NHS England

Spotlight on specialised services

Introduction

Specialised services support people with a range of rare and complex conditions, often at times when they are in greatest need. They can involve treatments provided to patients with rare cancers, genetic disorders or complex medical or surgical conditions. They deliver cutting-edge care and are a catalyst for innovation, supporting pioneering clinical practice in the NHS.

Specialised services are not available in every local hospital because they have to be delivered by specialist teams of doctors, nurses and other health professionals who have the necessary skills and experience.

These services include a range of treatments, from interventions that most of us have heard of, such as chemotherapy, radiotherapy and kidney dialysis, through to pioneering procedures that are currently only carried out in small numbers, such as using a patient's own tooth to restore their sight, and hand transplants. We also support trials of treatments, such as PrEP (Pre-exposure prophylaxis, a drug to prevent HIV), and an evaluation of mitochondrial donation, a form of IVF in which the future baby's mitochondrial DNA comes from a donor egg to avoid passing on inherited diseases.

Unlike most healthcare, which is planned and arranged locally, specialised services are planned nationally and regionally by NHS England. The list of services for which NHS England is responsible – numbering 146 across the country – is set out in legislation.

In practice, NHS England:

- **Supports service transformation**

  While planning of specialised services is national and regional, NHS England works closely with local areas and providers to improve joined-up care for patients who need specialised treatment. The new Sustainability and Transformation Partnerships – where the NHS and local councils have come together in 44 areas across the country to make proposals about how care is delivered – provide an opportunity to improve how we work in the future.

  We also carry out reviews of entire services, such as congenital heart disease and radiotherapy, to see where things can be improved, and to ensure services are keeping up with best-practice.

- **Sets national standards of quality and access**

  Over the last few years NHS England has set new national standards for specialised services to ensure patients get high quality care. We do this by publishing national service specifications that describe our expectations of providers and clinical policies that ensure equity of access to services.

- **Ensures value for money**

  As demand for NHS services continues to rise, and finances continue to be stretched, we have a responsibility to invest every single pound wisely. We continue to drive for efficiency, and sometimes need to make extremely difficult decisions about which new treatments to fund. We will continue to invest in evidence-based new ways to improve outcomes for patients.

The budget for specialised services – £16.6 billion in 2017-18 – has increased more rapidly than in other parts of the NHS, but it is under pressure. The number of patients needing specialised services is rising due to an ageing population and advances in medical technology. Part of the increase in budget is needed to cover the cost of the rising demand for services that are already provided by the NHS. However, some of it is needed to fund the cost of the hundreds of new drugs, medical devices and treatments that patients, clinicians, pharmaceutical companies and medical device manufacturers want to introduce into the NHS each year.

We have a legal duty to fund certain new medicines and devices recommended by the National Institute for Health and Care Excellence (NICE), but we also make available additional funding each year for other new treatments.

For these new treatments, we have to make complex decisions about which represent the best value for patients and taxpayers. This means comparing different treatments for different groups of patients and deciding which are of highest priority for the funding available. To do this we have developed a process of 'relative prioritisation' to determine which new treatments should be adopted for routine use.

We have a duty to patients and to taxpayers to ensure that new treatments are supported by convincing evidence of safety and effectiveness, that they are affordable and offer value for money, and that decisions about them are fair and transparent. Doctors, other healthcare professionals and patient and public representatives are involved at every stage of this decision-making process.

This pamphlet provides an insight into some of the life-transforming specialised services that are already being delivered and will continue to be rolled out over the coming years.

Highlights

Specialised services funded by NHS England are grouped into six National Programmes of Care: blood and infection; cancer; mental health; internal medicine; trauma; and women and children. This pamphlet highlights just a few examples of recent investments across these areas.

£16.6 billion
Planned spend on Specialised Services in financial year 2017/18

£15.4 Spent on Specialised Services in 2016/17

£130 million
Pounds invested in the modernisation of radiotherapy equipment

£340 million
Budget for the Cancer Drugs Fund (CDF)

£25 million
for the Commissioning through Evaluation programme evaluating 8 promising treatments

77,000
number of patients registered to receive drugs via the CDF since 2013

16,000
The number of patients treated by oral Hepatitis C treatments so far

10,000
Participants expected to participate in the **PrEP clinical trial** over the next three years

8,000
Acute ischaemic stroke patients to benefit from mechanical thrombectomy roll-out

146
Number of specialised services directly commissioned by NHS England

45
2-5 year olds with cystic fibrosis to benefit from ivacaftor

33
Newly commissioned treatments agreed in 2016/17

15
The percentage of total NHS spend Specialised Services accounted for in 2016/17 (as well as what we think it will count for in 2017/18)

13
Genomic Medicine Centres created

Blood and infection

Preventing HIV

An HIV prevention drug called pre-exposure prophylaxis (PrEP) is now being provided by the NHS in what is the largest single study of its type in the world.

