THE WHITEHALL REPORT 2019

MARWOOD GROUP

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INTRODUCTION

The English health and care system is a highly complex structure, subject to direct political intervention and indirectly impacted by wider policy objectives. It is a heavily regulated environment, with reimbursement responsibilities split between multiple organisations. Most publicly funded social care is paid for by local authorities, whilst health services can be commissioned either nationally through NHS England or at a local level through Clinical Commissioning Groups.

Part of its complexity is due to health and care systems never remaining static. It is vital that investors understand how the landscape is evolving when making decisions. With our latest Whitehall Report we provide you with insights into key recent changes.

Last year, we wrote about the long term funding settlement, but at the time little was known about how it would be used. This year, we can offer further clarity into where this money is going to be directed, and the objectives that the NHS is tasked with meeting.

With parliamentary and media attention focussed on Brexit, health policy makers have been quietly pushing forward with significant reforms. Earlier this year, the publication of the NHS Long Term Plan gave system transformation plans new impetus and set broad health objectives for the next ten years.

These objectives will focus public payers on redesigning a health and care system to meet changing population needs, whilst ensuring that a health service stretched by workforce challenges and underinvestment in capital programmes can meet the demands placed upon it.

We can see progression towards collaborative local healthcare systems – and the increasing blurring of the purchaser/provider split that has been a hallmark of the NHS since the 1990s. This has significant ramifications for how services are commissioned. As local areas continue to develop their five-year plans, Marwood will be paying close attention towards what it means for private providers – and the opportunities that it brings for investors.

Matt Hancock has now spent a year in post as Secretary of State. He has proved himself to be a more hands-off minister than his predecessor, Jeremy Hunt. The one area of his brief that he is heavily involved with is technology. The creation of NHSX, and a clear focus on the role of technology in the Long Term Plan, signpost his continued priorities in this area.

At the top, we have seen a further consolidation of power under Simon Stevens (the Chief Executive of the NHS). He has brought together NHS England and NHS Improvement, and now has overall responsibility for both performance and finance resourcing of the NHS.

Five years after being the architect behind the Five Year Forward View (2014), and the driving force behind 2019's NHS Long Term Plan, we are now seeing Simon Steven's vision of the future health system emerge – it is one of local health economies, collaboration in commissioning and provision, and out-of-hospital service delivery.

Social care has had another tough year, and there is limited likelihood of major reforms in the near future. The Green Paper, delayed for two years, is unlikely to see the light of day following the change in Government. Meanwhile a three-year spending review has been scrapped, which means short-term financial fixes may remain the preferred option. There is widespread political acceptance for reforming social care funding, but with a general election on the horizon, it is questionable whether Boris Johnson will choose to confront the issue head on.

Any hopes that Brexit would be resolved have been dashed. Theresa May's Government collapsed after failing three times to pass the Withdrawal Agreement in the House of Commons. Boris Johnson has taken on the mantle with a far more bullish tone on 'no-deal'. It remains to be seen whether he will dare to push it through against the will of Parliament, with an early general election seeming like an increasing certainty.

He may opt for an election purely on the basis that the Labour Party can hardly remain so divided. Plagued by an inability to tackle anti-Semitism within the party, and nearly as internally divided as the Conservative Party over Brexit, Labour has failed to capitalize on the Government's weakness, with a continued lack of clear, funded policy ambitions for health and care.

As a result, all eyes will remain fixed on Parliament, Brexit and a potential election. But, investors should remember that the NHS and social care services will carry on regardless. Whether Britain is in or out of Europe, or whether we have a Conservative or Labour Government, the public's health and care needs will still need to be met.

It is when the media and politicians are looking elsewhere that investors and operators need to pay even closer attention to what is going on in health and care. Policy will continue to be written, and funding allocations made, but there will be far less reporting dedicated to them. As always, we will be watching developments closely, and reporting back in our regular Thought Leadership notes.

Our annual Whitehall Report acts as an important reference document to decode the complexity of health and care in England. We hope our insights into the key developments affecting the regulatory, reimbursement, and policy levers impacting on the health, social care and pharmaceutical markets help support you to make the right decisions for your business.

We hope you enjoy our Whitehall Report, and would be more than happy to discuss further any topics that we have covered.

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KEY POLICY DEVELOPMENTS IN HEALTH AND SOCIAL CARE 1

A Future Vision Of The NHS: More Digital, More Local, More Integrated

January 2019 saw the publication of the NHS Long Term Plan (the LTP). This vitally important document sets the strategic direction for the NHS over the next ten years. It follows from the Summer 2018 announcement of £20.5bn additional funding for the health service, and provides a clear steer on where this new money is likely to be spent.

It doesn't represent a radical change, but instead broadly maintains the direction set by the Five Year Forward View (2014). Importantly it also comes with the backing of a five-year funding plan, an implementation framework with costed commitments, and local health systems that are increasingly structured and incentivised to deliver the LTP objectives.

The NHS Long Term Plan: A new service model for the 21st century

The LTP sets out specific objectives for acute hospitals, mental health, and primary care – and these will be detailed in Section 2. However, it also outlines five guiding principles that will have a deep impact on the way that the NHS functions. These will underpin more specific work carried out in particular health sectors.

1 Shifting the point of care out of hospital and breaking down barriers between primary and community health services

2 Redesigning the whole system – rather than just acute hospitals – to relieve pressure on emergency hospital services

3 Enabling people to take control of their health through improved personalised care

4 Digital transformation to underpin a shift in how care is delivered and how people experience services

5 A local focus on population health and partnership working

Behind these guiding principles are two critical drivers that recur throughout the LTP – **improved use of technology in all sub-sectors** and **system transformation that supports collaboration across providers.**

Improved use of technology

It is hardly groundbreaking to propose technology as the solution to find efficiencies and improve effectiveness in the health service. However, the reality has often proved very different, and the last two decades have seen numerous failed attempts to deliver on this promise – whether it was the disastrous nationally-led National Programme for IT, which was abandoned at a cost to the taxpayer of nearly £10bn, or locally-driven initiatives that have improved individual services but have usually failed to spread the learning more widely.

However, the LTP arrives in a very different technological landscape to previous strategies. Concepts like AI, machine learning and robotics have reached a point of maturity where they can begin to provide tangible cost-effective solutions to public funded health systems. There has also been a paradigm shift in technological sophistication. It is shaping how people interact with technology, and their expectations of service delivery; the technology itself has evolved to provide solutions previously not possible; and commissioners and policy-makers are developing more informed approaches to engaging with the industry.

The fragmentation of technology spending – split between different national bodies, and across local partners has been an historic problem. As a result, it is hard to gain a clear view on what has actually been spent on technology, but in recent years there has been a significant gap between the level of announced funding, and the amount actually reaching the frontline.

The creation of a central team – NHSX – may reflect the Secretary of State's passion for technology. Yet, it is more than just re-arranging the pieces. NHSX is set to provide a centralised steer, with local systems given clear instructions about what they can spend money on. One big shift is that expensive solutions will need to be signed off by local partners, rather than individual providers. This is to help reduce the level of local fragmentation, creating interoperability standards that embed integrated IT systems.

PRIORITY AREA	KEY POINTS
Digital First Primary Care	The establishment of a 'digital first' primary care offer was one of the headline-grabbing items in the LTP – with the potential to radically reshape the health service's traditional model. It would guarantee patients the right to choose a telephone or online appointment rather than a face-to-face consultation. All patients should be covered by this right by 2023/24. A pilot in partnership with GP at Hand showcased both the possibilities and challenges of the model. Whilst increasing patient and workforce satisfaction, it captures younger, healthier individuals. It also creates structural challenges to the traditional payment model, which NHS England will need to address to ensure the healthcare budget remains in check.
Outpatient Units	Improved use of technology is viewed as a key piece of redesign of outpatient units. There is a growing recognition that many outpatient visits can be avoided if remote monitoring and better connected health technologies are utilised. The LTP Implementation Framework sets an ambition to reduce outpatient appointments by 30m per year nationally. The estimated saving for the NHS in reduced appointments would be £1.1bn a year.
Community Services	There are several barriers that community care staff face when trying to effectively deliver care in community settings. Whilst some require improved infrastructure, or alternate connection options, others are related to failures in creating interoperability standards, or the lack of intuitive systems that minimise the need for training. The LTP expresses a clear intention to equip all community care workers with mobile digital services that allow them easy access to care records and plans. Given that there are over 63,000 NHS clinical staff currently working in a community nursing or health visitor capacity, and may well rise given the increasing focus on community-based mental health support services, there is a great opportunity for private sector solutions that mitigate these barriers to ensure care can be delivered effectively and efficiently.
Health Apps	In the UK, smartphone ownership has risen from 55% to 81% of the population over the last five years – and Apps are seen as a pathway to encouraging people to take greater ownership over their care. This could be an essential piece of the prevention jigsaw, as wider public health budgets continue to be squeezed. However, the initial ambition of the NHS is already being scaled back from the all-purpose 'digital frontdoor' envisaged in the LTP. There were concerns from existing providers about the role of the NHS as both gate-keeper and content producer. Despite this scaling back, there remains a strong sense that health apps will play a greater role in the broader health landscape in the future.

Collaboration rather than competition

The LTP sent a clear signal across the healthcare landscape – there will be no change in direction for system transformation. There is an expectation that all local stakeholders will work collaboratively to improve outcomes in their local health economies. To achieve this Integrated Care Systems (ICS) will have taken over from Sustainability Transformation Partnerships (STPs) in all parts of England by 2021.

An ICS is an advanced STP. The focus is on moving from individual to collective decisions. This means ICS' will be responsible for agreeing a system control total to create a shared financial target across a local area. They will also submit a collective operational plan to NHS England and NHS Improvement, rather than individual provider plans. As a result of this extra responsibility they will enjoy greater freedom from centralised oversight.

ICS will be the primary body for making shared decisions on how to use resources, design services, and improve population health. Commissioning decisions will be taken at a system level, enabling greater streamlining of services – even if specific decisions over procurement and contract awards will continue to be made by individual providers.

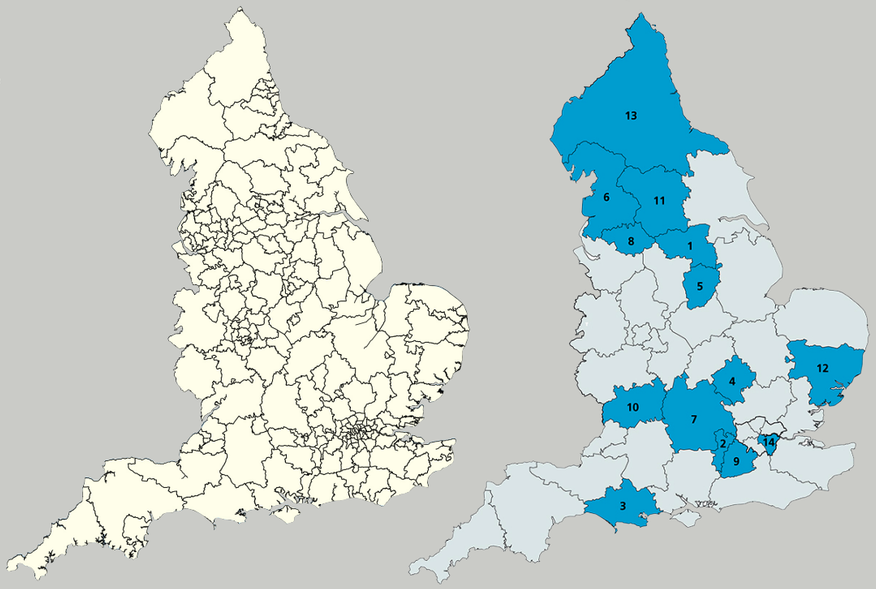
The LTP envisages that most ICS' will be served by a single Clinical Commissioning Group (CCG). This suggests a continued reduction in the number of CCGs. 2020 may prove to be a transformative year, with 86 CCGs proposing mergers. The mergers mean that CCGs will hold larger budgets over greater numbers of people. In the case of North West London CCG, it will control over £4.3bn and cover 2.2 million people.

How the private sector integrates into these new arrangements remains unclear. For those who sell medical devices and pharmaceuticals into the NHS, the rationalisation of CCGs may lead to a reduction in sales and marketing cost. Larger contract values may favour more established manufacturers, as they may be better placed to trade off pricing pressure in order to generate greater sales volume.

The role of private providers within the ICS remains undefined. There is an expectation that the contracts for an Integrated Care Provider (ICP) – the body which acts as a 'lead' provider responsible for delivering integrated services commissioned from local providers – will only be held by public statutory providers. It is not possible to legally disqualify independent providers from holding ICP contracts, but they have been framed in such a way as to make them unenticing to the private sector.

However, private providers are still likely to be an important part of the process. Even as the system transforms, it is not necessarily creating additional capacity for NHS-funded services. The private sector is an important delivery option – often providing overflow capacity where the NHS cannot. This is particularly true in mental health and learning disability services, where the private sector has long been a key partner in service delivery. Whilst there is a risk that an increased focus on collaboration may be an incentive for local systems to bring services in-house, without legislative changes to remove the Any Qualified Provider rule, it will be hard to do this without risking legal challenge.

A constantly changing care landscape



Data: Geographical coverage of CCGs (2015) and geographical coverage of Integrated Care Systems (2019)
Source: ONS, NHS England

NHS Services Protected But Lack Of Certainty Over Capital And Workforce Budgets

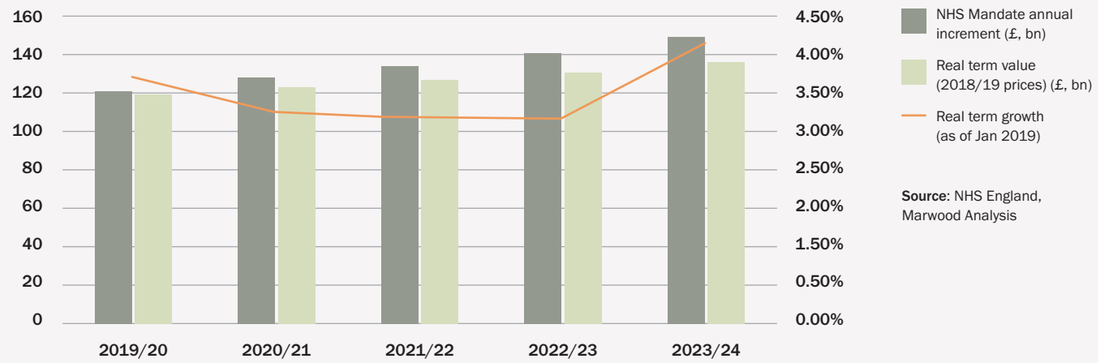
Extracting funding commitments from the Treasury – outside of a spending review – is no easy feat. It is testament to both the importance of the NHS to any Government's electoral popularity, and the seasoned lobbying experience of Jeremy Hunt and Simon Stevens, that a five-year funding plan was agreed. Whilst many commentators feel it might not be as much as what is needed, it is also viewed as more than might have been expected.

The overall uplift was billed as an average increase of 3.4% a year. However, the actual commitment is for '*a £20.5bn real-terms increase by 2023/24*'. The difference is important to note – it doesn't commit to 3.4% per year. After an injection of cash to get the NHS back on track in 2019/20, the health service must navigate some leaner years before finally receiving a significant boost in 2023/24. This backloading is not uncommon in governmental spending – it allows short-term positive press coverage, whilst pushing the main impact into later budgets, which may end up being another government's responsibility.

The money arrives with significant commitments attached, and an expectation from Government that improvements need to be seen. They will be particularly conscious that public overall satisfaction with the NHS has fallen to 53% – 16 percentage points below its historical peak in 2010.

However, a considerable amount needs to be spent just to get the NHS back to expected targets, let alone deliver the wider transformative programme. There is a risk that – without strong management – the NHS could revert to short-term fire-fighting.

Expected increases in the overall NHS budget (2019/20 – 2023/24)



Source: NHS England, Marwood Analysis

The continued government turmoil has created further uncertainty. The change in Government has led to the cancellation of the three-year Comprehensive Spending Review, and has been replaced by a one-year agreement due in early September. The failure to provide longer-term funding certainty risks creating critical disconnects for the delivery of the LTP, as Public Health, Capital, and Workforce budgets were not included within the £20.5bn funding uplift.

Commitments to deliver transformation are reliant on creating a workforce skilled in the right areas, and investing in estate management to provide 21st century services. Without longer-term plans, it will be difficult for the system to be proactive. Health Education England has published their interim NHS People Plan – setting out their vision of how to resolve the workforce crisis - without any clear guidance on how it be paid for in the long term.

Capital budgets continue to be raided to prop up overspends in revenue, and a recent investigation found that as little as 3% of £2.5bn in capital expenditure promised in 2017 has been allocated to frontline projects. Matt Hancock has signalled that a new Health Infrastructure plan will be created, but NHS Providers has warned that even with improved planning, there will still be a £6bn maintenance backlog to overcome.

The lack of a spending review will also be of significant concern to local government, because this means that the social care funding crisis will not be resolved for another year. They will also hope that concerns over special educational needs budgets will see additional funding from the Department for Education. Early indications from Boris Johnson suggest that – with one eye on a possible general election – he is willing to turn on the public spending taps. He has given a vague promise to fix the social care crisis, and a rather firmer commitment to increase spending on schools by an additional £4.6bn per year by 2022/23.

A new Prime Minister: What Boris Johnson could mean for health and social care

Brexit: The end of May, and the beginning of Boris

At the time of publishing the Whitehall Report 2018, we were digesting the impact of the Government's white paper on the future relationship with the EU. This formed the basis of the Political Declaration and Withdrawal Agreement that was agreed between the Government and the EU in November 2018, and then subsequently rejected three times by the UK parliament.

The final failure of the deal marked the end of Theresa May's brief, and calamitous, stint as prime minister. Her legacy will be her failure to secure Britain's exit from the EU, but also her misjudged decision to call a snap election in 2017. This cost the Conservative Party its Parliamentary majority, forced it into a coalition with the DUP, and created a toxic atmosphere around social care that has hamstrung reform attempts ever since.

May's resignation created the opening for Boris Johnson to become Britain's prime minister in July 2019. It is still early days in his premiership. However, Johnson has been remarkably bullish about the possibility of no-deal – although, as someone with a noted liberal approach to the truth, the extent to which it is a negotiating tactic to secure enough concessions from the EU to pass a deal in the Commons will become clearer the nearer we get to the October 31st deadline.

Health and social care – like other public sector issues – continue to be buffeted by the Brexit negotiations. Civil servants are routinely re-assigned as no-deal contingency planning moves up and down the priority list. Meanwhile, Matt Hancock remains in charge, as the Secretary of State, but government reshuffles have meant a new ministerial team with their own priorities sitting alongside him.

Boris' promises: The impact on health and social care services

As Prime Minister, Johnson may find that his optimistic statements made during the Brexit campaign may carry more weight than they used to. In particular, he will be acutely aware of the '£350m a week for the NHS' promise made by pro-Leave campaigning in 2016.

It is a totemic figure that has stuck in the public consciousness. Johnson knows that it will be mentioned at any point when the NHS is perceived to be failing. As a result, he has made early, public commitments to support the health service. This includes the announcement that £1.8bn has been released for capital projects, including an additional £850m found to support improvement works in 20 hospitals.

A big positive for the NHS is that Simon Stevens – the Chief Executive of the NHS and arguable the most powerful figure in the UK health system – is an old friend of Boris Johnson, dating back from their university days. He, alongside Matt Hancock, will be making sure that the new Prime Minister commits to as many public funding commitments as possible.

The future for social care on the other hand remains less clear. Johnson has previously stated that a cross-party consensus must be required to resolve the issue. Given his polarising personality, it is hard to imagine his opponents engaging on this. If it is led by an independent figure, there is a risk that it proposes solutions that the Government will not sign-up to – and end up gathering dust like the many previous reports that were commissioned to find a solution and then never acted upon.

Brexit or bust: The increasing likelihood of an early general election

Faced with the same parliamentary gridlock that brought down May's Government, it seems increasingly likely that Johnson will gamble on an early election – potentially even before the extended deadline to get a Brexit deal agreed by 31 October 2019. It is a high-risk proposition, with political fatigue affecting large parts of the UK population and a new election giving people the opportunity to punish the governing party for failing to deliver Brexit. Johnson will also be aware that European divisions over Europe in the 1990's split the Conservative Party for two decades, and helped Labour maintain power for 14 years.

However, the Labour Party remains a divided and unpopular opposition force. Little political capital has been gained from the disarray in the Conservative ranks, and their social policies have not gained traction with the electorate. The Corbyn-factor looms large – in this era of personality politics, he remains strongly supported by a hardcore faction of party members but is widely mistrusted by larger sections of the population that Labour will need to attract to enter office.

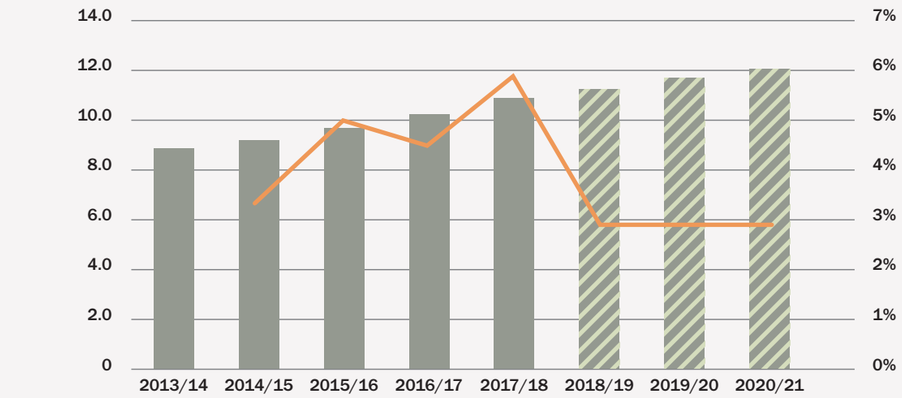
Even if an early election is not called, it seems inconceivable that the Government will last until 2022, which is when the next election is due to take place under the Fixed Term Parliaments Act. Johnson will want to control the election date, but with the loss of the Brecon and Radnorshire by-election cutting the Government's working majority to a single seat, and an increasingly hard-line stance on no-deal, it is possible that remain-supporting Conservatives will be instrumental in forcing a new election.

Primary Care: General Practice

Key Messages

- General practice will be a key beneficiary of £4.5bn additional funding for primary and community care services announced in the NHS Long Term Plan
- Primary Care Networks are changing the way primary care functions in England. They have brought together groups of GP practices (combined population of 30k-50k patients) with the aim of scaling up and providing a wider range of integrated care services like community or out of hospital services
- The creation of a 'Digital First' primary care service is a key policy objective and is likely to provide opportunities for digital healthcare companies over the next five years across telemedicine, electronic health records, and e-prescriptions
- Primary care digitisation objectives are supported through £1.4bn targeted additional funding
- Increased scrutiny and regulation of online providers is likely to reduce patient safety concerns highlighted in the past and ensure better alignment of clinical practice between online and offline primary care providers

Funding for GPs may increase more slowly than in recent years but is still likely to grow above the rate of inflation



	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21
Funding (£,bn)	8.8	9.2	9.7	10.2	10.9	11.2	11.6	12.0
YoY% change	-	3.9%	5.7%	5.1%	6.7%	3.3%	3.3%	3.3%

Data: National funding levels for General Practice (2013/14 – 2020/21)

Source: NHS Digital, General Practice Forward View, Marwood Analysis

Payers

NHS funding for general practice

The NHS Long Term Plan (LTP) set out the vision for the NHS over the next 10 years. It announced a real-term funding increase of £4.5bn a year by 2023/34 for primary medical and community services. This funding will be ringfenced and it is expected that the primary and community care budget will grow faster than the overall NHS budget. Primary Care Networks (PCNs) will be the main recipients of this additional funding.

In 2017/18 the NHS spent just under £10.9bn on general practice in England. The General Practice Forward View (GPFV) published in 2016 announced additional funding, which should bring annual funding to £12bn by 2020/21. This acknowledged that general practice had been neglected with funding directed towards ensuring sustainability in acute care and this needed to be rebalanced in view of the wider policy objectives.

Although the funding package provided additional money for general practice, it was not new NHS funding. Instead it came from the overall NHS budget, which means that the money had to be redirected from other services' budgets to fund it. In 2018, NHS England confirmed the funding increase was on track to reach the 2020/21 objective. However, the GP Partnership Review commissioned by the Health Secretary and published in January 2019 notes that funding increase has had a limited impact on GP practices. This is partly due to the complexity of the bidding process.

NHS funding for infrastructure and technology in general practice

NHS capital funding has been limited over the past few years. However, specific funding for the development of the primary care estate and technology – known as the Estate and Technology Transformation Fund (ETTF) – was included in the £1bn Primary Care Infrastructure Fund. This fund started in 2015/16 and runs until the end of 2019/20. Between 2019/20 and 2023/24, the ETTF is expected to benefit from £1.4bn additional targeted funding for primary care – which will also support primary care digitisation.

The impact of this funding has been mixed. It was expected to be used to extend existing buildings to grow capacity and/or expand services, build new facilities to support the delivery of hospital services in the community, or to introduce new IT systems that enable sharing patient records between various care professionals. By February 2018, 866 projects had been completed. However, the ETTF Fund has been significantly oversubscribed, leading to delays.

New NHS capital funding is expected to be announced in a future Spending Review, which was initially due in Autumn 2019, but may be delayed due to the July 2019 government change. This should clarify the amount of funding that could become available to finance future primary care estate projects.

The development of Primary Care Networks is outlined as a policy priority in NHS England's General Practice Premises Policy Review published in June 2019, which announced that alternative premises reimbursement arrangements would be piloted to simplify estate management. The Review also suggested that Primary Care Networks should assess and plan for their future estate needs as soon as possible.

