THE WHITEHALL REPORT 2021

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Introduction

The Marwood Group publishes its Whitehall Report 2021 against a backdrop that sadly remains dominated by Covid-19. However, with 80% of over 16's having received both vaccination doses and a relaxation of the lockdown restrictions across the UK, there is increasing optimism that the worst of the pandemic may be behind us. Challenges of course remain – and the impact will be felt for years to come – but for the first time in nearly 18 months, health leaders can move from operational survival to strategic planning.

Our report covers the key policy, funding and regulatory developments from August 2020 through to August 2021. Readers will note that the year has been a mixture of the government forging ahead on select policy issues, whilst attempting to manage the pandemic. As a result, a number of lower priority, or potentially politically unpopular, decisions have found themselves delayed. Even as we go to press, the Prime Minister is attempting to steer crucial funding decisions for social care past a sceptical Conservative backbench, whilst attempting to negate any politicisation of the issue by Labour.

Where Brexit had once dominated the headlines, it now competes with Covid-19, mostly drifting in and out of the public consciousness. A Christmas Eve deal meant that Britain formally left the EU in January 2021 – marking the end of nearly 50 years of being part of the European community. For many, the hard work will just be beginning – as functional working relationships must be forged from the deal and a new regulatory regime established.

The tumult of the last few years has reinforced the importance of understanding government policy and decision-making when considering investing in health and social care. Politicians have shown their willingness to turn on the funding taps in order to safeguard delivery, whilst service transformations that often take years can happen in weeks once political will is aligned to policy-maker objectives.

With the NHS more than halfway through a five year funding settlement agreed in 2018, and another three-year settlement that focusses on elective recovery leading to another boost, the austerity that marked the Coalition government seems like a different era – even if the impact of that economic restraint can be felt to this day. It shows again that often public spending is a political choice, not a direct consequence of economic trends – and this is particularly relevant in the current environment.

In previous years, the resignation of a Health Secretary would've been major news. However, the only surprise over Matt Hancock's departure was that it hadn't happened sooner. Other than helping push technological adoption up the NHS agenda, there is little to suggest that he will leave a lasting legacy on the service.

The appointment of Sajid Javid as the new Health Secretary represents a return to front-bench action, and many in the NHS will be pleased that a relative heavyweight has been appointed, particularly one with deep experience of how the Treasury operates – critical as difficult conversations over funding loom in multiple directions.

Equally, the announcement that Amanda Pritchard will replace Simon Stevens as the chief executive of NHS England, was anticipated by many. It will be difficult – if not impossible – to fill Simon Stevens shoes but the appointment of a well-respected insider may strengthen the NHS.

The health and social care services landscape continues to evolve, whilst remaining on the cusp of even greater change. If 2021 was primarily about responding and emerging from the pandemic, 2022 seems set to ask searching questions about the future of the health service.

The Health and Care Bill is expected to continue through Parliament in Autumn 2021 and provides the legislative basis for many of proposals already set in motion by policymakers. However, no attempt to reform the NHS happens without a bruising parliamentary and media battle, and with a Health Secretary yet to demonstrate their commitment to legislation inherited from their predecessor, it sets the stage for an interesting few months.

The extent to which early September announcements on more funds for social care represent little more than a larger sticking plaster to see the Government through the next election remain unclear. Investors and providers will feel that they have been here before, and whilst any new money will be gratefully received, the detail should be closely examined to understand exactly what it will achieve in the longer-term.

Life sciences continues to benefit from Government support and the increased visibility it received through the pandemic. Clearly a sector identified as part of the 'Brexit Dividend', the government unveiled a 10-year strategy for life sciences in July 2021. It reflects the ambition to position Britain as a global leader and help companies establish and scale up operations creating new high-skilled jobs in the UK.

The independent sector will always have a role to play across health, social care and the life sciences. It is clear that the NHS cannot alone meet the challenges ahead and social care is dependent on private providers from children services through to complex older people care. Changes to how services are tendered externally could impact operators but the risk of insourcing should be considered in view of the broader policy, reimbursement, and competitive environment.

The Whitehall Report offers insights into key recent changes in health and social care that help to support you make the right decision for your business. The critical message is that although the complexity of the UK's health and social care system should not be underestimated, and so understanding the key issues in regulation, policy and reimbursement will help investors and operators to benefit from tailwinds and navigate headwinds.

We hope you find our Whitehall Report a useful reference document to decode the complexity of health and social care in England and that it supports you to make the right decisions for your business.

We 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

Moving forward: Health funding in the wake of a pandemic

The NHS is such a totemic service in the UK that it remains relatively well protected even during periods of economic restraint. Whilst health services were underfunded during the austerity period under the Coalition government, it did better than many other government departments which saw their budgets slashed.

However, Covid-19 has demonstrated the extent to which the government is prepared to protect the health system. Planned spending for the health and social care increased by £60 billion in 2020/21 – up to £211.7 billion from £150.4 billion in 2019/20.

This funding reflects the cost pressures necessary to bring the pandemic under control. It included procuring personal protective equipment for staff, developing NHS Test and Trace, paying for the use of the independent sector to reduce waits for care, and improving discharges from hospitals.

It is worth noting that a substantial share of this Covid-19 funding is non-recurrent and therefore unlikely to be maintained in the budgets once the pandemic ends. However, even though the funding boosts may not be sustained, the NHS still sits within its five-year funding agreement and should be well placed to receive budget uplifts above 3% until 2023/24.

There have also been several additional increases to health spending over the past year.

The most recent, and controversial of these came in early September 2021 when the Prime Minister announced reforms to the social care system in England. The announcement was accompanied by an increase of 1.25% in National Insurance Contribution (NIC) from April 2022 to be hypothecated for health and social care. This has sparked controversy within the Conservative party, as the tax rise breaks a manifesto commitment.

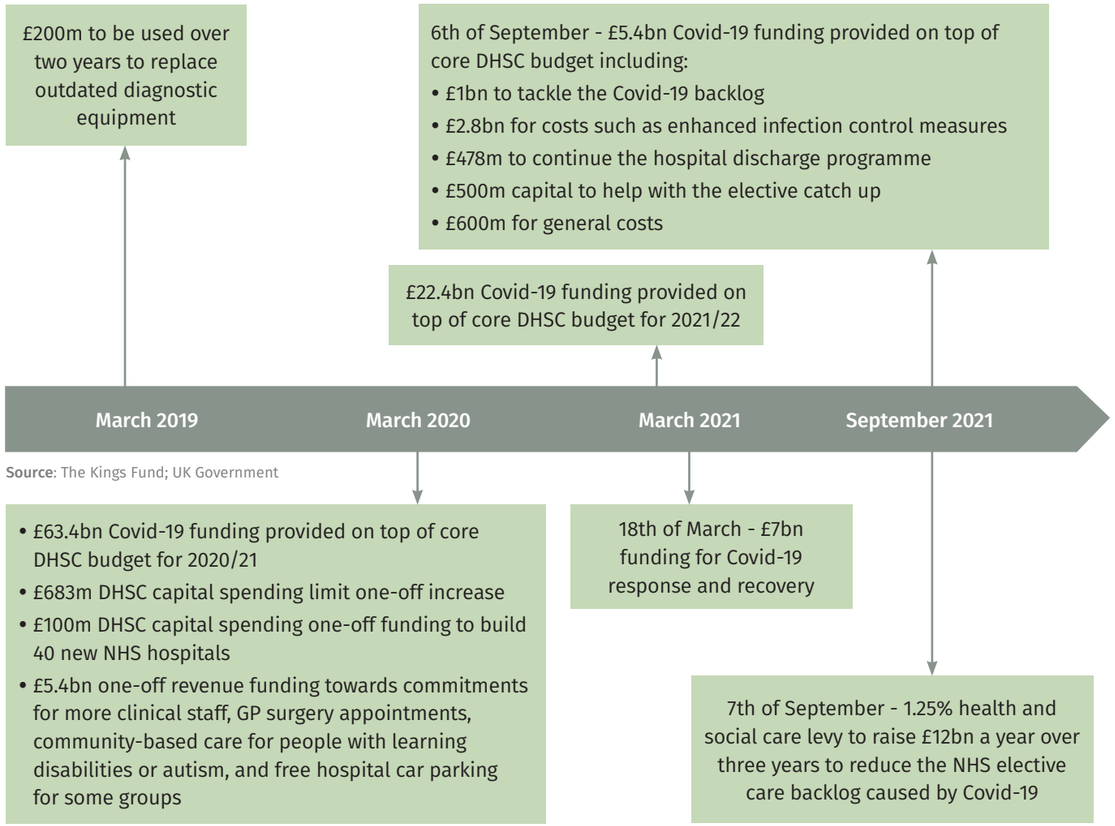
The 1.25% increase is expected to raise £36bn over the next three years "to fund the biggest catch-up programme in the NHS's history, tackling the Covid backlogs". Alongside this, adult social care will be reformed to stop people facing "unpredictable and catastrophic costs", by revising the thresholds for means testing, and there are plans to publish a White Paper on Integration in the next year. There is criticism that the new funding will be used, at least for the initial three years for the NHS rather than social care. Nonetheless, the 1.25% increase in NIC will apply across England, Scotland, Wales and Northern Ireland, and the devolved nations will get an extra £2.2bn in health and social care spending as a result of the levy. The reforms proposed for social care will only apply in England.

