NHS England

Spotlight on specialised services

Second edition 2018/19

Introduction

Specialised services provide care to patients 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 often a catalyst for innovation, supporting pioneering research 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, neonatal critical care and kidney dialysis, through to pioneering procedures that are currently only carried out in small numbers, such as using an artificial cornea to restore vision to blind patients. We also support trials of treatments, such as Pre-exposure prophylaxis (PrEP), a drug combination used to prevent HIV.

Unlike most healthcare, which is planned and arranged locally, by Clinical Commissioning Groups, specialised services are planned nationally and regionally by NHS England. The list of services for which NHS England is responsible – numbering about 150 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. Sustainability and Transformation Partnerships and Integrated Care Systems have brought the NHS and local councils together in 44 areas across the country to plan how care is delivered. This provides an opportunity to improve the coordination of specialised services.

  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 how services are provided. We also publish clinical policies that ensure equity of access to treatments and services.

- **Ensures value for money**

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 decisions about which represent the best value for patients, the NHS 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.

In this second edition, this pamphlet provides an insight into some of the new life-transforming specialised services that are already being delivered.

£17.7 billion

Planned spend on Specialised Services in financial year 2018/19

£16.6 Spent on Specialised Services in 2017/18

7 genomic laboratory hubs will form a national genomic testing network

13 new Forensic Child and Adolescent Mental Health Services for young people with complex mental health needs have been commissioned by NHS England

About 150 Specialised services are directly commissioned by NHS England

31,000 patients receiving new hepatitis C treatment

800 people who have highly active relapsing MS can now benefit from a new 'once a year' treatment

81 different types of cancer have been treated using **52** different medicines or treatments

£700,000 is being invested by NHS England in a new technique which helps restore the sensation of hearing to some children born with profound deafness

1,000 people over five years could benefit from a new innovative stroke prevention procedure

13,000 people are being recruited for the **PrEP IMPACT trial** to prevent HIV infection

Highlights

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

Blood and infection

Using pig genes to treat bleeding

Factor VIII derived from pig genes and genetically engineered hamster kidneys are being used in a revolutionary new treatment for haemophilia. NHS England now commissions susoctocog alfa for treating bleeding episodes in patients with acquired haemophilia A. Susoctocog alfa is made using the factor VIII gene isolated from the pig genome. The purified protein temporarily replaces the human factor VIII as it is different enough to either go undetected or only be partially detected by the antibody to the human factor VIII (also known as cross-reaction). However, the protein is still similar enough to allow coagulation to occur, which controls bleeding. In contrast to current bypassing agents, susoctocog alfa is measurable in a routine haemostasis laboratory, enabling more accurate and guided dosing. Susoctocog alfa is expressed in a genetically engineered hamster kidney cell line which secretes recombinant porcine factor VIII into the cell culture medium.

There have been significant changes in the treatments becoming available for haemophilia. Haemophilia is a range of bleeding disorders caused by lack of sufficient blood clotting proteins. One example is Emicizumab which is used to treat patients with haemophilia A for whom factor VIII treatments are not effective. This represents a major breakthrough in treatment for these disorders.

"We are delighted that NHS England is playing a leading role in tackling hepatitis C and eliminating this deadly virus. A key challenge will be the fact that hepatitis C often has no symptoms in the early stages and it is thought that less than half of those living with the virus have been diagnosed. It is therefore vital that anyone who is at risk asks to be tested."

Judi Rhys, Chief Executive of the British Liver Trust

Rolling out new treatments to cure Hepatitis C

Over 31,000 people have been treated with new hepatitis C drugs that can be taken by mouth, as a result of NHS England's strategy to make treatment available to those with the greatest clinical need. This amounts to about 20 per cent of the approximately 160,000 people in England estimated to be infected with hepatitis. NHS England has also established operational delivery networks across the country to guide the clinical use of hepatitis C drugs. The new *Hepatitis C in the UK* report shows provisional data indicating a 14 per cent reduction in hepatitis C virus related deaths up to 2017.

In April, the single largest medicines procurement ever to be undertaken by the NHS was launched. NHS England's ambition is that through innovative collaboration with pharmaceutical companies, England can eliminate hepatitis C as a public health concern by 2025 – 5 years ahead of international goals set by the World Health Organisation. This would involve securing the drugs needed at an affordable price and pharmaceutical company support would also be very helpful to the operational delivery networks to

identify more people who are living with hepatitis C who would benefit from treatment.