GP contract reform

There are three types of GP contracts:

- The General Medical Services (GMS) contract, agreed nationally
- The Personal Medical Services (PMS) contract, agreed locally
- The Alternative Provider Medical Services (APMS) contract, agreed locally and allowing independent providers to deliver primary care services

In January 2019 the British Medical Association (BMA) and NHS England agreed on the terms of a new General Practice Contract. This articulates a five-year framework designed to implement the objectives of the LTP. It introduces a new Network Contract Directed Enhanced Services (DES) for Primary Care Networks, which was integrated within existing GMS, PMS and APMS contracts in July 2019.

The Network Contract DES outlines seven national service specifications, covering medication reviews, care homes support, personalised care, anticipatory care, supporting early cancer diagnosis, cardiovascular disease detection, and local action to tackle neighbourhood level inequalities.

There is £1.8bn attached to the Network Contract DES between 2019/20 and 2023/24 – or £1.47m for a PCN covering 50,000 patients over the next five years. This additional funding primarily seeks to address staffing issues. It includes a reimbursement mechanism to support the recruitment of over 20,000 additional staff, including new primary care roles, like physician and nurse associates as well as other healthcare professionals to create multi-disciplinary teams.

The new contract will also support other LTP objectives around digitisation. It specifies that by 2021 all patients should have the right to 'digital-first primary care'. This will involve being able to access their personal records, order repeat prescriptions and access video consultations.

Traditional GP and nurse roles will continue to be funded as currently, through the GMS contract and will benefit from an additional £978m funding by 2023/24. NHS England is planning to update local PMS and APMS contracts as soon as possible. These contracts will see an increase in core funding for price per weighted patient equivalent to the new GMS contract.

Policy And Legislation

NHS Long Term Plan

The LTP outlines a growing emphasis on PCNs, which are based on neighbouring GP practices working together locally, but encompass more than just GP services. PCNs are expected to offer a range of primary and community services, including physiotherapy, community nursing, or dementia services. These services are expected to expand service provision outside of hospital and reduce the reliance on hospital care. As of July 2019, nearly all GP practices have joined one of the c. 1,300 PCNs. While joining a network is not mandatory, GP practices are being incentivised to join as significant funding will be distributed through PCNs in the next five years.

Primary Care Networks: an opportunity for infrastructure funds?

PCNs are local networks of GP practices serving populations of 30,000 to 50,000 patients – the average GP practice has around 8,500 patients on their list. They bring general practices together to enable them to work at scale and improve their ability to recruit staff, manage funding and estates, and provide a wider range of primary and community care services to patients. The NHS Long Term Plan confirmed that PCNs will be central to the transformation of primary care services in England, supporting the delivery of services outside of hospital.

As of July 2019, nearly all GP practices have joined a PCN on a voluntary basis. A major incentive is that it allows them to access specific funding, share staff and develop estates. Successful implementation will lead to a major shift in how the NHS delivers primary care services. This is likely to create opportunities for players in the community and primary care service provider segments.

These developments may be of particular interest to infrastructure funds. New premises will be needed to support the development of new services, as some services move out of secondary care into the community, or expand existing services. Given the slight shift in the GP employment preference from a partnership model to salaried or locum models, GPs will be less likely to own the premises, creating potential investment opportunities for infrastructure funds.

A 'Digital-First' offer for primary care

Alongside the establishment of Primary Care Networks, a major shift in how people access and experience care will come through the 'digital-first' primary care offer. The LTP guarantees patients the right to choose a telephone or online appointment rather than a face-to-face consultation. All patients should be covered by this by 2023/24.

Whilst some surgeries have been implementing these models in recent years, it represents a gear change in the roll-out. Given the length of time it has taken to encourage GP surgeries to embed even online booking of appointments, it is likely that the plan to ensure full patient coverage by 2023/24 will be viewed as ambitious – and may provide room for private providers to fill likely capacity gaps.

How is the NHS preparing for a digital first primary care offer?

1 The NHS will create a new framework for digital suppliers to offer their platforms to primary care networks on standard NHS terms.

2 The NHS will ensure that new 'digital first' practices are safe and create benefit to the whole NHS. This means reviewing current out-of-area arrangements and adjusting the GP payment formulae to ensure fair funding without inequitably favouring one type of GP provider over another.

3 NHS England will review GP regulation and terms and conditions to better support the return to practice and increased participation rates of GPs wanting to work in this way.

Testing the model – GP at Hand working with Hammersmith & Fulham CCG

An evaluation of the GP At Hand pilot with Hammersmith & Fulham CCG showcased the model's possibilities and challenges. It found broad patient and workforce satisfaction, but higher than expected patient churn and a patient group unrepresentative of the wider population. It demonstrated that the traditional primary care model does not necessarily reflect the needs of today's users, but equally it showed the potential risk of creating a system suited to those who are already most well equipped to navigate it – and leaving behind more vulnerable users.

The pilot also illustrates systemic challenges related to creating a digital service model. Currently, funding is predicated on location. CCGs are funded for patient populations, and GPs have patient lists that are reflective of need. The virtual model will distort out-of-area registrations, and also capture younger, healthier patients – which may lead to significant impact on funding. NHS England is currently consulting on changes that should mitigate unintended inequities of the digital first model.

General Practice Forward View

The announcements in the LTP build on the General Practice Forward View (GPFV), published in 2016. The GPFV remains a key document that signalled a renewed policy and funding focus on general practice services. It set the initial vision for the transformation of general practice services in England, recognising that they are increasingly the frontline of service delivery.

The GPFV also formalised the objective of widening access to general practice services outside of normal working hours and introducing seven-day a week service provision. NHS England reports that this has been rolled out across England. However, there is significant variation in out-of-hours provision and services available locally.

Regulation

Quality in General Practice

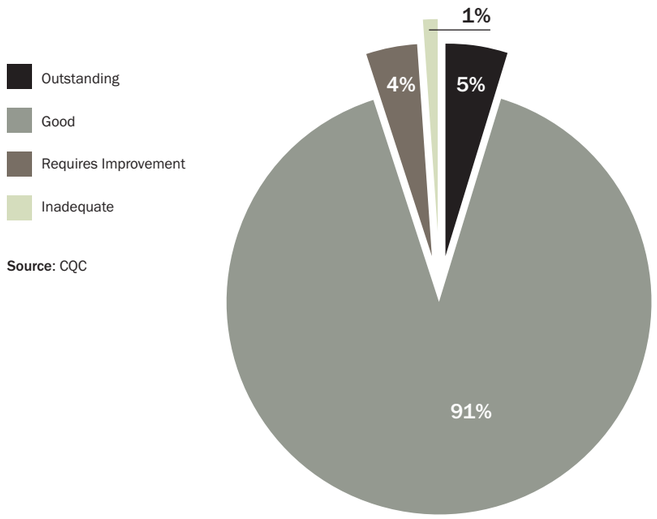
Overall, general practice services are of good quality and have improved over time. In the State of Care 2017/18 report, CQC notes that general practice face pressures from workforce recruitment and growing demand, which can affect the quality of care. A major issue is the lack of same-day appointment.

The quality regulator sees collaborative working across general practice and wider primary care professionals as a positive development, outlining that PCNs have the potential to address challenges and improve patient access.

CQC now relies on a risk-based approach. Under this approach, GP practices that have been rated good or outstanding by CQC's inspection teams are inspected less frequently, with gaps of up to five years between inspections. When inspecting better performing locations, inspections particularly focus on the well-led element. This allows CQC to direct more efforts and resources on the small number of practices that require improvement or are rated as inadequate.

In the year 2017/18 there was a slight improvement in GP ratings. 91% of GP practices were rated good, compared to 89% in the previous year, and 5% were rated outstanding, up from 4% previously. CQC identifies leadership and team culture as key elements responsible for driving improvement. These are also critical to practices looking to work more collaboratively across primary care.

CQC ratings of GP Practices (2017/18)



Source: CQC

Regulating digital providers

The emergence of independent online primary care providers challenged CQC's traditional regulatory framework. Whilst these solutions, which include online consultations and symptom checkers, make-up a very small part of GP services, they are expanding rapidly. CQC defines online providers as 'healthcare services that provide a regulated activity by an online means.' This involves transmitting information by text, sound, images or other digital forms for the prevention, diagnosis or treatment of disease and to follow up patients' treatment'.

CQC has now been granted legal powers to rate online providers. Provider rating started from April 2019, with the high profile GP at Hand (Babylon's NHS service) rated Good. CQC uses its usual five key questions during the inspection process to determine the overall quality of a service. The regulation of online providers is likely to be an area of focus, keeping with the regulator's objective to support new models of care and innovation and as the number of online providers grow. This will give an opportunity for CQC to refine its approach to regulating online providers and work with the sector to define what achieving high quality takes.

In early inspections, CQC findings outlined concerns around safety, especially in terms of medicine prescription. The key issues included failing to talk to patients when prescribing high volumes of opioids, antibiotics, and inhalers, and failing to properly share patient information with GPs. Following re-inspection, CQC found improvements in safety, including better processes to verify patients' identity, and limiting the list of medicines that GPs are able to prescribe online.

A further regulatory challenge also concerns the use on non-England located healthcare services. There are a number of providers that offer regulated healthcare services over the internet, but are not physically based with England – meaning they fall outside the scope of CQC's regulatory power. Although they are highly unlikely to be commissioned by the NHS to deliver services, they may still directly advertise to consumers.

Regulation and policy create a favourable environment for online primary care providers and digital services

The LTP sets out the objective to make 'digital-first' primary care available to all patients by 2020/21. This means that patients will be able to access online consultations. Patients will be given a choice to use these services as alternatives to a face to face GP consultation and will be able to choose between their practice's service or one of the new digital GP providers that have contracts with the NHS. The strengthening of the quality regulation framework will support the policy objective.

This is likely to create opportunities for telehealth companies to sell their services to GPs or to operate as stand-alone alternative providers under contract with the NHS. These services have already been developed over the past few years. As they will deliver health services, they will need to register with CQC and will be regulated in a similar way as traditional GPs, being subject to CQC inspections and rated against the five key questions. Companies wishing to compete in this space will likely have to demonstrate how their services match CQC's standards as a condition of contract.

It is believed that these services will eventually expand to include other digital services like e-pharmacy, digital mental health, digital physiotherapy etc. This reflects trends in the transformation of primary and community care services increasingly working together. These services could be additional investment opportunities for new investors or potential horizontal integration opportunities for existing investors in primary care.

Primary Care: Dentistry

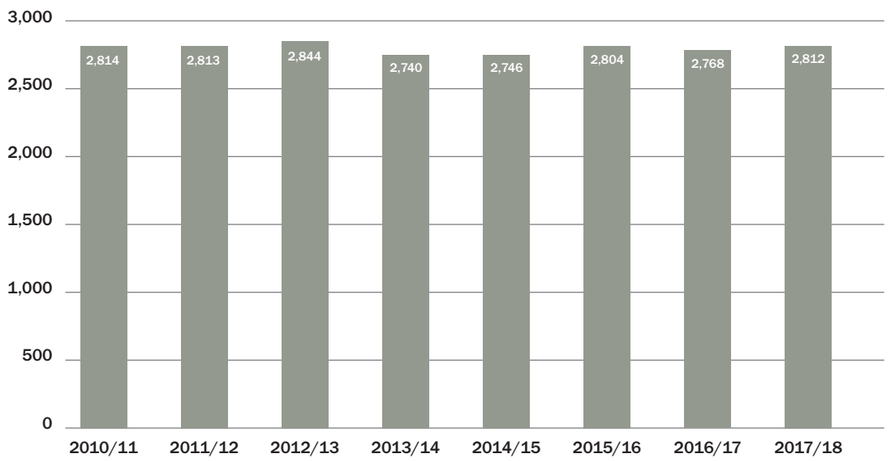
Key Messages

- Dental services provision in England primarily consists of independent, small or single-handed practices, alongside a few larger corporate groups that operate across multiple locations. Most dental practices offer a mixture of NHS and private-pay services, but some focus on the pure-NHS or pure private-pay sectors
- Between July 2016 and July 2018, 22.1m adults and 6.9m children had an appointment with an NHS dentist. Currently more than 24,000 dentists are performing NHS activities
- The cost of NHS dentistry is split between the user – through a patient charge – and by NHS direct payments to dentist. Recent increases to the patient charge have averaged 5% per year. This has led to an increasing proportion of NHS dentists' revenue coming from the patient charge - 29% in 2017/18, an increase from 23% in 2011/12
- The NHS dental contract is set for reform – once a model is found that all stakeholders can agree to. The new contract will blend capitation and activity-based payments, and move away from the current activity-based UDA system. This is expected to occur in a phased manner from 2020/21
- Private pay dentistry is expected to continue to grow, supported drivers that include an ageing population with increased dental need, a continuing demand-supply gap for NHS services, a rise in low-cost private dental options, and a perception of quality associated with private-pay

Overall NHS income for dental practices in England has remained broadly flat since 2010

Data: Total RPI-adjusted NHS income for dental practices in England (2011/11 to 2017/18) (£, m)

Source: British Dental Association, Marwood Analysis



Payers

The majority of dentists in England provide both NHS-funded and private-pay services. They are exposed to two major payers; the NHS and individual private payments. In addition, a small but growing amount of activity is funded through dental insurance and capitation plans like Denplan.

NHS funding trends

Unlike the majority of NHS services, dental services are not free at the point of need. Patients are required to contribute to the cost of services through a co-payment, known as the 'patient charge', unless they qualify for an exemption. This creates two separate revenue streams for NHS dental practices.

Direct NHS payments

In 2018, direct NHS payments to dentistry amount to about £1.98bn - representing 71% of the total NHS income for dentists. The amount paid directly by the NHS varies year-on-year, but has gradually been declining in recent years. Government spend on dentistry per head has fallen by £4.95 in the last five years - to £36 from £40.95.

Patient charge (co-payment)

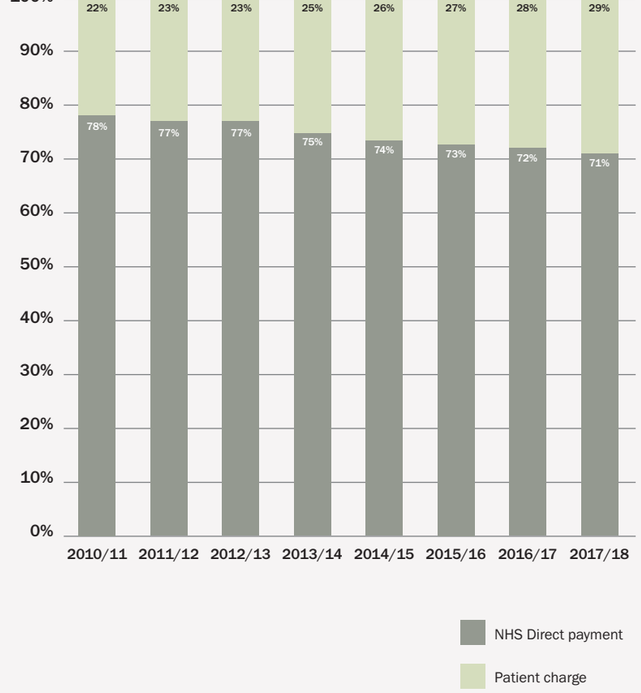
Dentistry is one of the few areas of the health service where individuals have to make a contribution to receive services. Known as the patient charge, in recent years it has increased much faster than direct NHS payments. This has meant the burden of funding NHS dental services has increasingly shifted towards patients.

In 2011/12, patient charge revenue contributed to just 23% of the total dental revenue. By 2017/18, it had increased to 29%. This growth in the patient contribution to overall dental practice income is expected to continue in the next few years. Annual increases have offset dental income decline as a result of minimal increases to direct NHS payments.

There are three different levels of charge (known as 'bands'), depending on the type of treatment. In the past four years, patient charges have increased by about 5% per annum across all bands.

TREATMENT BAND	TYPE OF TREATMENT	PATIENT CHARGE (2019/20)
Band 1	Check-up, diagnosis, treatment planning and maintenance	£22.70
Band 2	Fillings, root canal, tooth extraction	£62.10
Band 3	Complex treatment that includes laboratory element	£269.30

Change in NHS Direct Payments v Patient Charge Revenue (2010/11 - 2017/18)



Source: British Dental Association

Private-pay trends
Consumer demand for private services has been increasing, and the private-pay market now has returned to levels not seen since 2011/12. The subsequent decline in private-pay reflected the impact of the economic recession combined with significant increases in funding in NHS dentistry. Most private payments are directly out-of-pocket as few private insurance plans cover dental services.

Demand has re-emerged due to limited NHS funding, increased patient charges, and an increasing tightening of the availability of the range of services available on the NHS. Demographic change is also expected to drive increased demand for private dental care. Older age is correlated with increasing dental need and this represents an increasing population within the UK.

Alongside this there is continuing demand for cosmetic services not accessible on the NHS. Marwood recently conducted a survey of dental practices, and demand for cosmetic services was the leading reason identified by dental professionals for why people were choosing private pay options.

In addition, when Marwood has spoken to people, we have found that there is a perception of quality associated with private-pay dentistry. This is driven by the belief that private dentists have more time with patients and can therefore be more thorough in their check-up and treatment delivery. They are also seen to have access to better equipment; provide a wider range of services; are more accessible in terms of appointment times and availability; and are more likely to have a personal relationship with their patients.

Policy And Legislation

General Dental Contract Reform
Dental policy rarely garners much political attention, and sector conversations are dominated by attempts to reform the 2006 NHS General Dental Service contract, which remains highly unpopular with the dental profession, and viewed as not fit for purpose by the British Dental Association. The activity-based payments system is blamed for dentists spending too much time chasing agreed activity targets and being incentivised to focus on treatment rather than preventive activity.

Understanding NHS dental payments: Units of Dental Activity
Dentists providing NHS services are currently reimbursed on the basis of the Units of Dental Activity (UDA) system. Each dental practice that provides NHS activity will have a contract specifying the volume of UDAs they should deliver annually. Treatments will be valued at between 1 and 12 UDAs. This is supposed to reflect the complexity and length of time different treatments will take. It aims to ensure dentists are not disincentivised to provide complex, lengthy treatments. Dentists earn between 1 and 12 UDAs depending on the type of treatment provided. The unit price of UDAs is agreed on a practice by practice basis, leading to variation between practices.

Under the current contract, dentists carry most of the financial risks. If a practice fails to achieve the volume of UDAs they committed to deliver, their NHS payments are adjusted to reflect lower volumes. However, there are no requirements on commissioners to fund over-delivery of UDAs. This balance is meant to ensure that dentists do not under-deliver to NHS patients by over-committing to private provision, but also allows NHS England to help manage the cost to the NHS by not rewarding over-delivery. When practices miss their UDA volumes for three consecutive years, NHS England may also reduce the contractual volume of UDAs a dental practice can deliver.

Reforming the dental contract: Pilots and prototypes
Recognising concerns with the 2006 contract, the government commissioned Professor Jimmy Steele to review the dental sector, and to consider options for improving the system. The Steele Report (2009) laid the foundations for reform and argued that the payment system should incentivise prevention rather than treatment.

At the time of the first evaluation, 73 sites were testing different models of providing new clinical pathway and payment models, including capitated budgets. A further 50 planned to join the piloting in two further waves in 2018/19.

The most recent evaluation has suggested that after an initial decrease, patient numbers start recovering after a few years. However, establishing the precise impact of these reimbursement changes is complex. In view of these challenges, implementation of the new contract keeps being postponed. In the short-term, the UDA payment system is likely to remain for the majority of dental practices. It is unlikely that any new contract will be implemented before 2021. If introduced earlier, then it is expected to be rolled-out on a regional basis, beginning in the most deprived areas. It has been suggested this process could take between 4 and 5 years. This will avoid any 'big bang' across to the sector. Recent reports suggest that the new contract may not end up being compulsory – although no official confirmation on this has been issued.

General Dental Contract Reform

Recently Marwood surveyed dental practices across England. We found that nearly half of respondents did not feel like they knew whether the upcoming general dental contract reforms would be good or bad for their patients or for their practices. Given the programme is officially due to roll-out nationally from April 2020, it is concerning how disengaged many dental professionals are from the impact of the reforms.

The lack of engagement may reflect the fact the slow pace of change in the sector. It is over a decade since the Steele Report, and eight years from the first NHS England pilots. This view is reinforced by Eddie Crouch, vice chair of the BDA's Principal Executive Committee, who has said that '*many have switched off to the detail of what is being tested through the prototypes due to its complexity*'.

Marwood also found that dental professionals are split on whether the reforms will be good or bad. For those that had an opinion, over 40% felt it would make no difference to either patient or practice experience. However, dentists were almost equally divided (27% and 29%) on whether it would be good or bad for patients.

Just over a third (34%) felt it would be bad for the practice, and 22% felt it would be good for practice. However, and perhaps reflecting inertia in the sector, only half of those who felt it would be bad for practice suggested they would actively reduce their NHS hours as a result.

This figure may reflect a wider distrust of policy-making by medical professionals, and a general cynicism from the sector due to their experiences of the 2006 payment reform process.

However, given how central the reforms could be to the overall sector, Marwood would suggest that understanding the impact they may have is critical for those operating dental groups – particularly those with multi-site locations, which may have multiple viability decisions to make depending on individual practice locations, and patient mix.

Prevention and access

Overall, dentistry is not a major priority in healthcare policy. Outside of the contract reform, there are limited policy initiatives, and these are mostly focused on increasing oral health prevention and ensuring access to services for priority groups. Achieving these two policy objectives is partly dependent on funding, which has been constrained, and efforts are prioritising children and the most deprived patients.

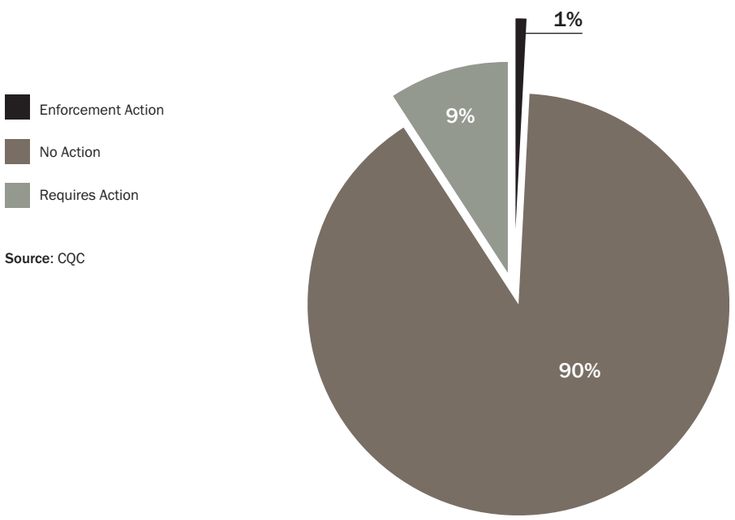
In the longer term, oral health across the nation is likely to continue the trajectory of the past 50 years, with gradual improvements linked to prevention policies and wider lifestyle changes. This will eventually alter the type of work dentists do and may require a different skill mix to respond to shifting demand and needs.

Regulation

Compared to most healthcare services, the regulatory regime governing dentistry is light-touch. This is because CQC considers that dental services represent a low risk to patient safety. Since 2015, CQC has carried out comprehensive inspections of 10% of dental practices each year.

The latest State of Care report confirmed that dental practices deliver high quality services. 90% of services inspected in 2017/18 (1,201 practices) were considered safe and required no action. 9% of services needed to improve in specific areas and were rated as 'requiring action'. Enforcement actions were taken for 1% of the services inspected, meaning that they needed to significantly improve the quality of their services. This represents a slight improvement from CQC's findings in 2016/17 when 2% of services were subject to enforcement action.

CQC Inspections of Dental Practices (2017/18)



Source: CQC

Acute Hospital Care

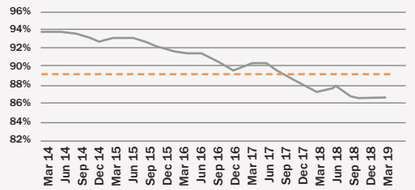
Key Messages

- Additional NHS funding is expected to provide some relief to the acute sector which has experienced significant strain due to the combination of below inflation funding growth, set alongside rapidly increasing demand over the past few years
- Attendances at A&E are the highest since current records began in 2010. 2.7 million people attended A&E in July 2019 (up 4.7% on the previous year). Only four (of 119) major A&E units hit the target to see 95% of patients within four hours
- 4.4 million people are currently waiting to receive elective care treatment, and hospitals are not hitting their target that 92% of patients should receive elective treatment within 18 weeks of referral. The NHS Long Term Plan calls for reducing waiting lists through the use of the private sector
- Waiting times for elective care are under review. This could change the way NHS acute providers' performance is measured, and could lead to slight relaxation of waiting times in elective care
- Targets for cancer treatment are likely to be strengthened in line with the objective of the NHS Long Term Plan to improve cancer survival
- Both the NHS and the private acute sectors are facing workforce challenges. The policy to address these challenges is focusing on the NHS, but efforts to increase training numbers may indirectly ease pressure on recruitment in the private sector

NHS performance against key indicators has been progressively declining

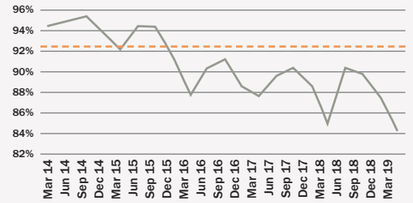
Elective Care Waiting Time Performance

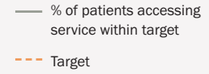
(Target=92% of patients receiving treatment within 18 weeks of referral)



A&E Waiting Time Performance

(Target=94% of patients seen within 4 hours)



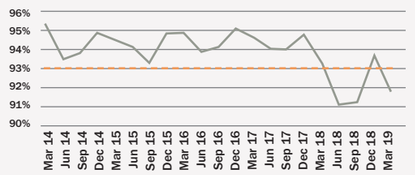


Data: Overall performance against measured NHS standards (2014 – 2019)

Source: NHS England

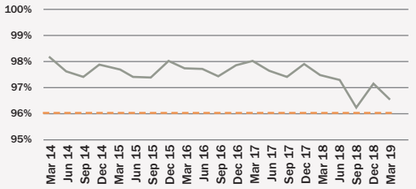
Cancer Waiting Time Performance - Urgent Referrals

(Target=93% of patients seen by a cancer specialist within a maximum of two weeks from GP referral for urgent referrals where cancer is suspected)



Cancer Waiting Time Performance - Decision to Treatment

(Target=96% of patients wait no longer than 31 day wait from diagnosis to first definitive treatment)



Payers

Acute Trusts' deficits

Over the past few years, the NHS acute sector experienced enormous financial pressure as NHS funding growth did not keep pace with increasing service demand. Despite emergency cash injections and social care funding targeted towards relieving some of the pressure on hospitals caused by delayed transfers of care, significant deficits have been recorded since 2014/15.