Alongside funding boosts to meet the immediate needs caused by the pandemic, the government has remained keen to showcase its longer-term commitment to the NHS. Many of the announcements will be welcomed by health system leaders – as it finally pays long overdue attention to capital and infrastructure costs. These may be big, media-friendly projects that are perfect for any future election campaign, but it is also investment that is desperately needed.

This includes increasing the overall capital expenditure budget and continuing with plans to build 40 new NHS hospitals. Although, here the Department of Health Comms team is going into overdrive, with it reported that local hospitals are required to refer to new wards as a 'hospital'. This does raise questions over what the final '40' new hospitals will look like in reality.

Investment in new diagnostic equipment – £200m spread between 2019 and 2021 – can help to replace aging diagnostic equipment such as MRI, CT scanners and breast screening equipment. This will be vital in helping to deliver against a clear priority to both recovery the UK's post-Covid elective backlog, and also reform diagnostic pathways for the future around community-based diagnostics.

Funding Announcements for Department of Health and Social Care Since March 2019



Source: The Kings Fund; UK Government

The NHS continues to benefit from its five year funding settlement agreed under the previous Prime Minister, Theresa May, in July 2018. A further £5.4 billion of revenues was pledged in the March 2020 budget until the end of this parliament (May 2020). This funding is intended to support commitments for more clinical staff, more GP surgery appointments, more community-based care for people with learning disabilities or autism, and free hospital car parking for eligible groups.

With a new funding cycle potentially to be agreed against a backdrop of a general election and a elective waiting list that is unlikely to been resolved, there may be quiet optimism that the NHS does not have to return to the austerity of the previous decade.

Ministers are in the process of agreeing a three-year commitment with the NHS. Funding details are to be confirmed but it appears the focus will very clearly be on recovery before seeking to transition to social care in the longer term.

The number of people waiting for care has risen to the top of the priority list

Covid-19 has had a devastating impact on waiting times that were already at the highest level in over a decade. It has been estimated that the overall waiting list could balloon up to 13 million people as the NHS begins to return to routine elective care, with waitlists reaching record highs of 5.4 million in June 2021. This is up from 4.4 million shortly before the start of the pandemic.

Resourcing the NHS appropriately is a critical government priority, and top of the list is making inroads into the elective care waiting list. Out of the 5.4 million people waiting in June 2021, 340,000 were waiting over 52 weeks.

The factors which have contributed to this poor performance are complex and overlapping. Treatment has been delayed due to decisions to postpone care to prioritise Covid-19 patients, reduced capacity and throughput due to infection control measures, and an accumulated latent demand driven by patients worsened or not seen during the pandemic.

In May 2021, £160 million was introduced to help tackle the high numbers of patients on waiting lists, with additional non-financial support given to hospitals to implement innovative ways of managing the backlog. The focus of these efforts was mostly on reducing the overall size of the waiting list (i.e., total volume) and especially on decreasing the number of long-waiters.

In more recent months, the debate has shifted from the long-waiters (which typically have diagnoses and non-urgent care requirements) to reducing clinical uncertainty within the backlog. This has shifted the focus to those on the waiting list for whom a diagnosis or decision to treat is not yet available. This may be those who are newer on the waiting list and therefore have had a relatively shorter wait.

While the NHS Long Term Plan aimed to eradicate waits of 52 weeks or more, with financial sanctions for breaching this standard - long waits continue to be a reality of the state of the NHS.

Experts view meeting record demand levels within NHS current capacity as unrealistic, with estimates that spending would need to increase by a further £560 million a year to meet the 18-week standard by 2024.

As hospitals are operating at the edge of their capacity, additional funding has been the only lever to support waiting list reductions. This can be used for innovative pathway redesign in NHS settings, but it is also an opportunity for commissioners to make use of operational capacity in the independent sector.

Over the last year, many private providers have created stronger relationships with their local systems. As these evolve into formal Integrated Care Systems (ICSs), providers who proactively engage may find themselves well-placed to provide essential overflow capacity to the NHS.

There may be unique opportunities for independent acute healthcare providers to provide capacity across newly formed ICSs to stem the rapidly growing elective care backlog. Equally, clinical diagnostic companies who have gained a foothold in the NHS market may find themselves well placed to meet future demand exacerbated by suspension of elective diagnostic activity during the pandemic, a generally ageing population, and new technology.

Post-Brexit: New freedom and old challenges

Although many of the challenges faced by the health and social care system remain the same as those experienced in 2020, the way the policy, regulation and reimbursement landscape has evolved due to Brexit and Covid-19 continues to add complexity and nuance to their management.

Readers will be familiar with many of the challenges that have faced the system for years. Issues such as the insufficient workforce, slow system transformation, inadequate funding, and increasing waiting lists are not new. But Brexit implementation brings new angles to these challenges, and the UK does have new found freedoms that can help to address them.

The emergence of Covid-19 helped to shift media focus away from the reality of Brexit – whilst forcing a more cooperative relationship between Britain and the EU in the face of a global health threat. This has obscured some of the challenges, but they will re-emerge as the pandemic threat eases, and policy-makers have to talk through the practical challenge of making the deal into a reality.

In some areas, new freedoms will bring significant impacts, either directly or indirectly. The primary impact areas will be on life sciences and regulatory approval of pharmaceuticals and medical devices. Here Britain will be looking to navigate a narrow ground between regulatory innovation and regulatory de-alignment. Regulators will seek to capitalise on being outside of the EU's more bureaucratic environment, whilst not putting in place rules that end up requiring companies to create duplicate processes. For all the Brexit flag-waving, due its size, the EU will continue to look like a more attractive market if regulatory standards shift too far apart.

The government clearly views life sciences as potentially being part of the Brexit dividend and a leader in the new global facing Britain. In July 2021, a new strategy for the Life Sciences sector was announced. Spanning across the next 10 years, the vision is centred on building the UK up as a global leader, capitalising on the success of the AstraZeneca-Oxford University Covid-19 vaccine, and seeking to attract investment. With a special investment programme of £1 billion, and new autonomy thanks to the Medicines and Healthcare products Regulatory Agency, the government is determined to drive growth in the UK's life sciences sector.

Regulating medicines and medical devices

The United Kingdom is a net importer of medicines and medical devices from the EEA. Post-Brexit, landscape pharmaceutical products are no longer regulated by the European Medicines Agency (EMA). Instead, regulatory oversight in this sector now lies with the Medicines and Healthcare products Regulatory Agency (MHRA).

Medical devices and pharmaceutical products that previously fell under the scope of EU regulations are now the responsibility of UK regulators. There have been significant attempts to smooth the transition for manufacturers, with medium-term solutions enabling companies to automatically convert historic EMA approvals into the UK system and for drugs to be approved on the basis of a positive opinion from the EMA's decision-making body. These solutions seem set to provide a flexible system for the next two years whilst longer-term processes are established.

As the UK is now outside the customs union, new customs checks are required at ports when moving medicines between the EEA and the UK. To make this smoother for businesses, the trade deal going forward includes specific clauses to ensure that both the UK and EEA formally recognise each other's good practice in medicine manufacturing.

