



Newcastle Academic Health Partners

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Working together as Newcastle Academic Health Partners

NEWCASTLE ACADEMIC HEALTH PARTNERS

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Introduction

Newcastle Academic Health Partners harnesses clinical and academic expertise to make sure patients will benefit sooner from new treatments, diagnostics and prevention strategies. The partnership brings together the Newcastle upon Tyne Hospitals and Northumberland, Tyne and Wear NHS Foundation Trusts with Newcastle University.

We will deliver **world-class healthcare** through collaborative scientific research, education and patient care.

We will focus on delivering scientific advances that improve physical and mental health in **age-related chronic diseases** such as dementia and musculoskeletal disease. It will also seek to improve understanding and treatment of:

- cancer
- diseases that affect the brain and nervous system
- diseases affecting children

Translating clinical research into practice, we will develop:

- improved diagnostic, prevention and treatment strategies
- an innovative health education programme

Included in this brochure are some examples of how work performed in Newcastle has already led to significant benefits for our patients.



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The development of a novel class of anticancer drugs, PARP inhibitors, has attracted multi-million dollar investments in clinical trials

Newcastle research selected the DNA repair enzyme known as PARP as a promising target for cancer therapy. The first-in-class PARP inhibitor drug, rucaparib, was developed at Newcastle in collaboration with Cancer Research UK and Agouron Pharmaceuticals. It subsequently became the first PARP inhibitor to be used to treat a cancer patient in a clinical trial. Currently, at least eight PARP inhibitors are being developed, and nine major pharmaceutical companies have to date invested around \$385 million in clinical trials. Over 7000 patients worldwide have been treated with PARP inhibitors in trials since 2008, demonstrating the importance of basic and translational research on drug discovery by pharmaceutical companies. In April 2015, rucaparib was designated as a Breakthrough Therapy for ovarian cancer by the FDA, which will accelerate its development.

Improving the quality and length of the lives of Duchenne muscular dystrophy patients through the application of multidisciplinary care

In the 1960s, boys with Duchenne muscular dystrophy would only live around 15 years; by the 1990s survival had risen to around 19 years. Young men with this condition can now live to around 30 years of age. This significant improvement is possible thanks to the implementation of coordinated multidisciplinary patient management, developed as a result of research and clinical practice pioneered by the multidisciplinary teams at Newcastle University and the Newcastle Hospitals. Guidelines for the care of patients with Duchenne muscular dystrophy, published in 2010, were developed by an international working group led by Newcastle University. These guidelines achieved NICE process accreditation in the UK and have been adopted globally as the definition of best practice.





Mental health: setting up the Northern Centre for Mood Disorders

Mental health problems are very common, with around a quarter of all people experiencing symptoms during their life. Two particular types of mental health problem, depression and bipolar disorder, are set to be two of the leading cause of disability in UK by 2020. To help address this common and disruptive problem, the university has joined forces with the Northumberland, Tyne and Wear NHS Foundation Trust (NTW) – the region's mental health and disabilities care provider – to form the Northern Centre for Mood Disorders (NCMD). The NCMD will be a focus point for developing and implementing cutting-edge therapies.

Current research being carried out at the university concentrates on investigating the underlying pathology of mood disorders and providing targeted therapy.

Some examples of current research include:

- Using cognition as a marker of the underlying brain pathology, especially the variability of performance between patients and controls;
- Use of lithium in treatment of bipolar disorder, especially its mode of action on the brain and on the HPA axis;
- Innovative treatments such as ketamine to increase the effect of ECT or reduce its side effects.

The partnership between the university and NTW allows these cutting-edge advances to be taken up into clinical practice with minimal delay.

A second-line option for conscious sedation of children during dental procedures

Anxiety before dental procedures is common in children, and is often managed using conscious sedation. Previously, nitrous oxide inhalation was the only method widely used in primary care, and patients who could not be thus sedated were referred for the expensive and more risky option of general anaesthesia. In 2010, NICE published the first national guideline on medical sedation, which stated that administration of the sedative midazolam should be considered alongside the standard technique of nitrous oxide inhalation. The recommendation is based mainly on a series of randomised controlled clinical trials carried out in Newcastle and funded by the Department of Health. Midazolam is now established as a second-line sedation option across the UK.