In 2018/19 the sector is expected record an overall deficit of £558m. If confirmed, this will be an improvement on the £960m deficit recorded in 2017/18. 48% of NHS Trusts are forecasted to end the year in deficit, slightly up from 44% last year. In 2017/18, 90% of providers in deficit were acute hospitals.

Following the £20.5bn Funding Settlement, the annual NHS budget will grow at an average rate of 3.4% between 2019/20 and 2023/24. This is significantly faster than previous annual increases of 2.1% on average between 2010/11 and 2018/19. Therefore, the LTP sets the objective to return to financial balance by 2020/21.

To achieve this, NHS Improvement will set-up a Financial Recovery Fund. It will set out a multi-year plan to ensure return to financial sustainability for Trusts experiencing risks to continuity of services. In addition, the Provider Sustainability Fund introduced in 2018/19 will be continued in 2019/20, although the amount of financial support will be reduced from £2.45bn to £1.25bn. This funding will be available to Trusts that accept their 'control total' – i.e. the budget proposed to them by NHS Improvement.

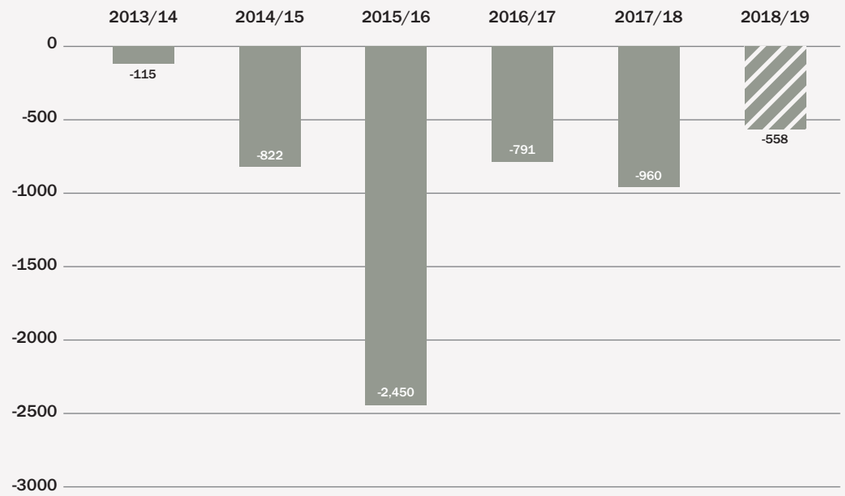
NHS Long Term Plan and the role of the private providers in the acute sector

Financial problems in the NHS has a knock-on impact on private sector acute providers. Many rely on referrals from the NHS as a revenue stream. Private providers reported a significant slowdown in NHS referrals over the course of 2018. For some, this had a negative impact on profits, with Ramsay Health Care reporting a 4.8% decrease in its UK revenue in 2017/18 compared to the previous year.

The LTP and its Implementation Plan offer some reassurance to those more reliant on NHS referrals because in addition to announcing financial support for Trusts in deficit, they confirmed that reducing waiting lists for elective care and eliminating long waits will be a priority. There is also a reminder to commissioners and NHS Trusts about their responsibilities to ensure patient choice, including through the use of the private sector to deliver elective care.

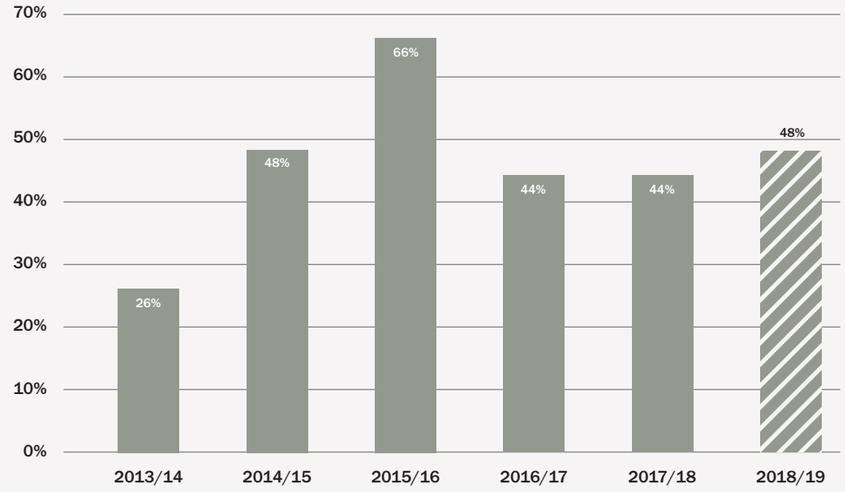
Given that waiting lists continue to reach unprecedented lengths, opportunities to support NHS providers reducing numbers are likely to arise over the next five years.

NHS Trusts' overall deficit (2013/14 - 2018/19) (£, m)



Source: NHS Improvement

Proportion of NHS Trusts in financial deficit (2013/14 - 2018/19)



Source: King's Fund

Payment system and tariff reform

NHS acute services are primarily commissioned locally by CCGs. Providers are paid for activity delivered via a National Tariff system. The National Tariff is a catalogue of activity-based prices for different acute services, classified under diagnosis-related groups (DRGs). This payment system is also known as 'payment by results' (PbR) and gradually replaced block contracts in the 2000s.

The LTP confirmed that the Tariff will be amended over the next few years. The reform will build on NHS England and NHS Improvement's work since 2013 on the development of new payment approaches that enable more integrated care services. New payment systems include population-based capitated budgets. Some local areas are already trailing this approach, which intends to remove traditional budget barriers between acute, primary and community care - alongside improving patient outcomes.

Given the current pressure and the emphasis on the fact that there is no 'one-size fits all' when it comes to transformation, the full roll-out of new payment models will take time and implementation will differ across local areas.

Following consultation, NHS England is due to publish the Integrated Care Provider (ICP) contract during Summer 2019. The ICP contract will be available to commissioners and providers on a voluntary basis. It aims to remove legal and funding barriers to integration and will give a lead provider (likely to be an NHS Trust) responsibility for service integration in their local area.

Specialist services are funded by NHS England. In 2019/20, the budget for these services was £19.1bn - 16% of the total NHS budget. There are 146 specialised service areas, for rare conditions that often have low patient numbers but high-cost treatments. It can include highly innovative treatment options that are provided outside of England, such as Proton Beam Therapy, which until 2018 was only delivered by clinics in the United States.

Policy And Legislation

Efficiency and productivity

Despite additional funding, the growing demand for services means that the efficiency challenge in the acute sector will likely continue over the next five years. The LTP sets out that in return for increased funding the NHS must achieve productivity growth of 1.1% a year. This is lower than the 2-3% annual efficiencies outlined in the 2014 Five Year Forward View, but remains slightly higher than historic efficiencies of 0.8%. The Plan outlines how it intends to improve efficiency and save £1.1bn using technology. This aims to both decrease the time demands on staff and increase the convenience of service for patients.

Areas where efficiencies could be made have been identified in the 2016 Carter Review. These include operational cost, procurement expenditure, workforce planning, and estates management. It found that addressing variation could deliver £5bn of efficiencies.

Progress towards achieving efficiency to date has been relatively slow and subject to local variation. Reports from the National Audit Office and from a House of Lords inquiry have the need for more coordination and clear plans to achieve greater efficiency and minimise performance variation.

Opportunities and challenges for robotics in surgery as a way to support efficiency and reduce variation in NHS acute hospital care

Publication of the LTP confirmed that efforts to improve acute sector efficiency will continue over the next five to ten years. Coupled with a strong policy focus on innovation in the acute sector, there could be a fresh push towards increasing adoption of minimally invasive surgery robotic tools.

The NHS will introduce the Versius surgical robot in 2019 to support a range of keyhole surgeries, and are looking to invest further in the development of robotic surgery. A framework for the acquisition of robotic surgical equipment is in development, with the NHS Supply Chain issuing a Prior Information Notice in May 2019 for robotic surgical equipment and accessories.

The notice outlines their intent to launch a major new commercial agreement in 2020. The agreement is likely to include laparoscopic, orthopedic and general surgery robotic equipment. They intend to spend £10m in the first year of the contract and £50m over the length of the contract in total.

However, adoption challenges remain, and the journey of robotic surgery in the NHS has not been incident free. A patient undergoing robotic cardiac surgery at Newcastle's Freeman Hospital died due to complications in 2015. The incident raised concerns about the level of training needed before surgeons should be allowed to perform robotic surgery. As a result, it is important that investors consider the wider policy and regulation environment these systems operate in, and how it might develop in the future.

Waiting times

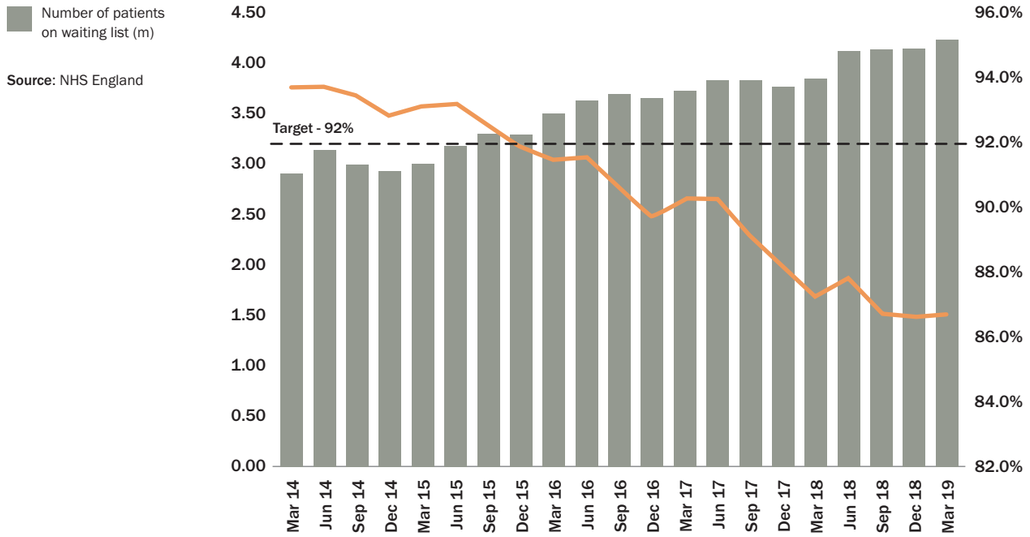
Performance against key waiting time targets have progressively slipped. In July 2018, the NHS National Medical Director, Professor Stephen Powis was tasked to conduct a clinical review of waiting times standards across the NHS, including elective care, accident and emergency (A&E), cancer and mental health targets. An interim report was published in March 2019. It proposes a series of new access standards, which will be tested ahead of final recommendations publication in Spring 2020.

Elective care

The total number of patients waiting for elective care treatment has increased almost continuously over the past few years, reaching 4.4m in August 2019 – surpassing the previous record high that was last reached in September 2007. Although the 2018/19, NHS Planning Guidance outlined that the total number of patients waiting for elective care treatment number should be reduced to 3.84m by March 2019, at that date, 4.23m patients were waiting for elective care treatment.

In parallel, the percentage of patients accessing elective care treatment within 18 weeks has been below target since February 2016. Under the NHS Constitution, patients diagnosed with a non-urgent condition have a right to commence treatment within 18 weeks of referral. Metrics measuring this performance were introduced in 2012. They state that 92% of patients who have been referred for elective care should start treatment within 18 weeks of referral. As of May 2019, only 86.9% of patients on elective waiting lists were seen within the 18-week target.

Number of patients on waiting lists (m) and % of patients accessing elective care treatment within 18-week target since March 2014



Source: NHS England

The interim report on waiting times review notes that the introduction of standards for accessing elective care treatment have supported improvement. However, they put too much emphasis on the 18-week referral to treatment target, with little focus on how much longer patients wait when the target is missed. The interim report recommends testing a new approach to measuring performance that would take account of the average wait, or consider reviewing the 2012 metric, without suggesting the level at which it should be set. Both approaches will be tested ahead of the final recommendations due in Spring 2020.

The interim report also suggests that NHS Trusts make use of private providers when necessary to help reduce waiting times when patients have been waiting for more than 26 weeks. This is in line with the spirit of the LTP, and adds a useful clarification that there would be a requirement on NHS Trusts to find alternative arrangements for patients, rather than the patients themselves having to do so. If implemented, this could support referrals to private providers.

Cancer care

The LTP sets out ambitious objectives to improve access to cancer services and survival rates. This will focus on ensuring swift access to early diagnostics. Currently, waiting times for cancer are measured by the amount of time it takes for a patient to see a doctor – there are eight different metrics measuring access.

The interim report on waiting times suggests that a diagnostic standard should be introduced, recommending that patients identified by GPs as urgent are given diagnostic results within 28 days of referral. This will be tested, and a final recommendation will be made in Spring 2020.

£400m additional funding will be distributed through the Cancer Alliances to support rolling out Rapid Diagnostic Centres. Cancer Alliances bring together NHS Trusts and other health and care organisations to improve the way cancers are diagnosed and treated.

The NHS already outsources some cancer services to private cancer care providers. For example, in March 2019, Northumbria Healthcare FT announced that it would outsource chemotherapy treatment for 120 to 150 patients per year to the privately-owned Rutherford Cancer Centre. The focus on increasing early diagnostics and establishing new metrics to ensure that patients access these diagnostics within short timelines may benefit those operating in this space.

Workforce

The acute sector is facing significant recruitment and retention issues. There have been difficulties recruiting to a permanent workforce, with a vacancy rate of around 9% across the NHS. This figure masks specific challenges recruiting to rural areas, and within particular medical specialities.

Brexit has also added pressure on future recruitment with non-UK EU nurses' registration falling significantly since the outcome of the referendum. Meanwhile, nearly 10% of NHS hospital doctors are from the EU. They currently have full working rights in the UK and benefit from 'mutual recognition' of qualifications. This is likely to continue for those already working in the UK. If a Brexit deal is agreed, the UK has indicated that it would seek to maintain such a mutual recognition system.

In June 2019, Health Education England released the NHS Interim People Plan. This is a policy document which outlines a series of changes expected for 2019/20 centred on the NHS workforce. It is anticipated that a full report which articulates a five-year plan will be released later in 2019. The interim plan emphasises the need for improvements in both the retention and recruitment of staff. It highlights the shortfall of nurses as particularly important. It presents greater use of technology as a central tool to improve the quality of patient care. Finally, it outlines how a greater delegation of control will be given to local areas allowing them to make decisions over future workforce planning.

Improved NHS staff retention may reduce the reliance on agency staff in the longer term. NHS Trusts have often used agency staff to maintain staffing at a level that provides safe care. In recent years, NHS Improvement – the financial regulator for the NHS – has paid close attention to agency spend as part of an ongoing efficiency drive across the NHS. As a result, Trusts are subject to an overall cap on the amount they spend on agency staff every year, and a cap on the hourly rate for staff.

Trusts have increasingly looked at encouraging staff onto permanent contracts and developing Staff Banks as an alternative flexible workforce model. However, in medical specialisms where there is a real skills shortage there has been limited success, as medical professionals are aware of competition for their services between providers.

Regulation

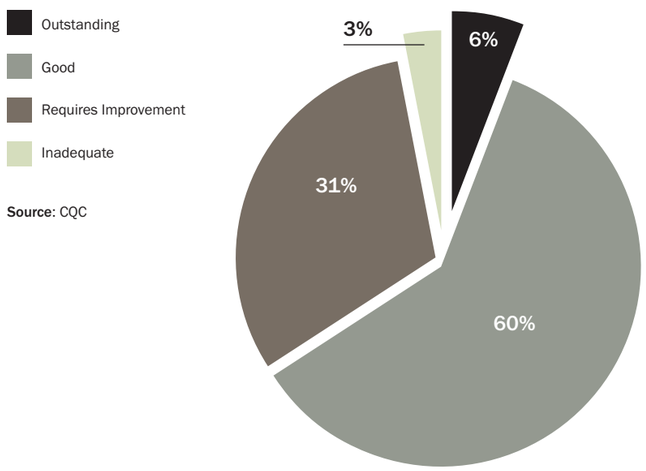
Quality regulation and financial oversight

NHS Acute Trusts (and independent acute providers delivering NHS services) are regulated by CQC. NHS Improvement has separate financial regulatory powers of NHS Trusts. In 2019, NHS improvement has integrated closely with NHS England, but retain their status as an independent financial regulator.

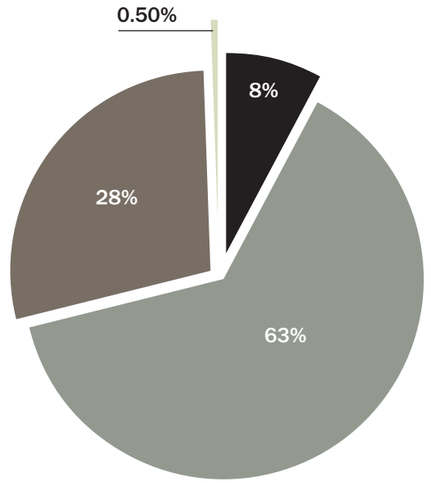
Care Quality Commission

In 2017/18, CQC inspections of NHS acute trusts showed overall improvement in the quality of care. 66% of acute hospitals were rated good or outstanding, compared to 61% in the previous year. However, quality varies across the type of acute services provided. End of life and intensive/critical care services perform the best, with 74% rated good or outstanding, while only 53% of A&E services were rated good or outstanding. This reflects the pressure A&E services are facing. CQC also outlined that it has a specific interest in maternity and gynaecology services – 34% require improvement and 1% are inadequate.

CQC ratings of NHS Acute Trusts' core services (2017/18)



CQC ratings of Independent Acute Trusts' core services (2017/18)



Source: CQC

Since 2017, CQC uses a targeted approach to the regulation of the NHS acute sector. This follows the completion of CQC's comprehensive inspections of the NHS acute sector carried out between September 2013 and June 2016. Whilst the 5 Key Questions remain not all core services are liable to be inspected. However, Safe and Well-Led remain key parts of any CQC inspection – as they are seen as good barometers of the overall quality of a provider.

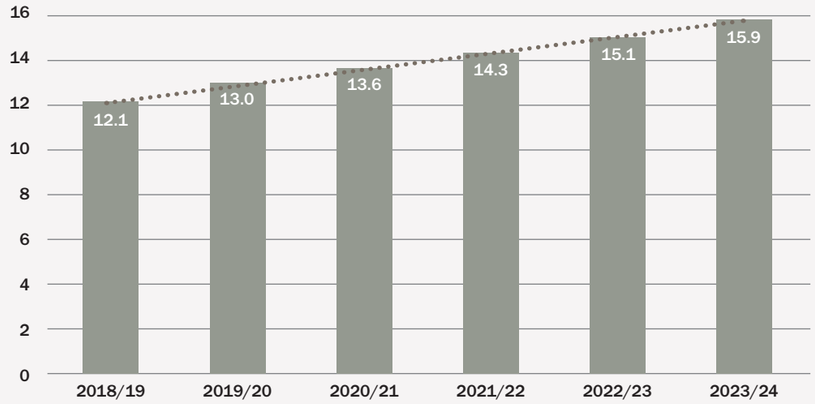
CQC also regulates private acute providers. Overall, the private sector performs better than the NHS sector, with 71% of private providers good or outstanding. However, it is difficult to provide a like for like comparison as NHS Trusts tend to offer a wider range of core services, including those that tend to receive poorer ratings (such as A&E).

Mental Health

Key Messages

- The overall NHS mental health budget is expected to increase from around £12.1bn in 2018/19 to £15.9bn in 2023/24. This will be primarily delivered through local clinical commissioning groups, with centralized commissioning of specialised services increasingly devolved to the local level
- The NHS Long Term Plan has committed to increasing investment in mental health services at a faster rate than the wider NHS budget. This will lead to an additional real-term spend of £2.3bn annually by 2023/24 – equivalent to 4.6% per year on average
- Mental health priorities in the NHS Long Term Plan focus on early intervention, effectively supporting people in crisis, and improving community-based care. Children and young people's services are a primary focus, with clear KPIs measuring access and waiting times
- Traditionally, private providers have been more focused on delivering inpatient services. Reducing length of stay and out of area placements are likely to remain system objectives although overall increasing demand may mitigate against reductions in inpatient volumes
- Regulation has continued to pay close attention to the mental health sector, with recent guidance focusing on the use of force, inappropriate use of seclusion rooms for people with learning disabilities, and reminders of the importance of maintaining the built environment to safeguard patients

Mental Health funding will increase faster than spending on the wider NHS budget over the next five years



Data: Projected Overall Expenditure On Mental Health Services in England (£, bn)

Source: NHS England, Marwood Analysis

Payers

NHS funding

The mental health service landscape in England is complex. Care delivery is split between NHS Mental Health Trusts, and for-profit and not-for-profit independent providers. Services are often identified by their setting – either being viewed as 'inpatient' or 'community'. The majority of mental health provision is funded by the NHS, primarily through CCGs, although some specialised services (such as secure care) are funded by NHS England.

In 2018/19, the NHS spent an estimated £12.1bn on all mental health services, or about 11% of the total NHS budget. The majority of NHS community and acute mental health services are funded locally by CCGs. NHS England funds specialised services, including secure services and eating disorder services. Since 2016, when significant funding commitments were made to mental health, the overall funding trajectory for the sector has been broadly positive.

A total of £3.9bn additional funding was made available between 2016/17 and 2020/21. However, CCGs were expected to find most of this money from other areas – essentially a reallocation of non-mental health commissioned services spend to mental health rather than new funding.

Only a small part of this money was spent directly by NHS England and qualifies as new funding.

To ensure that the money is made available, CCGs have been instructed to increase their spending on mental health by at least the same percentage as their annual increase to their overall budgets. This is known as the Mental Health Minimum Investment Standard. In 2018/19, all CCGs met the Investment Standard for the first time.

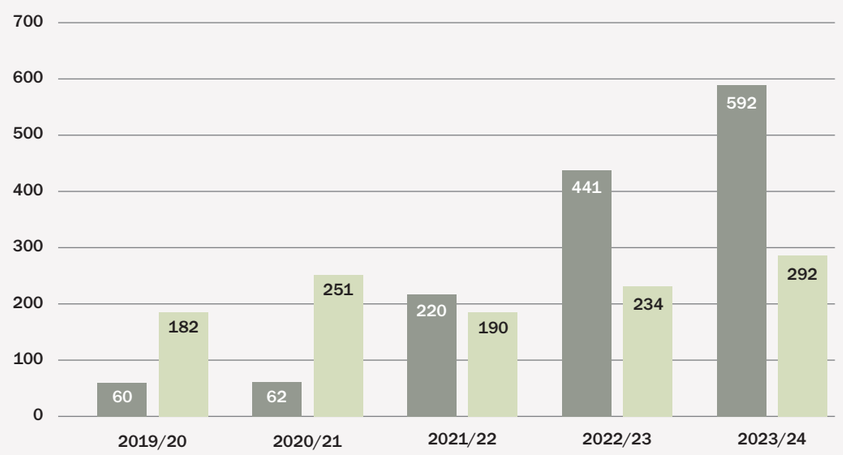
CCGs are slowly being given increasing devolved powers over NHS England's role in mental health commissioning. Beginning in July 2016 a small number of CCGs have been given greater responsibility. Whilst £640m had been previously handed out to groups it is expected that the majority of the specialised commissioning budget, totalling £1.9bn, will be devolved as well.

The NHS Long Term Plan (LTP) in January 2019 confirmed spending on mental health services will increase by an additional £2.3bn in real-terms between 2019/2020 and 2023/24 – leading to nearly £16bn in annual spending by end of the funding period. This is viewed by NHS England as the minimum investment level. CCGs and other local partners could potentially choose to provide additional financing.

	2019/20	2020/21	2021/22	2022/23	2023/24
Total NHS Budget for services (£, bn)	120.5	126.9	133.1	139.8	147.8
Overall Projected MH Budget (£, bn)	12.95	13.63	14.33	15.06	15.86

Source: NHS England, Marwood Analysis

Funding the new mental health objectives in the NHS Long Term Plan (£,m)



Source: NHS Long Term Plan Implementation Framework

* Funding includes the expansion of community mental health services for Children and Young People aged 0-25; funding for new models of integrated primary and community care for people with Serious Mental Illness (SMI) from 2021/22 onwards; and specific elements of developments of the mental health crisis pathways

** Funding includes the continuation of previous waves such as mental health liaison or Individual placement support funding; pilots as part of the clinical review of standards, and other pilots such as rough sleeping. - funding to be distributed in phases in consultation with regional teams including: funding for testing new models of integrated primary and community care for adults and older adults with severe mental illness, community based integrated care, rolling out mental health teams in schools and salary support for IAPT trainees.

Outside of NHS provision, there is a small private-pay market that covers both CQC-regulated activity (such as eating disorder or addiction services for individuals who are not assessed as meeting thresholds for NHS services, or who prefer to pay privately) and some services that do not offer regulated activities (such as self-styled Wellness Clinics).

Mental health payments

The introduction of a tariff for mental health services has been under consideration for a long time. Implementation has been problematic as it needs to avoid creating perverse incentives that would keep people who require inpatient treatment out of hospital, or lead to greater levels of hospitalisations than are necessary.

A blended model has been proposed by NHS England as a fair way to fund mental health support. Blended payments involve trusts being paid a fixed amount based on the expected activity level and then a volume-related amount to reflect actual activity. This change is seen as an important way to ensure mental health services can reach the goals set out in the LTP.

