."

"Involving patients has made a tremendous difference to my work"

“Patients are experts in their own illnesses. They provide a personal insight into a disease or condition and bring additional knowledge that only they have”

Making research happen

The Medicines for Children Research Network (MCRN) has established groups of young people across the country to advise on research projects. Together these groups make up a 70 strong national Young Person's Advisory Group (YPAG). The YPAG was recently contacted by the UK Dermatology Clinical Trials Network (UK DCTN) for advice on whether or not young people would be prepared to take part in an acne prevention study.

UK DCTN develops ideas for independent dermatological clinical studies that will benefit patients. Carron Layfield is UK DCTN's manager and is responsible for coordinating the involvement of patients and the public in this process. When the study looking at acne prevention was proposed Carron knew that they would need to find out if young people would be prepared to take part. She contacted MCRN for advice and after learning about the YPAG she designed a survey for the young people to complete. Says Carron Layfield:

“The answer was a resounding ‘yes’. Forty young people completed the survey and 70% said they would be happy to participate in this acne prevention study. If the response had been ‘no’, we wouldn't have taken the idea any further so it was absolutely essential that we had input from young people. We're only in the very early stages but we're looking forward to working with the young people's group again as we develop this research idea further.”

Designing a patient friendly approach

The POETIC study is supported by the Cancer Research Network (NCRN). It is currently open in over 80 centres throughout the UK, recruiting around 100 patients per month. Patient representatives worked closely with the POETIC research team to enhance the study's management and design. This input was crucial in helping to overcome the challenge of approaching patients about the study at the same time as breaking bad news about a cancer diagnosis. Maggie Wilcox is a

patient member of the POETIC trial management group. She recalls how patients influenced the recruitment method,

“This trial was dependent on taking tissue and blood samples at the time of diagnosis. There was a lot of protectionism amongst the medical professionals. One surgeon said, ‘you can't possibly ask a patient to take part at the diagnosis stage’. I responded by saying, ‘you can't possibly not ask them. If you don't ask them you are denying them that choice.’ We suggested that they introduce the idea of research as soon as possible. So when the screening clinic sends letters it should let the patients know that they may be asked to participate in research.”

Patient representatives contributed to the content and language used in the study information leaflets and consent form. For the second stage of the study they helped the research staff to develop a patient-friendly approach and a system so patients didn't have to decide on the spot. Instead they were given a form and a stamped addressed envelope and adequate time to make a decision. By taking on board the patients' views the study team improved the patients' experience of taking part in the study and increased the chances of successful recruitment. Maggie

Wilcox continues to provide a patients' perspective on several trial management groups. She says:

“I have felt extremely valued and respected by all the people involved in the trial. I feel that I have an equal place at the table and if there is ever anything I don't understand I can ask for it to be explained to me in layman's terms.”

Work has now commenced to draw up a Network-wide PPI programme. The next stage will be to develop an implementation plan to provide detail around how *The Way Forward* is put into practice. Derek Stewart looks to the future,

“This is an opportunity to build on the experience and achievements of the last five, or more, years. It's where our work becomes even more focussed on improving research for the benefit of patients. The Government talks about building a ‘Big Society’, well we're already doing it, we're just not celebrating it. But that's all about to change.”

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Richard Stephens, patient, carer and research participant, contributes to workshop discussions



Collaboration proves crucial to recruitment success

For industry one of the biggest benefits of working with a Topic-specific Clinical Research Network is being able to tap into the expertise and support offered by Clinical Studies Groups (CSGs). One such CSG recently played an important role in the performance of an AstraZeneca sponsored study supported by the National Cancer Research Network (NCRN). As a result, the study overcame unforeseen obstacles and led the world in terms of recruitment.

A Clinical Studies Group is a UK-wide body of expert clinicians, scientists and consumer representatives who analyse the research landscape - in the UK and internationally - and decide which studies are needed to address the needs of their patients. CSGs then develop proposals for research studies to meet those needs and seek funding opportunities to finance them. Equally, CSGs consider studies that are proposed by other clinicians or by pharmaceutical, biotech or medical device companies and provide advice about their feasibility and how they may maximise their chance of success. CSGs also play an important role in running studies accepted onto the Clinical Research Network Portfolio.

NCRN works closely with the National Cancer Research Institute (NCRI) and both organisations share 22 CSGs. The Melanoma CSG recently played a significant role in study NCRN063 to ensure it met and eventually exceeded recruitment targets in the UK.

NCRN063 is a global, multi-site study looking at the safety and effectiveness of

an experimental drug for treating malignant melanoma. The drug is aimed at a minority of melanoma patients with particular characteristics in their tumour samples. Six UK sites participated in the study, with an overall recruitment target of 10 patients.

When NCRN063 opened in July 2009 it was expected that between 25-50% of patients screened would have the appropriate tumour type to be eligible for the study. By January 2010 study teams had screened 47 patients yet had only recruited four of the 10 patients required. With the successful screening rate running at only one in 12, there was a real chance that research staff could become disillusioned with the study. Jenny Gray, NCRN Industry Lead, explains:

“Recruitment was due to close, in all countries, in March 2010. To recruit to time and target we had to sustain a high screening rate and the key to this was keeping the study at the forefront of people’s minds. We achieved this with the help of Network managers, who maintained the profile of the study at recruitment sites, and by ensuring communications activities

were coordinated with AstraZeneca. But crucially, the study profile also benefitted from the influence of the Melanoma CSG. The Chair, Dr Paul Lorigan, and the chief investigator for NCRN063 in the UK, Professor Mark Middleton, communicated directly with principal investigators to support the study.”

Thanks to the concerted efforts of the Melanoma CSG, AstraZeneca and NCRN, screening remained high throughout all six UK sites. In the last two months of the study, the successful screening rate picked up markedly and study teams recruited 12 more patients. Ultimately this meant the UK led the world for recruitment, screening 69 patients and enrolling 16. This achievement is more significant given that a second commercial melanoma study, in the same patient population (NCRN058), was running at the same time and also delivered to time and target.

NCRN063 was one of the first AstraZeneca studies adopted on to the Clinical Research Network Portfolio. Ruth Coy, AstraZeneca Clinical Project Lead for the study, is clear about the benefits of working with NCRN:

“NCRN provided a coordinated process for admissions and approval. For NCRN063, this shortened set-up time meant that approvals were received only six days after full ethics approval. Sites were then able to get local approvals more quickly.

“The Network can also provide us with information about similar studies. If we found some of the sites were working on a study with a similar population, this could make the recruitment of patients more challenging. A positive aspect of Network



Dr Paul Lorigan chairs the Melanoma CSG

“The reason why the Melanoma CSG is having a positive impact on the set-up and delivery of studies, is down to the ability, enthusiasm and reputation of members, coupled with their willingness to collaborate and work as a team”

support is that they have access to a list of sites, with particular expertise, who are interested in taking part in clinical research. That kind of knowledge and support is extremely useful.”

CSGs are part of that support network and for Dr Lorigan, the expansion of the National Cancer Research Network is having a positive impact on the influence of the Melanoma CSG:

“Because the NCRN is increasing in strength, we are at a point where we can provide better geographical coverage of the UK, and maintain the profile and activity of studies in an increasingly competitive environment, guaranteeing timely delivery of good quality data.”

Professor Middleton sees the cohesiveness of the melanoma clinical research community and expansion of NCRN as key industry selling points:

“The CSG creates a forum in which clinicians across England can share information, which provides a coherent, nationwide approach. The effect is that studies have a Network-wide profile and we can recruit to studies across the UK. If you look at the sites in NCRN063, they all screened at least nine patients. In other countries, recruitment was much patchier because some centres succeeded and others didn't. All the centres in England contributed and our system is seen as more efficient as a result.

“This is vital in engagement with industry as we can use it as a selling point. We can say, ‘You get a coherent response to your trial from the UK.’ We police ourselves and if it's not going well within a centre the chief investigator will address any problems that arise.”