How better risk stratification for lung transplant has benefitted cystic fibrosis patients



Lung transplants can represent the last hope for cystic fibrosis patients (CF) with end-stage lung disease. However, surgery often has a poor outcome for one particular patient group, who carry a bacterial infection caused by the difficult-to-treat *Burkholderia* genus. In 2001, joint research began between Newcastle University and Newcastle Hospitals, which found that the poor outcome was the result of just one species, *Burkholderia cenocepacia*, and that other species of *Burkholderia* were not as dangerous. This finding was incorporated into international guidelines. Since 2008, most transplant centres worldwide have adopted a risk stratification approach to listing patients for transplant. Consequently, more than 30 CF patients per year worldwide now receive lung transplants that would otherwise have been denied.

Use of non-invasive ventilation to improve survival and quality of life in patients with motor neuron disease

Motor neuron disease (MND) is a debilitating disease with poor prognosis; most patients die from progressive respiratory failure within three years of onset. Research carried out at Newcastle as a collaborative effort between the clinical specialities of Respiratory Medicine and Neurology has sought to improve the quality of life of patients with this devastating disease. A randomised controlled trial conducted in Newcastle from 2000-4 provided robust evidence that non-invasive ventilation (NIV) for patients with MND can significantly improve quality of life and increase survival several fold. Findings from this trial informed international clinical guidelines for management of MND, and NIV use has subsequently increased in the UK, Europe, in the US and Australasia. In the UK, the number of MND patients successfully established on NIV in 2009 increased 3.4-fold since 2000 and since 2009 has further increased almost two-fold.





Increased range and adoption of evidence-based treatments for refractory moderate-to-severe atopic eczema

Atopic eczema is a disabling long-term skin condition affecting around 2% of the UK adult population. The mainstay of treatment remains topical steroids and moisturisers, but many adult patients with atopic eczema have resistant disease that can significantly impair quality of life. Newcastle University researchers working alongside clinicians from the Newcastle Hospitals Trust found two treatments that were effective for adults with this type of atopic eczema: whole-body UVB phototherapy and systemic (tablet) treatment with the immunosuppressant drug azathioprine. UK and European guidelines now recommend UVB phototherapy and azathioprine for atopic eczema, and survey data indicate that both are now widely used to treat the disease in the UK.



pGALS: a novel and simple approach for musculoskeletal examination of children

In response to a lack of confidence among clinicians when conducting paediatric musculoskeletal examinations, Newcastle experts working in the Great North Children's Hospital developed a quick, accurate and child-friendly examination technique. This technique, known as pGALS (paediatric Gait, Arms, Legs, Spine) effectively identifies joint abnormalities to aid diagnosis and referral to a paediatric rheumatology specialist. pGALS is now taught in more than half of the medical schools in the UK, including widely at postgraduate level, and has been integrated into the mandatory professional examination for the Royal College of Paediatrics and Child Health. In addition, the technique has been described in a number of leading textbooks and e-learning resources. pGALS is becoming known, taught and used worldwide with translations in different languages and is being adapted for local cultural and social contexts.



Simple, non-invasive, diagnosis of liver fibrosis severity in non-alcoholic fatty liver disease (NAFLD)

Non-alcoholic fatty liver disease (NAFLD) is the most common liver disease in the developed world with a prevalence of up to 25% in the general population. Until Newcastle validated its new diagnostic test, the only accurate way to determine the severity of NAFLD was by liver biopsy, an expensive and invasive procedure which is associated with morbidity and occasional mortality. Studies lead by Newcastle have established a non-invasive fibrosis scoring system (the NAFLD Fibrosis Score [NFS]), which is capable of accurately differentiating patients with and without fibrosis. The system has now been incorporated into two international guidelines, allows biopsy to be avoided in up to 75% of patients and could save the NHS nearly £2m annually.

Curing chronic granulomatous disease in children through early bone marrow transplant

Chronic granulomatous disease is a rare but very serious inherited disorder of the immune system that leaves sufferers vulnerable to potentially fatal bacterial and fungal infections. The Great North Children's Hospital is one of only two diagnosis centres in the UK. Researchers at Newcastle, funded throughout by Newcastle Hospitals, found that bone marrow transplant led to very high cure rates, survival rates and quality of life. This led to a change in national clinical policy, and doctors at both specialist disease centres in the UK now recommend transplantation. Between 2003 and 2008, only 11 transplants took place in the UK; but between 2008 and 2013, this increased to 36 transplants.