Given the import/export of medical products was valued at £27 billion in 2019 creating a smooth transition is vital. However, the final deal still fell short of industry requests for it to cover full mutual recognition.

To ensure that the UK market does not buckle under the strain of additional checks, the government has stated that it will accept EU conformity assessments until June 2023. This gives policy makers more time to hammer out a longer-term deal or create an alternative complimentary process. The UK also joined a medicines access consortium with Switzerland, Australia and small non-EU countries to pool resources and jointly accept applications to reduce delays in new drugs coming to market.

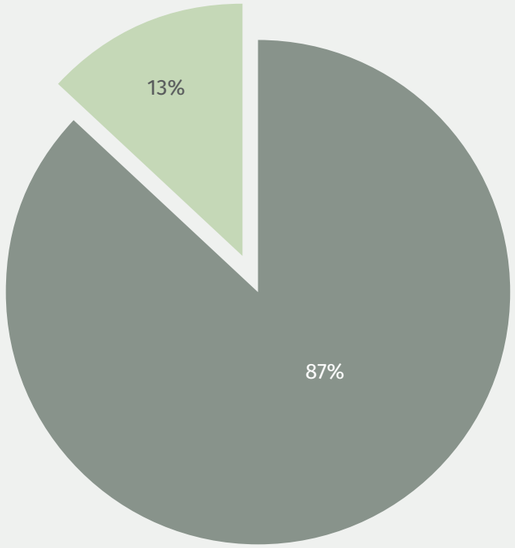
The change also creates the potential for manufactures to get rapid market access via innovative MHRA pathways. This would be of tremendous benefit to the UK life sciences sector, the NHS and investors more broadly.

Addressing staffing shortages in health and social care

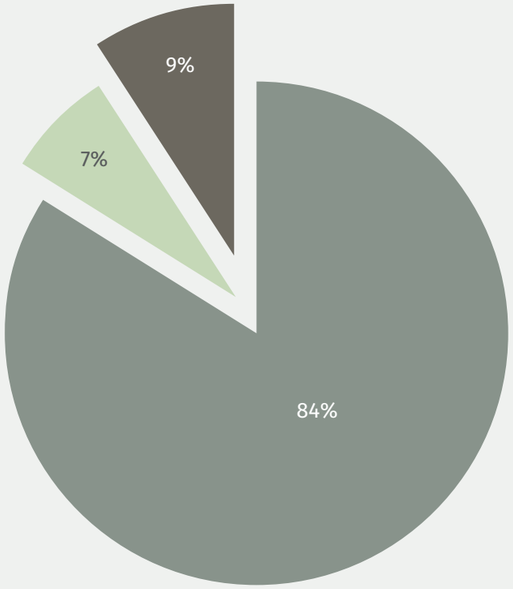
As with all policy, the implementation and reality of NHS strategic plans will rely on the workforce to deliver it. As a whole, the NHS continues to experience significant recruitment and retention issues, particularly to its permanent workforce.

Local systems have also recognised that the NHS is reliant on other staff groups that are not directly employed by the NHS. This includes GPs and dentists, professions for which there are well-established challenges in staffing.

Non-British Staff Make up 13% of all NHS staff



16% of the Adult Social Care Workforce are Foreign Nationals



Britsh Non-British Non-EU

While policy on the one hand has sought to devolve workforce planning to the local level, there is recognition that many recruitment and retention drivers are in the national sphere, such as training places in university or industry. In a bid to improve retention in the sector, the government revised its initial 1% pay rise proposal and determined that NHS staff would receive a 3% pay rise instead. While this may help keeping current staff placated to some degree, there are still challenges in attracting new recruits to the sector.

The overall impact of Brexit on the workforce is mitigated for skilled medical professionals. Placed on the shortage occupation list, employers may face less barriers than other sectors. However, in a globally competitive environment, Britain must still ensure that it is seen as a welcoming country for international recruits.

Social care providers face a more challenging environment. The workforce was hit hard through the pandemic and pressure to compete with other industries that are also recruiting as the economy bounces back may also create regional pressures. Already reliant on international recruits more willing to work for lower wages, it is unclear how many who left during the pandemic will return.

The skills shortage is significant enough that social care employers have been reported as offering bonuses of up £10,000 for particularly in-demand roles.

In a positive move Senior Care Workers and Registered Managers have been added to the shortage occupation list. This may help to meet a gap in more senior positions but staffing lower skilled roles is likely to remain a key challenge – and many will argue that until social care is funded to a level that enables the uplifting of social care assistant salaries then workforce challenge will remain.

Although numbers of EEA and non-EEA staff in health and social care have changed over time and their make-up has varied, overall inbound migration within certain sub-sectors has been positive despite Brexit. For example, although the number of EEA-qualified nurses has decreased, the decline has been offset by a greater rate of increase of non-EEA nurses entering the market. This is positive given that from 01 January 2021, all workers arriving from the EEA and non-EEA countries are subject to the same immigration rules.

As noted, migration from outside the EU has risen sharply, especially for nurses. This is positive as recent estimates outline that a minimum of 5,000 more nurses per year will need to be recruited from abroad in order to make up the current workforce shortfall in the NHS. These efforts would need to take place concurrently with measures to increase domestic training capacity. In a move intended to signal commitment to the NHS, the government is planning to recruit an additional 12,000 nurses from overseas by 2024/25.

Although supportive immigration policies are required, Brexit has not introduced new barriers to recruiting staff from non-EEA nations where a growing proportion of staff in health care services are being sourced from. While pandemic-related restrictions of movement continue to undermine and delay international recruitment to the NHS, it is not yet clear to what extent the Health and Care Worker Visa and the Immigration Health Surcharge exemption will support the UK to maintain its status as an attractive location for international health workers.

With the 'pingdemic' worsening the Brexit-induced shortage of workers, it is expected that social care providers will continue to struggle to recruit adequately into 2022. This will add to existing skill shortages and compound the pressure on the social care workforce. As the UK government, policymakers, and operators grapple with the complexities of trade deals and policy shifts that can aid or hinder the sector, there is still much to understand about how providers will match supply to demand by ensuring a stable, well-qualified workforce is available to deliver services.

NHS reforms: Change on the horizon

A new Public Health England

In August 2020, the government announced that Public Health England was to be replaced by the new National Institute of Public Health. This comes after Covid-19 highlighted the need for a single body to be responsible for the challenges in maintaining and responding to global health threats. The new body now covers NHS Test and Trace, the Joint Biosecurity Centre, and the old Public Health England.

In April 2021, Matt Hancock, the then Secretary of State, announced that the new body would be called the UK Health Security Agency, with Dr Jenny Harries leading the new organisation. Dr Harries had been Deputy Chief Medical Officer until April 2021, working first-hand with the challenges raised by Covid-19.

The Health & Care Bill: A new vision for health delivery?

Almost since the introduction of the Health and Social Care Act (2012), clinicians, commissioners, local councils, and wider stakeholders have been united in their desire to significantly reform it. Due to this broad consensus, the direction of travel for future reforms has been set iteratively, building on new ways of working and coalescing around the need to better integrate services, reduce bureaucracy and support improved working between the NHS and social care.

With the last two years being among the most challenging in the NHS' 72-year history, the government has finally determined that patchwork policy solutions are no longer viable.

In July 2021 - with new Health Secretarty Sajid Javid inheriting the legislation from his predecessor - the Health and Care Bill was laid before parliament.

The legislation represents the culmination of changes that have been expected since the publication of the NHS Long Term Plan in 2019 – so they build on work the system has been focused on for many years.

Proposed reforms formally recognise the need to bring together NHS organisations, local government and other partners at system level recognise they need to deliver joined up approaches to improve health and care. Importantly the reforms will also provide the Secretary of State for Health extensive new powers to direct NHS England and to intervene at different levels of the health system.

This will shape how public sector services are delivered, and will impact the demand in specific services areas. The way in which reforms are implemented will ultimately determine whether they impact on fundamental issues of sustaining public pay services in the face of rising demand.

A defining feature of the legislation is the formal embedding of Integrated Care Systems (ICS). It signals a significant restructuring and a potential move back towards greater centralisation in the NHS. Critically, the reforms focus on unpicking key aspects of the Health and Social Care Act of 2012.