“the Melanoma CSG, NCRN and NCRI have a shared ethos: we all want to give nationwide access to new drugs”

Dr Lorigan agrees that melanoma studies benefit from a collaborative approach that unites the Melanoma CSG and the wider clinical research community:

“The reason why the Melanoma CSG is having a positive impact on the set-up and delivery of studies is down to the ability, enthusiasm and reputation of members, coupled with their willingness to collaborate and work as a team. It's similar to a top football team in many ways: it's all good and well having talented players, but if they fail to work together, with a common aim, they will not succeed.

“The same can be said for the wider research community in that the Melanoma CSG, NCRN and NCRI have a shared ethos: we all want to give nationwide access to new drugs. The reason why the Melanoma CSG works hard to adopt commercial studies such as NCRN063 onto the Clinical Research Network Portfolio is because Network involvement brings studies in line with this ethos, as it gives more melanoma patients in England the opportunity to take part in clinical research.”

The results of NCRN063 are eagerly awaited. It is generally agreed that developing several types of such targeted therapies – so that treatments can be matched to specific individual patients – will be an important step forward. However, Dr Lorigan feels the research community needs to find smarter ways of working and a more effective way of acknowledging the amount of work that

goes into recruiting patients to targeted therapy studies such as NCRN063:

“What needs to be recognised is that conducting studies into targeted therapies involves a great deal of time and commitment, which is not reflected in terms of recruitment figures. While only 16 of 69 patients screened were eligible for NCRN063, all 69 had to be seen, consented, screened, and then advised on other options if they were not eligible. This involves many hours of work for all of the team that is not subsequently acknowledged as research activity. A standard chemotherapy study with no patient selection based on molecular testing would have recruited most of the patients and these numbers would have been recognised as an example of high performance.

“Of course, we need to find smart ways around this and that's exactly what we are doing. In 2011 we will have studies that are appropriate for a limited number of patients conducted alongside studies that are applicable to a much higher number of patients. This is an excellent example of key investigators collaborating to resolve a problem, securing access to novel therapies and maximising opportunities for patients to be involved in clinical trials.”

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Prescribing the Network remedy

Supplementary Prescribing was introduced in 2003 allowing trained and registered nurses and pharmacists, among other medical professionals, to prescribe any medicine within the framework of a patient-specific clinical management plan agreed by a GP. Then in May 2006 Independent Prescribing by nurses, pharmacists and optometrists was introduced. This further extends prescribing responsibilities to any medicine for conditions within their competence, but excludes pharmacists from prescribing controlled drugs. Professor Marjorie Weiss is

Head of Pharmacy Practice at the University of Bath and the chief investigator of the Comparing the Consultations of Different Prescribers study which is funded by the Leverhulme Trust. She describes the rationale behind the study:

“We know lots about GP consultations but nurse and pharmacist prescribers are relatively new and less is known about their prescribing style. So this is a descriptive study which compares the communication and consultation styles of four types of primary care professionals; GPs, nurse prescribers, NHS pharmacist prescribers and community pharmacists. We plan to recruit 20 professionals from each group and to record 10 consultations from each, so that’s 800 consultations in total. The recorded discussions must be around the patient’s medication. And for each consultation a questionnaire will be completed by the patient to gather their views on the process of the consultation and whether or not it was satisfactory.”

“Also, there is very little support out there for new prescribers. This study will give us lots of data to analyse and ultimately we hope to use the information to develop a training tool to assist prescribers to hone their skills. We’re not sure exactly how it will work yet but we expect that it will be web-based and feature some of the anonymised examples from the consultations. So it will be a way of sharing good practice, but it will also be educational and could support ‘Continuous Professional

As patients we want to feel confident that we are getting the best possible care, whilst getting the treatments and medicines we need quickly and easily. Since 2003 the Department of Health has extended prescribing responsibilities to a range of health professions to improve patient access to medicines and to make better use of the skills and expertise of healthcare professionals. Until recently there has been very little work to evaluate how these new prescribers are doing. Now the Primary Care Research Network (PCRN) is helping to deliver a study which may well improve prescribing services to patients and could even help to set a benchmark for future prescribing standards.

Development’ which we know is an issue for nurse and pharmacist prescribers. They need to stay updated on the current issues and ideas around prescribing and this tool could go some way to addressing that need.”

PCRN has supported the study since it opened in October 2009. Ruth Riley is a research officer at the University of Bath and a member of the study team. She has been liaising with PCRN from the outset and gives her views on the progress to date:

“PCRN has engaged all the participants so far. They have been exceptionally proactive and responsive to our recruitment needs. They have also made sure that the practices can access the NHS Service Support Costs that they are entitled to and that’s really important to the practices. The main problem that we have encountered is that the NHS pharmacist prescribers are few and far between in primary care.”

NHS pharmacist prescribers that actually prescribe for patients do appear to be quite a rare beast. Often employed by a Primary Care Trust (PCT) or a GP practice, their role may include responsibilities such as medicines management, prescribing advice and pharmacy clinical governance roles. But without hands-on consulting and prescribing contact with patients they are not able to participate in the study. Other NHS pharmacist prescribers may work exclusively for a GP practice on a whole range of pharmacy issues including running specific clinics for patients. It’s this group that the study team needs to reach.

Peter Kirmond is an NHS pharmacist prescriber and strategic business manager at the Wellspring Surgery in Bristol. He runs

Since 2003 the Department of Health has extended prescribing responsibilities to a range of health professions



hypertension and diabetes clinics at his practice and reviews and prescribes patients' medication to make sure they get the best from their medicine. Peter heard about the study through PCRN and participated earlier in the year. He says:

"I read about the study in PCRN's bulletin and thought the study looked really interesting for a number of reasons; firstly because it's really very relevant to my practice and secondly because I'd heard they were having trouble recruiting pharmacist prescribers. But more importantly, when you go on the prescribing training it's quite intense. You learn about consultation theory and structure, and the consultations are videoed and watched back. But once you have that qualification it's hard to find relevant continuing education. I think it would be really useful to develop something that could help to refresh and fine tune prescribing skills and that keeps you up to date with new ideas around best practice."

"This is where the value of having a nation-wide Network lies"

Sarah Gallagher is an advanced prescribing nurse practitioner and a nurse partner of Portland General Practice in Cheltenham. She prescribes for acute and day emergencies, family planning and conditions such as asthma. Sarah is also the research lead for the practice and was contacted directly by PCRN to take part in the study. She believes that nurses, GPs, and pharmacists are very different animals and agrees that professional development is also an issue for nurse prescribers:

"As part of my initial training I had to observe 100 hours of GP prescribing. It was really interesting to compare the amount of information that a nurse gives and a GP gives. I think nurses definitely go into more detail about medicines and how they work, how to take them, and any possible side

effects. In addition to that training my PCT requires me to go on five prescribing updates per year. But there is very little out there and the quality varies. If this study leads to a developmental tool it would make a lot of nurse prescribers very happy. So I was pleased when the PCRN brought this study to my attention."

The challenge now for PCRN is to help make the study a success. To date the Network has helped recruit the full quota of GPs, 17 prescribing nurses and three NHS pharmacist prescribers. Jane Bridger, manager of PCRN South West, says:

"PCRN is uniquely placed to continue to support the study team to find the participants they still need. The first push got us over half way there and we're confident that we will engage three more prescribing nurses very soon. We weren't tasked with finding community pharmacists because the study team had their own contacts in that area, although we have made contacts where we could. But recruiting the NHS prescribing pharmacists is the bigger challenge - mainly because there are less of them. We've recruited three so far in the South West but we need to cast a wider net. This is where the value of having a nation-wide Network lies. The study team are now in contact with PCRN in Central England and Greater London about opening up sites further afield. Plus our experiences with this study have opened discussions about further collaborative work with the Royal Pharmaceutical Society in the future."

Professor Weiss praises PCRN's continuous efforts to overcome the barriers to recruitment:

"The PCRN hasn't sat back, they have been really flexible and proactive and adjusted their recruitment strategies accordingly. It would have been incredibly difficult to achieve this level of recruitment independently; the Network has definitely played a key role. They have done such a good job that we are now extending



Top: Peter Kirmond, NHS prescribing pharmacist
Bottom: Sarah Gallagher, advanced prescribing nurse practitioner

the study to Birmingham and London. This is good news because support for new prescribers is a hot topic. If we can eventually offer a resource which provides an opportunity for prescribers to reflect on their communication and consultation skills then this should improve the service that patients receive."