England remains one of few countries where numbers of patients receiving new oral treatments for hepatitis C continue to increase year on year.

Preventing HIV

The prevention of HIV remains a major challenge. When HIV was first identified the only weapon to fight the spread of HIV was safer sex. When highly effective antiretroviral treatment became available, it was discovered that people with HIV who are effectively treated, with no detectable HIV virus in their blood, cannot pass on HIV. NHS England is therefore funding a 'test and treat' approach in HIV. This means instead of waiting until a patient with HIV has developed symptoms; treatment can start immediately at the point of diagnosis. There is also now evidence that early treatment also improves the outcomes for people with HIV.

More recently, evidence is growing to show that in people who are HIV negative and at significant risk of acquiring HIV, pre-exposure prophylaxis (PrEP) may be effective in preventing the infection. NHS England has launched the pre-exposure prophylaxis (PrEP) IMPACT trial which has recruited almost 8,000 participants at 140 clinic research sites in less than a year since it started. People in the trial take anti HIV drugs in order to reduce the likelihood that they will acquire HIV. With advice from researchers, NHS England and local authorities are supporting an increase in the size of the trial to 13,000 people to ensure that the data produced will more accurately indicate the likely 'real life' usefulness and design of a sustainable

PrEP programme, should a decision be reached to routinely commission a PrEP service.

These measures form the foundations of HIV prevention and contribute to efforts to end HIV as a public health threat by 2030.

Internal medicine

New way to remove the pancreas without causing diabetes

Total pancreatectomy with islet cell auto transplantation (TPIAT) can relieve the severe pain associated with chronic pancreatitis (CP) while preventing or reducing what would otherwise often be a severe form of diabetes that occurs when the pancreas is removed. TPIAT involves the infusion of islet cells (which produce insulin) taken from the patient's own pancreas, back into their liver. Following removal of the pancreas, the islet cells are removed and prepared for transplantation, then infused slowly back into the patient.

There are many underlying causes of chronic pancreatitis, including genetic causes, and excessive alcohol intake, however in many cases no specific cause is found. The worst aspect of the disease is the abdominal pain that is typically very difficult to manage and often results in patients frequently attending hospital. Removal of the pancreas may stop or reduce the severity of the pain but will cause diabetes which is often very difficult to manage. Many patients with diabetes produce some insulin and also glucagon (another hormone that regulates sugar in the body), but when the pancreas is removed both insulin and glucagon cannot be produced. This leaves many patients after their pancreas has been removed, with no warning of hypoglycaemia and this may be very disabling for them and demanding on carers.

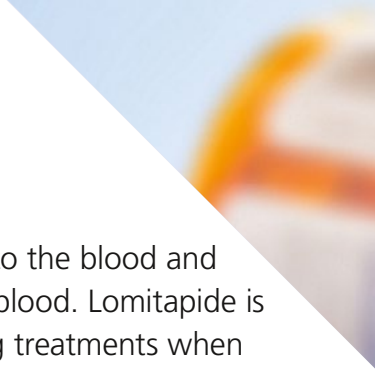
We expect the number of patients who will benefit from this treatment will increase to about 75 patients a year.

Equality of access for men to osteoporosis drug

Around 400 men a year with osteoporosis that has not improved with other treatments, can now benefit from the drug teriparatide. NICE is developing guidance on non-bisphosphonate (including teriparatide) treatment of osteoporosis including for men. However, NHS England has concluded that there is sufficient evidence to commission teriparatide after other treatments have failed for the secondary prevention of osteoporotic fragility fractures in men. This interim decision allows earlier access for patients until NICE publish their appraisal of the drug.