One way it proposes to do this is by making changes to competition and procurement rules, especially the Public Contracts Regulations. Reforms will also make ICSs the legal replacement of Clinical Commissioning Groups (CCGs). ICS are to be comprised of a Health and Care Partnership and a separate NHS organisation. The reforms also provide the Health Secretary with extensive new powers to direct NHS England and intervene in activity across the health system. These new powers have attracted criticism but this must be set against the complaint that legislative changes in the 2012 Act made politicians less accountable for day-to-day problems with the NHS.

In many ways the ICS NHS body will be most like existing CCGs, they will merge some of the functions currently being fulfilled by non-statutory STPs/ICSs with the functions of a CCG and will be responsible for the day to day running of the ICS. Meanwhile, the ICS Health and Care Partnership will bring the system together in an area, support integration, and develop a plan that addresses the needs of the system, be they - health, public health, and social care needs – much like STPs do now.

Choosing what you value: Stability and competition in NHS-funded service delivery

A key aim within the proposals is to remove the barriers to integration and give more freedom to commissioners to determine the right way to run local services by reducing the need for costly procurement exercises. In practice this will mean that local areas - following guidance by NHS England – will be able to determine their own mechanisms for choosing providers. These will be based around clearly defined criteria but provide a much greater emphasis on responding to local factors. It also will provide guidance on when a commissioner does not need to procure externally.

Local contracting is expected to change as it enables commissioners to avoid externally tendering and designing provider selection for local need. Furthermore, a key addition of the new ICS procurement will be considering decisions that deliver the highest social value in local communities.

The proposed Provider Selection Regime will give clear opportunities for the independent sector to retain contracts without going through a re-tendering process. Whilst a competitive landscape may lead to commissioners continuing to use competition to put pressure on price, there will be opportunities for direct awarding of contracts to providers.

Determining when New Services Should be Tendered Externally

SELECTION TYPE	WHEN IT CAN BE EMPLOYED	IMPACT ON PROVIDERS
Continuation using existing providers	• The type of service means there is no alternative provision • The alternative provision is already available to patients through other means • The incumbent provider(s) is judged to be doing a sufficient job and the service is not changing, so no overall value in seeking another provider	• Contracts frequently have extension periods built in – often adding 2 years onto contract length • Commissioners may choose to sacrifice longer-term savings gained through competitive tendering for short-term savings in retaining existing providers • The independent sector may benefit from having existing contracts extended
Selecting the most suitable provider when a service is new or changing	• The decision-making body considers a set of criteria and following this, if they believe that one provider is the most suitable (may or may not be the incumbent), they can award the contract without a tender process	• Larger scale providers may benefit from a likely shift towards contracting over regional areas rather than individual localities • Smaller providers may be viewed as unable to cope with potential changes in service requirements that expand expected volume in contracts
Selecting a provider by running a competitive procurement	• The decision-making body may not identify a provider/group of providers that is suitable without running a competitive process, or may wish to use a competitive process to test the market	• This would maintain the status quo. Public tender may be used to support competition to drive down prices

Guidance on the new Provider Selection Regimes provided by NHS England is expected to work its way into contracting language over the next five years as it is integrated into local commissioning across England.

Readers should note the importance placed on providers' ability to integrate with other providers, transition capabilities to ensure the NHS is not locked into provision with a single provider, the push for innovation, and the premium placed on knowledge and awareness of local factors when service planning. Providers with the resources to meet local tender specifications and able to demonstrate ongoing investment in innovative and integrated services may be well-placed to benefit from these changes.

Determining Provider Value: Guidance on What Commissioner Should Consider

CRITERIA	NHS ENGLAND GUIDANCE NOTES
Quality (safety, effectiveness and experience) and innovation	• Long-term quality and user satisfaction through scrutiny from quality sources (CQC, Healthwatch) • Providers should justify upward or downward trends, as well as how quality will be maintained or improved as any change • Innovation is highly valued over ease of use of current providers
Value	• Take into consideration the value of the offer in the longer- as well as shorter term • Technical challenges to transitioning to a different provider constitute a consideration of choice for decision-makers. Providers should consider that difficulty of transition to another provider may limit success in procurement
Integration and collaboration	• Providers must be aware of local plans and strategies to ensure integration of their services - this will be valued more highly than price • Unnecessary fragmentation of services impacting on the quality and completeness of wider patient journeys will be a reason to turn down a provider
Access, inequalities and choice	• Patient choice should be built in where appropriate. In addition, providers ought to be aware of how provision of services fits into reducing or exacerbating health inequalities
Service sustainability and social value	• Providers should ensure services contribute to the sustainability of the NHS, but also recognise how they might impact local healthcare workforce • Should the proposals negatively impact the stability, viability or quality of other services immediately or over time, the wider benefits of the proposal must be justified • Providers also need to consider the wider socio-economic and environmental impacts of their proposals

An evolving regulator - CQC's new strategy

The Care Quality Commission (CQC) is the independent regulator of health and social care services in England. Their purpose is to ensure that services provide people with 'safe, effective, compassionate and high-quality care' alongside a role in encouraging care services to improve.

Since introducing a new regulatory model in 2014 CQC have inspected every registered provider of health and social care services in England – and provided a rating of their quality. For nearly all services, this rating is publicly available and can be used as independent quality benchmark across the sector.

A comprehensive regulatory environment – underpinned by provider registration, monitoring and inspection, public ratings and statutory enforcement powers – creates high barriers to entry and can reward high-performing providers by offering an independent quality benchmark. This information also provides a vital source of information for investors sizing up potential transactions, although the complexity of the detail can make it seem like a potential barrier without expert advice.

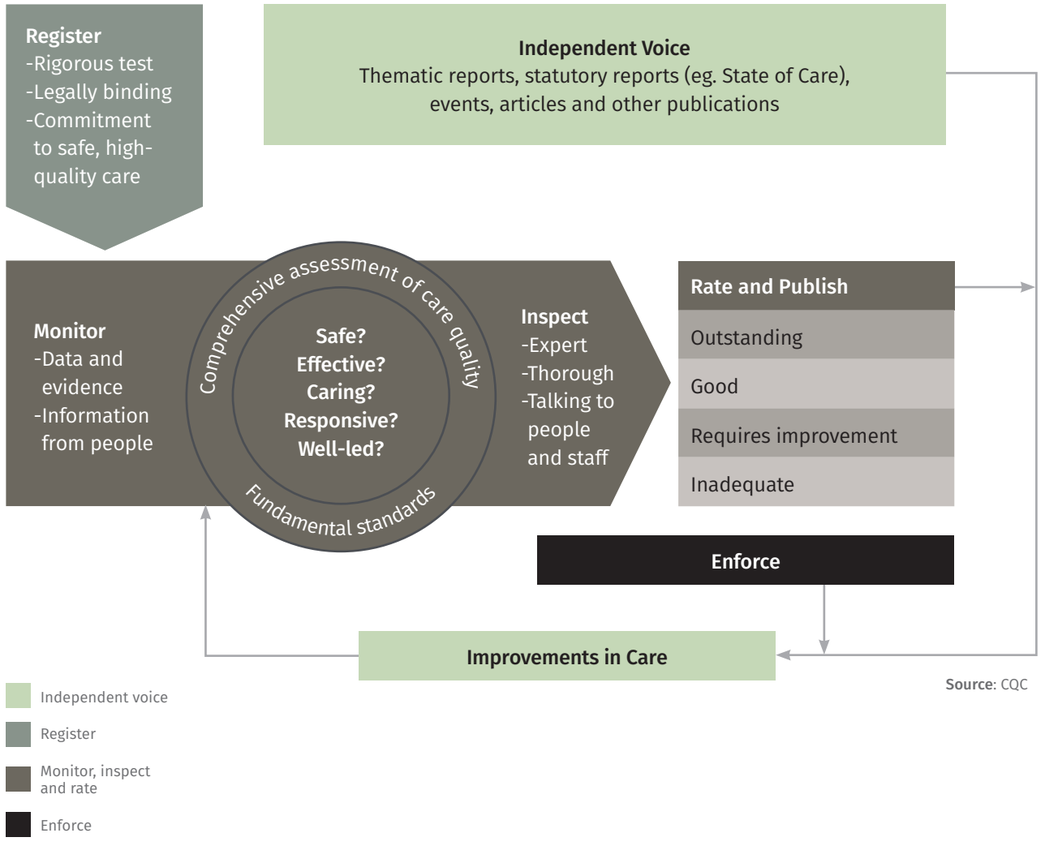
However, regulation can never be static if it is to remain relevant. The growth of digital providers over the last five years – offering anything from virtual GP appointments to remote phone-based apps offering weight management advice from a healthcare professional – demonstrates the need for regulators that can adapt to innovation.