Tony Crockett is a GP participant in the study. He's a big advocate of PCRN, so much so that he has become the 'GP Champion' for PCRN South West - a role that involves encouraging and supporting other practices to become involved in the research offered by PCRN. He says:

"Building a community of confident prescribers would almost definitely reduce the burden on GPs and improve services to patients. And this is an excellent example of why PCRN is so important. In PCRN we can see that research in primary care is being properly funded and organised and measures are in place to ensure it is of the highest quality and relevant to those that matter most - the patients."

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"PCRN has engaged all the participants so far. They have been exceptionally proactive and responsive to our recruitment needs"

Children benefit from broader protection

For parents with babies under five years old, meningitis is a disease to fear – and with good reason. Meningitis kills more children under five than any other infectious disease in the UK, with 50% of all cases occurring in this age group. However, recent research into vaccinations, assisted by the Medicines for Children Research Network (MCRN), is already making a real difference to the protection of children against meningitis and other pneumococcal diseases.



Children in England are routinely vaccinated against meningitis and other pneumococcal diseases

Until recently, children in England were routinely vaccinated with a vaccine that protected against seven of the most common types of streptococcus pneumoniae bacteria – the bacteria responsible for causing invasive diseases such as pneumonia, blood poisoning and meningitis. But for one global pharmaceutical company, the challenge was to produce a vaccine that would include inactivated extracts from thirteen pneumococcal bacteria rather than just seven, giving children a much broader level of protection. The result of much painstaking research development work was a new vaccine, Prevenar 13.

Dr Matthew Snape is a consultant vaccinologist who played a major role in the research into the use of Prevenar 13. He explains:

“Vaccine policy in the UK is determined centrally, and we give our vaccines at different times to other countries in Europe or the US. That meant we needed to test the Prevenar vaccine here in England, to see if it would be effective when given as part of our particular immunisation programme. If it could be proven that Prevenar 13 was a better pneumococcal vaccine, and that it worked in our schedule, there was the potential to adopt it across the whole of England.”

For the research study to be a success it was vital that the investigative team was able to gather data in sufficient quantities – and that meant encouraging parents to consent to their child taking part in the research. With its expert, in-depth knowledge of NHS sites and study delivery, MCRN was able to help by recruiting children to the research study.

As a consequence of the study's findings, Prevenar 13 was proved to be a more effective vaccine and, as a result, it has now been adopted as part of the routine vaccination programme for all children across England. This means that children can

“In the case of Prevenar, we have a good example of how a study supported by the Clinical Research Network has directly influenced the health of every child”

benefit from a broader protection against pneumococcal disease. Says Matthew Snape:

“In many areas of medicine it can take a long time to carry out research and then see the results of that research come to fruition in a change to treatment. In the case of Prevenar 13, we have a good example of how a study supported by the Clinical Research Network has directly influenced the health of every child. That ability to make a difference in a relatively short timescale is one of the exciting things about working in the field of immunology.”

But that is not the end of the story, as MCRN is now supporting a new follow-up phase of Prevenar research.

In this new research study, researchers are going back to children who took part in the original trial, to examine the ongoing effects of Prevenar, and investigate how long immunity from pneumococcal disease persists after the vaccine is given.

With the help of MCRN staff on the ground, enrolment of children on this new study has been higher than predicted in research

centres at Oxford, Bristol, Southampton and St George’s Hospital in London, and the study seems destined to complete on schedule – a major concern for all researchers.

One of the interesting aspects of the study is that researchers are visiting the children in their own homes to carry out the blood tests required for the research. Whilst this does add to the logistical challenges of the study, it is also more convenient for parents and a less stressful option for the children than attending a hospital clinic. Another aspect is the collaboration between academic researchers and the pharmaceutical company, which is funding the study but not sponsoring it.

In all, MCRN believes that Prevenar represents a significant success story –

not only because it proves that research studies involving children can be carried out efficiently, but because it has led to a positive change in vaccinations. Says MCRN’s Assistant Director, Vanessa Poustie:

“Research is, and always has been, a core activity for the NHS, but in dealing with the day-to-day priorities it can be hard for health professionals to focus on activities that are about improving treatments for the future. This study, and others that we have supported, show that research isn’t just an academic exercise – it can, and does, result in positive changes for large numbers of children.”

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“This study shows that research isn’t just an academic exercise”



Prevenar vaccine gives children broader protection



Study gets specialty treatment

Ear, Nose and Throat (ENT) surgery is the third biggest surgical specialty within the NHS, employing around 600 ENT surgeons. It is also estimated that there are around one million ENT patient contacts in the health service each year. Yet until recently this potentially research rich field has remained relatively research poor. Now, with support from the Comprehensive Clinical Research Network (CCRN), one ENT study is paving the way to making the UK world-leaders in this area of research.

Also known as otolaryngology, ENT is the branch of medicine and surgery that specializes in the diagnosis and treatment of ear, nose, throat, and head and neck disorders. The enthusiasm and expertise of researchers in this and other specialty areas is key to the success of CCRN and to harness this CCRN has created 26 Specialty Groups. The 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.

Data taken from the Clinical Research Network Portfolio confirms that ENT is less research active than most other Specialty Group areas. In early October only 22 ENT studies were being supported by CCRN, whereas the same data showed Cardiovascular as the most active specialty area, supporting 213 studies. This includes all studies that are open to recruitment and those that are co-adopted by another Specialty Group or Topic-specific Clinical Research Network. Martin Burton is an ENT consultant at Oxford Radcliffe Hospitals NHS Trust and a clinical lecturer at the University of Oxford. He also leads the Thames Valley Comprehensive Local Research Network (CLRN) ENT local Specialty Group and is a member of the national ENT Specialty Group. He says:

"It's true that the national ENT Specialty Group has been one of the smaller Specialty Groups to date, although the number of members is growing. We are focusing on building the ENT portfolio of studies which we review when the national group meets and look at how members can contribute to the studies."

And that's exactly what happened with one Thames Valley based study which has since become one of the largest ENT studies of its kind, with a national and international

"It's a great example of the research funding following the research"



Chronic glue ear affects around one in every 20 children

profile. Mahmood Bhutta is a research fellow at the University of Oxford and the Medical Research Council's unit in Harwell. He is the chief investigator of the Genetics of Otitis Media study and believes that its success is down to the Network:

"I am a member of an international consortium which collaborates on similar studies. Our study is one of the largest for this disease in the world. There are studies of this kind taking place in Australia and the Netherlands which have been going for longer but their rate of recruitment is less. We are out-performing these other studies and I believe that is purely down to the Network infrastructure."

The Genetics of Otitis Media study is looking for potential genetic susceptibility to chronic middle ear inflammation (otitis media) in children, in particular a condition known as "glue ear". Chronic glue ear affects around one in every 20 children and may lead to hearing loss and delayed language development. Treatment requires small tubes called 'grommets' to be inserted into the ear and is the most common operation carried out on children in the UK. Mahmood Bhutta explains the potential patient benefit and the why the Network is so important:

"If we can find out which genes are triggering the condition then we may be able to develop medicines to target them. That could mean that 30,000 children per year won't have to undergo an operation."

“the Network puts us in an excellent position for the future. We have a real opportunity here to become world leaders for this type of study”

But statistical calculations tell us that determining the link requires DNA from at least 1000 families affected by the condition, that's approximately 4000 individuals. That's a big challenge and it simply wouldn't be possible without the Network. Thames Valley CLRN has supported us in a number of ways. They have provided staff who have increased our capacity to do the research locally but also they have provided the mechanisms to generate interest nationally.”

Martin Burton is also the clinical lead for this study, he explains:

“Thames Valley CLRN has been exceptionally responsive to our needs as the study has grown. We couldn't have done it without their support. Firstly by funding Jane Lambie – the lead research nurse. But then by providing the mechanisms to publicise this study across the country – through the Portfolio and the ENT Specialty Group meetings. Then, as more sites came on board, we were able to go back to the CLRN for more support to increase our capacity to manage and administer more centres and process all the associated paperwork etc. It's a great example of the research funding following the research.”