This will help the shift away from block contracts, which have historically been the default payment system for inpatient mental health services and introduce more transparency and consistency in the prices commissioners pay for mental health services. Moving to a tariff-based payment system would also align mental health payments on inpatient physical health services.

NHS-led provider collaboratives

NHS England is putting in place actions that will enable it to devolve significant amounts of its specialised commissioning function to the local level. The creation of NHS-led Provider Collaboratives is underway and, over the next 5 years, these groups will increasingly become a key element of the local mental health landscape. The lead provider within the collaborative will take on commissioning responsibility for adult low and medium secure mental health services, CAMHS Tier 4, and adult eating disorder services.

System objectives for improving mental health will be agreed by the Collaborative and will include cross-sector representation – including independent sector providers. However, following a political backlash, it was confirmed that the lead provider must be an NHS organisation.

Policy and Legislation

Mental health in the NHS Long Term Plan

Mental health has been a priority within wider healthcare policy for several years. The LTP makes clear that mental health remains a priority policy area. It builds upon previous policies by emphasising that people will be treated outside of inpatient units where possible. This will be achieved by improving early intervention policies, more effective support for people in crisis and stronger community-based mental health support.

Expanding access to services is at the core of mental health policy, which focuses on preventative and early intervention services. The aim is to target mental health needs before they reach the point of crisis, increasingly manage ongoing mental health conditions within community settings and reduce the reliance on inpatient care. There will always be a need for some inpatient settings, but these should be focussed on individuals with the highest acuity needs.

The LTP builds on earlier policy documents, such as the Five Year Forward View for Mental Health (FYFVMH) published in 2016. The FYFVMH outlined a future vision of community-based mental health service provision focusing on early intervention and prevention. It also restates the importance of improving children and young people's access to mental health services. A key point that was set out in an earlier Green Paper. This set out the need to establish Mental Health Support Teams that could be accessed through educational settings.

KEY MENTAL HEALTH PRIORITIES OUTLINED IN THE NHS LONG TERM PLAN

Adults	Children and Young People
• New models of primary and community care will give 370,00 adults greater control and choice over the support they receive by 2023/24	• Funding for children and young people's mental health services will grow faster than both overall NHS funding and total NHS spending
• An additional 380,000 people per year will be able to access NICE-approved IAPT services by 2023/24	• 70,000 more children and young people will access treatment by 2020/21
• Crisis pathways will improve, and more non-mental health staff will be trained to provide mental health support	• 345,000 additional children and young people will be able to access NHS funded support and school based teams by 2023/24
• Mental health liaison services will be available in all acute hospital A&E departments	• Mental health support will be embedded in schools and colleges
	• Funding will be made available for upstream preventative support

Mental Health Act review

The Mental Health Act (1983 and amended in 2007) determines how someone with mental health problems can be sectioned (i.e. detained in hospital without consent for assessment or treatment) and their rights under section. Over the past ten years, the number of people sectioned under the Mental Health Act has increased significantly, with detentions increasing by over a quarter between 2012/13 and 2015/16.

The increase in detentions has led to calls for its reform. The Conservative Party pledged to replace it with new legislation and commissioned an independent review to form reform recommendations. This review was published in December 2018 and investigated how to address increasing detention rates, the higher detention rate of ethnic minorities, and how to modernise the functioning of the Act.

It recommended reform in four areas:

- Ensuring individuals receiving treatment have their views and choices respected
- Ensuring the powers of the Act are used in the least restrictive way
- Ensuring patients are supported to get better so they can be discharged from the Act
- Ensuring patients are viewed and treated as rounded individuals

The government was expected to introduce legislation that acts on these recommendations. However, reform attempts are unlikely in the short term, as finding space in the Parliamentary calendar may prove difficult due to time taken up by Brexit-related discussions. A new government may also change the focus on health priorities.

Use of force

In November 2018 the Mental Health (Use of Force) Act was passed which aims to provide clarity and accountability to the use of restraint by mental health professionals. The legislation created new statutory requirements meaning hospitals are legally required to record and report the use of force on mental health patients receiving NHS treatment, this includes private providers.

There is concern that the use of restraint appears to be increasing, from 781 episodes per 100,000 bed days in 2013/14 to 954 episodes per 100,000 in 2017/18. However, more effective and consistent reporting could be a contributing factor to this increase. CQC and NHS Improvement have created a national improvement programme which seeks to address the existing unwarranted variation in the use of restraint across acute adult mental health inpatient wards.

Regulation

Regulation of independent mental health providers

As far as possible, CQC regulation of private providers mirrors the regulation of NHS providers, with some slight variation in relation to specific requirements relevant to NHS organisations. July 2018 CQC guidance on monitoring, inspection and regulation for independent healthcare providers clarified the regulatory approach for independent mental health services.

Data quality has been an ongoing concern within the mental health sector, and CQC confirmed that it would start introducing CQC Insight for private providers of inpatient mental health services from the fourth quarter of 2018/19. CQC Insight – already a staple of CQC's NHS Acute Hospital monitoring – is a tool that allows CQC to have an ongoing view of a providers' quality. Providers will be required to collect and share information on a range of quality indicators, for instance inpatient mental health providers will be required to provide specific information on substance misuse and services for people with a learning disability.

CQC will allow longer inspection intervals for private providers that have been rated 'good' or 'outstanding'. This will allow CQC to focus its regulatory efforts on lower quality providers that 'require improvement' or are 'inadequate'. CQC also intends to carry out more unannounced inspections. However, it has acknowledged that the nature of mental health conditions means that notice needs to be given to providers. This will generally be 48 hours.

Frequency of inspections

RATING	MAXIMUM INSPECTION INTERVAL
Outstanding	Up to five years
Good	Up to three and a half years
Requires Improvement	Up to two years
Inadequate	Up to one year

CQC review of segregation

CQC published an interim report on their findings on the use of restrictive practices on people with a mental health condition. The focus of the interim report was the use of segregation on inpatient mental health wards. CQC highlighted that shortcomings were found in how both independent and NHS providers handed individuals with the most challenging behaviour. This included issues with the duration of segregation and the lack of a care plan to support patients returning to an open ward.

CQC State of Care Report on mental health

In October 2018, CQC released a State of Care report with included mental health services. The report summarised the core service ratings of 515 NHS mental health trusts and 293 independent mental health providers. As with the previous year the majority of providers, both NHS and independent, provide either a Good or Outstanding service.

The report acknowledges some concerns about the safety of core NHS services with 37% designated as Requires Improvement and a further 2% as Inadequate. The independent mental health sector had only slightly better figures with 30% Requires Improvement and 3% deemed Inadequate.

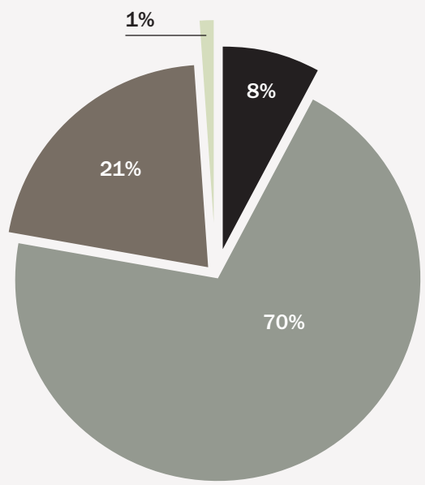
CQC highlighted the increasing financial constraints that mental health trusts are working under. They also point to an overall general trend of improvement despite the increasingly difficult financial climate. CQC expressed serious concerns over the state of mental health wards for working age adults, many of which were deemed to be located in unsuitable buildings, requiring investment in infrastructure.

State of mental health care services

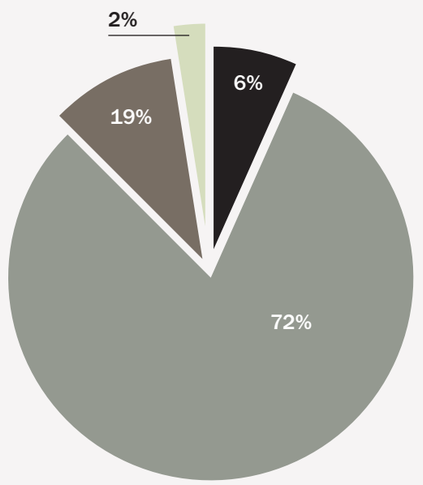
In April 2018, CQC published a report titled "*The state of care in mental health services 2014 to 2017*". The report follows the completion of the first wave of comprehensive inspection of specialist and acute mental health services in England. These services are provided by 54 NHS Trusts and 221 independent providers. Overall, CQC found that the majority of services were good or outstanding and notes that community mental health services performed particularly well.

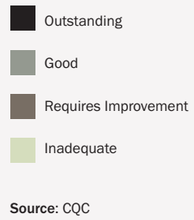
Common themes among those performing poorly include patients being located a long way from their home, effectively cutting them off from local family and friend support networks. CQC expressed concerns about out-of-area placements, which are estimated to have increased by 39% between 2014/15 and 2016/17. The report also outlines safety as a key area for improvement, including making sure that buildings are fit for purpose with appropriate sightlines, no ligature points, and secure access to stairwells.

CQC ratings of NHS Mental Health Trusts' core services (2017/18)



CQC ratings of Independent Mental Health Providers' core services (2017/18)





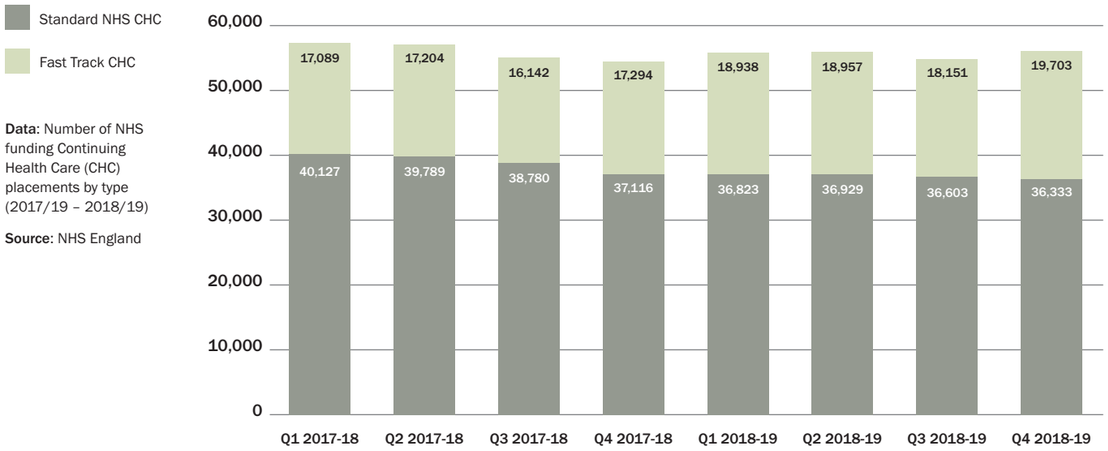
Source: CQC

Complex Care

Key Messages

- In healthcare, complex care can be used to describe services that cover a wide range of conditions that require high levels of ongoing support. These can include, but are not limited to, advanced neurological conditions, serious brain injuries, spinal injuries, and palliative care
- Treatment occurs in a variety of care settings including highly specialised care in acute hospitals, ongoing therapy in community rehabilitation centres, or support for needs in the home
- The National Continuing Healthcare Funding framework was updated in October 2018. Changes did not make wholesale changes, but aims to reduce unwarranted variation in local funding decisions across the country
- CCGs have been asked to generate £855m in efficiency savings from the national budget for continuing healthcare services. NHS England reported that over £500m was saved in 2017/18. There is some scepticism across the sector about whether this can be achieved without finding ways to restrict access to care
- Wider policy drivers that seek to move care into the community may create a positive growth environment for community based complex care providers

Last 2 years saw a 9% decline in standard CHC placements and a 15% increase in fast track CHC, the total remaining broadly flat



Data: Number of NHS funding Continuing Health Care (CHC) placements by type (2017/19 – 2018/19)

Source: NHS England

Payers

NHS Continuing Healthcare Funding

The majority of long term complex care is funded through the NHS Continuing Healthcare (CHC) budget. CHC is a comprehensive package of NHS-funded care intended to support individuals with high and complex needs outside of hospital settings. CHC funding often supports individuals suffering from neuro-degenerative diseases such as advanced multiple sclerosis or Parkinson's disease, or those impacted by the consequences of acquired brain injuries or strokes.

However, having one of these conditions does not guarantee funding. Eligibility is determined through a needs assessment and is managed by local CCGs. In recent years, spending on CHC has grown quickly, driven by increased demand. NHS England estimated in September 2018 that expenditure will increase to £5.2bn in 2020/21, an increase of 44% on 2015/16 funding levels.

CHC expenditure is becoming a source of budgetary pressure for CCGs. Individuals will often have high acuity needs leading to expensive care packages, often with conditions that will require recurrent spending over multiple years. The nature of the injuries and illnesses that CHG can cover also means it can be difficult to anticipate how many packages will be required and for how long.

There are inconsistencies in CCGs' decision-making around funding packages of care and access varies across local areas. Whilst CCG spend around 4% of their total budget on CHC on average, this masks a variation of between 1% and 10% of budget across individual CCGs.

CHC assessment decisions: the 'primary health needs' concept

CCGs are legally required to provide CHC funding to anybody who is eligible. Eligibility is determined following a needs assessment which establishes whether the individual presents a 'primary health need'.

A definition of a primary health need is not included in primary legislation. But the concept has been developed to mean care needs that mostly fall under the responsibility of the NHS (i.e. needs that go beyond social care, which is the responsibility of local authorities).

A primary health need is subject to a degree of interpretation by those carrying out CHC assessments. National guidance has been published to support local commissioners and harmonise the assessment process.

A decision about eligibility for a full assessment for NHS continuing healthcare should usually be made within 28 days of an initial assessment or request for a full assessment.

Given the wider funding pressure on healthcare, NHS England has requested CCGs make £855m savings on CHC spending by 2020/21. Some of these savings are expected to come from administrative improvements to the assessment process. However, this alone is unlikely to cover the full amount of savings required. This creates a tension between CCGs' statutory obligation to provide CHC funding to those eligible and centrally-driven saving targets. The risk of legal challenges to decisions perceived as too restrictive is likely to induce CCGs to take a careful approach to funding decisions.

In January 2018, the House of Commons Public Accounts Committee (PAC) questioned how CCGs would be able to achieve the £855m efficiency savings without restricting access to care. NHS England reported in March 2019 that CCGs had delivered £530m of savings in 2017/18 and that they expected to save an additional £227m in 2018/19. The government has also provided a breakdown of areas where savings are expected to be generated.

NHS funded nursing care

Those who are not eligible for CHC funding and live in a nursing home may eligible for NHS funded nursing care. All CCGs are required to pay a weekly standard rate, which is set at £165.56 in 2019/20. This is a 4.7% increase on the previous year. Payments are made directly to providers and are intended to cover some of the individual's nursing care costs.

Policy and Legislation

Reviews of the efficacy of Continuing Healthcare Funding

Following a 2017 National Audit Office report, the PAC carried out its own inquiry into CHC, and published its recommendations in January 2018. It found unacceptable variation in the number of people being found eligible for CHC funding, and that this was due to inconsistency in interpreting the assessment criteria. It also found significant variation in the length of time people were waiting for assessments, with over a third of people waiting for more than 28 days.

It made recommendations on how each of these should be addressed e.g. by holding CCGs accountable for delays in care, improving CHC awareness in general public, improving quality of CHC assessments, and implementing formal NHS England oversight over CCGs.

National CHC framework update

The Government fully endorsed the PAC recommendations in April 2018, and this was followed by the Department of Health and Social Care publishing an updated national framework in October 2018.

The new National CHC framework looks to further refine the definition of a primary health need to reduce national variation whilst still leaving local CCGs responsible for determining eligibility. It does not make radical alterations to the existing system. However, it does make some important clarifications to concepts contained within the framework. This may help to reduce the variation between different areas.

CCGs will continue to be responsible for determining an individual's eligibility for CHC and for commissioning appropriate services. NHS England will have oversight function over CCGs provision of CHC.

Key changes in the new National CHC Framework include:

- Further clarifying the concept of 'primary health need'. The new framework states that an individual is considered to have a primary health need if 'it can be said that the main aspects or majority part of the care they require is focused on addressing and/or preventing health needs'. This defines the element of care that the NHS is responsible for funding

- The majority of assessments should take place in an individual's usual place of residence (i.e. at home or in a care home) in order to assess the level of needs with more accuracy. Whilst assessments can take place in a care home, individuals should not normally be discharged directly from hospital into long term care

- CCGs will be asked to develop their own dispute resolution processes to deal with disagreements at a local level, and as quickly as possible

Wider complex care policy

Despite the recent focus on CHC, complex care does not gather significant policy interest. Whilst the government is aware of the growing demand for complex care, there are no specific strategies managing this element of healthcare provision. Part of the reason for this is that complex care services cover a wide range of conditions, and relevant policy announcements tend to be fragmented across a number of different strategies, such as mental health or learning disability. This can reduce national visibility on key issues affecting those with complex needs.

Regulation

Regulation of independent complex care providers

As far as possible CQC regulates private providers and NHS providers equally, with some slight variation to reflect specific circumstances. The July 2018 CQC guidance on monitoring, inspection and regulation for independent healthcare providers clarified the regulatory approach for independent complex care services. The only notable reference to complex care is a clarification that inspections of these providers are likely to involve a mix of regulatory experts, including community and mental health care professionals, as well as acute and specialist practitioners.

Patients receiving long term, complex care can be found across a range of services. These include community rehabilitation services, palliative care services, or specialist community centres. Higher acuity services will likely be registered as a healthcare location and regulated as an independent healthcare provider. However, for lower acuity support delivered in a person's home or in a care home, the provider may be registered as either a care home or a domiciliary care provider.

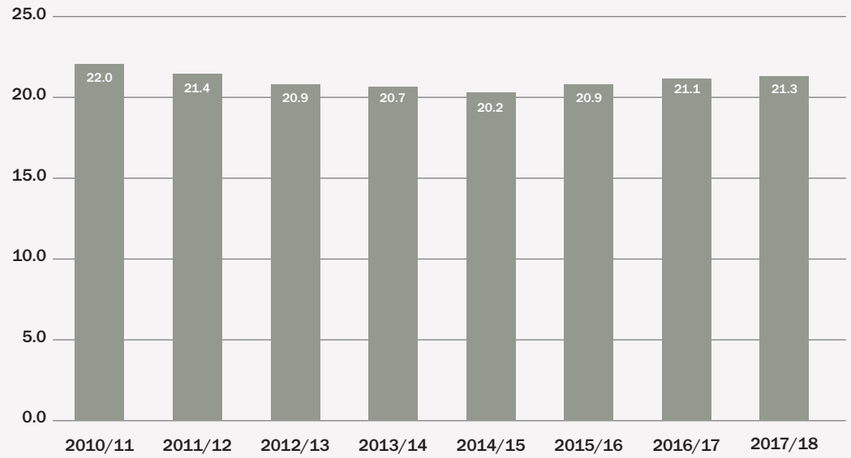
In recent years, CQC have undertaken a thematic review into people's experiences of end of life care in England. This followed the independent review into the Liverpool Care Pathway. One of the outcomes of CQC's work was an identification that people are not engaged early enough in the process. This often means that their end of life care needs are not appropriately managed – and they may be placed in acute care setting when their preference may be for an alternate care setting.

Older People's Care

Key Messages

- Older people care services in England refer to services supporting individuals over-65 years old in their activities of daily living. Care provision is delivered mostly by private providers; either within an individual's home (domiciliary care) or in residential or nursing care homes
- The UK's population aged 65 and above is increasing – projected to reach 18.7m in 2045, with nearly 25% of the population being over 65
- Total public expenditure on all-age social care services is over £21bn annually. Local authorities are responsible for over £15bn of direct expenditure on social care services – with more than £7bn directed towards older people services. This is further supported by £1.8bn annual Better Care Funding, which primarily targets older people services
- Pure private pay is estimated to make up more than 40% of the older people care market
- Local authorities have limited ability to increase their spending power. However, a 'social care precept', introduced in 2016/17, enables them to raise additional revenue for the specific purpose of spending on social care. Furthermore, local authorities can raise council tax by up to 3% per annum without a referendum
- The Social Care Green Paper – following a two year delay - remains unpublished. Boris Johnson – as new Prime Minister – has promised to fix the crisis in social care. However, specific proposals remain unclear, and an early general election may lead to further delay

Whilst adult social care expenditure has increased in recent years it is still £700m below 2010/11 levels



Data: Total expenditure on local authority arranged care for all-age adults in England (£bn)

Source: NHS Digital

Payers

Overview of social care funding

Social care provision is the responsibility of local authorities. They are statutorily responsible for ensuring service levels in their areas, carrying out needs assessments on individuals, and signposting people to appropriate services. However, unlike most NHS services, older people social care services are not free at the point of need. Most individuals are required to either fully or part-fund the cost of their care.

There are two main payers for social care in England: local authorities and individuals. People who require social care services and are looking to access publicly funded support are subject to both a needs assessment and a means assessment. The needs test is carried out by local authorities in accordance with national criteria, and they are responsible for determining whether the individual meets the eligibility threshold.

Once needs have been established, a means assessment takes place. To be eligible for local authority funded social care, an individual must have less than £23,250 in assets and savings. For domiciliary care, this does not include the value of their house. For care home services (nursing or residential), the value of an individual's house is taken into account. In practical terms, this means that a person will be required to pay for their own care until they have reached a point where their total assets and savings fall below the qualification threshold for local authority funded care.

The total value of adult social care arranged by local authorities is estimated at £21.3bn in 2017/18. Of this, £15.2bn was funded by local authorities. User contributions total £2.8bn and NHS-funding (primarily through the Better Care Fund) totals a further £2.6bn.

Adult social care was the largest spend area for local authorities amounting to 43% of total spend on main services in 2016/17. Since local authorities are the primary public payers, the changes in local authority funding since the start of the decade have had a significant impact on the funding landscape for older people's services.

Government funding for local authorities has been reduced by successive governments by approximately 49.1% in real terms from 2010/11 to 2017/18. The reduction is forecast to be 56.3% in real terms by 2019/20. Whilst there have been moves to offset this by giving councils more freedom over local revenue raising – the introduction of the social care precept, and the ability to retain a greater proportion of business rate revenue – these changes do not meet the shortfall driven by reductions in central allocations.

Against this backdrop and taking into account demographic changes and rising care needs, the Local Government Association have estimated that without further reforms, there will be a £3.56bn shortfall in social care funding by 2025. It is expected that more than half of English local authorities will have to deploy reserves to meet social care service obligations in 2019. A State of Local Government Finance survey found 8% of responding councils are concerned they will not be able to provide the minimum legal standards of services to residents.

Raising revenue locally: Council Tax and the social care precept

Council tax has historically been one of the primary levers available to local authorities to control their revenue. However, in 2012, the Government introduced a cap of 2% on annual council tax increase. Local authorities wanting to introduce higher council tax increases were required to hold a local referendum. Given the backdrop of austerity, local authorities did not try to push through these increases, recognising its likely failure if put to a public vote – and the potential damage it would do to their political reputation.

In recognition of the pressure on social care funding, central government has slowly been releasing the levers of control and allowing local authorities more flexibility over revenue raising.

- In 2016/17, the social care precept was introduced. This granted local authorities the right to apply an additional 2% annual increase to council tax. Any revenue raised this way must be spent on social care

- In 2017/18, the social care precept maximum increase rose to 3%

In 2018/19, the maximum council tax uplift (without a referendum) was increased to 3%. It remains at 3% in 2019/20. These adjustments have meant that total council tax bills could grow by up to 6% in 2019/20. The majority of local authorities have made full or close to full use of this increased flexibility.

Domiciliary care services

In 2016/17, approximately 581,000 adults in England received domiciliary care services representing 75% of all individuals who received either short or long term care. It is estimated that local authorities spent approximately £2.74bn on providing care services for older people.

The 2017/18 NHS Digital Activity and Finance report shows that there was a 9.2% rise in long term community care funding for older people on 2016/17 levels. This begins to reverse a decline in the total amount of funding and the number of people funded for home care from 2009/10 to 2014/15.

Private providers delivering local authority contracts have been under pressure due to the constrained funding environment, alongside rising organisational costs driven by national living wage uplifts and a growing proportion of the client base with higher acuity needs. This has led to increasing numbers of domiciliary care contracts being handed back to local authorities.

Care home services

Estimations put local authorities spending on care home services for older people at around £4.95bn in 2016/17. In 2016, there were nearly 5,500 care home providers in the UK, operating a total of 11,300 care homes. Bed provision is split between residential and nursing services with a total capacity in England of around 459,000. Just over half (52%) are in residential homes.

Approximately 41% of the care home market consists of those who pay for their own care (self-funders). However, this is subject to regional variation with more self-funders in the south of England. Care home fees are significantly greater for self-funders than the rates paid to local authorities to provide care for those eligible for state support.

The Competition and Market Authority's (CMA) Care Home Mark study found that the average fee for local authority-commissioned residential care was £621 per week whilst nursing care cost an average of £741 per week, but this masks significant variation across regions. In comparison, the cost to self-funders was £846 per week on average. Fees for both local authority and self-funded care tend to be cheaper in the north of England.

Additional funding for social care
Whilst the sector is under significant pressure, the outlook has slightly improved due to the Government committing an additional £2bn to the sector. This is a one-off payment, and so does not address the ongoing issues in how to sustainably fund social care in the longer-term. However, it does protect the sector against collapse in the short-term.

The funding was announced in March 2017. Local authorities will receive the money between 2017/18 and 2019/20. This money is ring-fenced and must be allocated to social care services. It was released in addition to the funding previously announced in the 2015 Spending Review. The likely delay of the Comprehensive Spending Review means that there may be minimal clarity on future funding arrangements, and social care may again be reliant on short-term funding fixes.