Towards prevention of mitochondrial diseases: changing government policy

Research at the Newcastle Hospitals' Fertility Centre and Newcastle University, the only centre licenced in the UK, showed the feasibility of an IVF-based technique to prevent the transmission of mitochondrial disease from mother to child. As a consequence, the UK Government asked the regulator responsible, the Human Fertilisation and Embryology Authority (HFEA), to conduct both a scientific safety review and a public consultation exercise. The findings from both these consultations and from a separate Nuffield Council on Bioethics report were supportive, to the extent that in February 2015 both the House of Commons and House of Lords voted in favour of allowing mitochondrial donation as part of IVF treatment, to avoid serious mitochondrial disease. When the regulations come into force in October 2015, the HFEA will licence and regulate these techniques, to the clear benefit of affected families.





MAGIC – MAKING Good decisions In Collaboration

Collaborative work between Newcastle and Cardiff has provided pioneering evidence-based implementation work in shared decision making (SDM - involving patients in decisions about their care and treatment) via a Health Foundation-supported implementation programme (MAGIC – MAKING Good decisions In Collaboration - www.health.org.uk/programmes/magic-shared-decision-making).

One element of this multi-faceted MAGIC programme was the development and dissemination of Brief Decision Aids (BDAs), which support in-consultation discussion between clinicians and patients about the risks, benefits and consequences of treatment/care options. These BDAs have now been nationally disseminated through the patient.co.uk website (patient.info/decision-aids), the second most accessed health web site in the UK. Each BDA is accessed over 2000 times per month, and