New drug to reduce heart disease for patients with inherited high cholesterol

Familial hypercholesterolemia (FH) is an inherited disease that results in very high levels of harmful cholesterol (a type of fat made by the body). It greatly increases the risk of heart disease, often leading to early death. Patients with a rare and severe form of the disease called homozygous FH have two copies of the faulty gene that causes the disease rather than one. Lomitapide is thought to work in a different way to established cholesterol lowering drugs. Lomitapide



decreases the amount of cholesterol released into the blood and therefore reduces the level of cholesterol in the blood. Lomitapide is taken in addition to existing cholesterol lowering treatments when these have not provided sufficient benefit, and requires a very low fat diet to be used safely. Many patients starting lomitapide will be receiving lipoprotein apheresis (which 'filters' the blood to remove cholesterol), and some of these patients will be able to reduce the frequency of apheresis or stop it completely. Lomitapide provides an additional treatment option before the consideration of liver transplant. It is expected that around 30 patients a year will benefit from this drug.

Cancer

Providing faster access to lung cancer immunotherapy drug for cancer patients

In June 2018, NHS England announced that a new lung cancer drug called pembrolizumab would be available for routine use on the NHS. New trial results have shown that this drug can be used to treat certain types of untreated lung cancer that has already spread to other parts of the body, giving patients over an extra year of life.

Pembrolizumab would have cost around £84,000 per patient at its full list price. However, NHS England and the pharmaceutical company that makes the drug have agreed a confidential arrangement for reimbursement which means that this treatment can be routinely available on the NHS. This is the first drug to be made available via changes to the cancer drug fund (CDF) which aims to benefit patients, the NHS, taxpayers and the pharmaceutical industry.

"We have to make sure that any new treatment we recommend works well and is a good use of NHS resources. Recent changes to the CDF mean we have more flexibility in our process so we can grant early access to promising drugs whilst more data is gathered on their long-term benefits."

Meindert Boysen, director of the NICE Centre for Health Technology Evaluation

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 and ensure that resources are used wisely.

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

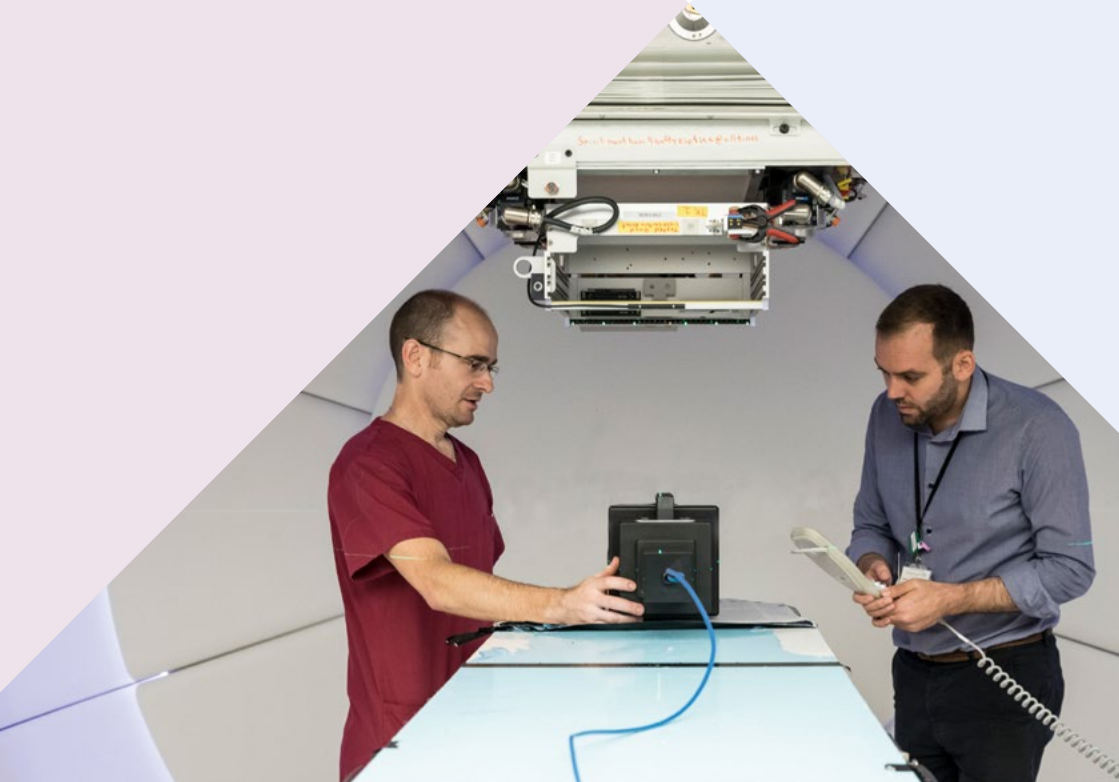
Since the CDF reforms came into effect nearly 15,700 patients have benefited from the 52 drugs treating 81 different types of cancer. Of these patients, around 5,000 have received treatment sooner than they would have under the previous system. Patients also benefit from new cancer drugs at least four months earlier under the reformed CDF.