Jane Lambie is the lead research nurse for the study, paid for by Thames Valley CLRN. She says:

“I'm funded to support the study for its duration. Initially that was across eight recruiting sites in the Thames Valley area but before long we were fielding calls from around the country from sites wanting to contribute. This was good news because we had underestimated how long recruitment would take, but as more and more sites have come on board recruitment has accelerated.”

But the Network has done more than just generated interest. Sites outside of Thames Valley are also benefitting from Network support. Janet Wilson is a professor of otolaryngology and head and neck surgery at Newcastle University and an honorary ENT consultant at Newcastle-upon-Tyne Hospitals NHS Trust. She is also the lead for

Northumberland, Tyne and Wear CLRN's local ENT Specialty Group and, like Martin Burton, a member of the national ENT Specialty Group.

“It's definitely the Network that has raised awareness of this study,” says Professor Wilson. “But not only that, our CLRN has facilitated our participation here in the North East by funding expert paediatric research nurse sessions for one day a week to screen and recruit patients on the ward where children come for grommet operations. So it's the CLRN that made our participation possible. It's not always a large amount of money which can stand in the way of research activity – especially given current NHS pressures. For the first time the Network and Portfolio system make research cost effective for NHS institutions. That can be the difference between research happening or not happening.”

The study opened in April 2009 and by October last year had engaged over 500 families; more than 2000 individuals. It was open at 16 sites with five more in the pipeline. Mahmood Bhutta believes the success of this study could pave the way for further research:

“We hope the next stage of our research will be to undertake a genome-wide association

study where we would look to recruit at least 4000 children affected by ear glue. That's an even bigger challenge but the Network puts us in an excellent position for the future. We have a real opportunity here to become world leaders for this type of study and to take this research forward to the next level and look at developing medicines to target the condition.”

Professor Janet Wilson agrees and looks to the future:

“Historically there hasn't been much of an ENT research culture. But the NIHR Networks and other NIHR initiatives, such as the NIHR Fellowships scheme, are helping to change all that. The ENT Specialty Group in particular provides us with a forum to discuss and support studies by bringing them together in an ENT portfolio. It offers a system of mutual support and instils confidence that we will be able meet recruitment requirements because it gives us access to other ENT specialists and their patient populations. Plus it's more patient focussed. We still have a way to go but it does bring a real sense of hope for the future of UK research.”

More info about this article:
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Left: Mahmood Bhutta, chief investigator of the Genetics of Otitis Media study
Right: Jane Lambie, lead research nurse, recruiting the very first family into the study

MHRN helps clinicians and researchers to work hand-in-hand

A pilot scheme organised by the Mental Health Research Network (MHRN) in East Anglia is providing trainee psychiatrists the opportunity to get involved with one of the region's key psychiatry research projects.

For the first time, under the East Anglia Hub Trainee Psychiatrist Scheme, the interests of individual trainees can now be matched with on-going research projects within the East Anglia region, giving junior clinicians the chance to gain valuable hands-on research experience within a real project, and providing research directors with suitably qualified staff to implement the research projects.

The scheme is being spearheaded by Dr Jesus Perez, a consultant psychiatrist with Cambridgeshire and Peterborough NHS Foundation Trust and Hub lead for East Anglia MHRN. It offers up to six trainee psychiatrists the opportunity to work alongside some of the UK's top researchers on one of around 40 studies and trials being undertaken throughout Bedfordshire, Cambridgeshire, Suffolk and Norfolk.

Dr Perez had observed that trainees were struggling to find research projects to match their interests, and identified that the MHRN Hub could play an active role as coordinator to not only match students with relevant projects, but also to help researchers secure the essential clinical expertise and experience that they need to complete their research.

As he explains, this approach delivers a win-win situation for both trainee and researcher:



Senior registrar Antonio Metastasio reviews patients files for the SEPEA study

"All trainee psychiatrists should look to get some research under their belt to help improve their employment prospects when they qualify, and this initiative effectively helps match trainees with their preferred area of study. The researcher gains a clinician to help support their research, and the trainee secures valuable and relevant experience.

"However, we recognise that sometimes, there might not be an exact match between a trainee's interests and a particular project, so our role is also to facilitate discussions between the two parties to ensure that the skills that the trainee brings to the project are well-utilised," adds Dr Perez.

One such trainee is Antonio Metastasio, a senior registrar with the Cambridge and Peterborough Foundation NHS Trust. Dr

"it is a fantastic opportunity to be involved at the cutting edge of research"

Metastasio applied to join the scheme and was put in touch with the Social Epidemiology of Psychoses in East Anglia (SEPEA) study, which examines effective mental health service provision in diverse, rural areas and is being coordinated by Dr James Kirkbride, who is based in the Cambridge University Department of Psychiatry.

The study looks at how social factors influence psychotic disorders in diverse, rural populations. As a clinician, Dr Metastasio supports the research by reviewing the files of patients who have presented with a potential first episode of psychosis, and giving each patient a score using the OPCRIT system, a standard designed to facilitate a polydiagnostic approach to mental illness.

His involvement with the research has required a significant time commitment, but he is confident that the skills he is practicing will give him an extra insight into this area of adult psychiatry. For Dr Metastasio, securing these strong research credentials will be a huge asset for the future in a competitive jobs market.

“Being involved in this study does require several hours’ commitment each week, not only examining patient records but also reading around the subject, so it is not a task to be undertaken lightly, but for those with a particular interest in research, it is a fantastic opportunity to be involved at the cutting edge of research,” adds Dr Metastasio.

Although Dr Metastasio does not come into direct contact with the patients, his analysis of the patients’ notes is increasing his personal understanding of early stage psychosis, which he recognises as one of the core challenges faced by adult psychiatry professionals. He says:

“Analysing the patients’ notes have given me a greater understanding of the importance of recording all the relevant information to

the diagnosis; there are a number of key questions that need to be answered when patients present with potential early-stage psychosis, but often these answers are not correctly or appropriately recorded – and this, itself, is a valuable finding that we can feed it back to practitioners to assist with continuity of care for patients as they move through the mental health support structure.”

Although the scheme has initially only been open to trainee psychiatrists, Dr Perez believes that it can easily be expanded to involve other professionals, such as psychologists and nurses who can bring a different perspective to the research:

“The closer we can bring practitioners and researchers, the better it will be for psychiatric treatment across the NHS, and if we can further extend this to cover not only clinicians but also all those involved in different aspects of psychiatric care, the benefits are multiplied.”

A number of other MHRN Hubs are looking at instituting similar schemes to team up clinicians with researchers, and Dr Perez hopes that the scheme will achieve a national roll out in the coming years:

“Matching research projects and students can be quite time consuming, but it does have clear benefits to not only the participants, but health services as a whole, as it helps deliver psychiatry professionals who carry their interest in research throughout their careers.”

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Dr Jesus Perez is spearheading the East Anglia MHRN Hub Trainee Psychiatrist Scheme

“The closer we can bring practitioners and researchers, the better it will be for psychiatric treatment across the NHS”

ASCEND: taking recruitment to new heights

Diabetes is one of the biggest health challenges facing the UK today. By 2025 it is estimated that more than four million of us will have the condition. Predominantly treated in primary care, it's an issue faced by GPs every day and if not well managed diabetes can lead to serious complications including heart disease and stroke. Aspirin is known to reduce the risk of these complications in some people but can also have negative effects. It's unknown whether the benefits of aspirin outweigh the risks for diabetic patients with no history of cardiovascular disease. Two Clinical Research Networks have been working together to support one study hoping to answer this important question.

Jane Armitage is a professor of clinical trials and epidemiology and an honorary consultant in public health medicine at the Clinical Trial Service Unit and Epidemiological Studies Unit at the University of Oxford. She is also the chief investigator of the ASCEND randomised trial and explains the aim of the study in more depth:

"About 80% of people with diabetes don't have complications but their risk of heart attack and stroke is considerably higher than for someone without diabetes. Taking aspirin every day can reduce that risk by 25%, which would seem like a good statistic. But aspirin can cause other problems such as increasing the risk of bleeding. So it's not clear if diabetic patients who haven't yet suffered a heart attack or stroke should be advised to take aspirin as a preventative measure. ASCEND is trying to work out the risk/benefit balance."