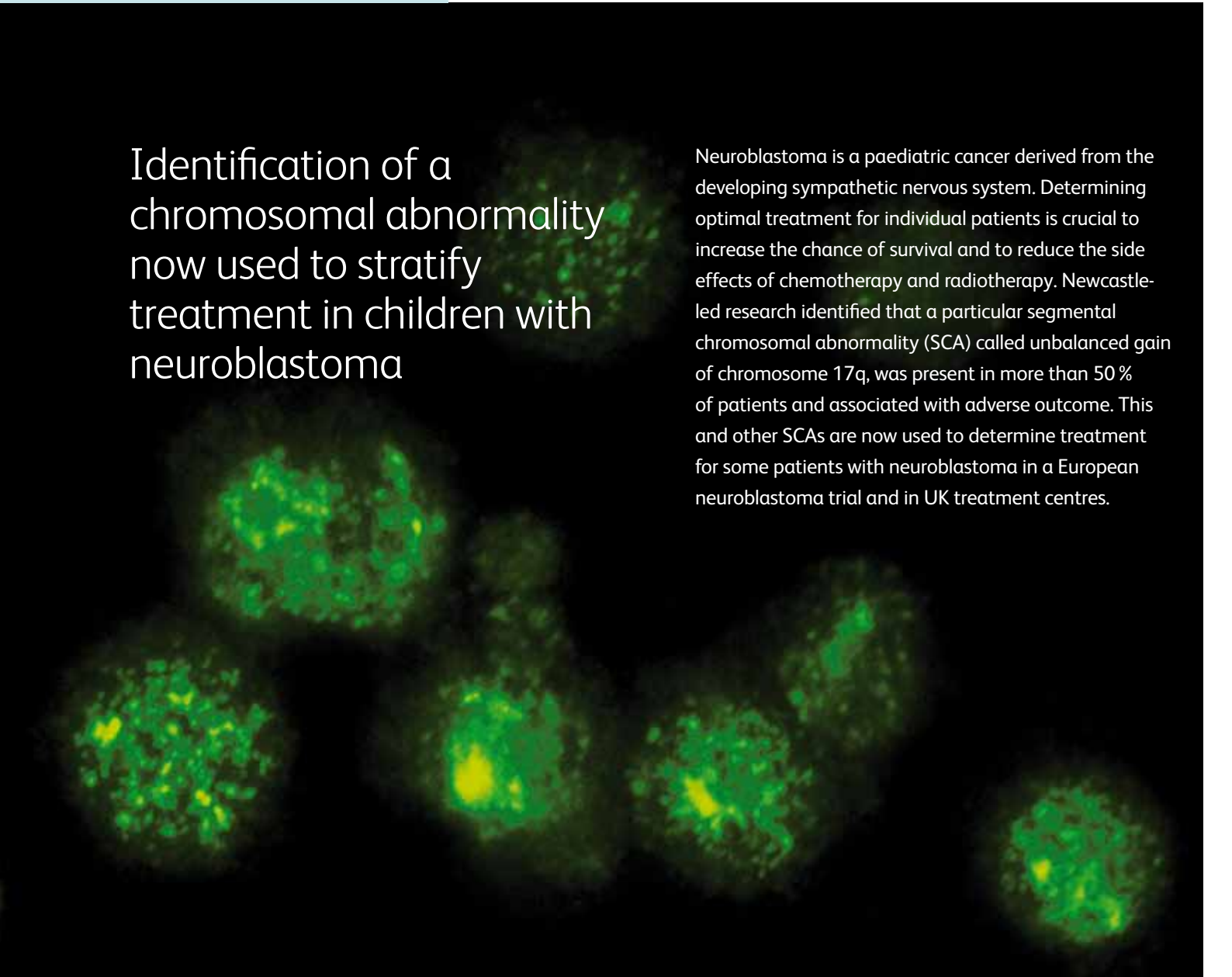

many are downloaded by clinicians for multiple use. A questionnaire from 2012 showed that 86% of clinicians agreed that BDAs would “help me discuss options with patients.” The MAGIC programme won the “Best Established Impact” category at the 2015 Faculty of Medical Sciences impact awards.

In addition, extensive materials from the MAGIC programme have been included in the Health Foundation Person-Centred Care Resource Centre (personcentredcare.health.org.uk/). There are over 40 separate sets of wide ranging resources including, for example, patient prompts, training materials, case studies, videos, and guidance for NHS Boards. This easily-accessible site provides tools and resources for clinicians and organisations seeking to implement shared decision making in practice.



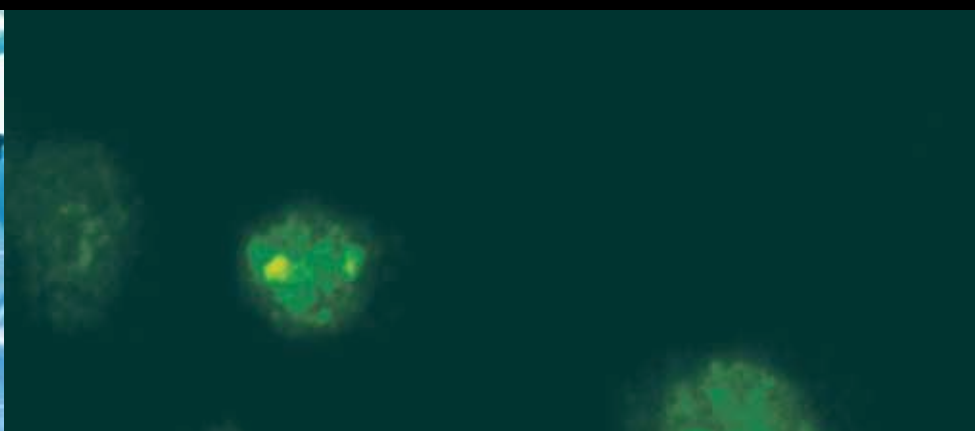
Uncovering the genetic basis of atypical haemolytic uraemic syndrome leads to improved treatment

Research at Newcastle has had a profound effect on the prognosis for patients with atypical haemolytic uraemic syndrome (aHUS). By researching the genetic causes of the disease, the molecular mechanisms responsible are now understood. This research led to the establishment of national NHS diagnostic service for genetic screening and treatment with a drug called eculizumab. In January 2015, NICE recommended eculizumab as a Highly Specialised Technology for treatment of aHUS under certain conditions. For these patients, progression to end-stage renal failure can be prevented and patients already on dialysis can be successfully transplanted.



Identification of a chromosomal abnormality now used to stratify treatment in children with neuroblastoma

Neuroblastoma is a paediatric cancer derived from the developing sympathetic nervous system. Determining optimal treatment for individual patients is crucial to increase the chance of survival and to reduce the side effects of chemotherapy and radiotherapy. Newcastle-led research identified that a particular segmental chromosomal abnormality (SCA) called unbalanced gain of chromosome 17q, was present in more than 50% of patients and associated with adverse outcome. This and other SCAs are now used to determine treatment for some patients with neuroblastoma in a European neuroblastoma trial and in UK treatment centres.





Innovations in the treatment of chronic myeloid leukaemia have almost doubled 5-year survival rates.

A novel class of drug known as tyrosine kinase inhibitors for the treatment of chronic myeloid leukaemia (CML) has been evaluated in Newcastle-led international clinical trials performed at the Sir Bobby Robson Cancer Trials Research Centre. One of these drugs, imatinib, was found to almost double five-year survival rates with few side effects, and has become the “gold standard” of treatment worldwide. Patient quality of life has significantly improved, with increases in physical and psychological wellbeing. Subsequent follow-up studies found an estimated eight-year overall survival of 85%. Imatinib is now recommended in national and international guidelines and is the standard treatment for CML.