Whilst HIV infection rates in England are falling due to increased prevention, diagnosis and treatment programmes, this major new NHS England-funded trial is assessing the full additional potential of PrEP, by gathering clinical evidence on optimal targeting, uptake and implementation on a large scale. This will pave the way for, and inform, roll-out after the trial.

The trial is expected to include 10,000 people over the next three years and will be delivered by around 200 sexual health clinics across the country.

In addition to investing in the PrEP trial, NHS England already invests in a 'treatment as prevention' (known as TasP) policy to start HIV treatment earlier for people with diagnosed HIV to protect HIV-negative partners. This programme, combined with other prevention measures, has led to a drop of over 20 per cent in new HIV diagnoses in large London clinics.

Rolling out new oral treatments for Hepatitis C

The largest single investment in new treatments for the NHS in 2016/17 was for new oral Hepatitis C treatments that can cure the disease.

NHS England has embarked on a sustainable roll-out strategy and we now have evidence that the investment in these game-changing treatments and the prioritisation by the Hepatitis C operational delivery networks of patients with greatest unmet clinical need, has significantly reduced deaths and liver transplants. By the end of August 2017, approximately 20,000 patients will have been treated, which amounts to more than 10 per cent of the total estimated infected population. Since we have followed NICE guidance to focus on those at greatest clinical need, this has led to a rapid reduction in mortality (by around 10 per cent) and an unprecedented reduction in liver transplants for Hepatitis C Virus of around 50 per cent.

Through our work on drug pricing, the NHS is able to increase the number of patients treated within available resources. Industry has responded positively to our successive drug procurements and moved to an innovative 'pay for cure' approach for all hepatitis C treatments. This means the NHS only pays for the drug if patients are cured, which frees up funds and allows consideration of other access issues. For example, there are a small number of people with advanced disease for whom the first treatment was unsuccessful, and they need to be retreated urgently. Although NICE are set to review evidence for future guidance including retreatment, in the meantime NHS England has approved a policy to allow those with the most advanced disease to be retreated. As well as improving access for these patients, the number of people to be treated overall will increase by 25 percent this year (2017/18).

"I'm a recovering drug addict and have had Hepatitis C for over 27 years. As part of my recovery, nine months ago I started to think again about treatment and engaged with one of the new medicines that is available. Within four weeks my Hepatitis C was undetectable with no side effects. I feel more motivated in my present endeavours and I'm about to start at university this September. Curing my condition has enabled me to wave goodbye to the last remnants of my drug use and today I feel I have a purpose in life."

Leslie Chandler, patient aged 60

Cancer

Increased access to advanced brain tumour treatment

By 2019, more than 6,200 brain tumour patients a year will be benefitting from a precise and effective form of specialist radiotherapy known as stereotactic radiosurgery and radiotherapy (SRS/SRT), up from just over 2,400 in 2014/15. By improving access to these advanced forms of radiotherapy, fewer people undergo more invasive and costly treatments such as surgery, and spreading the new services across all regions of England has made it possible to treat more people closer to home.

> "I have a condition called Neurofibromatosis Type 2 (NF2) which predisposes me to developing tumours on my brain and spine. I've had radiosurgery three times now, to treat seven tumours. I am not a big fan of having surgery so radiosurgery suits me – it's pain free and I only need to stay in hospital a couple of nights. After each treatment I've been back at work the following week and back exercising. The procedure is also scar free, no signs that you have ever had it. I've received great care and I'm feeling really well."
>
> **Bronwen Robson, brain tumour patient from Sheffield**

Services are delivered using a number of different platforms, including Gamma Knife, CyberKnife and specially configured linear accelerators. The technology delivers precisely directed beams of radiation to the tumour, meaning that there is less of risk of damage to surrounding healthy tissue and fewer side effects for patients.

The increased number of SRS/SRT treatments is being delivered for significantly less than they were prior to the awarding of new provider contracts in 2016, due to efficiencies of around 25 per cent.

Upgrading radiotherapy equipment

We have invested £130m to kick-start the biggest upgrade in NHS cancer treatment in at least 15 years, which will transform cancer care for hundreds of thousands of patients across England.