ADDITIONAL DEDICATED ADULT SOCIAL CARE FUNDING	DISTRIBUTION OF FUNDING (PER YEAR)		
	2017/18	2018/19	2019/20
2015 Spending Review	£105m	£825m	£1,500m
2017 Statement on additional funding	£1,010m	£674m	£337m
Total	**£1,115m**	**£1,499m**	**£1,837m**

As the funding is allocated to local authorities directly, they are responsible for deciding how it should be spent. However, they must be able to demonstrate that spending is contributing to wider policy objectives. In particular, it should support reducing the length of hospital stays and help the discharging of elderly patients into the most appropriate care setting. A specific focus has been placed on providing extra domiciliary care services, to help older people stay in their own home as long as possible.

Policy and Legislation

The new Prime Minister, Boris Johnson has announced that his government will 'fix the social care system' as a priority. However, no further announcements have been made at the time of writing this report. Translation of political rhetoric into policy and follow up with action is yet to happen and this space will be keenly watched by investors, industry and the general public alike.

There has been a growing political recognition of the need to provide a sustainable funding solution for social care. There is also a clear message from both the NHS and social care about the need to recognise the additional costs to the NHS of failing to resolve problems with older people's care.

The challenge is that solving the problem is likely to require a financial solution, and the experiences of the Conservative Party at the last election in trying to introduce social care reform policies will have made political parties wary of suggesting the radical change that the sector may require.

Sustainable solutions to funding social care

The House of Lords Economic Affairs Committee released a report in July 2019 on social care funding in England. It proposed that the government should immediately invest £8bn in adult social care. This would return quality and access to care to levels last seen in 2009/10. It also suggests that free personal care should be introduced in the next five years, so that there is a universal free service by 2025/26. Free personal care would be estimated to cost £7bn.

The report broadly rejects the idea that private insurance could be used to fund social care costs, but does note that if personal care was covered by the state, it is possible insurance could emerge to cover accommodation costs.

To fund social care, the report is clear that it should not be reliant on locally raised revenue, and instead be allocated from a central government grant. Funding should also be granted via national taxation instead of a specific hypothecated tax to cover social care, or via the use of a mandatory social insurance system. This would make social care funding less exposed to wider changes in economic conditions. However, it does note that the public are generally more receptive to new taxes when money has been ring-fenced for a specific purpose.

Reducing entitlements could also raise substantial revenue. Restricting winter fuel and TV licences for those over 75 to the least affluent could save £1.4bn, whilst reducing exemptions from NHS prescription charges could raise another £1bn.

Social Care Green Paper
For more than two years, the Social Care Green Paper – or the lack thereof – became something of a running joke for the sector. Announced following the 2017 general election, which saw the Conservative majority slashed – in part due to the negative press around social care funding proposals, it was delayed multiple times. Following the collapse of the May Government, it is now unclear whether it will ever see the light of day.

However, even if it is not published, the need to reform social care remains urgent. The seven principles for social care, outlined by the then Secretary of State for Health and Social Care, Jeremy Hunt, in March 2018 illustrate the need for wide reform.

1 Quality
2 Whole-person integrated care
3 Greater individual control over care
4 Workforce
5 Supporting families and carers
6 A sustainable funding model for social care
7 Security for all

Two key challenges to achieving this will be funding availability and accessing an appropriate workforce. The Hunt speech did not give detail on how the funding challenge would be addressed and the sector remains reliant on short-term funding fixes.

The workforce challenge was initially expected to be addressed as part of a joint Health and Social Care Workforce Strategy. However, with the emergence of the NHS Interim People Plan in April 2019, the social care workforce question has been decoupled.

This means that critical questions around how to make the social care profession appear more attractive to workers and enable the development of new career pathways for social care staff remain unaddressed.

This is of particular importance to the sector as it currently experiences high turnover and vacancy rates, and may be impacted significantly by Brexit due to the large number of lower skilled workers employed from EU countries.

Regulation

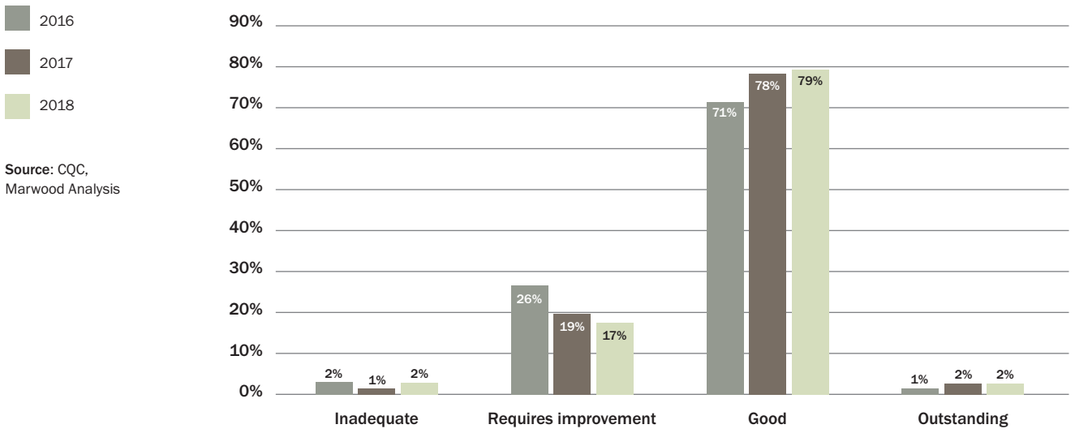
CQC is responsible for regulating adult social care services. Its main function is to register, inspect and monitor providers. In recognition of the pressure facing providers, inspections will be increasingly targeted at poorer performers, with outstanding and good providers given a greater gap between inspections. CQC retains the right to carry out comprehensive inspections at any time if they believe there is a risk to the safety or wellbeing of users.

Between October 2014 and February 2017, CQC completed its first wave of comprehensive inspections of adult social care services, inspecting a total of 24,000 services. They found that overall 77% of adult social care services were rated as Good.

RATING	FREQUENCY OF INSPECTION
Outstanding/ Good	Within 30 months
Requires Improvement	Within 12 months
Inadequate	Within 6 months

Despite the pressure on providers, only a very small minority were found to be Inadequate. However, CQC has stated that it remains concerned about the number of providers rated as Requires Improvement, and those that do not improve on re-inspection.

CQC ratings of ASC providers (2016-2018)



Source: CQC, Marwood Analysis

Quality in adult social care

Quality is a key aspect of any care service provision. It is also a parameter that varies depending upon the observer's vantage point. What might be good to a service user may fall short of what a regulator expects and may, in turn, be adequate from an industry perspective. In such a scenario it is important for investors to assess potential acquisitions in this sector with an objective measure to assure themselves that they are not buying an underperforming asset.

Quality in adult social care providers is progressively improving as demonstrated by a sustained increase in Good and Outstanding rated providers. This is a positive sign for the sector as a whole. Poor quality is closely linked with poor financial performance and risk of failure as well, and hence should be closely investigated during the investment decision-making process.

It is, therefore, advisable for investors to dig deeper into the quality perspective and understand the potential for improvement of assets they are evaluating. They should examine closely how the assets stack up against the CQC's 'Five Key Questions' that underpin all inspections and ratings.

Between 2014 and 2017, 95% of locations were rated Good or Outstanding for 'Caring', and 85% Good or Outstanding for 'Responsive'. However, this falls to 75-76% for the 'Safe' and 'Well-Led'. These measure the value of a strong senior management team and engaged corporate leadership, a mark of high-quality services. This can be both at a corporate level – instilling values that are embedded across a range of locations – or locally, through a care home manager that recognises and creates a culture of excellence.

Well-led and Safe key questions embed the importance of having clear policy, procedures, governance and audit systems. These build on the high-quality care given on a daily basis and add assurance that if things go wrong, they will be managed effectively, and lessons will be learnt. Increasingly, care home operators and their investors are making use of experts to provide an independent view on the quality – as well as the financial – aspect of their care homes. This may involve auditing specific parts of the portfolio, carrying out on-site mock inspections, or reviewing governance arrangements. This helps drive improvement, and enables them to share good practice across their portfolio of locations.

Whilst CQC inspections can be challenging, the best performing providers see them as an opportunity to identify improvements and drive up the quality of their services. With quality seen as a key differentiator for many investors, improving CQC ratings should be understood as an essential part of any providers' business model.

Market oversight and preventing provider collapse

The Care Act 2014 introduced a new market oversight role for CQC. From April 2015, CQC became responsible for monitoring the financial sustainability of social care providers that local authorities would find difficult to replace if they were to close. This is separate to their core quality regulatory function and was introduced to prevent another major provider collapse similar to that of Southern Cross in 2011.

CQC's Market Oversight Team focuses on providers who either have a large national profile, or those that hold a large presence in a particular geographic region making them difficult to replace in case of failure and consequent service disruption. It includes both domiciliary care and care home providers. They will work closely with providers and local areas in the event of any concerns over a provider's status.

In November 2018, CQC warned local authorities about the potential collapse of Allied Healthcare, a domiciliary care provider. This resulted in local authorities transferring their contracts to other providers to maintain service continuity. This event has reignited concerns over the financial viability of providers and the need for their monitoring. This is likely to invite increased scrutiny of key eligible providers' financial stability from CQC's Market Oversight Team.

It should be noted that the CQC cannot intervene in case of concerns over the stability of providers they are monitoring, their role is limited to warning the relevant local authorities about their concerns so they can make arrangements to deal with potential service disruption in case of catastrophic provider collapse.

CMA care home market study

The CMA published the findings of their study on the residential and nursing care homes market in November 2017. The study was triggered by ongoing concerns that lack of transparency, information and advice for care home users was impacting consumer rights. It examined how well the care home market is working for those that pay for their own care (self-funders) and for those individuals whose care is paid for by the state. It produced three key recommendations:

- Create an independent body to provide advice on local authority fee levels to improve investor confidence
- There should not be forced equalisation in pricing between local authority-funded and self-funded care within care homes
- Care homes should be given guidance around consumer protection laws, but tougher action is planned for providers who do not comply

In March 2018, the government accepted the recommendations in principle. Further action has been delayed, as it was expected to be taken forward as part of the Social Care Green Paper.

In December 2018, the CMA told Care UK, one of the largest providers of care homes in the country, that it must refund over 1,600 residents for a compulsory 'administration' fee. This fee could be as much as £3,000 for an individual resident. This repayment has been ordered by the CMA amidst a wider investigation into a number of care homes over contract terms which potentially breach consumer protection law.

Learning Disability

Key Messages

- Learning disability service can come in a number of different forms, and reflects the varying level of need that exists within the sector. At the lowest acuity end of the spectrum, community services and supported living are the primary modes of support. However, residential and inpatient beds can be required for the highest acuity individuals
- There are estimated to be around 1.2m people with a learning disability in England, over 900,000 of whom are aged 18 or older. This is projected to grow by 10% by 2027 in line with general population increase
- During the period of austerity, spending on statutory learning disability services was well protected compared to other local authority services. By 2016/17, spending on people with a learning disability had reached £5.9bn
- The policy landscape continues to seek to move people with a learning disability out of inpatient care into more appropriate care settings. The NHS Long Term Plan has set a new ambition to reduce inpatient levels to 30 inpatients with a learning disability and / or autism per million adults, and no more than 12 to 15 children per million, will be cared for in an inpatient facility
- Failure to meet previous targets for moving people out of inpatient settings is partly the result of historic complexities in reimbursement – with payment responsibilities shifting from health to local authority commissioners, and with few incentives provided for local authorities to meet these costs
- New supply growth to meet these policy objectives has been limited by CQC's tough regulatory line on registering new sites that have could be interpreted as 'campus-style' settings, with more than 6-beds. However, following a loss at the Court of Appeal, CQC may revisit their position in the coming year

Policy drivers look to move individuals into lower-cost care settings

	Person with learning disability			
Care Setting	Mental Health Hospital	Residential Social Care	Community Setting	No formal support
Payor	NHS England or CCG funded	LA funded	LA funded	N/A
Ave cost per person	£180K per year	£65k + additional health costs	£27k + additional health costs	No cost available
No. of people	2510	29,000	100,000	700,000
	Policy drivers focused on moving people into lower acuity settings			

Data: Estimated number of people with a learning disability, and cost of care, in different care settings

Source: National Audit Office

Payers

The three primary payers for learning disability service are NHS England, CCGs, and local authorities. NHS England and CCGs are responsible for funding most inpatient services, whilst local authorities finance community services. With national policy initiatives focussing on moving individuals with learning disabilities out of hospital into community settings, local authorities are increasingly responsible for a higher proportion of overall spend on learning disability provision.

Since 2010, the number of adults identified with a learning disability has risen substantially. As providing appropriate learning disability services is a statutory responsibility, this has placed additional pressure on local authority budgets compounded by the impact of large decreases in funding from central government. These pressures are likely to continue as the number of working age adults (18-64) with learning disability receiving social care is projected to rise by 72.5% between 2015 and 2040. In 2016/17, £5.24bn (of an estimated £5.9bn) expenditure on learning disabilities was spent on the 18-64 age group.

Funding pressures are subject to regional variation, determined by the local prevalence of learning disabilities and different approaches to service delivery. This can lead to significant variance in the required annual spend across local authorities.

Funding incentives to shift payments towards community care options

To support the move towards community care, the Transforming Care Programme was established in 2015. Initially, NHS England provided Transforming Care Partnerships (TCPs) with short-term support of £30 million over three years from April 2016, and £100 million of capital investments over five years for housing infrastructure.

However, this funding has not enabled expected changes, and in July 2017, NHS England announced that an additional £76m will be spent on the programme to accelerate the development of community learning disability services and increase service capacity. This isn't all 'new' funding, as it includes £53m released through the decommissioning of specialist inpatient services.

The announcement is recognition that progress on closing inpatient services has been slower than expected, in part due to difficulties in redirecting inpatient funding towards the development of community services. NHS England has announced that funding will extend into 2019/20 however they have yet to specify to what level it will be funded or how long this money will be guaranteed for.

Alongside short-term funding incentives, it also sought to keep the overall sum of money payers spend on learning disabilities the same but reallocate using mechanisms that incentivised the shifting of care from inpatient to community settings. To encourage commissioners to change how they commission services, a 'dowry' system has been developed for particularly high-cost individuals. In these cases, the money will follow the individual. This would support a long term budgetary shift from NHS to local authority expenditure for a small number of people with learning disabilities with higher levels of need.

Policy and Legislation

The NHS Long Term Plan

In recent years, learning disability policy has focussed on a shift from inpatient to community service provision. The LTP outlines how the health service plans to build on this momentum which has seen the number of children or young people with a learning disability or autism receiving inpatient care reduced by almost a fifth. The language used paints a positive picture on what has actually been the failure to achieve the ambitions of the Transforming Care Programme – where the shift to move people out of inpatient facilities has been slower than planned.

It has set a goal of reducing inpatient provision of care for young people with a learning disability or autism to half by March 2023/24. One way the NHS plans to achieve this is by giving greater control over budgets to local providers. This devolution of financial decisions has been designed to reduce avoidable admissions, support shorter inpatient care visits, and end out of area placements. In addition, the LTP notes that, where possible, people with a learning disability or autism should be able to access a personal health budget.

The LTP outlines how the new Sustainability and Transformation Partnerships (STPs) and Integrated Care Systems (ICSs) will implement national standards over the next five years that will apply to all NHS funded services. This will create greater consistency of care received across areas, alongside a greater devolution of autonomy.

The LTP Implementation Framework sets out expectations that local system plans will clearly identify how they will reduce inpatient usage, and suggests that targeted funding will be available to support the development of new housing options and suitable accommodation in the community.

Transforming Care Programme

To support the move to community service provision, 48 regional Transforming Care Partnerships (TCP) were established across England. Consisting of representatives from CCGs, NHS England's specialised commissioners, and local authorities, the role of a TCP is to oversee and implement the vision outlined in the Transforming Care Programme.

The initial objective of the Transforming Care Programme was to close 35% to 50% of inpatient beds by 2019. The scale and implementation of the transformation towards community care varies significantly by local authority, and across regions, with those in the North expected to see most of a change due to a greater reliance on inpatient beds, and the planned closure of a specialist learning disability hospital. However, progress has been slow, with NHS England announcing in March 2019 that numbers had only been reduced by 20% since 2015. The issue has been kept in the public eye due to continued criticism from Norman Lamb, a former Health Minister and leading Liberal Democrat politician, who played a key role in designing learning disability policy reform.

Out of area placements

The events exposed at Whorlton Hall have placed the issue of out of area placements (OAP) back in the public eye. It highlighted the potential risks of placing highly vulnerable people into inpatient settings a long way from commissioner oversight.

Whilst reduction of OAP have been a policy objective for a while, data is now being formally recorded, with NHS Trusts tasked with monitoring the number of patients they send out of area for treatment. This is part of a government effort to minimize OAP in mental health services (including learning disabilities) for adults within acute inpatient care by 2020/21.

OAP cost more to the NHS and have a negative impact on the person receiving care. However, the failure to place an individual within their local area is usually the result of a lack of available appropriate local capacity. This highlights that commissioners often must balance competing policy objectives: the requirement to provide timely services to those in need against the objective of reducing OAP. An out of area placement may be all that is available at that moment in time for a given patient.

NHS Digital report on out of area placements for mental health in England published in April 2019 shows that these initiatives are failing to impact the number of OAPs. The number of OAPs in England increased from just over 600 in April 2018 to over 750 in March 2019.

Whorlton Hall and the Winterbourne View Legacy

In May 2019, Whorlton Hall – a mental health hospital – hit the headlines following an undercover Panorama exposure of staff abusing people with learning disabilities who were inpatients at the site. Whilst the events themselves were shocking for those working in the sector, it could not help but also bring back memories of the 2011 Winterbourne View scandal. Acknowledged failures in 2011 led to an overhaul of CQC's inspection regime, and a focus on moving people with learning disabilities out of institutional settings. This policy driver has been embedded for eight years but has proved very difficult to deliver. Despite dedicated funding, targets have been missed, and the NHS Long Term Plan has effectively reset the ambition and the timescales.

Various reasons have been given for failure to achieve this ambition. Changes in central government led to the departure of the policy's most influential champion. Whilst locally, a lack of appropriate alternatives, alongside the very high cost of some individuals, has meant few incentives for local authority commissioners to engage with the programme. An increased focus on ending out of area placements has also meant that commissioners are no longer able to move people out of an inpatient setting only to place them many miles away from their home area.

However, it continues to be a central plank of the Government's learning disability policy, and it remains to be seen whether the events at Whorlton Hall will inject urgency into the drive to place people with high acuity learning disability needs in appropriate community settings.

Remuneration of sleep-in shifts

In July 2018, the Court of Appeal published an important ruling on the long-standing and complex issue of back-pay for sleep-in shifts (i.e. when employees are present on the premises in case their help is needed by residents, but they are otherwise allowed to sleep). It ruled in favour of Mencap (Royal Mencap Society v Tomlinson-Blake), and stated that employers were not liable for paying National Minimum Wage payments whilst the worker was asleep.

The Court of Appeal ruling is a key decision for the wider sector, which had been facing total liability bills of over £400 million to fund backpay to care workers, and large increases to future salary projections. Many providers, in a sector with a large voluntary presence, had argued that this would be unaffordable.

However, it is not the end of the story. An appeal by Unison will be heard by the Supreme Court, although not before October 2019. A timetable is yet to be confirmed.

Given the tight financial constraint on the sector, and the potential future wage inflation if the decision in the Mencap case is reversed, it remains an area that providers and payers continue to keep a close eye on.

Regulation

Since the introduction of a new regulatory approach, CQC has inspected all providers of learning disability services. As a result, it is now possible to take a view on overall sector quality. Across NHS and private providers, inpatient wards for people with a learning disability were rated as 73% Good or Outstanding whilst 27% were rated as Requires Improvement. In adult social care, providers that had been registered as having a learning disability specialism outperformed those that did not.

CQC inspection of learning disability providers is not particularly joined up for the independent sector. Inpatient learning disability services are captured as part of CQC's mental health inspection activity, whilst learning disability services being delivered through residential, nursing or domiciliary care are inspected by CQC's adult social care directorate. This can lead to a fragmented regulatory experience for providers operating across health and adult social care.

TYPE OF PROVIDER	LEARNING DISABILITY SPECIALISM	INADEQUATE	REQUIRES IMPROVEMENT	GOOD	OUTSTANDING
Community social care	With specialism	<0.5%	8%	89%	3%
	Without specialism	1%	14%	84%	1%
Domiciliary care agencies	With specialism	<0.5%	9%	87%	3%
	Without specialism	1%	18%	79%	2%
Residential homes	With specialism	1%	10%	88%	1%
	Without specialism	2%	22%	75%	1%
Nursing homes	With specialism	1%	14%	83%	1%
	Without specialism	1%	29%	66%	1%

Source: CQC

Thematic review into the use of restraint and seclusion

Alongside their regular inspection regime, CQC also has the power to undertake thematic inspections. These inspections look at particular care issues in depth across a range of providers, in order to gain understanding of practice in the sector. They have recently carried out a thematic inspection exploring the use of restrictive practices on people with learning disabilities or autism in mental health settings. Following publication of these report, CQC have announced that Phase 2 will look at the use of these practices in adult social care settings.

This second phase will look at whether restraint and seclusion are being used as de facto tools to manage challenging behaviour rather than using more appropriate de-escalation techniques. Even if a provider is not selected as part of the thematic inspection process, this focus – and the events at Whorlton Hall – mean that CQC is likely to be paying close attention to the experiences of vulnerable people. Providers should ensure that their policies and procedures are in line with national guidance, and that staff are appropriately trained in their use.

Building and registering suitable accommodation for people with learning disabilities

'Building the right support' (October 2015) set out a national service model for learning disability services. It reinforced the objective to move people out of institutional care models into more appropriate accommodation. It includes specifications for new buildings that NHS England would be prepared to fund out of capital budgets. These buildings are highly likely to contain regulated activities, which means it is also necessary that they satisfy CQC that they would provide quality care. To support providers, CQC published 'Registering the right support' in June 2017, which set out CQC's approach to registering services for people with learning disability or autism.

Since its introduction there has been criticism that CQC has taken a very rigid approach to interpreting the policy, with the result that several providers have seen their registration applications rejected. The most common reason given is that it does not meet the 'six-bed rule' set out in the national service model, or that the proposal would create a congregate setting of care. This has also increased pressure on commissioners, as it has placed an additional barrier on supply entering the market.

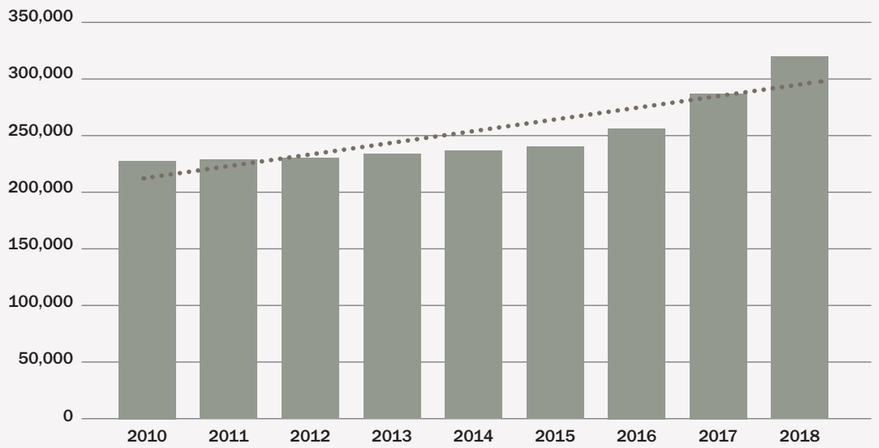
Providers have appealed against CQC decision-making, and a recent tribunal decision may have wide reaching implications for CQC's future approach. It firmly criticised the decision-making process by CQC – in particular for not having given full consideration for what the service user wanted. In May 2019, CQC announced that they would review their guidance material and are currently seeking feedback from the sector. This provides a clear opportunity – in light of growing criticism of their approach – to soften their approach to the registration of residential accommodation for people with a learning disability.

Special Educational Needs and Disabilities

Key Messages

- The number of children and younger people assessed as requiring additional support for Special Educational Needs and Disabilities (SEND) has consistently grown since the introduction of the Children and Families Act in 2014 – passing 300,000 individuals in January 2018
- 6.3% of pupils with an Education, Health & Care (EHC) Plan, or SEN Statement of Support, are taught in Independent Special Schools. An increase of 2.1 percentage points between 2010-2018
- The policy landscape has remained stable since the introduction of the Children and Families Act. However, pressure on local authority budgets has raised concerns over their ability to meet statutory service requirements.
- The Government committed an additionally £350m for SEND, and is currently reviewing the funding allocation process. Newspaper reports suggest that a further £800m for SEND support may be announced as part of a wider policy packages for schools
- Parents are increasingly taking local authorities to tribunals to assert their right to choose the provider – when cases reach a tribunal, they are usually determined in favour of the parent

Since 2010, the number of people that require SEND support has grown year-on-year



Data: Number of Children and Young People with EHC Plans or Statements of SEN

Source: Department for Education

Payers

Local authorities

Local authorities are responsible for the vast majority of education funding for children and young people requiring SEND support. The budget comes from the Department for Education and is contained within the 'Dedicated Schools Grant' (DSG). The DSG is split into three blocks - the schools block, the high needs block, and the early years block.

If a child is identified with a SEND requirement and is educated in a mainstream school, the first £6000 will be met out of the school's core budget, which is allocated to them by the local authority from its schools funding block. If the cost of providing a child with support exceeds this figure, then the school can access top-up funding from the local authority's high-needs block.

If a child with SEND is attending a state-funded special school, then their school receives a funding of £10,000 per commissioned place. This is sourced directly from the school's local authority' high needs block, and represents the assumed required level of per pupil funding.

When a child with SEN's is to be placed in an independent special school, the price is negotiated on a case by case basis and providers are not limited to the £10,000 cap. Costs at independent special schools can vary significantly. This is partly due to the fact they tend to provide services at the highest acuity end of the spectrum – where costs can sometimes be more than £250,000 per year per placement. It was reported in 2018, that a sample of 110 councils spent £480 million per year paying for children with SEND to attend independent special schools.