The CDF remained within its budget of £340m in 2017/18, demonstrating the new CDF has already achieved its target of being a successful and sustainable deal for patients, taxpayers and industry.

Highly innovative proton beam therapy service due to open in England

By late 2018, the NHS will have its first ever high energy proton beam therapy service based at the Christie NHS Foundation Trust in Manchester, followed by a second service which is expected to open in 2020 at the University College London Hospital (UCLH) NHS Foundation Trust.

Proton beam therapy is a different type of radiotherapy. It uses a high energy beam of protons rather than high energy X-rays to deliver a dose of radiotherapy to patients with cancer. It works best on some very rare cancers including tumours affecting the base of



skull or the spine. Proton beam treatment can be a safer form of therapy because it enables the radiation treatment to be delivered where it is needed with minimal damage to surrounding tissue. The treatment is particularly suitable in children because they are more at risk of the side effects and long term risks from radiation exposure.

Since 2008, patients who could benefit from proton beam therapy, and meet the agreed clinical criteria, can access treatment overseas – in Switzerland, Germany or USA – via the NHS Proton Overseas Programme. Patients and their families are away from home for 8-10 weeks and the NHS funds the travel and accommodation costs.

Improving survival rates for people with brain cancer

Every year approximately 9,000 new cases of brain and other central nervous system and intracranial tumours are diagnosed in England. The survival outlook is poor, with only around 14 per cent of people with brain cancer expected to survive for 10 or more years. 5-amino-levulinic acid (5-ALA) is a dye used in brain cancer surgery. The purpose of the dye is to 'light-up' cancerous tissue and help the surgeon remove as much of the cancer as possible, therefore improving prognosis.

As part of a series of measures to improve outcomes for patients with brain cancer, NHS England has committed to making sure the dye is routinely offered to all patients from July 2018.

Hope for people with advanced blood cancers

Indolent non-Hodgkin's lymphoma is a slow-growing blood cancer. A combination chemotherapy treatment of bendamustine with rituximab offers an additional first-line (initial) treatment option at an advanced stage of the condition and has different side effects and toxicity compared to existing treatment. It is expected that approximately 930 patients will be eligible for this treatment each year.

Mantle cell lymphoma (MCL) is a rare form of non-Hodgkin's lymphoma. Chemotherapy is the main treatment for patients with MCL. Bendamustine with rituximab offers an additional first line treatment option with different side-effect and toxicity profile which means that it expands the choice of treatments for patients to manage recurring or unresponsive MCL. It is expected that approximately 190 patients will be eligible for this treatment each year.

High quality care for patients undergoing lung surgery

In 2017, NHS England published a new service specification for thoracic surgery services to drive improvement in clinical outcomes for patients undergoing this type of surgery. The development of the specification was guided by research findings that demonstrate a clear link between units undertaking higher numbers of procedures and improved lung cancer mortality and survival. Since 2017, we have been working closely with hospitals that deliver these services to ensure that the new standards are met and patients receive high quality care.

Mental Health

Supporting young people with mental health conditions in the justice system

We have commissioned 13 new Forensic Child and Adolescent Mental Health services (FCAMHs) for young people with complex mental health needs. These will ensure that beds are available at the right place and the right time for young people who desperately need them.

These services work with agencies across the health and justice, education and third sector providing support and advice for professionals who are also caring for these vulnerable young people.

The commissioning of these services by NHS England ensures there is continuity of well-coordinated care that is available across the whole of England, especially in some areas where previously there was no provision.

Increasing access to Mother and Baby Units for mothers with mental health problems

Four new, eight-bed Mother and Baby Units (MBUs) have been commissioned in areas of the country where women face particular issues in accessing services. MBUs provide specialist inpatient care and support to mothers who experience severe mental ill health during and after pregnancy. The number of beds in existing units is also increasing, with an overall expansion in capacity of 49 per cent (based on MBU capacity in 2015). By the end of 2018, there will be over 150 MBU beds in England.