Around 4 in 10 of all cancer patients are treated with radiotherapy, which typically uses high-energy radiation from a machine called a linear accelerator ('Linac'). Over the next two years over 100 older Linac machines used by hospitals across the country will be upgraded or replaced, so that patients can access the latest leading-edge technology regardless of where they live. The newer machines are faster and therefore allow more patients to be treated. This should help manage increases in patient numbers and tackle cancer waiting times.

Recent advances in radiotherapy using cutting-edge imaging and computing technology have helped target radiation doses at cancer cells more precisely. As a result, they enable better outcomes, with improved quality of life for patients and reduced NHS costs in the long term, through patients experiencing fewer side effects.

Cancer Drugs Fund

The Cancer Drugs Fund (CDF) is a source of funding for cancer drugs in England. Following consultation, in July 2016 the way the Fund operates was updated to put it on a more sustainable financial footing.

The new-look CDF now provides patients with faster access to the most promising new cancer treatments, helps to ensure more value for money for taxpayers and offers pharmaceutical companies (who price their products responsibly) a new fast-track route to NHS funding.

Since the reforms came into effect the CDF has provided immediate access to patients for cancer treatments provisionally recommended by NICE. This has resulted in over 15,000 patients benefitting from 55 different cancer treatments up to 6 months earlier than the usual commissioning rules allow.

The Fund has also for the first time provided patients access to promising cancer treatments with uncertain long term benefits, whilst further clinical data is being collected. At the moment 2,000 patients per year are able to access these at significantly discounted prices to the NHS, and there are more in the pipeline which could benefit a further 3,000 patients per year.

The CDF remained within its budget of £340m in 2016/17, demonstrating the new CDF has already achieved its target of being a successful and sustainable deal for patients, taxpayers and industry.

Standardising chemotherapy drug dosing

Chemotherapy is the single biggest service area within our Specialised Commissioning portfolio, costing in excess of £1.5 billion. This award-winning project is improving patient experience and value on a national scale by reducing drug wastage, enabling the bulk purchasing and manufacture of chemotherapy drugs and freeing up pharmacist time for more patient-facing work rather than time-consuming bespoke pharmacy production.

Through the introduction of a standard approach to "dose banding", chemotherapy drugs can be better utilised, avoiding the need to discard expensive medication left over in vials through mismatch between doses prescribed, and the volumes contained in the vials, and sizes of syringes currently available. Standardisation also allows more chemotherapy to be available in "ready to use" forms so hospitals can hold stock of these doses, reducing waiting times for treatment – for all pharmacy patients, not just those receiving chemotherapy – and bringing down costs.

Dose standardisation has already achieved a 25 per cent reduction in price on a number of drug products, in a recent North West tender for pre-prepared doses of chemotherapy. There is emerging evidence of Pharmacy services already reducing the amount of a drug they purchase whilst delivering more doses, and more prescriptions, through better use of the drugs that dose standardisation enables.

The national programme recently won an award at the HSJ Value in Healthcare Awards, and was commended by the judges as "a great project that demonstrated very significant cost reductions whilst dramatically improving patient safety and patient experience."

Internal medicine

First precision drug for children with cystic fibrosis

Around 45 children aged 2 – 5 with cystic fibrosis will benefit from the first precision medicine for the condition available on the NHS, thanks to a deal struck by NHS England with the manufacturer to reduce the price, allowing more patients to be treated.

Hailed as a game-changing drug, ivacaftor is a high-cost medicine which acts on the chemical pathway that causes the condition and can slow disease progression, unlike other therapies that can only treat symptoms. Early evidence suggests that patients treated with ivacaftor have a reduction in the severity of their condition and the need for other treatments as well as fewer hospital admissions.

"My daughter started on ivacaftor in February this year and the results have been so amazing – tests show that progression of the condition is slowing. She also no longer needs to take a separate drug which helped her digest food, and has been so well since. This really has been life changing for us."

Claire Le Sueur, mum to Rosie, aged 2.

New treatment to tackle rare blood vessel condition

Originally used to treat rheumatoid arthritis, the drug tocilizumab is now also proven to be effective in patients with a rare condition called Takayasu arteritis (TAK), which causes swelling in the vessel walls of the aorta (the main blood vessel running from the heart to the rest of the body) and the main arteries.