As a result of these high cost placement, many local authorities are likely to try and place pupils in state-funded schools wherever possible – as these providers have less room for price negotiation.

Special schools

A special school is a school which specialises in catering to pupils who have SENDs. They can be state or privately run. For special schools with pupils aged over 11 they must make special accommodation for individuals whose needs fit into at least one of the following categories:

- communication and interaction
- cognition and learning
- social, emotional and mental health
- sensory and physical needs

Funding pressures

Recent reports suggest the sector is coming under increasing funding pressure. This has been driven by a significant rise in demand for SEND services – and increases in the number of individuals applying for EHC Plans. There were over 72,000 requests for assessment in 2018, up from 64,500 in 2017.

The Local Government Association projects a £667m high needs funding shortfall across local authorities in 2019/20, potentially rising to £1.2bn by 2021. Local authorities have a statutory requirement to fund these services. Often the independent sector acts as a provider of last resort – where other, less specialised placements, may have broken down. As a result, local authorities have limited negotiating power over the cost of placements.

The Department for Education has acknowledged this pressure and committed an extra £350m towards SEND funding in December 2018. This followed a wider £2.6bn boost to the DSG covering 2018/19 and 2019/20 in order to protect high needs funding from local authority raids to sustain the wider education spending budget.

In May 2019 the Department for Education initiated a 'Call for Evidence' regarding SEND funding. However, it avoided the question of whether the overall level of funding was adequate, but instead preferred to look at the process. It aimed to gain insight into how the allocation process could be improved, and what could be done to help young people who are at particular risk of exclusion or require alternative provision. The consultation closed in July 2019, with responses under analysis.

The pressure on SEND funding led to a group of parents taking judicial action against governmental policy. The claimants argued that local authorities were underfunded resulting in them being unable to meet demand. They claimed that this resulted in local authorities leaving SEND children inadequately educated or cared for, thus falling short of their statutory obligations. The hearing took place in June, with a decision due later in the year.

At a local level, there have been several judicial reviews against individual local authorities. These often relate to either changes to the overall high-needs funding levels, or changes to the assessment process for determining SEND needs. The outlook has been mixed with a successful appeal against cuts in Bristol, whilst a more recent decision found in favour of Surrey County Council's planned savings against the SEND budget.

Private payers

Local authorities provide the majority of SEND funding, but there are rare instances where the parents also contribute towards payment. This scenario can arise where a local authority deems a parent's request unsuitable but is willing to reconsider with the inclusion of a financial contribution towards the associated costs coming by the parents. It is an unusual scenario, as EHC plans that determine a child's requirements are put together by multi-disciplinary experts – and so should provide coverage for all appropriate care needs.

A parent can always pay independently for a place at a specialist school, if the local authority has rejected the application for a particular school. However, the cost of placements would make this unaffordable for many. There is anecdotal evidence that local authorities are looking to use guidance in the Children and Family Act Code of Practice around the 'effective use of resources' to avoid placing at more expensive providers – however, an embedded 'right of choice' makes it a difficult position to maintain and Tribunal decisions are regularly in favour of the parents.

Personal Budgets

A child or young person who has an EHC Plan has the right to request a Personal Budget. Local authorities are under a duty to prepare a budget when requested. This will involve them offering a description of the services with education, health and social care that are available. This allows the parent or carer responsible for the child to make use of this money to access support that would otherwise be unavailable and can be spent in the private sector. For example, a Personal Budget can be spent on enabling a child to access specialised learning support or access education otherwise unavailable. Personal Budgets cannot be used to fund school placements.

Policy and Legislation

Children and Families Act (2014)
The most recent piece of substantial legislation on SEND education was the Children and Families Act (2014). The Act provided a more holistic view of a child's needs and looked to provide integrated support between different parts of public funded support.

The key mechanism was the newly created EHC Plans, underpinned by a standardised assessment process, which would help to remove variation in support funding across England.

However, two other vital changes that have proved to have a critical impact on the SEND provision landscape were the explicit presumption towards placing pupils in 'mainstream' education, and also that parents could provide genuine input into deciding the most appropriate place to educate their child.

Education, Health and Care Plans
There has been a shift in how children and young people are allocated support if they have identified needs. SEN Support is for children who require additional assistance within the mainstream school setting, whilst EHC Plans are for those who have been identified as requiring a wider range of support. EHC Plans have replaced the previous 'Statements of SEN' system, however the qualification criteria to receive support has remained unchanged.

The overall number of pupils who have EHC Plans in England is increasing. It reached 253,680 by January 2018 – an increase of 11,495 on the previous year.

A further 34,000 continue to have Statements of SEN maintained by a local authority.

In creating an EHC Plan local authorities are required to acknowledge the views of the parents and young person alongside establishing the needs they have. It should take a holistic approach to meeting these needs, this means using services from the education, health and care sectors in conjunction.

How has the system changed: EHC Plans vs Statements of SEN
EHC Plans have replaced the old Statements of SEN as the tool used to assess, and record, the support requirements for children and young people with SEND needs

EHC Plans (new system)	Statements of SEN (old system)
• EHC Plans consider how the education, health and care sector work together when trying to meet an individual's needs	• Statements would only consider educational needs and support
• Personal Budgets can be attached to EHC Plans	• Statements of SEN did not involve Personal Budgets
• Parents' views given high importance	• Parents' views were not considered in the writing of a Statement
• Can apply until the age of 25	• Could only apply until the age of 16

Percentage of pupils with a Statement or EHC Plan by type of provision (2010 – 2018)

SCHOOL TYPE	2010	2011	2012	2013	2014	2015	2016	2017	2018
Maintained Nursery	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.1
State-funded Primary	25.8	25.8	25.9	26.0	26.2	26.2	25.5	25.8	26.3
State-funded Secondary	28.8	28.4	27.7	26.9	26.2	26.2	25.5	25.8	26.3
State-funded Special	38.2	38.7	39.0	39.6	40.5	41.4	42.9	43.8	44.2
Pupil Referral Unit	0.9	0.8	0.7	0.7	0.7	0.7	0.7	0.7	0.7
Independent	4.2	4.3	4.7	4.9	5.1	5.3	5.7	5.8	6.3
Non-maintained Special	2.0	1.9	1.9	1.8	1.7	1.6	1.6	1.5	1.4

Source: Department for Education

Parental choice and the local offer
The passage of the Children and Families Act (2014) increased the statutory duties expected of local authorities regarding children and young people with SENDs. They are now expected to put forward a 'Local Offer', which details the support available to people with SEND.

Additionally, if a child's EHC Plan names a specific school, including private independent schools registered as available, then they are required to place the child there assuming certain conditions are met. These conditions are that the school must be suitable for the pupil's age, ability and aptitude, the school must be equipped to cope with the pupil's specific SEND and placing the pupil there must not be unduly disruptive to the education of other pupils or be considered an inefficient use of resources. These are the only reasons a local authority is allowed to reject naming an independent school on an EHC Plan.

Currently, 6.3% of pupils with an Education, Health & Care Plan, or SEN Statement of Support, are taught in independent special schools. This represents an increase of 2.1 percentage points between 2010-2018 – and has been slowly increasing from its base level of 4.2% in 2010.

Growing tensions between parents and local authorities

The Children & Families Act contains two ambitions that is increasingly leading to tensions between local authorities and parents of children with an EHC plan. The presumption to mainstream has been a consistent theme – and reflects a wider policy idea that vulnerable members of society should not be placed in institutional settings outside of community as far as possible. However, there is a general feeling that – in part due to stretched local authority finances – it is not possible for children with SEND to receive a suitable education in many mainstream school environments.

As a result parents have increasingly pushed for inclusion within special schools, and potentially within the higher cost independent market. This has been reflected in the growing number of appeals against SEND decisions.

Local authorities tend to consider independent schools as a last resort for placing SEND pupils – in part due to the significantly higher cost involved. However, parents can request an independent special school. Should a local authority reject their request, they have the option to appeal the decision or request a judicial review.

There has been an increase in appeals registered with the SEND tribunal, between 2015 and 2017 they rose from 3,126 appeals to 4,988. The success rate of claimants was 89% (between September 2017 and August 2018). Judges noted that local authorities often lost at tribunals because they were unable to offer an alternative to the parents' proposal.

Government commitment to increase number of special schools

There has been a commitment by the Government to increase the number of specialist schools. Of the £350 million committed to SEND education, £100 million will be spent creating more specialist places in mainstream schools, colleges and special schools. This reflects the desire of parents to have the option to place their child in special schools.

It was announced in March 2019 that 37 new special schools would be built, creating over 3,100 additional places. Places at these new special schools will be assumed to be funded at the £10,000 per year rate. The Government is looking to register these new schools as 'Academy Trusts'. The guidance, additionally, also offers a mechanism for independent providers to submit applications to be involved in the programme. Despite this increase in provision it is expected that demand for SEND placements will continue to exceed supply.

Regulation

Section 41 and the registration of independent schools

If a private independent school wishes to be able to access Local Authority money for educating SEN pupils then they must register under Section 41 of the Children and Families Act. This allows parents to name the school of their EHC Plan and the Local Authority is obliged to fund the child's place assuming the conditions detailed above are met.

What is Section 41?

- Section 41 is a sub-section of the Children and Families Act (2014)
- A Local Authority only has a duty to consider a parent request for an independent school, if the school is registered under Section 41
- However, this does mean the school loses control over its admissions because if a Local Authority agrees to finance a child's place then the school is compelled to admit them
- As of June 2019, there were 297 schools on the list

School inspections

The main body that conducts school inspections in England is Ofsted, which is a non-party political government body. Ofsted is responsible for inspecting all government run schools. However not all independent schools are subjected to direct oversight from Ofsted, which only inspects about half of the independent schools. Those which are not will instead be inspected by either the Independent School's Inspectorate (ISI) or the Schools Inspection Service (SIS). Ofsted does play a role in reviewing the quality of the ISI and SIS's inspections.

In November 2018, Ofsted Chief Inspector, Amanda Spielman, formally wrote to the Department of Education stating that for the past three years Ofsted has only been able to monitor two inspections carried out by the ISI and SIS meaning this area of oversight has been absent. It was recommended that Ofsted increase the number of unannounced visits to ISI and SIS inspections.

For independent schools, this means that they will still be inspected by ISI and SIS. However, if these recommendations are approved by the Department of Education Ofsted will play a greater role in monitoring these inspections.

CQC And Ofsted Joint Inspections

Since May 2016, Ofsted and CQC have been carrying joint inspections of local areas in order to hold them to account over whether they are meeting their statutory responsibilities towards children and young people who have special educational needs or disabilities.

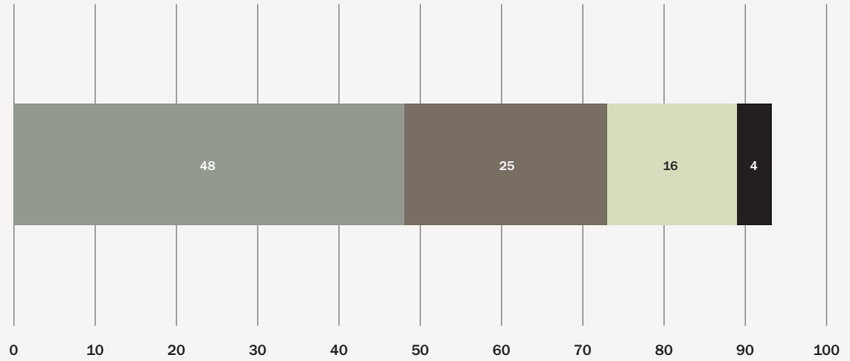
These joint-inspections are conducted over 5 days in local authority areas speaking to those responsible for organizing local services, and speaking to the providers. These are not individual provider inspections – and they also don't evaluate the quality of support provided to individuals.

Branded and Innovative Drugs

Key Messages

- The UK continues to be an attractive location for pharmaceutical developers and manufacturers, supported by a positive policy and regulatory environment – in 2018, the biotech sector alone raised £2.2bn in investment
- The policy focus on innovation and the ambition to strengthen the UK's position as a global leader in life sciences is creating a favourable environment for clinical research. This is supported by increasing join-up between the NHS and industry – including making most effective use of the NHS's unique patient dataset
- Funding on pharmaceuticals in the NHS remains constrained creating pricing pressures, but the new multi-year spending control agreement allows for annual spending growth of 2% on branded and innovative drugs
- New cancer treatments are expected to continue to be of interest to the NHS, in line with objectives of the NHS Long Term Plan to improve cancer survival rates and enable access to innovative medicines. NHS England's pricing agreements on CAR-T therapies also reflect a more flexible approach to funding access to advanced cell and gene therapies
- The ongoing battle for reimbursement of Orkambi, Vertex's cystic fibrosis drug, demonstrates that NHS England continue to take a firm line on value for money pricing

The UK continues to be a major global centre for clinical trials, research and innovation



Data: Number of Advanced Therapy Medical Products (ATMP) clinical trials taking place in the UK

Source: The UK's ATMP landscape, Alliance for Regenerative Medicine-Bio Industry Association, 2019

Payers

Spending controls

Voluntary Scheme for Branded Medicines Pricing and Access (VPAS)

In January 2019, the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) replaced the Pharmaceutical Pricing Regulation Scheme (PPRS). VPAS outlines a new agreement on branded medicines spending from 2019 to 2023. It was agreed between the Association of British Pharmaceutical Industries (ABPI), the Department for Health and Social Care and, for the first time, NHS England.

It is estimated that the NHS spent about £11.6bn on branded drugs in 2016/17. Containing pharmaceutical spend remains a key policy objective for the NHS, and the VPAS attempts to do this whilst ensuring access to needed medicines for patients. Like the PPRS, a key element of VPAS is a cap on the NHS's annual spending growth for branded drugs. The VPAS annual spending under the cap is fixed at 2% per year –this is more generous growth than the averaged 1.1% per year allowed under the PPRS between 2014 and 2018.

	2014	2015	2016	2017	2018	2018
NHS allocated growth within the branded drugs budget	0%	0%	1.8%	1.8%	1.9%	2%

Source: Department of Health and Social Care

When the cap is exceeded, pharmaceutical companies signed up to VPAS are required to pay back a percentage of their NHS sales to the Department of Health and Social Care. The pay back mechanism is derived from the difference between the 'allowed growth rate' and the 'forecast growth rate'. This is a key mechanism in ensuring the NHS doesn't heavily overspend on pharmaceuticals. In 2019, this equates to 9.6%, which is projected to save the NHS £930m. The amount a company will have to payback in 2019, would be worked out as follows:

Scheme Payment = Eligible Sales x Payment Percentage for that calendar year

As under PPRS, there are a number of exemptions. These include spending on vaccines, low-value sales, or sales by small pharmaceutical companies are some of the areas that are not taken into account.

Companies that decide not to join VPAS are, by default, subject to the Statutory Scheme that controls pricing decisions. Functionally it is similar to the VPAS, but since there is less negotiation between the ABPI and the Department of Health and Social Care / NHS England under this arrangement, it means that caps and pay back decisions are imposed on pharmaceutical companies.

NICE's cost-efficiency assessment

The National Institute for Health and Care Excellence (NICE) is responsible for assessing the cost-efficiency of medicines in the UK and provides recommendations for whether they should be reimbursed by the NHS. A key element of this appraisal is the measurement of a medicine's cost per Quality-Adjusted Life Years (QALY) resulting from using the treatment. The QALY takes into account both the length and quality of life. Generally, a cost of £20,000 - £30,000 per QALY is deemed to be cost-effective and should lead to a product being reimbursement on the NHS.

In 2009, NICE increased the QALY to £50,000 for end-of-life treatments and in April 2017 it introduced another threshold for very rare disease treatments, which may have a base QALY of £100,000 per QALY. However, the threshold for ultra-rare disease treatments is weighted by the number of years a drug or treatment can extend quality life and can go up to £300,000 per QALY.

Following this change, NICE recommended that the high-cost gene therapy product, Strimvelis, be made available for NHS reimbursement. Strimvelis reimbursement is particularly unusual as patients access the treatment in Italy, rather than on-site in an NHS facility.

For cost containment purposes, in view of the escalating costs of innovative treatments, NICE introduced a new threshold for expensive drugs. If a drug costs more that £20m per year in the first three years, a commercial discussion is automatically triggered between the company and NHS England, with the aim of mitigating the adverse financial impact on the wider NHS budget. Whilst NICE claims that the £20m annual cost is not a cap, and that products exceeding the threshold could still be reimbursed, it is an additional reimbursement hurdle for high-cost treatment options that impact on larger patient cohorts.

A review of NICE's evaluation methods is scheduled to take place in the summer of 2020. Although the review is not expected to change the QALY thresholds, it will review how NICE incorporates clinical and cost data and quality of life decisions into economic analyses. This could lead to some improvements in the appraisal process.

Pricing

Innovative drug pricing

Over the past 20 years, major advances in genome sequencing and microbiology have paved the way for the development of personalised medicines. These Advanced Therapy Medicinal Products (ATMPs) use gene, or cell-based products to offer treatment, or disease management opportunities, to patients who suffer from rare genetic diseases or certain cancers. They can also provide significant quality of life extensions for some with terminal illnesses.

It is an area that has caught the interest of pharmaceutical companies, developers and investors. There is a clear value proposition in these products; their benefits are well understood by patients, clinicians, and policy-makers, but they are high cost and face funding challenges within publicly funded healthcare systems that face competing demands for resources. However, pricing agreements between NHS England and two companies manufacturing Chimeric Antigen Receptor-T (CAR-T) therapies suggest that these challenges can be overcome.

NHS England's agreements on CAR-T pricing sends positive signals for ATMP developers?

In Autumn 2018, NHS England announced that pricing agreements had been reached on two CAR-T therapies, Kymriah and Yescarta. CAR-T cell therapy uses T-cells, which are taken from a patient's blood, genetically modified to integrate a chimeric antigen receptor, and reinjected into the patient to target cancerous cells.

The announcement means that NHS patients in England will be the first to access CAR-T treatments outside of the US. The drive to enable access to innovative treatments for NHS patients is further reflected in a policy commitment to this aim in the LTP.

Commercial arrangements between NHS England and manufacturers have not been disclosed. They are likely to have included discounts to list prices and it remains to be seen if similar deals can be reached for other ATMPs. However, pricing agreements on Kymriah and Yescarta will provide grounds for optimism for those developing cell or gene therapies and patients suffering from diseases targeted by these therapies.

There are currently 56 ATMP developers headquartered in the UK, representing 24% of all European ATMP developers.

NHS England's expanded role

Pricing of branded drugs is agreed on a drug by drug basis. While companies are technically free to set their price, drugs that are too expensive will not pass NICE's cost-efficiency test, and, by default, be excluded from NHS reimbursement.

The Department of Health and Social Care has traditionally been the key pricing negotiator for companies wanting to bring a new drug to the British market. However, NHS England increasingly intervenes in price negotiations, especially when new drugs have proven health benefits but high price points. This has also seen the Commercial Medicines Unit, who are responsible for managing most tenders for drugs used in hospital settings, moving from the Department of Health and Social Care to NHS England.

Since NHS England already has responsibility for allocating the majority of the NHS healthcare budget, this is a rational shift. It makes it easier for pricing decisions to be made within the context of wider expenditure on health services. For developers and pharmaceutical companies this will require some adaptation in terms of managing price negotiations and defining the right value proposition to NHS England.

Recent price agreements suggest that NHS England negotiations not merely a cost containment exercise. Alongside the CAR-T approvals, NHS England reached an agreement on reimbursing Ocrevus, a new drug that can slow the evolution of multiple sclerosis in May 2019, in spite of a previous NICE rejection.

Policy and Legislation

The UK policy landscape is overall favourable to the development of new drugs. Increasingly, this is focused towards innovative therapies, which include cell and gene therapies and biologic drugs.

NHS Long Term Plan

The LTP makes references to the introduction of cell and gene therapies and personalised medicines as examples of new treatments that a modern healthcare system should offer. Clinical priorities pinpoint to areas where demand for innovative treatments will be particularly strong. These include cancer, cardiovascular diseases, stroke, diabetes and respiratory diseases.

The continued policy focus on cancer, in particular, supports the development of innovative therapies. Opportunities already existed through funding support in the Cancer Drug Fund and the NHS Cancer Strategy. They have been further strengthened in the LTP, which announced that genome sequencing will be used to deliver highly personalised diagnostics to children with cancer, and adults suffering from certain rare conditions or specified cancers. This is expected to start in 2019. It builds on the 100,000 Genome Project, which started in 2012 and is sequencing 100,000 genomes from around 70,000 people suffering from rare diseases or cancer.

The 100,00 Genome Project placed the UK at the forefront of genetic medicine research. It is now expected to create opportunities for the development and deployment of 'tumour agnostic' cancer drugs in the NHS, which target tumours according to their genetic make-up rather than where they originate in the body. In June 2019, Simon Stevens, the CEP of NHS England suggested in a conference that the NHS is preparing to fast-track tumour agnostic cancer drugs similar to its fast-tracking of CAR-T therapies.

Life Sciences industrial strategy

Wider policy objectives relevant to the development of branded and innovative drugs are outlined in the Life Sciences Industrial Strategy. Partly developed in anticipation of Brexit and its impact on the life science sector, it aims to secure the UK's position as a global leader in clinical research and medical innovation. Headlines include:

- A commitment to increasing total R&D spending from 1.7% currently to 2.4% of GDP by 2028, which could see health R&D spending reach £14bn
- Supporting the creation of a cohort of healthy participants that will enable research into the hidden signs of disease and ways of diagnosing diseases early when interventions and treatments can be the most effective
- Continue to support genomic research through sequencing 1 million genomes by 2023

Given the focus on supporting research, these measures will be of particular interest to developers and those supporting them, such as Clinical Research Organisations (CROs).

Regulation

Marketing authorisations

New drug approval

Marketing authorisations for new drugs in the EU market are regulated by EU law and can be delivered centrally by the European Medicines Agency (EMA) or at national level by competent authorities. When delivered at national level under the mutual recognition or decentralised procedure, they can be sold across several EU countries.

Central assessment and regulatory approval by the EMA is compulsory for innovative cell and gene therapies, orphan drugs and new active substances intended for the treatment of AIDS, cancer, neurodegenerative disorders or diabetes. This was agreed to avoid the duplication of regulatory frameworks across Europe and ensure consistency, especially for cell and gene therapies. This greatly simplified the approach for developers wanting to bring their innovative treatments to EU countries, even though it can still be difficult to gain an EMA marketing authorisation.

To encourage the approval of innovative drugs addressing unmet need, the EMA has developed a fast track approval scheme, called PRIME (PRIority MEdicines). Under this scheme, developers receive early scientific and regulatory support, and their products can go through a shorter assessment, making it more likely to gain marketing approval. For example, both Kymriah and Yescarta benefited from PRIME before receiving marketing authorisations.

Medicines and Healthcare products Regulatory Agency (MHRA)'s role post-Brexit

Post-Brexit, the regulation of marketing authorisations in the UK will sit solely with the MHRA, which will become an independent regulator, most likely to operate outside of the EMA. The transition has already started to happen. The EMA relocated its offices from London to Amsterdam (Netherlands). While the MHRA remains a member of the EMA before Brexit is officially enacted, it no longer plays a lead role on new drug evaluations.

The MHRA has historically played a key role in shaping EU pharmaceutical regulation. This will be markedly reduced as a result of Brexit. However, its legacy is likely to endure for some time as EU regulation is complex and will take many years to amend. Under both a deal or no-deal scenario, the MHRA has signalled its intention to align closely with the EU regulatory framework. This means that developers and manufacturers can expect similar timelines and approaches to marketing authorisation as with the EMA. This should reduce risks for divergence between the two regulators when submitting two separate applications for marketing authorisations for the EU and the UK, which will be required in the future post Brexit.

In addition, the MHRA has indicated that it will offer faster assessment routes for certain medicines, like biologics. Its established Innovation Office will also continue to provide clinical and regulatory advice to developers. This arrangement for close collaboration between the regulator and the developer should help the UK to retain its attractiveness as a market for new drug development and launch.

Existing marketing authorisations continuity

The MHRA has indicated that it will continue to accept marketing authorisations which have been delivered centrally by the EMA or by another national competent authority through mutual recognition or the decentralised procedure. Manufacturers will have to request conversion of their marketing authorisations within 21 days of the final Brexit date, but conversion to a UK licence will be automatic. This means that manufacturers based in the EU will be able to continue selling their products in the UK. The EU is yet to confirm that it will offer a similar deal to UK based manufacturers whose marketing authorisations have been granted by the MHRA.

Clinical trials regulation

Before gaining a marketing authorisation, all therapies must complete the clinical trial process. The framework regulating clinical trials is set at EU level, with a new Clinical Trial Regulation (CTR) expected to be implemented in late 2020/early 2021.

The new Regulation seeks to harmonise the rules for conducting clinical trials throughout the EU and simplify the clinical trial submission and assessment process when trials are conducted in multiple EU member states. This is particularly relevant to innovative therapies addressing rare diseases as patient populations will, by definition, be small in individual countries necessitating cross-border collaboration to obtain the required patient numbers. The EMA is currently working on setting-up an EU portal and database to facilitate this cross-border collaboration. However, technical issues have led to significant delays.

The UK Government has agreed to align the future regulatory framework for clinical trials to the EU. The MHRA has confirmed that it intends to implement elements of the CTR. This includes increased transparency requirements and more consistent reporting of adverse events. However, it remains unclear whether the UK will get access to the clinical trial portal and database. The EMA has signalled that the default position would be for the UK not to participate in the database given that it would no longer be a member of the EMA. This issue would be subject to negotiations on the future relationship between the UK and the EU, which would take place following a withdrawal agreement.