The sudden emergence of Covid-19 and the restrictions on 'crossing the threshold' inspections – at a point when risk events were extremely high – also required a rapid rethink of CQC's inspection model.

There is also awareness that as much regulation may need to adapt, a sudden shift in direction will not benefit providers. Change is necessary, but change needs to be gradual – and build on the learning that has been embedded over the last seven years. The last thing under pressure providers need is wholescale changes to the way that they will be regulated.

We have set out the four key themes of the strategy along with our views on what it may mean. The overarching message is that individual providers should not expect seismic changes. The operating model is not going to change, and the ratings system remains in place.

CQC and its New Strategic Priorities



Source: CQC

STRATEGIC PRIORITY	MARWOOD'S REFLECTIONS ON CQC'S NEW STRATEGIC THEMES
People and communities	• CQC are always keen to demonstrate that people are at the heart of what they do. They may regulate providers, but they do so on the behalf of the people that use their services, so it is no surprise to see this embedded at the heart of the strategy. • It is essential that the CQC does not make more use of people's experiences, but how this translates into reality is difficult to track. As CQC continues to move towards more data orientated regulation, how does soft insight work alongside harder data points. The key question CQC faces is how to ensure that this is more than just a woolly ambition without placing too much weight on subjective opinion.
Smarter regulation	• Little will be unfamiliar to providers in the Smarter Regulation ambition. This clearly builds on the existing direction of travel set out in the previous strategy and that has been clearly developed over the last five years. It is the ongoing shift of using data more effectively to guide the inspection process. • It clearly signposts that there will be a shift away from scheduled on-site inspections, and that future regulation will employ a variety of levers to maintain a grip on provider quality. • Whilst inspections are not going anywhere for poorly performing providers, there seems to be a clear intent to lift the regulatory burden for providers where the risk appears to be low.
Safety through learning	• Having developed an unprecedented quality baseline across all registered health and social care services, CQC are well placed to have an overarching understanding of where the focus is needed. It has been clear for some time that 'safety' ratings have lagged behind other key questions. • There is a focus not just on ensuring safe processes, but also tying the issue back to leadership. Ensuring staff feel able to speak-up, and focussing on areas where there is a risk of culture driving poor quality care, gives the impression that CQC will viewing safety through an organisational culture lens.
Accelerating improvement	• CQC's remit to encourage improvement always felt as it was tacked on as an afterthought - particularly in healthcare where many bodies already tasked with a similar function. As a result, it has always been the least tangible part of CQC's proposition and there is little in the priority that changes that. The focus is primarily on working with others - both nationally and locally - to embed good practice across the system. • There is a clear focus on seeking to encourage innovation. Regulation can often be a block to the development of innovative new approaches. However, the barriers to entry exists for a reason. CQC indicates that by working in partnership it can seek to find a propertionate way of regulating new innovation and technology.

There is always going to be a divide between what a provider and a regulator considers to be proportionate. Whilst CQC recognises the regulatory burden should be reduced where possible, it frames this primarily as relating to 'inspection'. Many providers argue that data monitoring requirements are also substantial, and represents an ongoing rather than discrete cost to an operator.

There is also a degree of concern over whether a move to a more risk-based approach to regulation will make it harder to update ratings. If inspectors are focussing on the risk, then will they also be looking out for when providers have gone the extra mile?

It is too early to say whether this concern is justified. Ratings data taken during the pandemic is likely to paint an unreliable picture, as these inspections were primarily undertaken in response to perceived risks. As a result, rating downgrades would be more likely in these situations. The real question is whether a ratings decline is witnessed once on-site inspections return to pre-pandemic levels.

The most radical change proposal is the assertion that a core ambition for CQC is in the assessment of local system. This could be a major shift in how CQC operates but the strategy contains no concrete detail on how it would work.

As the health and social care landscape changes with the planned introduction of the Health and Care Bill and the establishment of statutory ICS organisations, the role of CQC in assessing quality across an area becomes increasingly important.

However, how this is done and who will fund it remains an open question. The scale of the challenge should not be underestimated. Whilst CQC has generated considerable experience in carrying out local area reviews – as thematic pieces of work or as part of joint-inspection activity with Ofsted – it has never been a core function.

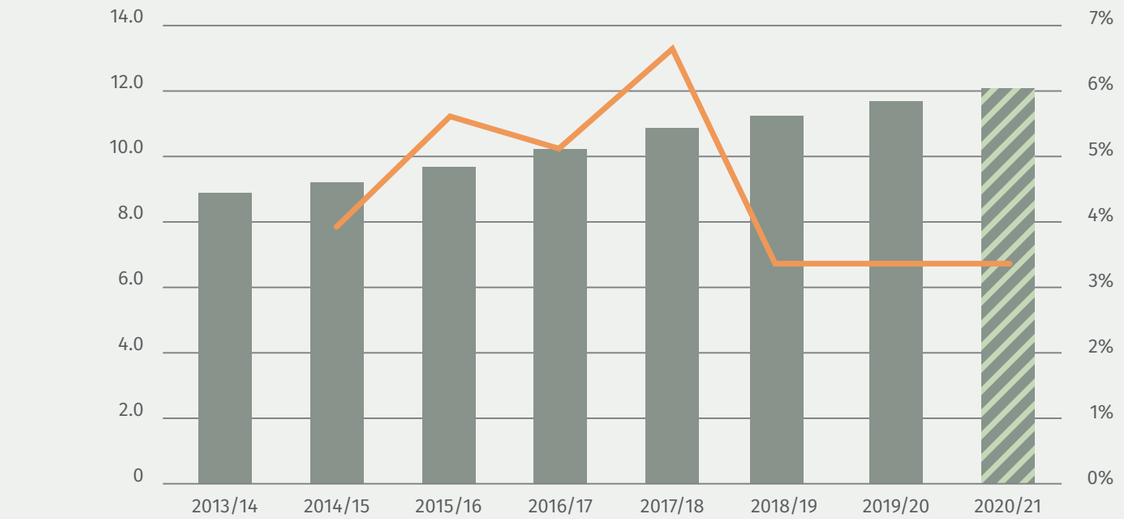
Local area reviews currently are carried out under direction by the Secretary of State. This limited the scope of how they could report and also questions the truly independent nature of the regulator. As Robert Francis, Chair of Healthwatch England noted, a question of credibility and authority arises if CQC is "continually being directed to go to the places the secretary of state chooses."

It would seem essential that if CQC are to be a credible regulator of local area health systems then they need this responsibility built into the core powers – with all eyes on the Health and Care Bill to see whether these emerge. Providers will be watching developments closely, as their fees cover around 90% of CQC's income and there may well be sector pushback if it is felt this money is being used to fund an expansion of CQC's inspection activity without clear additional benefit for providers.