A review of the latest evidence has allowed us to recommend this drug for routine use, offering patients another treatment option. Current treatment includes steroids and drugs that reduce the body's immune response, however both of these therapies have limited effectiveness and can have unpleasant side effects. If treatment is unsuccessful, TAK can lead to organ failure and damage to the blood vessels that may require reconstructive surgery. Tocilizumab is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a structure (called an antigen) that is found in the body, to directly tackle the cause of the disease. By suppressing the inflammatory response it reduces swelling in the blood vessels, effectively treating the condition. We expect this new treatment to benefit around 100 people suffering from TAK each year.

New drug for a new autoimmune disease

Around 100 patients with a newly classified autoimmune disease can now benefit from a new drug, rituximab, to target the specific condition.

Immunoglobulin G4-related disease (IgG4-RD) is more common in men and used to be treated as several unrelated disorders. But it is now recognised as a single condition caused by the blood's plasma cells creating antibodies which then damage a number of different organs. The disease in it's severe form causes significant disability and can be fatal.

For patients with this rare disease rituximab provides an alternative when they are no longer getting benefit from their treatments or suffer bad side effects. This drug reduces the damage to organs and can replace the need for other treatments, making it easier for patients to manage their disease.

Mental Health

Supporting mothers with mental health problems

We have expanded perinatal mental health inpatient services with four new inpatient mother and baby units (MBUs), to support mothers who are experiencing severe ill mental health problems and help them stay with their babies.

As many as one in five women experience mental ill health during pregnancy or in the year after birth, covering a wide range of conditions including depression, anxiety or in severe cases, post-partum psychosis which affects about 2 in every 1000 new mothers. Devastatingly, suicide is the second leading cause of maternal death after cardiovascular disease.

MBUs enable the treatment and recovery of the mother whilst ensuring the developing relationship with the baby and their physical and emotional wellbeing. They are staffed by clinicians with specialist knowledge and skills in the impact and effect of childbirth on maternal psychiatric disorder, and the treatment of the infant under these circumstances.

The new units are in East Anglia, North West, South West and South East Coast – putting resources in areas with the most need.

"Every woman should have access to a mother and baby unit and specialist care when they need it… They provided a safe, caring and learning environment for me and my daughter for the first months of her life – and we will always be grateful for this."

Katy Chachou (admitted to a Birmingham MBU at the age of 32 with her month old baby).

Trauma

Thrombectomy for people with stroke

We are rolling out mechanical thrombectomy, which will ultimately benefit up to 8,000 stroke patients a year once fully implemented, placing the NHS at the leading edge for innovative treatment options in stroke care internationally.

This treatment will benefit patients who suffer from certain types of acute ischaemic strokes – a severe form of the condition where a blood vessel to the brain becomes blocked, often leading to long term disability.

The complicated procedure involves inserting a piece of wire mesh (a stent) into a blood vessel, usually through the groin, before guiding it through the circulatory system and into the brain. The stent is then used to dislodge and remove the blockage and restore blood flow. If used within the first six hours of symptoms starting, it can significantly improve quality of life.

An estimated 1,000 patients will benefit from this treatment in 2017 alone, with numbers reaching around 8,000 a year once the treatment is phased in through development of workforces and systems and building on expertise.

Stroke is estimated to cost the NHS around £3bn per year, with additional cost to the economy of a further £4bn in lost productivity, disability and informal care. Treating patients with thrombectomy will not only decrease the risk of long-term disability, but it will also result in multimillion pound annual savings for the NHS and local authorities thanks to lower rehabilitation and long term care costs.

Auditory brainstem implants - improving hearing for profoundly deaf children

We are investing £700K in a new technique which helps restore the sensation of hearing to some children born with profound deafness. Auditory brainstem implants can help a small number of patients whose auditory (hearing) nerve is not working – most patients will be small children whose inner ear (cochlea) or nerve did not develop properly. We estimate around nine children a year could benefit from the operation, which involves inserting a device directly against the brainstem, bypassing the cochlea and auditory nerve.

> "The auditory brainstem implant has opened up the world of sound for Leia. She had her device switched on at 2 years of age and has had 4 years of learning to become aware of sound. To watch her joy at being able to respond to music and also now attempt to put sentences together with the words she has learned, was something we never thought would be possible. The ABI has made that happen and who knows how far she can take it."
>
> **Bob Armitage, whose daughter Leia has received an implant**

The implant helps the patient to recognise and discriminate different environmental sounds such as a doorbell and telephone ring. Following implantation, long-term professional support is crucial to encourage the wearer to learn to listen to and understand the new signals from their implant.

Hand Transplants

In 2016 two NHS patients in England became some of the first in the world to benefit from pioneering hand and upper arm transplants.