A second development has been the introduction of a new home-delivery service by the Northern Centre for Cancer Care. This service has been set up to deliver oncology drugs, including imatinib, directly to patients’ homes. The three advantages of the Oncology Homecare programme are: patient convenience, reduced pressure in clinics and presenting an economical advantage to the Trust while under strict budget constraints. Before the introduction of the service, patients were dissatisfied with medication supply: 78% rated it as “fairly bad” or “very bad”. A second audit of CML patients found that 80% of patients now rated the service as “very good”. Nearly 50 deliveries are made per month and this number is increasing.

Shaping the UK's dementia care policy to reflect the importance of an early, sensitively-communicated diagnosis of dementia

Newcastle research on dementia contributed two aspects that helped to shape high-level policy: first that prevalence of the condition was higher than previously suspected, with implications for care of the ageing UK population. Secondly, the long delay sometimes experienced by patients before a diagnosis of dementia was given led to distress both for patients and their families. This research informed policy documents such as the Prime Minister's 2012 Challenge on dementia, as well as national guidance in the form of commissioning packs. Patients benefit from more timely diagnosis with a better understanding of their needs and wishes and the NHS benefits through potential reductions in long term care costs.



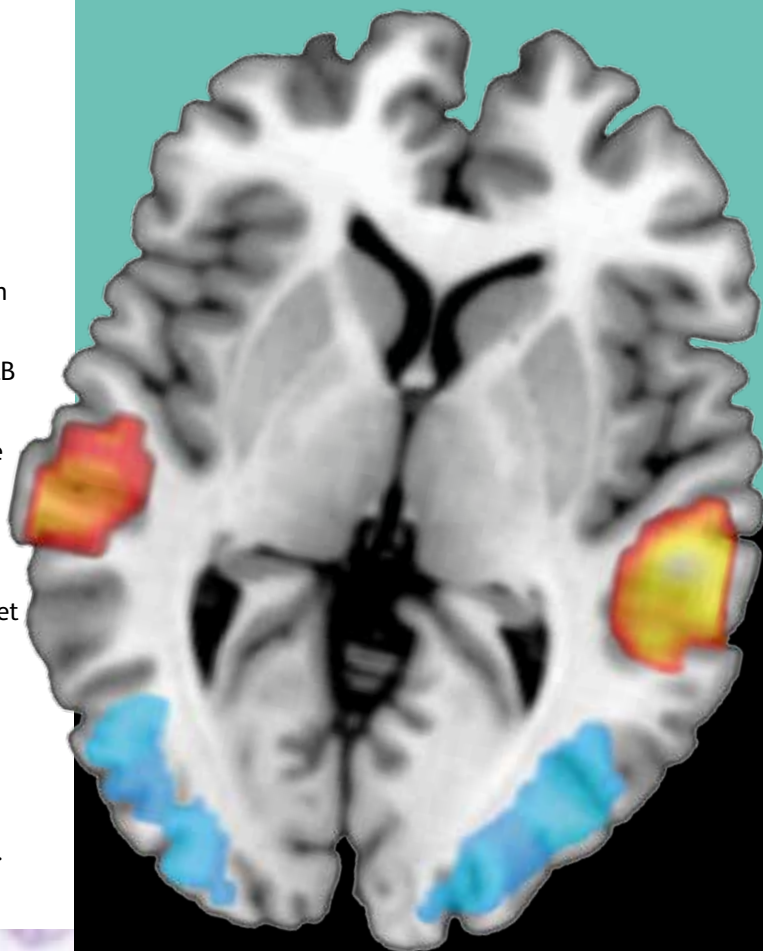
Developing the first drug to treat the symptoms of Lewy body dementia

Dementia is one of the greatest problems facing society today, both in terms of cost and also quality of life of patients and caregivers. Newcastle research identified that cholinesterase inhibitors (CHEIs), originally licenced for use in Alzheimer's disease, would be of greater benefit in two other types of dementia; dementia with Lewy bodies and the dementia associated with Parkinson's disease. CHEIs are now recommended in national and international guidelines as a treatment for the cognitive and psychiatric symptoms associated with both of these conditions, which previously had no effective treatment. CHEIs are also licenced worldwide for use in Parkinson's dementia, and are used off-licence across the world as a first-line treatment for dementia with Lewy bodies.