Key Messages for Primary Care: General Practice

- General practice is a key beneficiary of £4.5 billion additional funding for primary and community care services announced in the NHS Long-Term Plan (NHS LTP). This funding has driven major changes in the primary care landscape, and create opportunities for healthcare operators
- Primary Care Networks are set to change the way in-person care is delivered. It scales up primary care through GP Practices working together (combined population of 30,000-50,000 patients) to offer a broader range of integrated services using multi-disciplinary teams of healthcare professionals
- There is an expectation that much primary care could be delivered remotely, and Covid-19 has shown this is possible. The creation of a 'Digital First' primary care service is a key policy objective and an enabler of a government ambition to provide 50 million more appointments by 2023
- Covid-19 accelerated the transition to remote consultations, with NHS England reporting that over 99% of GP practices are now able offer remote working options. A funding injection of £270 million has enabled GP Practices to expand capacity and cope with increased demands and recovery pressures from Covid-19
- Primary care's digitisation objectives are supported through £1.4 billion targeted additional funding. This is likely to provide opportunities for digital healthcare companies over the next three years across telemedicine, electronic health records, and e-prescriptions. The NHS is also working to allow patients to register with a GP practice online, as part of a review aiming to reduce unnecessary bureaucracy

Funding for GPs May Increase More Slowly Than in Recent Years But is Still Set to Increase 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

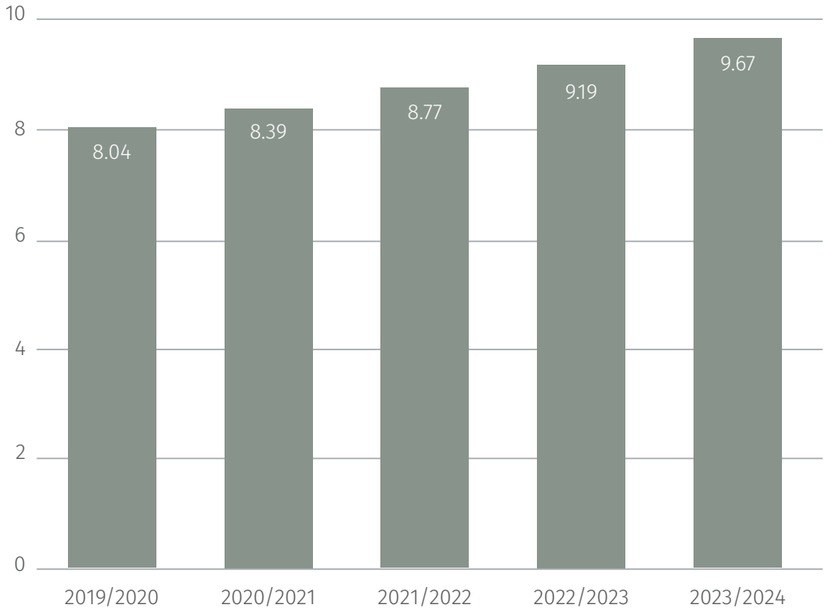
The NHS LTP (2019) set out the vision for the NHS for the next decade. It committed to increasing investment in primary medical and community health services as a share of the total national NHS revenue spend across the five years from 2019/20 to 2023/24. This amounted to a real-term funding increase of £4.5 billion a year by 2023/24.

The overall increase in spending reverses a trend over the previous decade, where GP funding rose more slowly than other parts of the health service. It is expected that the ring-fenced 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.

For the first time since 2013/14, CCGs have longer-term certainty in financial planning – with a five-year allocation set from 2019/20 to 2023/24. This is to support long-term service transformations and enable a funding shift towards more preventative service options that may release savings over time.

CCG allocations for primary medical care for all of England are anticipated to rise steadily, from £8 billion in 2019/20 to £9.7 billion in 2023/24. These figures exclude other potential income sources for GP Practices, such as centralised funding pots for specific improvements that are held by NHS England.

CCG Allocations For Primary Medical Care



Data: CCG Allocations for Primary Medical Care after adjustments for GP contract (2019/20 – 2023/24) (£, bns)

Source: NHS England, Marwood Analysis

GP contract reform to support the delivery of new care models

GPs hold a unique position within the NHS; in most cases they are contracted to deliver healthcare, rather than being directly employed by the NHS. The contracts that GPs work under outline obligations and provide details of funding.

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

The development of Primary Care Networks has required amendments to be made to existing contracts, but the core GP contracts remain the standard templates. In practice, most GPs hold GMS and PMS contracts.

In January 2019 the British Medical Association (BMA) and NHS England agreed on the terms of a new General Practice Contract. This articulated a five-year framework designed to implement the objectives of the NHS LTP. It introduced 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 £1.8 billion attached to the Network Contract DES between 2019/20 and 2023/24. This is to implement key elements of PCNs, as tying the funding to the PCN acts as an additional incentive for GPs to support uptake.

Additional funding primarily addresses 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 (MDTs). MDTs have the potential to improve access, with a recent analysis of practice appointments showing that 44% of appointments were with non-GP staff.

Despite the support of the BMA, the draft specifications in the new contract proved very unpopular amongst GPs, with many believing that the contract amendments were unworkable due to lack of resources and workload pressures.

Concessions were made by the NHS to update the GP contract framework for 2020/21. These cut back the PCN requirements and included a further £1.5 billion in funding to recruit 6000 more staff to provide more appointments.

NHS England also agreed to temporarily drop two of the planned network service enhancements - personalised care and anticipatory care will be introduced from October 2021, after it was announced they were delayed from the original introduction in April 2021. PCNs have only needed to deliver enhanced health in care homes, structured medicine reviews and support for early cancer diagnosis in 2020/21.

NHS funding for infrastructure and technology in general practice

NHS capital funding has been limited in recent years. However, improving infrastructure and technology is considered vital to improve access quality and outcomes for patients, as well as alleviate workload challenges for practices.

Estate and Technology Transformation Fund

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 £1 billion Primary Care Infrastructure Fund, which ran between 2015/16 and 2019/20. Between 2019/20 and 2023/24, the ETTF is expected to benefit from a further £1.4 billion additional targeted funding for primary care – which will also support primary care digitisation.

The ETTF has been 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. However, funding allocations have been delayed and the funding pot oversubscribed.

GP IT Futures

In January 2020, the GP IT Futures programme replaced the GP Systems of Choice as the new framework where commissioners buy their GP systems and associated products and services. The framework sets a high bar for suppliers by ensuring that all of their products will be able to communicate with each other across organisational boundaries.

CCGs have been allocated funds to support delivery of the new programme and it is anticipated that the new framework will make it easier for PCNs to choose the IT products and services that best suit their needs. In the context of Covid-19, the introduction of GP IT Futures and its reform of commercial landscape of primary care IT is hugely important.

In 2021, the government announced a £32 million investment in six health technology projects that will help transform the NHS by 2050, such as empower, which uses robotic muscular assistance to improve strength in individuals who have weakened muscle mobility. This follows an additional £50 million investment into artificial intelligence to improve diagnostics within the NHS in September 2020.

Policy and legislation

NHS Long Term Plan

The LTP emphasises the growing role of PCNs. These 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 depending on the need of their local communities. These services are expected to expand service provision outside of hospital and reduce the reliance on hospital care.

Nearly all GP practices have joined one of the 1,250 PCNs. While joining a network is not mandatory, GP practices are being incentivised to join as significant funding will be distributed through PCNs totalling over £1.4 billion by 2023/24.

In July 2020, NHS England announced a programme that would award digital-first providers with alternative provider medical services contracts. These could last 20 years in areas with insufficient supply of GPs. At initial set up, the programme had already spanned across 27 CCGs (20% of all CCGs). This will increase the provision of alternative therapy options for patients.

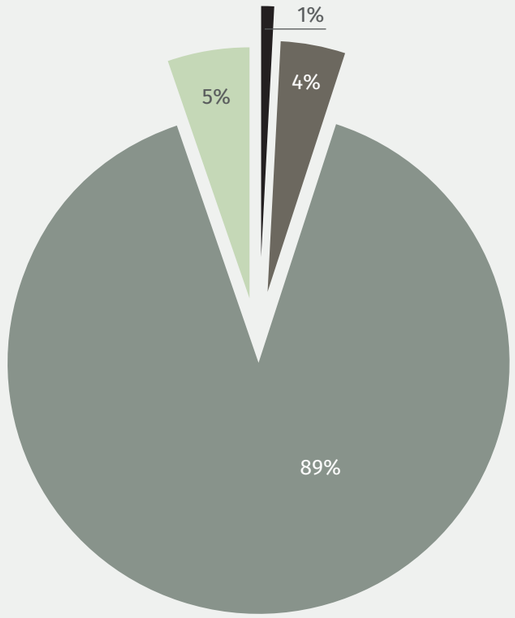
Regulation

CQC has moved towards a risk-based approach. Using this, 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. The risk-based approach allows CQC to direct greater efforts and resources on the small number of practices that require improvement or are rated as inadequate.

Overall, general practice services are of good quality and have improved over time. In State of Care 2019/20, CQC notes that general practice face pressures from workforce recruitment and growing demand. A major issue is the lack of same-day appointments – which can lead people to attend A&E with non-urgent conditions and strain on hospital services.

However, despite these pressures, patients are still highly satisfied with the quality of services offered. Overall, the quality of services remains high – with 94% of GP practices rated as good or outstanding in 2020. 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



Source: CQC

Importantly, when a provider operates as a standalone care provider it falls within the remit of CQC.