These transplants offer patients the only method of reconstruction that looks and functions like a normal hand and will, in time and with expert aftercare, move with strength and dexterity, sense its surroundings, feel warm to the touch and heal itself when injured.

People who have had a hand transplant also report a better quality of life and wellbeing, and the majority are eventually – after extensive physiotherapy – able to undertake daily living activities.

The centre performing this procedure in Leeds Teaching Hospitals NHS Trust is headed up by leading consultant plastic surgeon Professor Simon Kay, who successfully performed the UK's first hand transplant in 2012. The patient, Mark Cahill from West Yorkshire, has reported regaining almost complete use of his transplanted hand, allowing him to, for example, tie his shoelaces, carry his granddaughter and drive a car.

It is estimated that two to four patients a year may benefit from this cutting-edge surgery with two patients already having treatment in 2016-17.

Restoring vision with a patient's own tooth - osteo-odonto-keratoprosthesis service

Osteo-odonto-keratoprosthesis (OOKP), also referred to as 'tooth-in-eye' surgery, is a life-changing procedure restoring vision to blind patients. Clinicians at Sussex Eye Hospital, part of Brighton and Sussex University Hospitals NHS Trust, will treat up to five patients a year.

The technique uses the patient's own tooth root and alveolar bone to support an optical cylinder.

The procedure takes place in several stages. A graft is taken from the inner cheek and placed over the damaged cornea. Then a thin layer of tissue is cut from an extracted tooth and drilled through - to create a hole for the optical cylinder to sit in. This is then placed into the patient's lower eyelid for 3 months, to develop vascularization and promote growth of connective tissue. The final stage sees the tissue placed under the graft which has been cut for the optical cylinder to protrude from.

OOKP is performed on blind patients with damaged corneas, for whom traditional transplants are not suitable. All patients undergo various assessments to ensure the procedure is appropriate for them, including ocular, oral, psychological and radiological.

> "I went blind after a furnace exploded onto me with molten metal. I had been blind for twelve years before OOKP surgery, but after the bandages came off, I immediately saw faces and pictures on the ward." **Joseph, a patient who has undergone the procedure**

Microprocessor knees

For some patients who have lost a leg at or above the knee, microprocessor controlled prosthetic knees (MPKs) are now an option on the NHS.

An MPK is an artificial knee joint which includes a battery powered, built in, programmable computer that continuously controls both swing and stance based on real-time data of the user's gait.

MPKs provide enhanced stability and recovery from stumbles, therefore reducing falls. They provide better controlled sitting and standing, walking gait symmetry, stair and slope decent, obstacle management and a reduction in energy expenditure.

Patients with an MPK have reported improved individual mobility and independence. The device allows its user to select different modes for different kinds of activities too, allowing patients more freedom and choice.

This innovative equipment will be used to restore quality of life to around 500 people a year and in aiding patient health and well-being the MPKs are cost effective for the NHS.