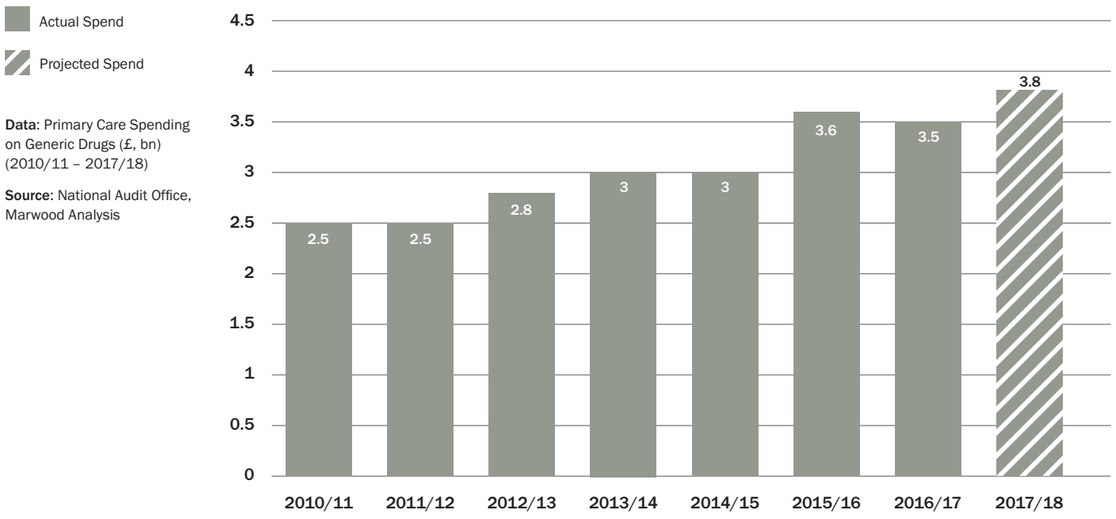
Getting access to the portal and database would facilitate UK-based developers' participation in cross-border cooperation and access to wider patient pools across Europe. However, it could increase timelines for clinical trial authorisations. Therefore, there may advantages for the UK to not fully participate in the CTR, as long as the MHRA can maintain short clinical trial authorisation timelines. In addition, there is a broad agreement that multi-national clinical trials can continue to be conducted, even if the UK does not have access to the EU portal and database.

Generic and Bioimilar Drugs

Key Messages

- With more and more biologic drugs approaching patent expiry in Europe, the NHS is keen to leverage the savings potential from their cheaper biosimilar versions. This is likely to make the UK an attractive launch market for biosimilar manufacturers
- Uptake of biosimilars in the UK has increased quickly over the past three years. This is expected to continue, supported by national policy and guidance to CCGs and NHS Trusts
- Priority clinical areas identified in the NHS Long Term Plan are likely to provide opportunities for oncology and diabetes biosimilars
- The UK generic drug market is mature, with policies and pricing mechanisms incentivising competition and quick market penetration expected to continue
- £3.8bn was expected to be spend on generic drugs in primary care in 2017/18 – an increase from £2.5bn in 2010/11. Overall spend on generic drugs is estimated at over £4.3bn
- Generic drug pricing will continue to be closely monitored by payers, regulators and policy makers following several high profile cases of pharmaceutical companies finding ways of manipulating the pricing system to push through substantial price increases

Generic drug spending in primary care has increased over time despite attempts to curb expenditure



Data: Primary Care Spending on Generic Drugs (£, bn) (2010/11 – 2017/18)

Source: National Audit Office, Marwood Analysis

Payers

Generic drug price setting

Generic drugs are copies of originator branded drugs which have lost their patent protection. They are usually substantially cheaper than their branded competitor – although the margin can vary substantially depending on the level of competition.

Companies are free to set their own prices for generic drugs sold in the UK. However, to counter excessive pricing, government policy encourages market entry to foster competition and ensure that prices decrease rapidly and remain low. The NHS Drug Tariff is used to establish the level at which community pharmacies are reimbursed by CCGs for the provision of medicines in primary care. This aims to incentivise generic companies or wholesalers to sell generic drugs to pharmacies at a lower price than the Drug Tariff. There are three categories of medicines in the Drug Tariff, and the Tariff price for a drug is dependent on which category it is placed in.

CATEGORY	DESCRIPTION	DRUG TARIFF
A	Drugs which are competitively available, including popular generics	Calculated monthly based on a weighted average of the prices from 2 wholesalers and 2 generic manufacturers
C	Drugs which are not competitively available (often branded drugs)	Set by manufacturer or supplier
M	Drugs which are competitively available	Calculated by the DHSC based on information submitted by manufacturers. Reviewed every 3 months

The increasing cost of generic medicines in primary care

Overall, the reliance on competition and market dynamics have brought generic drug prices down. UK generic prices are among the lowest in Europe and the widespread use of generic drugs is estimated to save the NHS £13.5bn a year. However, in June 2018, the National Audit Office (NAO) outlined that substantial increase in the number of 'concessionary' requests made by community pharmacies had resulted in £315m additional costs on CCGs in 2017/18.

Concessionary prices may be approved when pharmacies cannot purchase a medicine at the Drug Tariff's price or below, and so are often indicative of price increases of generics. NHS England did not advise CCGs that they should budget for similar pricing pressures for 2018/19. However, in March 2019, it was reported that the number of concessions granted had again risen sharply. Although their impact has not been costed, this is likely to have put pressure on CCGs' finances.

According to the Department of Health and Social Care, there are three possible reasons for the increase: medicine shortages; currency fluctuations; and increases in wholesalers' margins. It has also been suggested that no-deal Brexit preparations, shortage concerns and stockpiling might be responsible for the increase in the number of concessions in the first three months of 2019.

Biosimilar tenders

As the number of biologic drugs coming off patent is set to increase, cheaper biosimilar versions are emerging as a new area of interest to the NHS. It is estimated that increasing the use of biosimilars could save the NHS £200-300m per year by 2020/21. Biosimilar drugs are defined by NHS England as biological medicines which have been shown not to have any clinically meaningful differences from an originator medicine in terms of quality, safety and efficacy. They are similar but not identical to their originator.

Biologic drugs tend to be used in hospital. They are primarily commissioned through NHS England's Commercial Medicines Unit. In October 2018, it was announced that tenders had been awarded for the provision of adalimumab, the biosimilar version of Humira, to four manufacturers. This is designed to incentivise price competition.

The NHS spends £400m a year on Humira, making it the single most expensive hospital drug. The introduction of adalimumab biosimilars is expected to save the NHS £150m per year.

Policy and Legislation

Biosimilar policy

Given their cost-saving potential, it is unsurprising that biosimilars have attracted policy makers' attention. However, as they are not identical to the originator product, it means they cannot be automatically substituted and the decision lies with the responsible clinician, in discussion with the patient. Policy efforts are therefore focusing on encouraging commissioners, clinicians and patients in switching to biosimilars.

Opportunities in the UK biosimilar market

The UK is leading the way in biosimilar uptake in Europe. This has been enabled by proactive policy measures encouraging switching from biologic originators to their biosimilar versions. The *Commissioning framework for biological medicines (including biosimilar medicines)* supports commissioners in making decisions on biosimilars. It clearly states that all CCGs should be proactive in identifying the opportunities from biosimilars. The guidance recommends adopting a collaborative approach, involving clinicians, patients, providers (such as NHS Trusts) and CCGs.

Following the launch of adalimumab biosimilars, NHS England also issues specific guidance to NHS Trusts and CCGs. They have been instructed to ensure that 90% of new patients are prescribed a biosimilar and 80% of existing patients should switch to a biosimilar within the first 12 months of launch. At a regional level, Regional Medicines Optimisation Committees have been established to apply national guidance.

The Generic and Biosimilar Initiative (GaBI) estimates that nearly 50 best-seller biologic drugs will lose patent exclusivity over the next 10 years. Cancer, autoimmune diseases, and diabetes treatments account for over 60% of the biologic market globally. The LTP focus on cancer and diabetes means that there will likely be opportunities for those developing biosimilars in these therapeutic areas.

Guidance to CCGs on drugs that should no longer be prescribed

Generic drug price increases, coupled with wider NHS funding pressure and the ongoing requirement to find cost-savings from within the NHS budget, led to the establishment of a working group to identify pharmaceutical products that should no longer be prescribed. In November 2017, guidance was published outlining seven generic products, that had been subject to 'excessive' price inflation and should no longer be prescribed because there are more cost-efficient alternatives. This guidance is reviewed and updated regularly. The most recent update of June 2019 added two more generic drugs to the list.

The guidance is not binding on CCGs. They are free to develop their own formularies, which outline which drugs are available for prescription, taking into account clinical efficiency and price. However, given the level of financial pressure CCGs are under, it would be surprising if they did not use the guidance as an easy way to generate savings. This could lead to products listed as second or third line items, or removed from individual CCGs' formularies.

If GPs want to issue a new prescription for a product that is not on their CCG's formulary, they need to place a special request. In the medium to long term, these changes are likely to see prescriptions for these products decrease, as new patients will be prescribed alternative treatments.

The working group's interest goes beyond generic drugs that are strictly available upon prescription. The guidance identifies several drugs for minor conditions available over the counter but sometimes prescribed by GPs on the NHS, which should no longer be prescribed. The working group will continue monitoring NHS drug spending overall, including generic drug pricing and update its guidance as necessary.

Price control powers and information provision

Following political and media pressure as a result of well-publicised cases of price increases by generic drug companies, the Health Service Medical Supplies (Costs) Act gave power to the Secretary of State to intervene directly on generic pricing by formally requesting companies to reduce prices. The Act also formalised information sharing between generic drugs companies and the DHSC. Regulations implementing the provisions in the Act came into force in July 2018 and companies will now have to provide pricing information on a quarterly basis.

To date, it appears that the Secretary of State has not used their price control power to request direct price reductions. This may be because the information provision regulations are relatively recent, and so high-quality pricing information is only recently available. Alternatively, it is possible that confidential discussions have taken place behind closed doors, with little public scrutiny.

If the CMA's current regulatory action against generic drug companies is unsuccessful, the Secretary of State, Matt Hancock, may prove willing to use the powers. A report on the implementation of the regulations is expected by September 2019 and might provide insight on the future approach.

Regulation

Biosimilar marketing authorisation
As biosimilars are similar to but not identical to another biological medicine that has already been approved, their regulatory approval differs to that of small molecule generic drugs. The regulatory framework is set at EU level and the majority of new biosimilars are subject to EMA approval.

Over the past 10 years, the agency has continuously clarified its regulatory framework used to establish the similarity of biosimilar to the biologic reference product. This engagement helped reducing the average assessment time for biosimilar application approval from 200 days in 2015 to 175 days in 2017. In principle, no additional national clinical studies on switching are needed once a biosimilar has received EMA approval.

Post-Brexit, the MHRA will be responsible for delivering marketing authorisations to biosimilars. It is expected to align with EU regulation and the EMA's approach to biosimilar approval. The MHRA has also announced that it will introduce new assessment routes to support approval of new medicines in the UK in case of no-deal Brexit. Two of these new routes target biosimilars specifically, reflecting the wider regulatory and policy interest in these drugs:

- Targeted assessment process: the MHRA will evaluate the marketing authorisation application together with the EMA's Committee for Medicinal products for Human Use (CHMP) assessment reports submitted by the applicants. An opinion will be reached within 67 days of submission of a valid application to the MHRA
- Rolling review route: the MHRA will offer ongoing regulatory input and feedback to the applicant to help them getting the development of their drug right and avoid regulatory approval delays. The details of this new evaluation approach are currently being finalised by the MHRA

Investigations into generic drug pricing
In recent years, the CMA has taken an active interest in the pharmaceutical sector, in particular concerns around generic drug price increase. By July 2018, the CMA had formally opened six investigations into generic drug companies for suspected unfair pricing. They were launched after it became evident to the competition regulator that some companies had substantially increased the price of selected older generic drugs. In many cases, they used a 'de-branding' strategy, moving the drug from the PPRS to the Drug Tariff (category C), in order to benefit from the pricing freedom that the Drug Tariff allowed.

While some investigations are still ongoing, the CMA has refocused on anti-competitive agreements between generic companies, moving away from the unfair pricing issue. This led to statements of objection being issued by the CMA in May and July 2019 against a number of generic companies and their investors. They signalled that the CMA has provisionally found these companies to be in breach of competition law because they have allegedly agreed payments between them to retain market exclusivity for generic products.

This reflects the difficulties the CMA experienced in proving that price increase resulting from dominant positions are unfair. The difficulties were illustrated with the Pfizer and Flynn case (see box). The CMA could try again to demonstrate that unfair pricing took place in that specific case.

However, no updates have been published to date. The CAT's judgement is likely to have slowed down other CMA investigations into generic drug pricing and to have shifted their focus away from unfair pricing. In addition, it is unlikely that the CMA will open new cases until its views on Pfizer and Flynn Pharma are upheld.

Abuse of a dominant position: Pfizer, Flynn Pharma, and the CMA
The issues concerning Pfizer and Flynn Pharma date back to May 2013, and it is viewed by many as a key test battle over the ability of the CMA to demonstrate 'abuse of market' over generic price increases.

In 2012, Pfizer and Flynn Pharma undertook a 'de-branding' strategy. Pfizer sold the rights of Epanutin (the brand name of phenytoin sodium capsules) to Flynn Pharma while retaining manufacturing. Epanutin was subsequently 'de-branded'– effectively making it a generic that did not have any competitors. This allowed them to move from the PPRS to become a Category C Drug on the Drug Tariff. This allowed free pricing, and in the absence of any competitor products, the product was increased in price by 2,600%.

Following over three years of investigation, the CMA published its final infringement decision in December 2016. The CMA found that Pfizer and Flynn Pharma abused their dominant position to charge the NHS 'unfair' prices. The companies were fined a record total of £89.4m, including the maximum penalty for Flynn (10% of its global turnover). The CMA also instructed them to decrease the price of phenytoin sodium capsules.

Pfizer and Flynn appealed the CMA's decision to the Competition Appeal Tribunal (CAT). In June 2018, the CAT partly dismissed the CMA's decision due to a failure to demonstrate that the companies had charged excessive or unfair prices to the NHS. The CAT has now referred the case back to the CMA.

Medical Devices

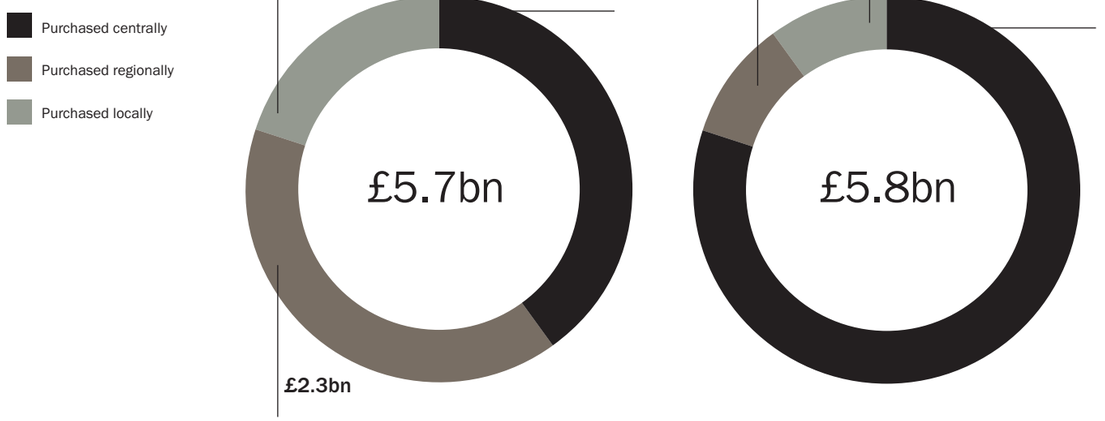
Key Messages

- NHS Trusts are the main purchaser of medical devices, spending £5.7bn on devices from simple clinical consumables to highly innovative diagnostic equipment
- NHS medical device procurement has been identified as a key area where price variation can be reduced, and savings can be made. This is being actioned through efforts to centralise procurement which is likely to lead to price pressure on medical devices but should also simplify sales management processes for manufacturers
- Government policy is overall supportive of the medical device sector, with a focus on encouraging innovation and facilitating market access for new cost-effective devices
- Brexit uncertainty creates some challenges to the industry but the MHRA has made extensive preparations to respond to a possible no-deal scenario, and is expected to maintain alignment on EU regulation for medical devices, minimising disruption for manufacturers

Policy drivers look to increasingly channel expenditure through centralised procurement processes

Data: NHS Trust spend on medical devices by purchasing source (2018/19 and 2020/21)

Source: NHS England, Marwood Analysis



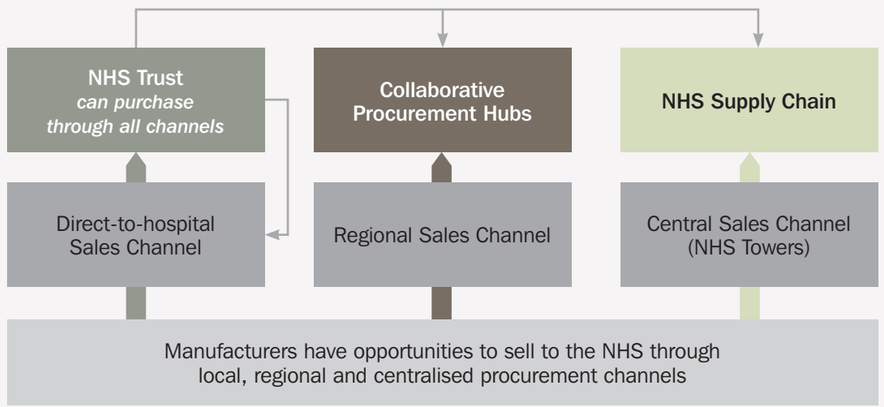
Payers

Centralising NHS Trust procurement

NHS Trusts are the main payer for medical devices. They spend £5.7bn each year purchasing a wide range of devices, ranging from small consumables like syringes to larger equipment, such as medical beds. The cost of the majority of medical devices used in hospitals is included in the calculation of the NHS tariff for the delivery of acute services.

NHS Trusts can purchase products direct from manufacturers or through regional hubs. However, they are now encouraged to purchase through the centralised NHS Towers, which replaced the NHS Supply Chain from mid-2018. There are 11 Towers, covering broad categories of medical devices. Each Tower is run by a service provider who undertakes the clinical evaluation of products and runs procurement processes on behalf of the NHS. They create a single point of access for manufacturers to sell their products to the NHS. This centralisation of procurement has been introduced to address price variation outlined in the 2016 Carter Review.

NHS Procurement channels



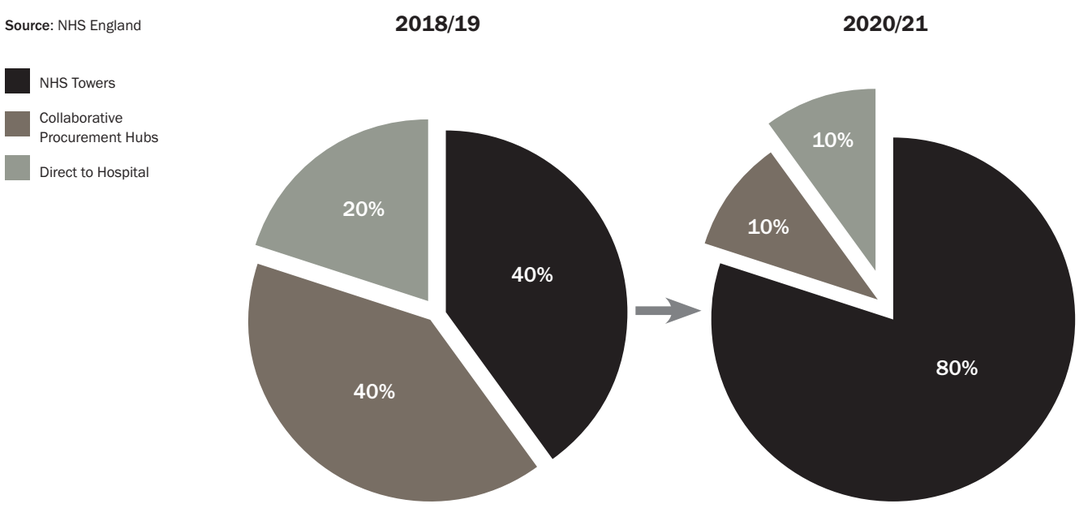
The Carter Review estimated that £700m could be released through more efficient procurement processes for goods and services. To achieve this, the Future Operating Model has been established. This looks to centralise a far higher proportion of NHS procurement, shifting the balance from the current 40% to nearly 80% of all goods and products procured centrally in the future. The challenge is that without legislative change, which is not expected, NHS Trusts cannot be mandated to use centralised procurement, and hospitals will remain able to choose the procurement channels they use. However, they are required to financially contribute to the Future Operating Model, as a way to incentivise purchasing through the NHS Towers.

Improving procurement efficiency continues to be a key objective under the NHS Long Term Plan (LTP). It has also been suggested that procurement could be further centralised in the future, through national teams, taking over purchasing functions currently held by individual Trusts. Whilst this remains a

suggestion, and has not yet been confirmed as official policy, Trusts have already made clear that they would oppose this move. This might make any change difficult to implement. NHS Trusts hold significant procurement expertise and knowledge, and their cooperation would likely be needed to ensure the success of the proposed approach.

Procurement channels shift under the Future Operating Model

Source: NHS England



Specialised commissioning

Specialised devices are paid by NHS England's specialised commissioning budget. These are known as High-Cost Tariff-Excluded Devices (HCTED) NHS Improvement and NHS England are responsible for determining which devices should be excluded from the tariff. Currently, 15 categories of devices are listed on the high-cost tariff. This includes lengthening nails for limb reconstruction, intrathecal drug delivery pumps, and bone conducting hearing implants.

Each year, NHS England spends over £500m on HCTED. Specialised Commissioning is also moving towards increased purchase centralisation, like NHS Trusts. The objective is similar and aims to reduce pricing variation and increase transparency.

In April 2016, NHS England introduced a new national approach to purchasing these devices. This is expected to save £60m per year. By the end of 2018, £250m worth of devices were commissioned through the new approach and 108 of the 126 NHS Trusts delivering specialised services were using it. Device Working Groups have been set-up within NHS England to lead on the development of clinical device specifications, which will inform future HCTED procurement. Clinical Commissioning Groups

Some medical devices used outside of hospital are primarily commissioned by CCGs. This includes for example wheelchairs, and other walking aids. Each CCG is responsible for deciding what medical devices are

included into their formulary and are funded in their local area. Decisions are based on NICE guidance on cost-efficiency of devices. Devices recommended by NICE's Technology Appraisal Programme and used outside of hospital must be funded by CCGs within three months of guidance being published.

CCGs normally use tenders to select manufacturers from whom they will purchase devices. Increasingly, these tenders are taking place at a regional level to increase purchasing power. This is likely to put some pressure on price, but will make it easier for manufacturers to target and identify potential clients as their number reduces.

Policy And Legislation

NHS Long Term Plan

The LTP outlined a number of favourable policy directions for the medical device sector. The focus on delivering services outside of hospital and preventing hospital admissions suggests that home-based and wearable monitoring devices may be needed so that patients' health can be monitored remotely. The objective to increase early diagnostics for cancer is likely to require additional testing devices as well as larger diagnostic equipment such as MRIs. Devices that integrate a measuring function may be able to support the NHS's continued efforts for improving the quality of care and reduce variation by providing the necessary data clinicians need to address these issues.

A positive policy environment for the adoption of innovative medical devices

Overall, there are positive policy headwinds for medical devices manufacturers in the UK. The Government is committed to supporting innovation in the sector, the MHRA stands ready to provide scientific feedback and early regulatory support to developers, and the NHS offers a unique real-life environment where new devices can be tested and adopted at scale.

Innovative in-vitro diagnostic medical devices are emerging as an area of particular interest for the NHS an could benefit from this environment. The in-vitro diagnostic sector plays a vital role in any healthcare system – capturing, testing and analysing samples that underpin the clinical diagnosis process. Innovation and delivery of improved diagnostic methods has been a key focus and growth driver of the industry in recent years, as new tests respond to the needs and priorities of the NHS around early diagnosis and improving patient outcomes.

Manufacturers developing these innovative devices are well placed to benefit from specific funding and support introducing their products to the NHS. The Accelerated Access Collaborative (AAC) has already identified seven categories of products, including five diagnostic tests, as rapid uptake products. They will benefit from £2m public funding and each manufacturer is expected to receive tailored support to ensure that their device reaches clinicians in the NHS and can be used in real-life for the benefit of patients.

It remains to be seen how successful this will be. However, as the AAC has now been formally established within NHS England and will continue to review and identify innovations for rapid uptake, this provides a new route for developers to bring devices to the UK market faster.

Accelerated Access

Collaborative & innovation

The Accelerated Access Collaborative (AAC) was set-up in 2018 in response to the Accelerated Access Review published in 2016. The review recommended bringing together industry, government and the NHS to facilitate removal of barriers to innovation. Its aim is to enable faster access to transformative innovations for NHS patients. Within its first year, the AAC has identified 12 rapid uptake products, the majority of which are medical devices. These products will be supported to scale and spread with support from local Academic Health Sciences Networks.

The AAC is set-up as a new unit within NHS England. It will continue to identify new innovations with high potential for patients and the NHS, provide support to developers, including helping them understand where the needs of clinicians and patients lie, and support the NHS to adopt innovations.

Life Science industrial strategy

In the 2018 Life Science Sector Deal, the Government announced that funding would become available to enable NICE to increase their support for medical devices, diagnostics and digital products. NICE is expected to increase the number of evaluations for these products. This determines their cost-benefits, and encourage NHS use of innovative devices meeting NICE's cost-efficiency criteria. NICE will consult on its evaluation method for medical technologies and diagnostics in Summer 2020.

The 2018 Sector Deal also suggests that artificial intelligence will be a key focus. The MHRA is working with NHS Digital on a proof-of-concept that aims to validate algorithms, including AI algorithms used in medical devices.

These announcements build on the recommendations of the Life Science Industrial Strategy. Published in 2017, it aims to maintain and further position the UK as a global leader in life sciences. For medical devices, this means encouraging new device discovery and innovation for the benefits of patients. The Life Science Strategy outlines initiatives to support early development studies, enabling manufacturers to access regulatory advice, the UK's prestigious academic network and the NHS for real-life testing.