CQC have been granted legal powers to rate online providers – bringing these providers in line with other provider types. The regulation of online providers is likely to remain an area of focus in the near-term, particularly with the rapid expansion of services during the pandemic. This is made clearer in CQC's regulatory definition of online providers as 'healthcare services that provide a regulated activity by an online means.' This provision involves conveying information by text, sound, images or other digital forms for the prevention, diagnosis or treatment of disease and to follow-up patients' treatment.

In early inspections of online providers, 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.

A further regulatory challenge 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 in 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 advertise their services to consumers.

Regulating digital providers

The emergence of independent online primary care providers has challenged CQC's traditional regulatory framework, and there is a complex regulatory landscape to negotiate. Given the rapid expansion in digital health providers, it is important to understand the regulatory distinctions between service offers.

From a regulatory perspective it is important to separate providers that offer virtual care directly to users from providers that sell their software into existing GP practices. This is because it would be the GP practice and not the video software itself that would be regulated by CQC.

Regulatory clarity is particularly critical as investor interest in the sector grows – as many emerging digital solutions have been created by tech specialists rather than healthcare professionals, and so may not have included expert regulatory advice in the initial build phase. Guidance on the changing regulatory landscape and alignment with regulatory expectations is an increasingly key aspect of assessing risks with a potential asset.

Spotlight on Digital First Primary Care

The NHS Long Term Plan committed that all patients would have the right to receive digital-first primary care by 2023/24. Although funding was provided to Primary Care Networks to ensure that this goal was reached from April 2021, full implementation is yet to be achieved.

Whilst uptake of e-consultations has historically been slow across primary care, Covid-19 has led to a radical shift in care delivery. Adoption has been hastened by necessity, but also through flexibility that has allowed Skype, WhatsApp and FaceTime to be used in the short-term. In the longer-term, these are likely to be replaced by bespoke clinical options, like e-consultation apps.

These changes are likely part of a larger trend, since GP at Hand hit a new milestone in August 2021 when it became the first NHS GP service to register more than 100,000 patients on a single list.

The NHS also put wider measures in place to roll out video conferencing in primary care including fast-tracking assurance of video products on the new Digital Care Services Framework.

The public seem willing to utilise these digital care services. An Ipsos MORI poll revealed that in the 3 months prior to the pandemic, only around 10% of patients were accessing remote GP services. From January to March 2021, that figure had risen to over 50% of patients accessing their GPs remotely.

GPs have expressed concern over the increased workload stemming from remote services. Some providers have reported turning off their e-consultations during evenings and weekends to stem the flow of demand. This may lead to further delays in accessing care, and ultimately adding to the increasing backlog of care that the NHS is attempting to manage.

Digital health services may soon expand to other services areas, like e-pharmacy, mental health, and physiotherapy among others. It is a major health policy focus area – although some work may still remain for policy-makers to convince healthcare professionals that digital solutions represent a transformative way to deliver healthcare services, and not an additional burden.

The system must also provide a operating environment that supports adoption – with policy and regulatory mechanisms that enable this. More information on this can be found in Section 4: Medical Devices.

Digital health services may soon expand to other services areas, like e-pharmacy, mental health, and physiotherapy among others. Some digital and medical device diagnostics have already been approved under the MedTech Funding Mandate 2021/22.

There is no doubt that digital primary care will grow in size, importance and revenue in the years to come. The impact felt by Covid-19 has only catalysed this transition.

More broadly, practitioners across the wider health system, who had hitherto been on the fence, have rapidly adapted to the changing environment and consumer demand.

We are also seeing the government increasingly put digital health at the heart of health policy.

Overall, opportunity in the sector may be significantly boosted by major policy initiatives, increasing consumer demand and new digital applications.

2014
- The NHS Five Year Forward View, which also publishes the Personalised health and care 2020

2015
- Local digital roadmaps

2016
- Sustainabilty and Transformation Partnerships
- Wacher review of Health IT; 16 NHS hospital trusts named global digital exemplars, and an £100 million digital fund will support the work of digital information flows (Sep)
- All patients have access to their full GP records through and online serivce
- “Endorsement” model for health apps, promoting transparency across the NHS

2017
- NHS Digital Academy to train and develop 300 digital leaders by 2021
- 7 mental health trusts will be mental health digital exemplars in the “Next steps for the NHS five year forward view”. An extra 5 million in funding will be allocated to help their digitisation (Mar)

2018
- Paperless operation in the NHS. Patients can view all information from health and social care interactions from April

2020
- Major transition to digital health services due to Covid-19 ceasing all elective care activity
- Aspiration that interoperable, real-time care records would be able to be used in the NHS (as per NHS Five Year Forward View)

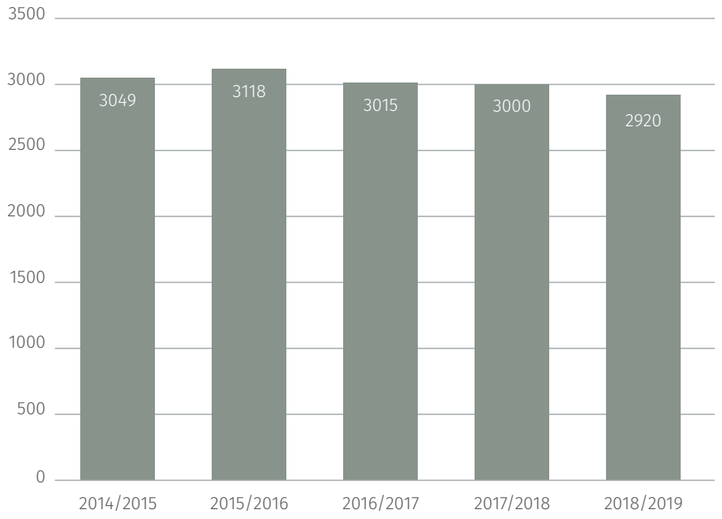
2021
- MedTech Funding Mandate selected technologies to be funded for use in primary care

Source: The King’s Fund, Marwood analysis

Key Messages for Primary Care: Dentistry

- Dental service provision in England primarily consists of independent or small 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
- In 2018/19 and 2019/20, over 22 million adults were seen by NHS dentists, making up 50% of the adult population, and 7 million children aged 18 or below were seen, making up 59% of the under 18 population
- There are over 33,000 dentists registered with the General Dental Council in England. Over 24,000 perform NHS dental activity. England has fewer dentists per person than Germany, France or Italy
- The cost of NHS dentistry is split between the user, who contributes through a patient charge, and the NHS, via direct payments to the dental practice. Recent increases to the patient charge have averaged 5% annually
- In 2020, a 5% increase in the patient charge was delayed until December 2020 due to Covid-19. There has not yet been a further uplift to the patient charge in 2021
- All routine dental activity was suspended in March 2020 as a result of Covid-19. NHS payments were maintained providing some stability for those operating in the public-pay sector. Since June 2020, dental practices have been able to resume practice, with treatments continuing even into the later UK lockdowns. However, there are capacity constraints due to requirements to ensure premises reduce avoidable transmission risks
- From January 2021, it was announced that dental practices needed to deliver 45% of their NHS treatments to avoid receiving a financial penalty, and from April 2021 through to 01 October 2021, dental practices must deliver 60% of their NHS contracts
- Private-pay dentistry was buoyant ahead of the emergence of Covid-19. The enforced closure of dental practices has hit revenues hard. However, pent-up demand and continued access pressures in NHS-provided care may enable some defensibility in the wake of a period of economic constraint

Inflation-Adjusted NHS Income for Dental Practices in England has Slightly Declined Since 2015/16



Data: Total RPI-adjusted NHS income for dental practices in England (2014/15 to 2018/19) (£, m; 2018-19 prices). Income derived from NHS England allocated funding to dental services, and patient charges.

Source: National Audit Office

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. There is a wide variety of out-of-pocket private payment options. Some dentists focus on high-end luxury dental services, but in recent years, chain providers have begun to offer low-cost private pay. The Bupa 'essentials' range, priced only slightly above the level patient's pay for NHS services is an example of this model. Smaller revenue streams come via 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 2019/20, direct NHS payments to dentistry amounted to about £2.89 billion. The amount paid directly by the NHS varies year-on-year but has gradually been declining in real-terms in recent years.