Bionic Eye

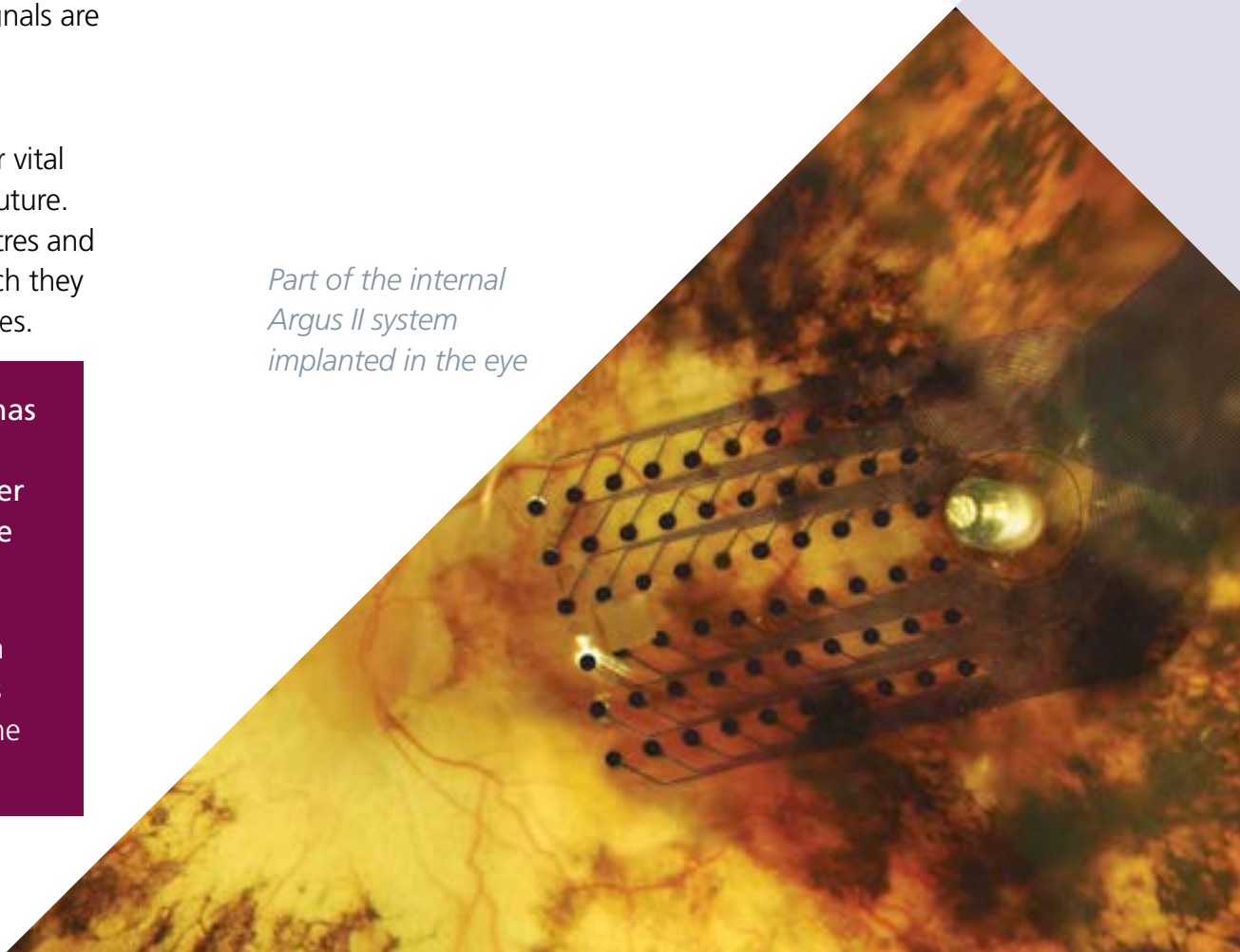
Ten patients are undergoing pioneering surgery to tackle Retinitis Pigmentosa (RP), an inherited disease that causes blindness.

Early studies have demonstrated that the Argus II, or 'Bionic Eye', restores a degree of visual function to patients who have suffered complete blindness due to the condition. Patients are given an implant into their retina and a camera mounted on a pair of glasses sends wireless signals direct to the nerves which control sight. The signals are then 'decoded' by the brain as flashes of light.

We are funding the testing of the Bionic Eye through our Commissioning through Evaluation scheme, designed to gather vital evidence for treatments that show significant promise for the future. Procedures will take place during 2017 by clinicians at two centres and patients will be monitored for a period of one year, during which they will be assessed on how the implants improve their everyday lives.

Grandfather-of-five from Lancashire, Keith Hayman, has been blind for 25 years and was one of three people who had been fitted with the bionic eye at Manchester Eye Hospital during a trial for Retinitis Pigmentosa. He says;

"Having spent half my life in darkness, I can now tell when my grandchildren run towards me and can make out lights twinkling on Christmas trees. These little things make all the difference to me."



Part of the internal Argus II system implanted in the eye

Women and children

Everolimus for children with brain tumours

For 20-30 children diagnosed with a rare condition causing benign brain tumours to grow, quality of life can now be dramatically improved by newly-funded drug, everolimus.

The drug is for children with subependymal giant cell astrocytoma (benign slow-growing brain tumours) associated with the condition tuberous sclerosis complex (TSC), and will be offered in cases where the tumours cannot be removed by surgery. These kind of tumours develop in 5-20 per cent of tuberous sclerosis complex patients, usually during childhood and adolescence.

Left untreated, tumours can grow to cause hydrocephalus (a build-up of fluid on the brain) and other associated symptoms such as headaches, nausea, vomiting, seizures, behavioural changes, facial rashes and visual problems. Everolimus works to reduce the size of the tumour which causes these problems and can remove the need to have potentially complicated surgery.

"To me everolimus is as close to a cure as we're ever going to get for TSC. We were told Seth (14 years old) would never be seizure free, and since taking everolimus he has been. Seth has had his tumour removed twice and we were told he'd need further brain surgery – thanks to everolimus he won't need this now. To say that is a relief is an understatement! As they go under anaesthetic you're saying goodbye not knowing whether you'll ever see your child alive again or whether they will be the same if they do wake up."