With diabetes reaching epidemic proportions it's estimated that the cost to the NHS is £3.5 billion each year, that's over £9.6 million per day, so the potential impact of this study for both patients and the health service is huge. For this reason the study set out to recruit at least 10,000 participants and follow them for five years to ensure that the findings are based on sound evidence. Once recruited, participants are randomly allocated to take aspirin or placebo and, separately, omega-3 fatty acids (fish oils) or placebo on a daily basis. If favourable results emerge it could lead to the widespread use of these treatments in diabetes and avoidance of thousands of strokes and heart attacks and associated treatment costs.

ASCEND opened to recruitment in 2005 before the Diabetes Research Network (DRN) existed. Dr Louise Bowman, ASCEND's clinical coordinator, describes how the study team began engaging patients:

"We searched registers of diabetes patients held in secondary care hospitals and sent invitation letters out to patients. But this method alone just wasn't achieving the expected numbers. We needed to tap into primary care. We tried to contact GPs but because we are an academic organisation we didn't get a great response. Plus, it needed a personal touch."

By 2007 DRN was up and running and recruiting to ASCEND. Sharon Parsons has managed Thames Valley DRN, where the study team is based, from its beginning. She recalls how they built links with GP practices before the Primary Care Research Network (PCRN) was set up:

"ASCEND was one of the first studies we worked on locally. Prior to PCRN there was a small primary care facilitation team in place. We worked with them by pairing up our DRN nurses with their facilitators. They introduced us to practices, which gave us a foot in the door."

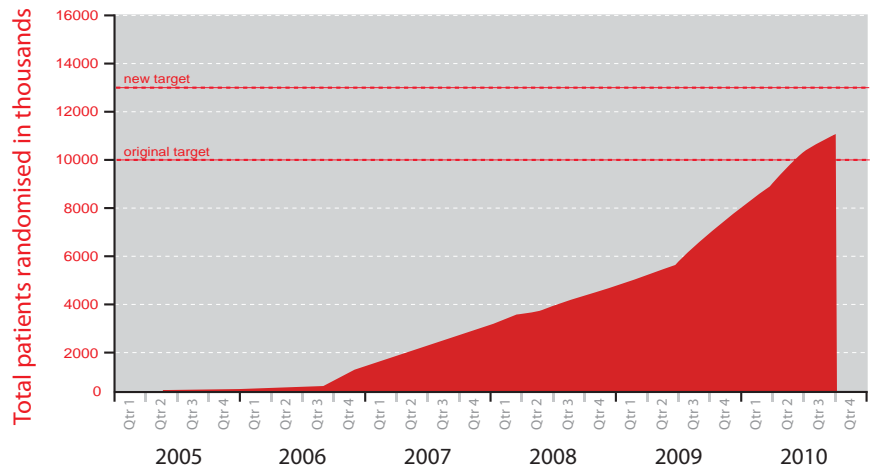
Recruitment rates began to improve but there was still some reluctance amongst GPs because of concerns over the regular use of aspirin. But then a couple of things happened in the study's favour. Firstly, some smaller studies reported conflicting evidence about the potential benefits of aspirin - which put ASCEND firmly on the research agenda. Secondly, PCRN began supporting the study in 2008. As the Network grew, so did the number of patients entering the study. Terri Harding manages PCRN Northern and Yorkshire. She recalls:

"It worked both ways because ASCEND was a straight-forward study; a gentle introduction to research for the practices, and the ASCEND team was keen to promote the study. Plus with our official branding we became more visible. Our remit was clear and the practices became more trusting and ready to participate and wherever possible we'd also introduce DRN staff to the practices and build relationships that way."



People with diabetes have an increased risk of suffering a heart attack or stroke

ASCEND recruitment figures



Diabetes Local Research Networks do not cover the whole of England but with DRN and PCRN joining forces the study now had total coverage of England and recruitment began to accelerate but then ASCEND reached a pivotal point. Louise Bowman explains:

“As we drew close to recruiting 10,000 patients it became clear that the incidence of heart attacks and strokes was lower than expected, probably because of the use of other effective treatments like statins and blood pressure lowering. So, to get a reliable answer to this extremely important research question, we needed to try to recruit more participants and follow them for longer. But our main funder, the British Heart Foundation, stipulated that we had to recruit the planned 10,000 patients within a certain timeframe before they would consider an extension. That simply wouldn’t have been possible without the Networks. They helped engage the final third of the total patients in a much shorter period comparatively. Between DRN and PCRN they identified 380 practices and sent nearly 60,000 invitations

“it’s this joint working at the local level that underpins our success”

to patients.”

Consequently ASCEND reached its 10,000 target on time and has been expanded to recruit 15,000 patients and follow-up will be extended to seven years. The study will continue to receive Network support but do the Networks still work together in the same way? Sharon Parsons believes they do:

“The same principles apply. Where the two Networks overlap the DRN nurses link up with their PCRN counterpart. PCRN have more knowledge of the practices’ research interests and workloads so we work together to decide which ones to approach. There is an agreement between DRN and PCRN

about this - PCRN will always make the first contact.”

Sarah Daniel, PCRN clinical trials coordinator for Durham and Teesside, has worked on ASCEND from the outset. She agrees:

“The main thing that has changed is the amount of studies we support. So we can’t afford the luxury of joint visits but we still work collaboratively, perhaps in a more targeted way. Our local knowledge has increased over time and it’s this joint working at the local level that underpins our success. In the North East we regularly meet with our local DRN team and discuss joint DRN/PCRN studies on the Portfolio. We recently considered how we might further boost recruitment to ASCEND. We decided to refocus on GPs that have not been contacted for a couple of years to see if they have new or existing patients that might be eligible to participate now but weren’t before.”

The Thames Valley DRN team also came up with innovative ways to engage more patients. Says Sharon Parsons:

“Every time we push the study the pool of potential participants becomes smaller. We began to feel that we’d exhausted primary care in our area. We thought the study team had secondary care covered but we realised that not all hospitals had taken the study on. We had to assume that they didn’t feel they could contribute at the beginning. But a lot has changed since then. We’re currently working with four new hospital sites that are now keen to contribute.”

By mid November almost 12,000 patients had joined ASCEND and the figure is increasing each week. Louise Bowman expects the study will reach its new target by mid 2011. When asked ‘what are the benefits of working with the Networks?’ she replies:

“Their route into primary care; their ability to identify and engage GP practices is invaluable. They are able to build relationships in a way that study teams cannot. Plus they were able to identify and overcome teething problems and obstacles such as accessing NHS Service Support funding for the larger practices to cover the costs of taking part.”

Dr Matt Hackett is a GP at Weardale Practice – one of the first GP practices that Sarah Daniel recruited into ASCEND in 2007. Sarah’s first visit was a joint visit with a DRN nurse but she has recently returned alone to ask the practice to do a second search for eligible patients. Dr Hackett feels he wouldn’t be able to contribute without PCRN’s support:

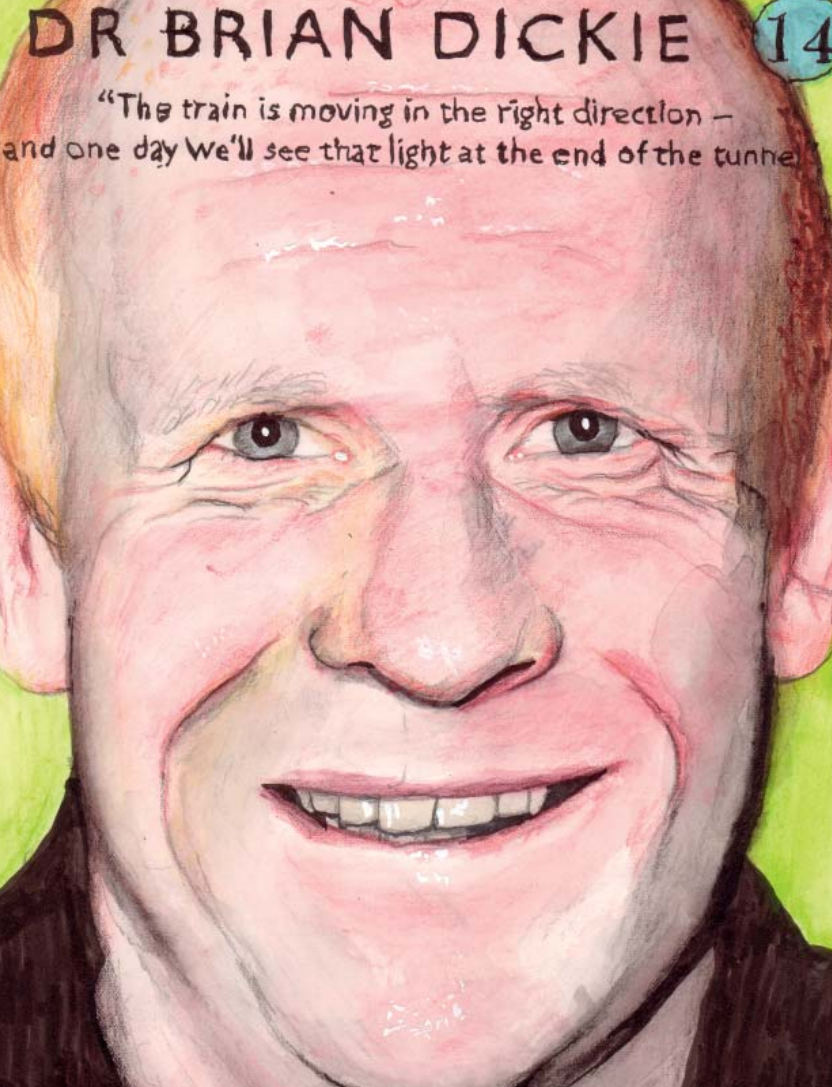
“The work of the PCRN in facilitating participation in research at practice level is essential to enable busy practices like ours, lacking in research experience, to contribute to important relevant research. This in turn influences and helps our daily practice of evidence-based medicine and the use of scarce resources in caring for our patients.”

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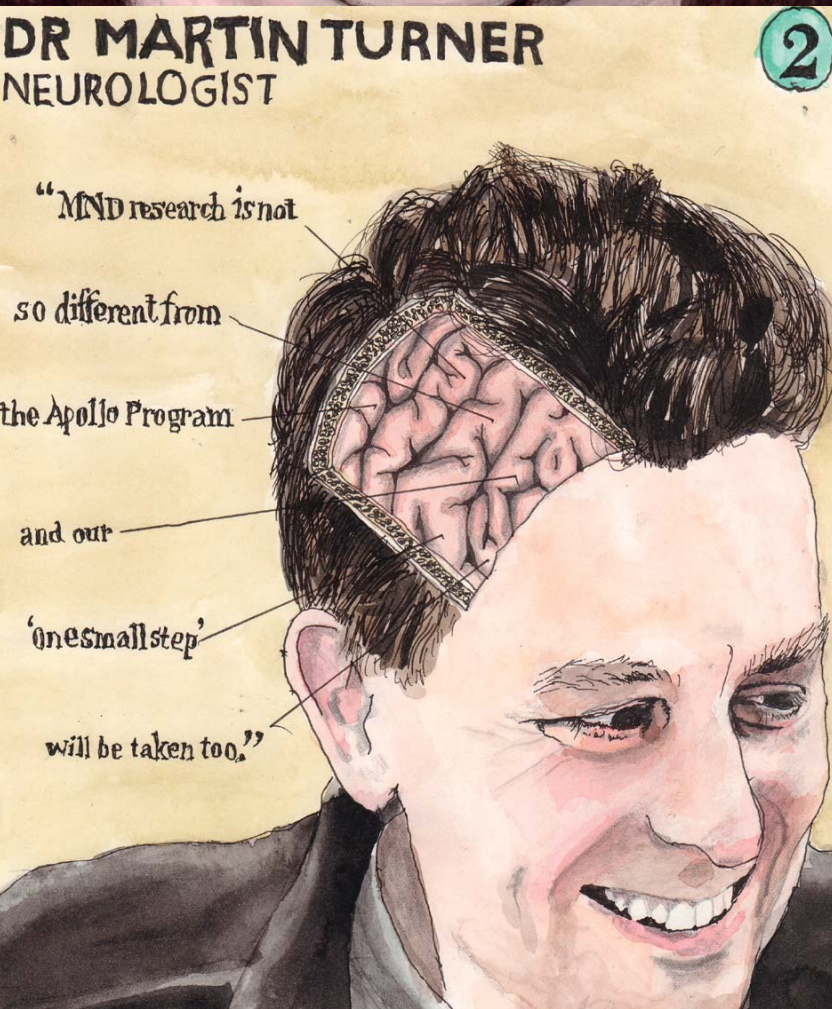
Aspirin is known to reduce the risk of heart disease and stroke



DR BRIAN DICKIE

14

"The train is moving in the right direction – and one day we'll see that light at the end of the tunnel"



DR MARTIN TURNER
NEUROLOGIST

2

"MND research is not so different from the Apollo Program and our 'one small step' will be taken too."

Change of gear for Motor Neurone Disease research

In 2007 two events took place which helped change the course of Motor Neurone Disease (MND) clinical research in England. The Dementias and Neurodegenerative Diseases Research Network (DeNDRoN) became operational and the Motor Neurone Disease (MND) Association took a conscious decision to become more involved in clinical and healthcare research. Three years on, the number of MND studies on the Clinical Research Network Portfolio has risen from one to 23, and exciting results are providing a focus for researchers and encouragement to the wider MND community.

MND is a neurodegenerative disease that attacks the upper and lower motor neurones and gets worse over time. The breakdown of motor neurones leads to weakness and wasting of muscles, causing increasing loss of mobility in the limbs, and difficulties with speech, swallowing and breathing. Ninety to 95% of MND patients have sporadic MND, which has no family history, whereas the remainder have the rarer, inherited form known as familial MND.

In 2007 the MND Association was focusing on funding laboratory research into the causes and mechanisms of MND. But, as the MND Association's Director of Research Development Dr Brian Dickie explains, they felt it was time to broaden the scope of their involvement:

Portraits by Patrick Joyce, artist, MND patient and study participant

“We were concentrating principally on basic science, which can assist in the development of future treatments, but clinical and healthcare research have the potential to have a more immediate impact on people diagnosed with MND by improving healthcare practice. In addition, our membership surveys showed that people with MND wanted to have more opportunities to participate in research and clinical and healthcare research offered the greatest opportunity for us to do that.”

Because MND affects around six in every 100,000 people in the UK it is known as an ‘orphan disease’. Orphan diseases are diseases like MND that, comparatively, do not affect many people. As a result, it’s more challenging to get funding for studies that try and address the cause of the condition.

Consequently, the MND Association needed research infrastructure that could support large scale recruitment of MND patients and full-time research staff to support research studies. When DeNDRoN was established the goal was to offer this capability to dementias and neurodegenerative research, but it was only when the MND Association and DeNDRoN discussed how the organisations could be of benefit to each other that both realised the impact effective collaboration could have. Piers Kotting, Assistant Director for DeNDRoN, explains:

“The MND Association has their own network of care centres across England acting as the main tertiary clinical service centres for MND. When DeNDRoN was established, some of these centres had a research base, but many were not involved in research at all.

“We worked with the MND Association to make the most of these centres, which have now become the focal point for MND research, both in terms of recruitment and infrastructure. DeNDRoN nurses now provide a full time research presence at these sites, playing an active role in identifying and recruiting patients, alongside the clinical care provided by the MND clinic staff. And they also link the MND Association network into the broader DeNDRoN Local Research Network, so that if patients are diagnosed and treated independently of MND

Association centres, they still have a route into MND research studies.”