Regulation

Incoming medical device and in-vitro diagnostic medical device regulations

The regulation of medical devices is currently established in EU law. The Medical Device Regulation (MDR) and In-vitro Medical Device Regulations (IVDR) are due to be implemented by May 2020 and May 2022 respectively. They will replace three directives – the Medical Device Directive (MDD), the Active Implantable Medical Device Directive and the In-Vitro Diagnostics Medical Device Directive – and ensure that medical safety is strengthened and that rules are applied consistently across the EU. The two regulations will strengthen pre and post-market oversight and increase safety requirements.

PIP: The scandal driving regulatory reform

The adoption of the new regulations was driven by the PIP silicone breast implant scandal. The scandal broke in 2009, when it was revealed that PIP, a French-based company had been manufacturing breast implants containing unapproved, cheaper industrial-grade silicone instead of medical-grade silicone. This cheaper product was more prone to rupturing, causing concerns about their toxicity.

Medical device classification

Medical devices and in-vitro diagnostic medical devices are classified in four categories based on their level of risk. To be classified as a medical or in-vitro diagnostic medical device, a product must demonstrate a medical purpose. This means that assistive technology products, i.e. aids for daily living may or may not be classed as a medical device. In case of borderline products, the MHRA – as the UK's national competent authority – is ultimately responsible for deciding whether a product is a medical device.

The MDR broadened the definition of medical devices. The scope of the regulation extends, for example, to all facial/dermal fillers, or coloured non-corrective contact lenses, some of which would have previously been classified as cosmetic products and did not have to comply with safety, quality and efficacy requirements contained in the MDD. Given that these requirements will be strengthened by the MDR, manufacturers will have been expected to take the necessary steps to comply. This includes collecting information on their devices' safety and quality and hiring a notified body to obtain certification of conformity with the MDR and be able to place a CE mark on their device.

Certification

Defining device classification is essential to any manufacturer as it will determine the regulatory pathway they need to undertake in order to obtain a CE mark, allowing the device to be placed on the market. Manufacturers can self-certify their Class I medical devices that are not sterile, do not have a measuring function or are not reusable and their non-sterile Class A in-vitro diagnostic medical devices. All other devices must undergo a conformity assessment. This is carried out by a Notified Body, an independent organisation which has been accredited to assess that medical devices are compliant with EU regulation.

Notified Bodies are appointed by national regulators, like the MHRA. In the event of no-deal Brexit, the MHRA will maintain UK-based Notified Bodies' legal status. Their activities will be restricted to conformity assessments of devices intended for the UK market only as they will no longer be able to perform conformity assessments of devices intended for the EU market.

Medical Device Classification Guide

	Medical Devices		In-vitro Diagnostic Medical Devices	
Conformity Assessment	Class III	High Risk	Class D	High public health risk, high personal risk
	Class II.b	Medium/High Risk	Class C	Moderate to low public health risk, high personal risk
	Class II.a	Medium Risk	Class B	Low public health risk, moderate to low personal health risk
Self-certification	Class I	Low Risk	Class A	Low public health risk, low personal risk

Post-market surveillance

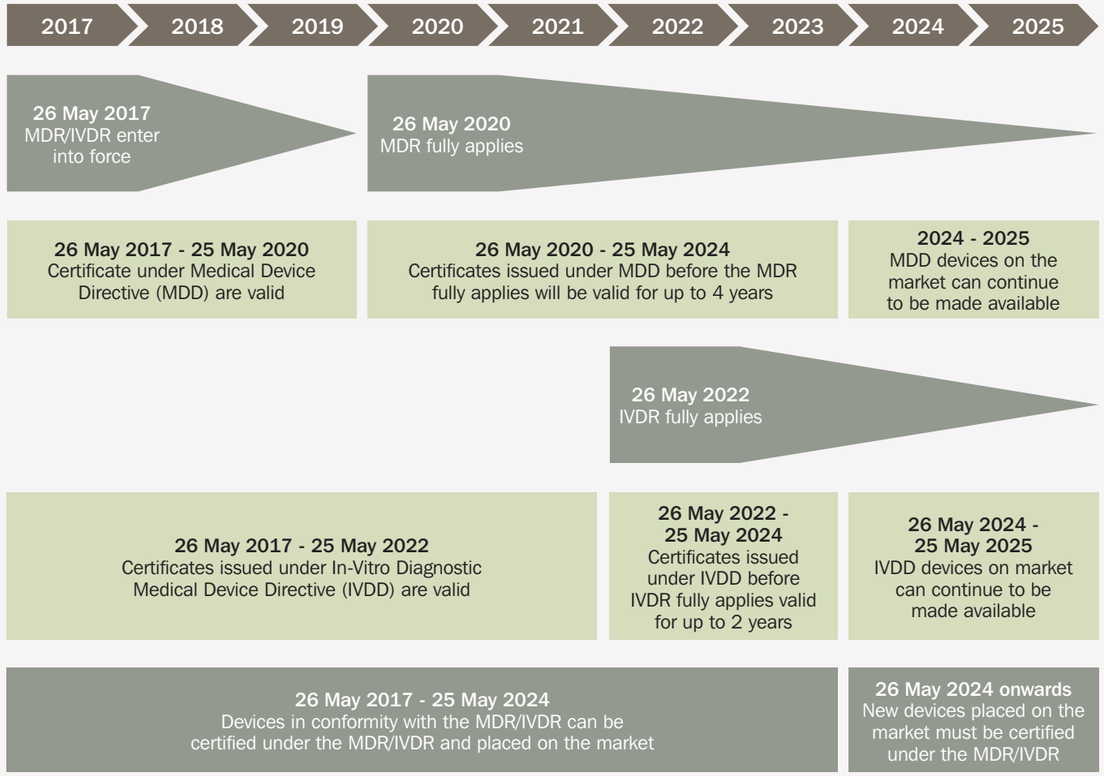
Device classification will also determine the level of post-market scrutiny manufacturers can expect. Surveillance efforts will primarily focus on higher risk medical and in-vitro diagnostic medical devices– although they will be strengthened for all devices under the MDR and IVDR. The focus of post-market surveillance will be on ensuring that devices are safe, and it will be easier to remove unsafe devices from the market.

Implementation

Implementation periods were introduced to give manufacturers time to prepare for the new requirements of the MDR and IVDR, especially obtaining re-certification. Although the UK is due to leave the EU, it is expected to align on these timelines. This means that manufacturers can expect a similar regulatory framework for medical device authorisation in the UK and in the EU.

If the UK leaves with a deal, it will remain subject to EU regulation on medical devices until the end of the transition period – currently set on 31 December 2020.
In case of no-deal, the MHRA has issued guidance stating that it would continue to accept CE marked devices manufactured in the European Union for an undefined limited period post Brexit. Devices that are already CE marked and sold on the market will continue to be accepted. The MHRA's intention is to align closely on EU regulation, but in the future, medical devices are likely to need to obtain a specific authorisation before being placed on the UK market.

Medical Device Regulation - implementation timelines



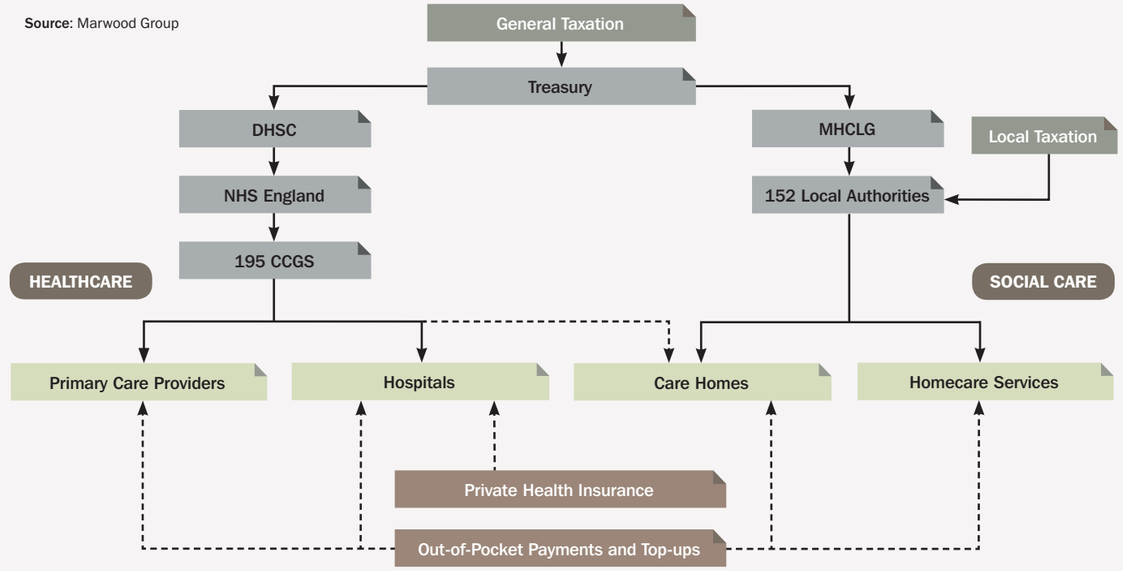
OVERVIEW OF THE HEALTH AND SOCIAL CARE SYSTEM IN ENGLAND 5

Key Messages

- The NHS is set to receive an additional £20.5bn funding in real-terms between 2019/20 and 2023/24, including £2.3bn for children and adult mental health services and £4.5bn for community and primary care services
- Other priority areas outlined in the NHS Long Term Plan (LTP) include cancer and maternity care, enabling and expanding the use of digital technologies in healthcare, prevention and early diagnosis of common diseases
- System transformation objectives will see an increasingly strategic approach to commissioning across local health economies. Providers will be expected to work collaboratively to improve population health outcomes
- Social care services, including older people's and learning disability services, are primarily funded by local authorities whose budgets have faced reductions in central government funding. The continued failure to publish a green paper on social care means long term sustainability for the sector remains unaddressed
- Local authorities have sought to protect social care funding at the expense of other services. The degree of funding pressure on providers contracting with local authorities has varied across the country

FUNDING FLOWS

Source: Marwood Group



DHSC: Department of Health and Social Care
MHCLG: Ministry of Housing. Communities and Local Government
CCG: Clinical Commissioning Group

POPULATION

Total

55.6m

Source: ONS

Life Expectancy

79.5yrs 83.1yrs

Source: ONS

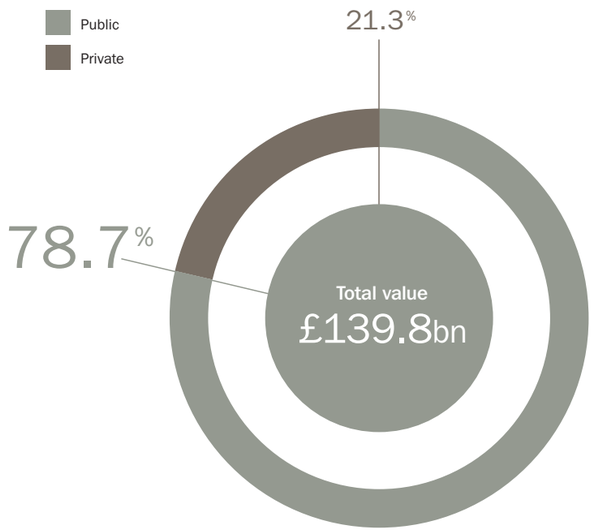
Population Distribution (%)

- 30.1% are aged between 0 and 24
- 51.9% are aged between 25 and 64
- 18% are aged over 65

Source: ONS (2017)

Public Healthcare Expenditure (NHS)

Source: OECD, Marwood Analysis



Share of expenditure is for the UK, the share of private expenditure is likely to be slightly higher in England

Policy Snapshot: The NHS Long Term Plan

Additional funding and a Long Term Plan for the NHS

The LTP was published in January 2019. It sets out priorities for NHS services over the next five to ten years, in light of £20.5bn additional funding to be allocated between 2019/20 and 2023/24.

The LTP outlines several areas set to benefit from this additional funding:

- Local children and adult mental health services funding will be ring-fenced and grow by an extra £2.3bn in real-terms by 2023/24. The focus remains on early interventions, eliminating out-of-area placements, and improving crisis care
- £4.5bn in additional ring-fenced funding by 2023/24 will deliver expanded community services and multidisciplinary primary care networks to support a shift in care provision outside of hospitals
- Cancer and maternity services are big winners in acute care services

There are expected changes to the way providers operate, with primary care networks set to take a leading role in healthcare provision outside of hospitals. In addition, a full chapter of the Plan is dedicated to healthcare digitisation. New initiatives are expected in this space and there may be opportunities for those developing innovative health technologies. NHS England have also proposed legislative changes that support integration but may impact on the ability of private providers to compete for NHS contracts.

Healthcare

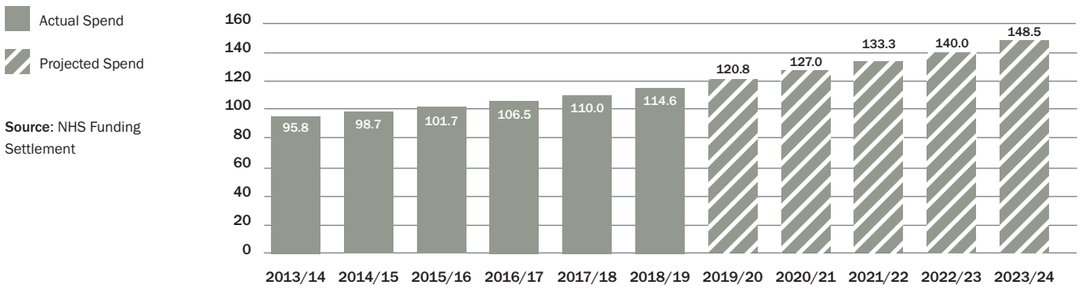
Funding

Healthcare funding in England is primarily public and comes from general taxation. Following a period of containment, public spending is set to increase above the level of inflation until 2023/24.

In July 2018, the Government announced that the NHS would receive a long-term funding boost above the rate of inflation. From 2019/20, the budget to be spent on services should increase by an average 3.4% per year and in real-terms until 2023/24.

The increased funding only applies to the NHS revenue expenditure. This is money spent on healthcare services by NHS England and CCGs. There are currently no longer-term funding plans for capital expenditure, workforce and public health. These were expected to be announced later in a 2019 Comprehensive Spending Review. However, the change of government has meant that these plans have been abandoned, and it is likely there will only be an initial one-year funding announcement in the Autumn budget. The new Johnson administration has announced some funding injection into capital expenditure, with over £800m in newly approved projects.

NHS Expenditure (£,bn)



Source: NHS Funding Settlement

Payment System

The NHS is the main payer in England. There are only limited additional healthcare costs to the individual under the public healthcare system, with charges for many users to part cover the cost of pharmaceutical prescriptions and dentistry.

There is relatively low usage of private medical insurance, with the majority of plans being offered as part of employer benefit packages. Out-of-pocket payments are most common in the dental sector, and there is some growth in out-of-pocket expenditure on services that provide faster, or virtual, access to GP appointments.

Private providers are able to deliver NHS services. Regulations introduced after the 2012 Health and Social Care Act created statutory requirements on CCGs that were designed to promote greater choice in healthcare providers. Discussions currently taking place are considering the possibility to amend these regulations. Whilst this could limit private providers' ability to tender for NHS contacts, these changes would require Parliament to pass primary legislation. Given the political uncertainty around Brexit, and the limited ability for the Government to pass legislation, there may be delays before this is introduced.

When first created, there were 211 CCGs. However, the number has reduced through a series of CCG mergers. By the end of 2020, there could be fewer than 150 CCG areas. Primary care services are commissioned by NHS England, usually through delegated powers given to CCGs. GP Practices are allocated a certain amount of money that will be based on number of patients, and estimated level of need.

CCGs are responsible for allocating funding to meet patient needs for local service provision across acute, secondary and the majority of mental health services. Acute care services provided by NHS providers are reimbursed according to a tariff system, which sets a fixed fee for every item of activity delivered by the NHS provider. Private providers delivering NHS services may be reimbursed in a variety of ways, including block contracts that guarantee volumes at a fixed price, and spot-purchase agreements where costs are more likely to be negotiated according to individual need.

Provider Landscape

Services are provided by a mix of public and private providers.

Primary care providers include independent GPs, dentists, community pharmacists and opticians. GPs provide the majority of primary

care services and are the first point of contact for most patients. GPs increasingly work in group practices and a growing number are employed by their practice. As of September 2018, there were 42,445 GPs, including locums.

The secondary care provision landscape is mainly composed of public hospitals (Trusts). Services are provided by consultants (specialist doctors), nurses and other healthcare professionals, such as radiotherapists and physiotherapists employed by the Trusts. There are two types of Trusts: NHS Foundation Trusts, and NHS Trusts. NHS Foundation Trusts have more flexibility and freedom to operate than NHS Trusts. There are a small number of private providers delivering acute elective care, as well as private provision of mental health, learning disability, and secure inpatient services.

Regulation

The healthcare system in England is subject to significant regulatory oversight, and these can lead providers to face competing priorities. There has been efforts to alight regulatory activity. CQC is responsible for the quality of care in health and social care services, and covers all public and private providers that carry out services defined under the regulated activities. CQC has inspected and rated every provider delivering healthcare services in England. This provides a comprehensive, and unique, picture into the quality of care across sectors. In the future, they intend to introduce more flexible and responsive inspections. Better performing providers are likely to be inspected less frequently, and increased use of data monitoring to inform more targeted inspections is being introduced.

Social Care

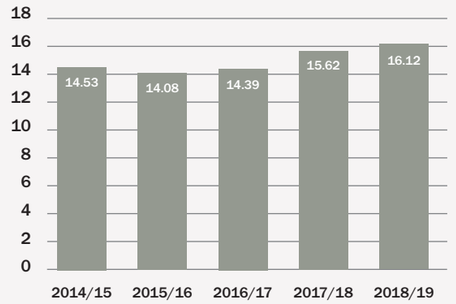
Funding

Social care services are funded primarily via public sources, through 152 local authorities (LAs), whose budgets are made up of a complex mix of national and local taxation. However, social care services are not free at the point of need. LA expenditure only provides a safety net and many people must pay for their own care privately.

Changes in local authority funding since the start of the decade have had a significant impact on the funding landscape for older people's services. Successive governments have reduced central funding for local authorities. Whilst there have been moves to offset this by giving local authorities more freedom over local revenue raising – the introduction of the social care precept, and the ability to retain a greater proportion of business rate revenue – these changes do not always meet the shortfall driven by reductions in central allocations.

These changes had a slightly negative impact on social care funding between 2014/15 and 2016/17, when average annual funding declined by 0.5%. In response, the Government announced an additional £3.5bn funding ring-fenced for social care to be allocated to local authorities between 2017/18 and 2019/20. This contributed to the increase in total local authority adult social care spending from 2017/18.

Local Authority Adult Social Care Expenditure (£,bn)



Source: Ministry of Housing, Communities and Local Government

Payment System

Social care providers are exposed to a mix of public and private payments.

Public payments come from local authorities and are due to cover the cost of care home or homecare services for older people who have been assessed as needing care and have less than £23,250 in assets and savings. For home owners applying for financial support in a care home, the value of their property is included in assets. Those who do not qualify for local authority funding pay for the cost of care home services out-of-pocket. Some people may choose to pay 'top-up' fees to stay in a care home that costs more than their local authority is willing to fund.

Local authority fees for care home services are set locally by each local authority in negotiations with care home providers. In 2017, the average weekly local authority fee was £621, while the average weekly fee charged to self-funders was £846.

Homecare services are usually paid for on an hourly rate basis. Rates are set locally by each local authority in negotiations with homecare providers. In 2018, the average hourly rate paid by local authority was £15.93. However, rates vary greatly across local authorities, and according to the complexity of the care provided.

Provider Landscape

The majority of social care service provision is delivered by private and voluntary organisations. The social care sector in England is highly fragmented. For example, no single operator provides more than 5% of the 471,463 care home beds across 16,392 locations. The 30 largest care homes supply 30% of the overall capacity.

In 2017, homecare agencies provided social care services at home across 8,614 locations, a 4.8% increase from 8,219 in 2015. Market share is difficult to assess as many of the larger providers operate older people homecare as one of a number of care revenue streams. However, estimates suggest that the top ten providers share around a quarter of the market.

Regulation

CQC is the main regulator of social care services. It is responsible for the quality of care in health and social care services, and covers all public and private providers that carry out services defined under the regulated activities. CQC ratings show that the majority of homecare and care home providers' services are of good quality.

Following the 2011 Winterbourne View scandal, regulatory scrutiny of learning disability services increased significantly. The scandal, which involved serious patient abuse, highlighted the over-reliance on inpatient settings and strengthened the view that individuals would be better served in community settings of care.

CQC inspection of learning disability providers is not particularly joined up for the independent sector. Inpatient learning disability services are captured as part of CQC's mental health inspection activity, whilst learning disability services being delivered through residential, nursing or domiciliary care are inspected by CQC's adult social care directorate. This can lead to a fragmented regulatory experience for providers operating across health and adult social care.

Political Environment

In July 2019 Boris Johnson became the new Prime Minister following the resignation of his predecessor Theresa May, and his victory in the subsequent campaign to lead the Conservative Party. He has inherited a minority government which relies on a confidence and supply agreement with the Democratic Unionist Party (DUP). Despite repeated claims that Johnson will not call an early general election, a recent by-election loss cut his working majority to one, and with key Brexit deadlines in the months ahead, has led to expectations that an election will be called sooner rather than later.

Brexit has dominated the political agenda since the 2016 referendum on Britain's membership of the EU led to a majority of voters in favour of leaving the EU. This leaves limited parliamentary time for passing legislation in other areas. As one of the prominent leaders of the campaign to leave the EU Johnson has stated that Britain must leave by 31 October 2019 with or without a deal.

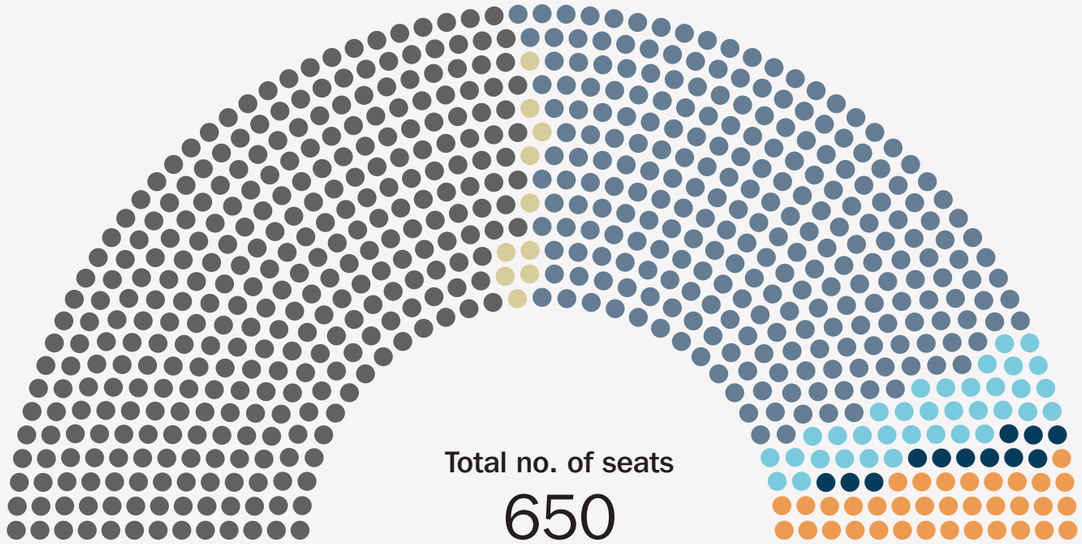
Composition of Parliament

Government
- Conservatives (311)

Confidence and Supply
- Democratic Unionist Party (10)

Opposition
- Labour (247)
- Scottish National Party (35)
- Liberal Democrats (12)
- Other (35)

Composition of the House of Commons (July 2019)



Glossary: Common Acronyms in Health and Social Care

A&E: Accident and Emergency

ABPI: Association of British Pharmaceutical Industries

APMS: Alternate Provider Medical Services

BDA: British Dental Association

BMA: British Medical Association

CAMHS: Children and Adolescent Mental Health Services

CAT: Competition Appeal Tribunal

CCG: Clinical Commissioning Group

CHC: Continuing Health Care

CMA: Competition and Markets Authority

CMU: Commercial Medicines Unit

CQC: Care Quality Commission

DHSC: Department of Health and Social Care

DRG: Diagnosis Related Groups

EMA: European Medicines Agency

EU: European Union

FYFV: Five Year Forward View

FYFVMH: Five Year Forward View for Mental Health

GDS: General Dental Contract

GMS: General Medical Services

GP: General Practitioner

GPFV: General Practice Forward View

HMRC: Her Majesty's Revenue and Customs

ICS: Integrated Care System

LA: Local Authority

LGA: Local Government Authority

MCP: Multispeciality Community Providers

MHCLG: Ministry for Housing, Communities, and Local Government

MHRA: Medical and Healthcare Products Regulatory Agency

NAO: National Audit Office

NHS: National Health Service

NHS FT: NHS Foundation Trust

NHSI: NHS Improvement

NHS LTP: NHS Long Term Plan

NICE: National Institute for Health and Care Excellence

NMC: Nursing and Midwifery Council

NMW: National Minimum Wage

PAC: Public Accounts Committee (House of Commons)

PACS: Primary and Acute Care System

PbR: Payment by Result

PCN: Primary Care Network

PHE: Public Health England

PHI: Private Health Insurance

PMS: Primary Medical Services

PPRS: Pharmaceutical Pricing Regulation Scheme

PRIME: Priority Medicines Scheme

QALY: Quality-Adjusted Life Years

SOF: Single Oversight Framework

STP: Sustainability and Transformation Partnerships

TCP: Transforming Care Partnerships

UDA: Units of Dental Activity

VPAS: Voluntary Scheme for Branded Medicines Pricing and Access

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