Lynn Murton, mother to Seth, aged 14, who has tuberous sclerosis complex

Children's Epilepsy Surgery Service

Following consultation we have reconfigured epilepsy surgery services for children to further centralise specialised surgery into four national centres of excellence, where surgical and clinical expertise in this type of surgery is second to none. We have also expanded the list of operations to be undertaken in these centres, in line with national and international expert clinical advice, due to the complexity of these cases.

In England more than 50,000 children and young people have epilepsy. Epilepsy surgery in infancy and early childhood is increasingly recommended because it may prevent many years of unnecessary seizures. Evidence shows that where complex procedures are concentrated in specialist centres treatment is more safe, effective and subsequently leads to better outcomes for patients. These changes will ensure that all children with epilepsy have access to a range of appropriate and high quality treatment options.

Widening access to medicines for children

For the first time, children and young people with certain conditions can now be routinely prescribed some medicines that previously would have been difficult to access.

When NICE issues guidance on drugs for use within the NHS, it usually recommends its use in groups of patients for which the medicine has been granted a licence. But drugs often only have a licence for patients over 18 because these are the group of patients on whom the medicine has been researched.

After carefully reviewing the evidence we concluded that there is enough to consider making some treatments routinely available in certain situations for children and young people. Conditions currently include severe Crohn's disease, cystic fibrosis, psoriasis, chronic immune (idiopathic) thrombocytopenic purpura, hidradenitis suppurativa and severely active ulcerative colitis.

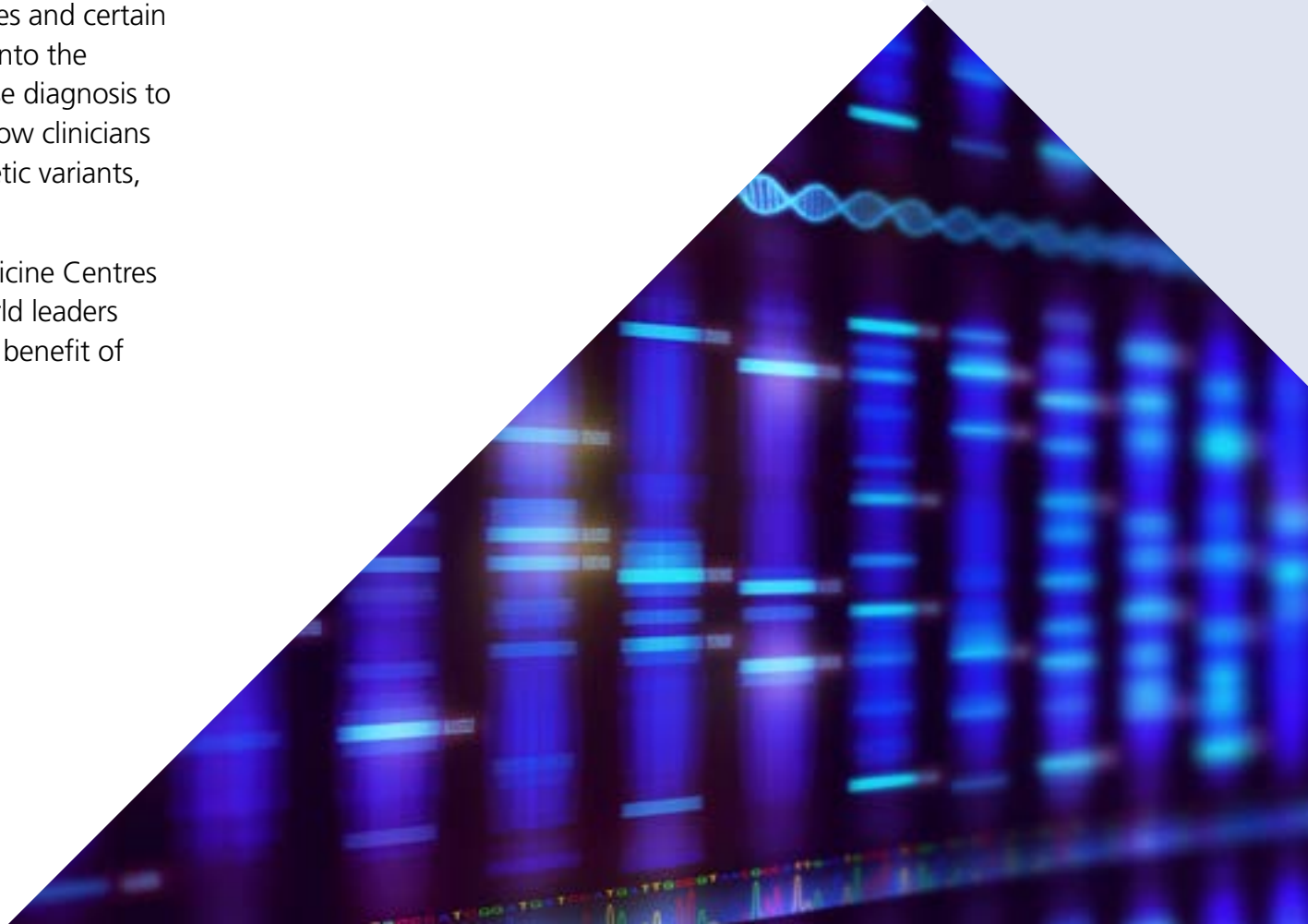
We estimate at least 30 children a year will now be eligible to quickly access medicines to treat these conditions without having to go through the Individual Funding Request route, and this number will grow as we review the evidence for more conditions, such as multiple sclerosis (MS).