New diagnostic criteria and development of the DaTSCAN imaging technique for identification of dementia with Lewy bodies as a distinct condition

Dementia with Lewy bodies (DLB) is one of the most common subtypes of dementia. Although DLB shares characteristics with Alzheimer's disease, the condition requires specific treatment and care. New diagnostic criteria generated at Newcastle allow diagnosis of DLB as a distinct condition from Alzheimer's, and these criteria have been incorporated into five authoritative national and international guidelines. The work also resulted in an accurate and sensitive diagnostic technique, commercialised by GE Healthcare as the DaTSCAN imaging tool. DaTSCAN was granted market authorisation for DLB diagnosis by the European Medicines Agency in 2011 and in the US it is the first FDA-approved radiopharmaceutical adjunct imaging tool to aid in evaluation of parkinsonian syndromes. These new diagnostic criteria allow appropriate treatment and management of DLB for the first time.



CRESTA (NHS Clinics for Research and Service in Themed Assessments) Fatigue Clinic

A new type of clinic, launched in 2012, provides specialist research, assessment and multidisciplinary therapy in a range of chronic conditions. These NHS Clinics for Research and Service in Themed Assessments (CRESTA) offer a new way of caring for patients with complex multi-morbidities in one multidisciplinary visit, and also aim to recruit patients to take part in trials. CRESTA is based at the Centre for Ageing and Vitality and is a partnership venture involving Newcastle Hospitals and Newcastle University. The clinic's vision is to better support the increasingly ageing population.

As part of the CRESTA, a specialist fatigue clinic was established in 2013 to address unmet needs of patients, identified during multidisciplinary studies by the Newcastle Fatigue Interest Group. Fatigue affects a quarter of the population and can severely affect quality of life, but remains poorly understood. The hope is that this specialist fatigue clinic, the first in the country, can investigate causes and perhaps identify ways to improve quality of life. Members of staff include a Professor of Ageing & Medicine, an occupational therapist, a specialist nurse, a physiotherapist and health psychologist. All clinicians are research active and have substantial experience at treating fatigue and dysautonomia. The clinic, which won a "Bright Ideas in Health" award in May 2015, aims to identify the service needs of the patients, to prioritise these needs, determine if each is being met and to plan targeted service enhancements.




Newcastle as a specialist centre for reflux and aspiration leading to lung disease

Although reflux is a common occurrence, it can cause lung damage if the acid is aspirated. This is of particular concern in patients who have undergone a lung transplant or who have chronic lung disease, but until recently these patients who presented with reflux had limited options as no specialist centre existed.

In response to this unmet need, an aerodigestive service was established in 2012 as a Knowledge Transfer Partnership (KTP) between Newcastle University and Newcastle Hospitals. This initial service ran until October 2014, and was awarded the highest grade of “Outstanding” by the KTP Grading Panel for its achievement in meeting KTP objectives.

The service investigates how reflux may damage lungs and affect lung function, and acts as a “one-stop-shop” for combined respiratory and gastrointestinal problems. To date, the service has reviewed 72 patients and 13 surgical procedures carried out. The service is run by a multidisciplinary team of members of University and NHS staff who meet regularly to decide on the best course of action for an individual patient. This form of stratified medicine has led to a pilot clinical trial, and it is hoped that this type of service will be rolled out nationally. The increasing patient cohort could increase financial revenue, not only from patient referrals but from interest from pharma.





An effective test for foetal abnormalities

Research performed in Newcastle evaluates a new method of detecting chromosome imbalances (gains or losses of part or all of a chromosome) in prenatal samples: array comparative genomic hybridization or chromosomal microarray (CMA).

Where a foetal abnormality is diagnosed on an ultrasound scan, around a quarter have an underlying major chromosomal anomaly, and this typically leads to developmental disability. Further investigation of chromosome abnormality usually requires invasive testing, for example amniocentesis, which carries a risk of miscarriage. Analysis of less common imbalances requires the foetal cells to be grown and examined (karyotyping), but this process is slow, labour-intensive and only detects large imbalances.