Another significant factor in the collaboration between DeNDRoN and the MND Association has been a long-term study looking at DNA to try to identify the genetic causes of MND. The study was initiated in 2003 and added to the Clinical Research Network Portfolio in 2006. It has collected over 3,100 DNA samples; more than half from people with MND and the remainder from unaffected ‘controls’ and family members. Recruitment initially came from three hub sites based at Sheffield, London and Birmingham but with the support of DeNDRoN the number of participating sites has increased to 17. Piers Kotting believes that Network support has made a real difference:

“In 2006, when the study was adopted to the Clinical Research Network Portfolio, it had been open for four years and had gathered samples from 832 patients and ‘controls’. In the following four years that figure has increased by 2297. Recruitment was initially a simple process because the hub sites gave us a captive audience. But once we’d exhausted this audience, recruitment could have easily stagnated. This has not happened because DeNDRoN has continued to grow, giving us the ability to steadily increase the number of research friendly sites contributing to the DNA study.”

Interestingly, the samples gathered for this study are now playing a crucial role in further research and helping to further advance our knowledge of MND. One such study, led by



Patrick Joyce, artist, MND patient and study participant

Professor Ammar Al-Chalabi at King’s College London, analysed the entire human genome to identify genetic signals for MND. The study used samples from eleven centres in eight different countries including 600 sporadic MND samples collected for the MND Association DNA study - with fascinating results. With a total of 12,000 DNA samples it was the biggest genetic MND study to date. But more importantly, the study made a significant breakthrough in our understanding of MND and the results were published in *Lancet Neurology* on 31 August 2010. Says Professor Al-Chalabi:

“The study established that a region of DNA in chromosome 9 plays an important role in the development of sporadic MND. We already knew that it played a role in familial MND, but we had no such evidence for sporadic MND. We narrowed the suspect gene list on chromosome 9 for sporadic MND down to just three genes and if we can go on to identify which of these is the culprit we may be able to understand enough to design a specific treatment for the condition.”

From Dr Dickie’s perspective, the success of Professor Al-Chalabi’s study reflects well upon the efforts of the MND community to advance clinical research over the last three years,

“This is ‘big science’ and is not something we could have supported on our own. You need money, samples, and the latest technology. You need the expertise of clinicians, the commitment of patients and an effective international research

‘the number of MND research studies on the NIHR Clinical Research Network Portfolio has risen from one to 23’

“anyone who has taken part in research should feel proud of the results that are now coming through”

infrastructure to support the work. DeNDRoN has played an important role in providing that infrastructure in the UK, but beyond that it has stimulated our involvement in ‘big science’, not just as a facilitator of MND research, but as a funder too.”

Aside from the success of Professor Al-Chalabi’s study, the other significant development in MND research over the last three years has been the ability of MND researchers to carry out large scale biomarker studies. Dr Dickie sees this as an important development:

“The biomarker studies we are funding are really exciting because they follow patients from diagnosis through the progression of the disease. If we can identify a disease specific ‘fingerprint’ which changes with time we can hopefully improve the speed and accuracy with which MND can be diagnosed as well as providing new ways of monitoring the effectiveness of new interventions.”

The biomarker studies are now making an impact. On 2 November 2010 a Portfolio study funded by the MND Association, in collaboration with the Medical Research Council (MRC), identified a common signature of nerve damage in the brains of MND patients. This is more positive news for

the MND community, who are starting to see some reward for their commitment to clinical research.

Patrick Joyce is one of the people with MND who has been able to take advantage of the research opportunities made available to him:

“I got involved because we’re all gasping for a breakthrough and I wanted to help people in the future. There has been a feeling of disconnection between MND patients and research, but the MND Association has listened to patients and is actively giving people opportunities to take part in studies. In the last year I’ve contributed to a DNA study, joined a drug trial and begun a biomarker study. There’s a hell of a lot of genetic research going on and it feels like there are new discoveries all of the time.

“I think anyone who has taken part in research should feel proud of the results that are now coming through. Identifying a genetic marker for sporadic MND and a common signature to nerve damage was unthinkable a year ago. I am proud of these developments and feel a sense of ownership of the results.”

Patrick was a plumber, but also an artist and while he has had to hang up his monkeywrench he’s continued to make

use of his artistic skills to bring attention to MND. Patrick the Incurable Optimist, as he is also known, is fronting the MND Association’s latest awareness campaign and has set himself the challenge of completing 100 portraits before he loses his ability to paint:

“I want to continue to work for as long as possible and use both my work and my story to help the Motor Neurone Disease Association create a movement of incurable optimism.”

If you’d like to see more of Patrick the Incurable Optimist’s portraits, read his blog, or just find out more about MND, you can visit his website at: <http://patricktheoptimist.org>

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www.dendron.org.uk

Patrick Joyce MND patient and study participant is fronting the MND Association’s latest awareness campaign



ONLY MONTHS TO LIVE. 100 PORTRAITS TO PAINT.

“I’M PATRICK AND I’M AN ARTIST. SOON I WILL LOSE THE ABILITY TO PAINT FOREVER THANKS TO MOTOR NEURONE DISEASE. BUT I AM DETERMINED TO CREATE 100 PORTRAITS IN WHAT TIME I’VE GOT LEFT, TO RAISE AWARENESS OF MND AND HELP FIND A CURE.” WILL HE MAKE IT? IS HE ANY GOOD? BRUSH UP ON PATRICK’S ART AT PATRICKTHEOPTIMIST.ORG

   patricktheoptimist.org



Photograph: Cheryl Nash/PA/PA

Getting stroke rehab research on the right 'TRACS'

Stroke rehabilitation research is notoriously difficult to do on a large scale but with the support of the Stroke Research Network (SRN) the TRACS study has achieved record recruitment levels, putting the UK firmly in the vanguard for this kind of research.

Traditionally stroke rehabilitation studies have been smaller single-centre studies because they are complex and require a lot of clinical intervention, and TRACS is no different. Anne Forster is a professor of stroke rehabilitation at the University of Leeds and Bradford Teaching Hospitals NHS Foundation Trust and the clinical lead for the Yorkshire Stroke Research Network. Professor Forster is also the chief investigator of the TRACS study. She explains why studies like TRACS are so complicated:

"Stroke rehabilitation research is difficult because it depends on people. Often a new treatment or a new drug is the intervention in a study, but in this type of trial it's the people that are the intervention. This makes the trial complex and a huge collaborative effort is required to make it happen."

TRACS (Training Caregivers After Stroke) is looking at a new way of training carers, or care-givers as they are also known, to look after stroke patients when they return home from hospital. The training aims to improve physical outcomes for the stroke patient and reduce the care burden on the care-giver. The study is evaluating both the clinical and the cost effectiveness of this structured training programme by comparing it to the standard stroke care package currently available through the NHS. Half of the participating stroke centres delivered standard NHS stroke care, whereas the other half integrated the TRACS training course into the standard care package. The carer's training takes place while the stroke patient is still in hospital and adds a much more focussed element to the 'normal' support available. Professor Forster explains:

"A stroke patient might return home with a range of disabilities. The carer's training is dependent on the patient's condition so it's tailored to each individual case. The duration and the timing of the course are not prescriptive, instead the course is competency driven and the patient's disabilities determine what skills the carer

"This is the way forward for stroke rehab studies"



Professor Anne Forster (middle) with members of the TRACS study team

needs to learn. The outcomes are measured by questionnaires completed by both the patient and the carer at six months and then at 12 months follow up."

TRACS began as a single-centre randomised trial. But after showing positive outcomes for both the carers and the patients on a small scale, the Medical Research Council (MRC) awarded funding for the study to be rolled out across the UK as a multi-centre cluster randomised trial. The study has been organised through the University of Leeds Clinical Trials Research Unit and by the time recruitment closed in January 2010 it had successfully recruited 930 patients from 36 stroke units, making it the world's largest stroke rehabilitation trial to date.