Supporting world leading research

100,000 genomes project

The 100,000 Genomes Project has been established to sequence the genomes – complete sets of people's genes – from 100,000 patients by the end of 2018, which will enhance our understanding of the genetic basis underlying rare or inherited diseases and certain common cancers. This will provide important insights into the prediction and prevention of disease to enable a precise diagnosis to be made, in some instances for the first time. It will allow clinicians to personalise treatments targeted to the specific genetic variants, which will lead to better outcomes for patients.

We have invested £30m to establish 13 Genomic Medicine Centres to carry out this work, which positions the NHS as world leaders in realising a new era of personalised medicine for the benefit of patients, and ensuring it is built into mainstream care.



Mitochondrial donation evaluation

We are making up to £8m available over five years to fund the treatment costs of a world-leading five year evaluation of mitochondrial donation – a form of IVF in which the future baby's mitochondrial DNA comes from a donor egg, to avoid passing on inherited mitochondrial diseases.

Mitochondrial diseases can be devastating, causing blindness, blocked heart, muscle wastage and weakness, learning disabilities, deafness and diabetes. An estimated 2,473 women of child bearing age are at risk of transmitting mitochondrial DNA disease and the lifetime treatment cost for a patient with serious mitochondrial disease is around £1.3m.

Wellcome is funding a five year research programme at Newcastle University and Newcastle upon Tyne NHS Foundation Trust to study the long term follow up of any children born following mitochondrial donation, and NHS England will fund the treatment costs. A total of 125 patients will be enrolled, with an estimated 25 progressing to treatment annually. The first patient is expected to be treated in Autumn 2017.

Evaluative commissioning and supporting research

Our £25m Commissioning through Evaluation (CtE) programme is testing an innovative approach to evaluating potentially promising specialised treatments, for which there is currently insufficient evidence to support routine commissioning (funding) within the NHS.

For each CtE scheme, new data is collected within a formal evaluation programme, undertaken in partnership with NICE, potentially leading to the development of a new or revised national clinical commissioning policy for future access.

We are currently evaluating eight treatments: Selective Dorsal Rhizotomy (SDR), a procedure used to relieve spasticity in children with cerebral palsy; three schemes evaluating the effectiveness of interventional cardiology procedures (left atrial appendage occlusion, patent foramen ovale closure and Mitraclip); two radiotherapy treatments (Stereotactic Ablative Body Radiotherapy (SABR) and Selective Internal Radiation Therapy) to treat patients with specific cancers; Rituximab as standard treatment for resistant idiopathic membranous nephropathy; and the Second Sight Argus II Retinal Prosthesis 'Bionic Eye'.

Each scheme has been developed with the support of national clinical experts and patient representatives and enables a small number of procedures to be funded, within a limited number of selected centres and a limited time-frame, while evidence on the relative clinical and cost-effectiveness of the procedures is gathered and compared to treatments available in the NHS.

NHS England also directly contributes to the cost of the trials on PrEP for HIV and SABR, and the evaluation of mitochondrial donation. We have made a commitment to fund research into Proton Beam Therapy once the new national service is operational in Manchester and London.

To keep up to date with all the latest specialised commissioning news, or to get directly involved with our work, please visit **https://www.england.nhs.uk/commissioning/spec-services/get-involved/**

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please contact 0300 311 22 33 or email **england.contactus@nhs.net** stating that this document is owned by the Specialised Commissioning communications team.

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