As many as one in five women experience mental ill health during pregnancy or in the year after birth. By 2021 there will be specialist community perinatal mental health teams covering all areas of England. These teams will provide specialist, community-based support and treatment options for women with moderate to severe mental ill health associated with the perinatal period.

Devastatingly, suicide is the second leading cause of maternal death after cardiovascular causes. MBUs enable the treatment and recovery of the mother while facilitating the development of the mother baby relationship in a safe and secure environment. They are staffed by clinicians with specialist knowledge and skills in the impact and effect of childbirth on maternal psychiatric disorder, as well as the care of the infant under these circumstances.

"Pregnancy and childbirth is an important time for all women and we know that many women experience some form of mental illness during this time. The Mother and Baby Units are for women who suffer from the most severe forms of mental illness and need additional care, not just related to their illness but to support the relationship between mother and baby at this crucial time, in the days, weeks and months after the baby is born."

Giles Berrisford, CRG Chair, NHS England

Trauma

Hundreds of patients each year will benefit from an innovative new stroke prevention procedure

NHS England has undertaken an evaluation of a procedure called Left Atrial Appendage Occlusion (LAAO) which places a device in the heart to stop blood clots forming which could otherwise then travel up to the brain causing a stroke. We have concluded that there is enough evidence to make the treatment available. LAAO reduces the risk of stroke in patients with atrial fibrillation (irregular heart beat), who cannot take blood thinning medication. Atrial fibrillation (AF) is the most common cardiac arrhythmia (abnormal heart rhythm) seen in clinical practice. Atrial fibrillation is usually treated with anti blood clotting medications. Some patients with AF may not experience symptoms relating to their arrhythmia whilst others may experience dizziness, shortness of breath or notice palpitations.

The evidence NHS England has considered suggests that in carefully selected patients who are unable to take anti blood clotting drugs, LAAO is effective at reducing the risk of stroke. It is expected that around 400 patients will be treated in the first year it is introduced; increasing to more than 1,000 patients treated each year by year five. There are risks from the procedure so it will only be available at specialised cardiac centres that carry out a significant number of these procedures.

Using brain implants to improve hearing for profoundly deaf children

We are investing £700,000 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 implant helps the patient to recognise and discriminate different sounds such as a doorbell and telephone ring. Following implantation, long-term professional support is crucial to encourage the wearer to learn to interpret and understand the new signals from their implant.

New 'once a year' treatment for multiple sclerosis (MS) patients

More than 100,000 people in the UK have MS and around 800 people each year who have highly active relapsing MS can now benefit from the drug cladribine. England is the second country in the world to provide access to this potentially important treatment option. This drug is taken for two weeks a year for two years and in comparison with the placebo treatment, appears to reduce the frequency of relapses by just over 50 per cent and the risk of worsening disability is reduced by about a third. More research may be needed to show how effective this drug is compared to alternative treatments.

Women and children

Operating on unborn children with spina bifida

Approximately 700 women per year in the UK will have an ultrasound scan performed in the first half of pregnancy that will diagnose the fetus as having a major form of open spina bifida (myelomeningocoele or myeloschisis). Babies born with this condition are often unable to walk, incontinent of urine and faeces, may develop hydrocephalus due to incomplete closure of the spinal canal and require a series of operations to drain fluid from the brain later in life.

For this reason many parents in the UK opt for a termination of pregnancy shortly after diagnosis although some choose to continue with the pregnancy.

Prenatal surgery provided by specialist centres in Europe to treat open spina bifida is a treatment option for parents choosing to continue with the pregnancy and has been available free to NHS patients for some time. Changes in funding arrangements may have resulted in patients no longer being able to access this surgery and therefore a clinical commissioning policy statement for provision of this service in Europe has been quickly put into place to ensure continued access.

Life changing surgical procedure for children with cerebral palsy

Selective dorsal rhizotomy (SDR) is a complex procedure aimed at relieving tight and stiff muscles for cerebral palsy sufferers, particularly in children, which can cause movement and balance problems. The treatment can allow children who were previously unable to walk to become mobile and independent. It involves operating on the nerves in the spine and has the potential to offer affected children improved mobility. The procedure will now be available immediately in named hospitals across England.