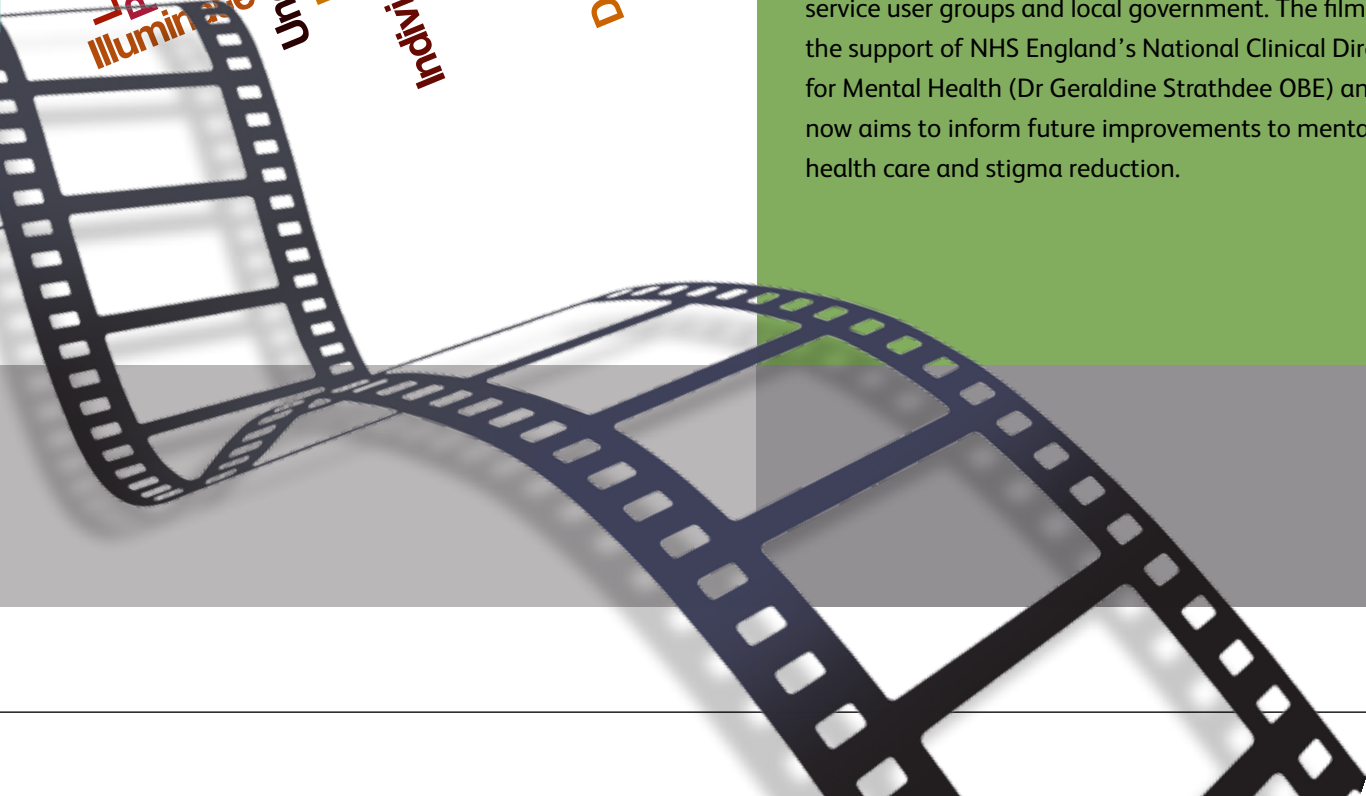
CMA is a new molecular test that can rapidly detect smaller (sub-microscopic) imbalances although interpretation is complex. In the EACH trial of over 1500 women, CMA detected an additional 3-4% more pathogenic chromosomal imbalances than karyotyping.

Interviews with parents, health professionals and commissioners indicated CMA was an acceptable test and there was uniform support for its integration into clinical practice. The results of the EACH study suggest that CMA is a robust, acceptable and likely cost-effective diagnostic test and should replace karyotyping in care pathways where the indication for foetal testing is an abnormality on ultrasound. The results of the EACH study were made available to a national working group, convened by the Royal College of Pathologists, who have also recommended the replacement of karyotyping with CMA in the NHS for this indication.



Co-production of a theory-based educational film about shared decision making in primary care for depression

Shared Decision Making (SDM) is a process through which patients, their relatives and doctors (or other healthcare professionals) work together to identify the best treatment option for an individual patient. SDM is a core component of the service improvement agenda for mental health. To raise awareness of the benefits of SDM for supporting recovery from mental health problems, including skills development for SDM in clinicians and service users, an educational film has been produced. Partially funded by NTW, the film is a joint effort between Newcastle University and mental health service users (who appear in the film as actors, and led on the design of the script and editing). The film uses a story-based approach of a patient's journey through the primary care mental health system. Co-production of the film with mental health service users – who are experts by experience - shows the positive contribution that they can make to service improvement. The film's première in April 2015 was attended by over 120 guests, including MPs, NHS staff, service user groups and local government. The film has the support of NHS England's National Clinical Director for Mental Health (Dr Geraldine Strathdee OBE) and now aims to inform future improvements to mental health care and stigma reduction.