So how has a study of this size and complexity been made possible? SRN staff have supported TRACS by working alongside clinical staff to recruit patients in all the participating stroke units in England. That plus careful performance management by Stroke Local Research Network managers ensured that TRACS stayed high on local research agendas until recruitment goals were achieved. Professor Forster continues:

"A sample of this size would not have been considered achievable a few years ago. It's incredible, and it's the Network infrastructure that has made it possible by transforming the delivery of research and facilitating truly national participation. It has been a massive team effort and a hugely collaborative approach. TRACS has really tested and demonstrated the power of the Networks and a new way of doing

research in the NHS that was not thought possible before. This is the way forward for stroke rehab studies and will facilitate rigorous testing of the research question and help drive forward improvements in clinical care."

So where is TRACS at now?

"We are coming to the end of the follow up period," says Professor Forster. "We expect to disseminate our findings in autumn 2011. Ultimately, if the findings are positive, we hope that the training programme will be rolled out nationally."

Dr Damian Jenkinson is the National Clinical Lead for the NHS Stroke Improvement Programme; an NHS initiative set up to provide national support for local improvement of stroke services and the implementation of the National Stroke Strategy. He recognises the importance of TRACS in the stroke rehab research landscape and, more importantly, the potential benefits for patients and carers:

"TRACS has been a very significant study for two reasons. Firstly, the results of TRACS should help provide important clarity on how stroke carers can best be supported. Secondly, the engagement of front-line clinical staff in the running of the trial has been hugely successful. Both these factors will help raise the quality of care and support for people who have had a stroke and their carers."

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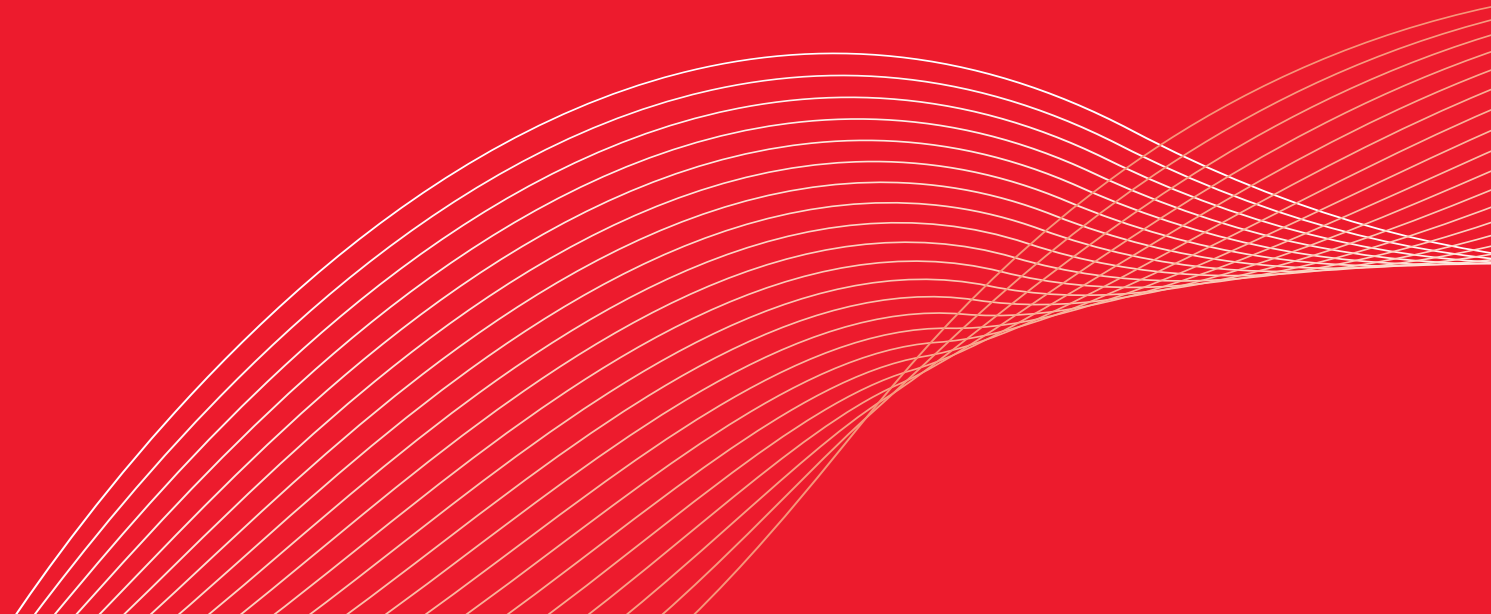
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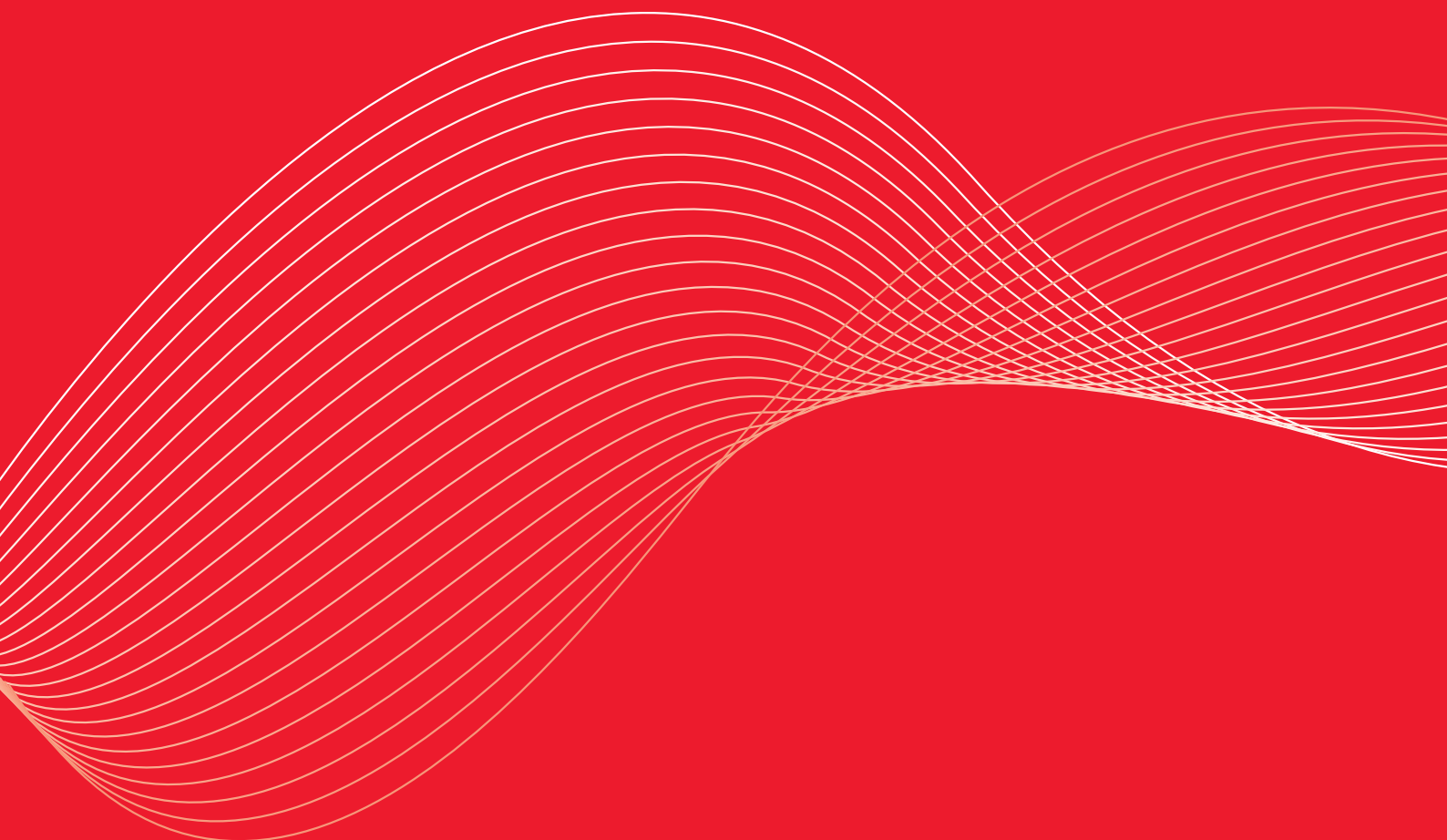
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