Rituximab for second line treatment for anti-NMDAR autoimmune encephalitis

Acute autoimmune encephalitis is a rare, debilitating neurological disorder which causes inflammation of the brain and in most cases it progresses rapidly into a severe syndrome including altered mental status, neurological and psychiatric symptoms or death.

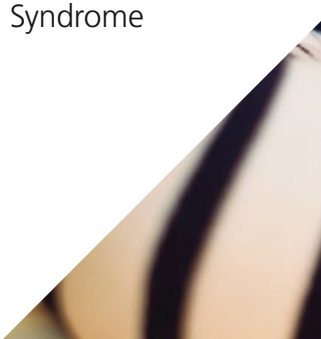
Acute anti N-methyl-D-aspartate brain cell-surface receptor (anti-NMDAR) autoimmune encephalitis (AE) is one of the commonest known types of autoimmune encephalitis, affecting particularly children and young adults. It leads to abnormal behaviour and cognitive problems, seizures and movement disorders.

Treatment with rituximab is available when first line treatment has not worked or not worked well enough. This is the case for around 40 per cent of patients and rituximab significantly improves the chances of a good outcome for patients in what can be a very serious condition. Rituximab may have serious side effects and NHS England has laid out clearly in the clinical policy that treatment can only be started with advice from a neurologist with specialised expertise in neuro-inflammation.

New hope for people who cannot be exposed to sunlight

DNA nucleotide excision repair disorders include Xeroderma Pigmentosa, Cockayne Syndrome and Trichothiodystrophy. Patients with these conditions need expert care from a wide range of specialist services including paediatrics, genetics, dermatology, ophthalmology, nephrology, neurology, audiology, endocrinology and paediatric dentistry. In particular, experienced and specialised dermatology input is required to manage the skin problems caused by these genetic conditions including severe photosensitivity, which may lead to severe burning and skin cancer especially in Xeroderma Pigmentosa.

The highly specialised service specification that has been developed is ensuring that a high quality, multidisciplinary team service is provided by a rare disease centre to adults, transition patients and children with Xeroderma Pigmentosa, Cockayne Syndrome



and Trichothiodystrophy. This will ensure patients get the expert care they need in one place and avoid the need for patients to attend different specialists, often in different hospitals at different times. The service will also ensure care is well coordinated, provide seamless transitional care for patients moving from paediatric into adult services and work with local services to help patients receive as much of their care as possible close to home.

This unique clinical service will establish a centre that will provide opportunities for research that would not otherwise exist.

Supporting world leading research making a real difference to patients

Cutting edge genomic technology

The NHS stands at the forefront of potentially the greatest revolution in healthcare this century – the mainstream use of cutting edge genomic technologies for quicker, more precise diagnosis of conditions and an opportunity for personalisation of treatment. As the 100,000 Genomes Project nears completion, NHS England's Board have recognised the need to build on the developments and infrastructure created through the project and have approved a strategic vision for genomics based on the creation of a NHS Genomic Medicine Service to begin operation during 2018/19.

The NHS Genomic Medicine Service will be provided by a national genomic testing network made up of seven Genomic Laboratory Hubs, each working with local clinical staff. The network will enable consistent, evidence based genomic testing to help ensure better prediction and prevention of disease, and allow many conditions causing ill-health to be identified and tackled earlier. The network will also ensure that diagnoses are more precise, guide better targeted and personalised treatments and interventions leading to improved outcomes and reduced side effects, while delivering enhanced value for the NHS.

The NHS Genomic Medicine Service will help ensure consistent and equitable care for England's 55 million population through the implementation of a single, national testing directory covering rare and inherited disorders and cancer. The testing directory will standardise genomic tests used across the country and will include technologies ranging from single gene analysis to the provision of a national whole genome sequencing service, supported by clinical interpretation, secured through a partnership with Genomics England Limited.

"Genomics is driven by the forensic capture of genomic sequences in combination with a careful and deep description of people's condition or phenotype. It is a complex field given the number of normal variations in our individual genomic code. The support of patients is critical; in finding an answer for each new participant, we build up the knowledge base that helps inform and decipher cases in the future."

Professor Sue Hill, Chief Scientific Officer for England and Senior Responsible Officer for genomics in NHS England

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.

Gateway reference number: 07603