A centre of excellence for clinical trials and the development and evaluation of new diagnostic tests



The evaluation of new technologies within the NHS is a crucial step in the development of diagnostic approaches. In Newcastle we have a unique capability in the evaluation of diagnostics and we understand the value of this expertise to companies. We are working with a wide range of UK-based companies to help them develop new products and services as early access to effective innovation is important for development of our clinical services and enabling access to our expertise is helping to support economic growth.

Newcastle is the only UK city awarded both an MRC/ EPSRC Molecular Pathology Node and an NIHR Diagnostic Evidence Co-operative (DEC). The Node exists to modernise pathology services through innovative training methods in molecular pathology, closer integration of clinical and academic pathology, and development of a clearer pathway between discovery science and the clinical application of diagnostic molecular pathology. The DEC develops methodologies to evaluate such diagnostic tests in a robust manner, with the aim of ensuring that good diagnostic tests reach patients in the NHS more efficiently. The Node and DEC therefore have unique but complementary skills. Both work closely with the in vitro diagnostics industry, and form an integral part in the Innovation Pathway led by the North East and North Cumbria Academic Health Science Network (www.ahsn-nenc.org.uk/).

In addition to the Node and DEC the region is, as a Genetics Medicine Centre, a major contributor to the 100,000 Genomes Project and has a NICE Technology Evaluation and Assessment Centre. Furthermore, last year we had the highest number of clinical research studies open to participants, more than any other Trust in the NHS in England. We are, therefore, ideally placed to provide expert advice and evaluation to companies operating in a wide variety of health technologies.

One example of the opportunities arising from our diagnostics expertise includes a rapidly formulated interaction between the DEC and Alere in 2014 that led to rapid coordination of regulatory issues and the analysis of a diagnostic test for flu in 812 patients across 3 UK centres in the winter of 2014-15, in a way the company had found previously impossible.



Excellence in research to transform health

A new partnership which harnesses world-class expertise will ensure patients in the North East will benefit sooner from new treatments, diagnostics and prevention strategies.

Bringing together Newcastle Hospitals and Northumberland, Tyne and Wear NHS Foundation Trusts with Newcastle University, the newly-formed “Newcastle Academic Health Partners” will deliver world-class healthcare through collaborative scientific research, education and patient care and mobilise the collective capabilities of the three organisations in support of economic growth.

The alliance will focus on delivering scientific advances that improve physical and mental health in common age-related chronic diseases such as dementia and musculoskeletal disease. It will also specialise in improving understanding and treatment of cancer, diseases that affect the brain and those affecting children.

Working across the two trusts, Newcastle Academic Health Partners will translate clinical research into practice developing improved diagnostic, prevention and treatment strategies as well as an innovative health education programme.

Sir Leonard Fenwick, Chief Executive for the Newcastle Hospitals explained: “Newcastle has a long-standing, international reputation for delivering trail-blazing health services. This wouldn’t be possible without the leading edge research carried out in partnership with Newcastle University, and we very much see this formal partnership, alongside new partners Northumberland, Tyne and Wear NHS Foundation Trust, as a springboard to cultivate even more pioneering research to benefit the people of the North East and beyond.”

John Lawlor, Chief Executive, Northumberland Tyne and Wear NHS Foundation Trust, said: “Northumberland Tyne and Wear NHS Foundation Trust aims to deliver world-class services and participating in research is a key part of doing that. Our service users have already benefited from research carried out in partnership with Newcastle University and we are excited about the opportunities provided by this formal partnership to deliver world-leading research to benefit our service users and, indeed, people around the world.”

Professor Chris Day, Pro Vice Chancellor in the Faculty of Medical Sciences at Newcastle University said: “This partnership is at the forefront of a revolution in practice which is developing and translating scientific advances made at Newcastle University into direct benefits for patients being treated in our partner NHS Trusts. This strategy has already led to major advances in healthcare within the region, as well as nationally and internationally”.

The partners have developed a five year plan that includes recruiting and training the next generation of researchers and providing national leadership in healthcare education. This collaborative approach is helping attract some of the brightest researchers and practitioners to Newcastle and the North East region.

For more information or interviews email: nahp@ncl.ac.uk

Faculty of Medical Sciences
Newcastle University
NE2 4HH

www.nahp.org.uk

Newcastle Academic Health Partners

nahp@ncl.ac.uk

Working together as Newcastle Academic Health Partners

The Newcastle upon Tyne Hospitals 
NHS Foundation Trust



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