Patient charge (co-payment)

Dentistry is one of the few areas of the health service where individuals must contribute financially to receive services. In recent years, the patient charge has been uplifted at a higher rate than direct NHS payments. This has meant the burden of funding NHS dental services has increasingly shifted towards patients.

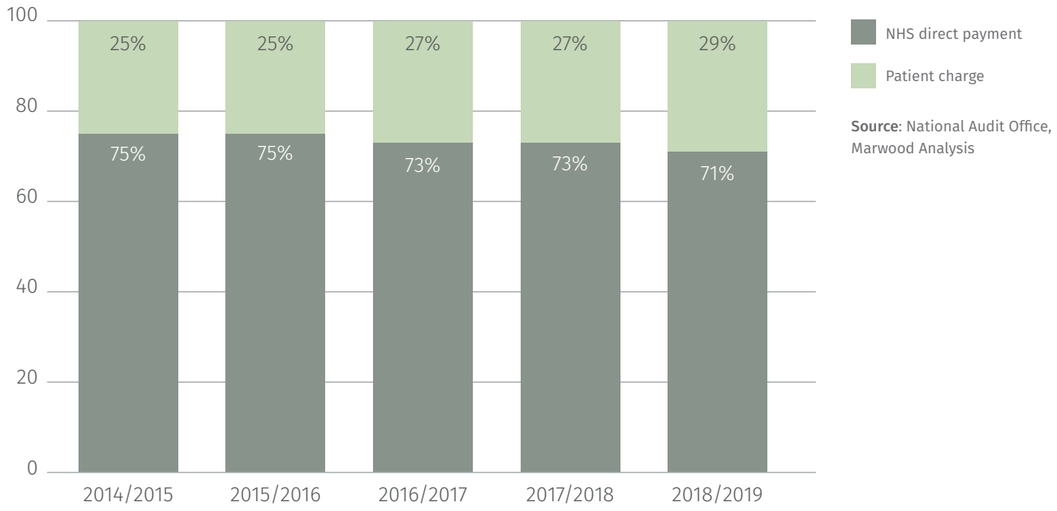
In 2011/12, patient charge revenue contributed to just 23% of the total dental revenue. By 2018/2019, it had increased to 29%. This growth in the patient contribution to overall dental practice income is expected to continue in the next few years. Annual increases have offset dental income decline as 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. In 2020, a 5% increase in the patient charge was delayed until December 2020 due to Covid-19. However, from January 2021, it was announced that there would be the standard 5% uplift on dental payments for 2021/22.

TREATMENT BAND	TYPE OF TREATMENT	PATIENT CHARGE (2021/22)
Band 1	Check-up, diagnosis, treatment planning and maintenance	£23.80
Band 2	Fillings, root canal, tooth extraction	£65.20
Band 3	Complex treatment that includes laboratory element	£282.80

Individuals can be exempt from the patient charge, with NHS England direct payments covering the full amount for their patient care. However, over half of all dental activity is performed on those eligible for the patient charge. Non-paying adults are also far more likely to be receiving Band 3 treatment - with about 50% of dental activity in this intensive bracket. This compares to just over 25% of paying adult's dental activity falling into Band 3 treatments.

Change in NHS Direct Payments v Patient Charge Revenue (2014/15 – 2018/2019)



Source: National Audit Office, Marwood Analysis

The private pay dental sector

The dental sector is one of the few elements of the healthcare system that has a clear and distinct private sector operating in parallel with the public sector. Whilst private pay exists throughout, the size of the market tends to be minimal compared to NHS delivery – or it provides services that are not offered through the public health system.

Whilst the private pay market was hit following the 2008 financial crisis, it has rebuilt itself and evolved significantly, with the emergence of medium - and large dental chains. The offer has developed to cover offerings to consumers at varying price points, including increasingly offering a direct low-cost model to compete with the NHS.

This model has evolved owing to the continuing increase in the patient charge. This charge has meant that unlike most elements of the healthcare system, people may view themselves as consumers as much as they view themselves as patients.

Marwood has 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.

Alongside this there is continuing demand for cosmetic services not accessible on the NHS. Marwood 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. This type of add-on services may suffer in the wake of the pandemic, but the underlying demand may remain in the longer-term.

Coronavirus and the potential impact on private-pay

Ahead of the emergence of Covid-19, the private-pay dentistry segment was buoyant. The pandemic acted as a complete brake on the market as all dental services were required to shut during the initial lockdown – as consumer demand continued to increase from its slump following the fall-out of the 2008 financial crisis.

As services resumed operation, there may be increased demand from people who would normally seek to access NHS care – as dentists are only required to deliver at 60% against NHS contractual requirements. Those that can manage a higher through-put can limit their NHS provision and seek to boost lost revenue through private pay provision. Pent-up demand for NHS services may also push those that can afford it to consider private pay options.

The longer-term re-emergence of private pay may be sustained as it will take time to unwind pent-up demand without additional government funding for dentistry – and at present it has not been visible as a priority area, so the likelihood of this may be limited.

The emergence of low-cost dental alternatives and the importance placed on accessing services at a convenient time may well sustain private demand. However, this demand may well be focussed among particular customer segments and geographic regions. The level of localised NHS availability and size of the backlog is likely to be a key driver in decision making.

The longer-term risk will be consumers choosing to forego private-pay options in the face of a sustained economic decline. However, given the demand pressures on the NHS, this could lead to increased interest in the low-cost private-pay model, with traditional NHS users paying slightly more to access a low-cost private option, and higher-end private-pay users switching down to save money whilst remaining within the private segment.

Policy and legislation

General dental contract reform

Issues with the 2006 General Dental Contract

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, and dentists earn 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. The unit price of UDAs is agreed on a practice by practice basis, leading to variation between practices and regions, meaning practices get paid different amounts for the same treatment.

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 aims to ensure that dentists do not under-deliver to NHS patients by over-committing to private provision, but also allows NHS England to 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.

Whilst the UDA system is expected to be replaced in the longer run, it is likely to remain the predominant model in use in the near-to-medium term while the NHS addresses barriers to introduce a new payment system.

Reforming the dental contract: Pilots and prototypes

General dental contract reform has been under discussion since 2006, when the government commissioned a review in recognition of widespread concerns. The Steele Report (2009) laid the foundations for reform and argued that the payment system should incentivise prevention rather than treatment.

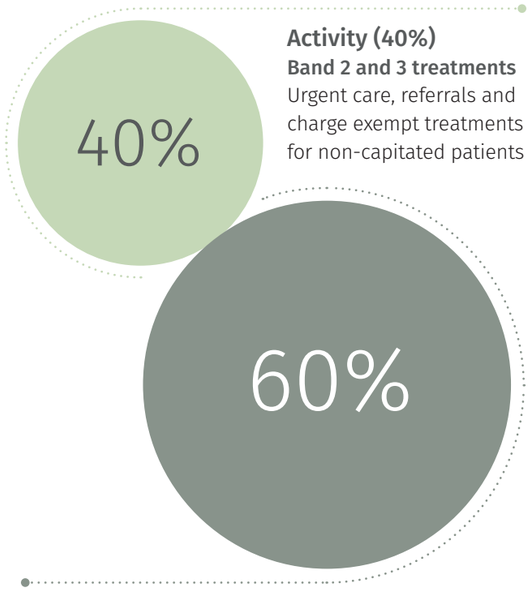
Over the last decade, a new clinical pathway focussed on prevention has been developed, with pilot areas testing different capitated payment models. There are currently 102 practices participating in the Dental Prototype Agreement Scheme, which introduces a form of capitation rate whereby dentists are rewarded for retaining patients on their practice lists and engaging them in preventive care.

The prototype also includes the participation of a larger range of dental care professionals to deliver patient care. This may broaden the skill mix of the dental team, and enable lower cost dental professionals to deliver elements of patient care.

There are three different remuneration methods being considered for the contract reform: full activity, full capitation, or a blended method of both. The blended method would involve a capitation approach to remunerate the first, more predictable part of the care spectrum whilst an activity-based approach could be used for the remainder of the care spectrum.

The blended payment model is the most likely method to be adopted. Two versions are being tested.

Blend A

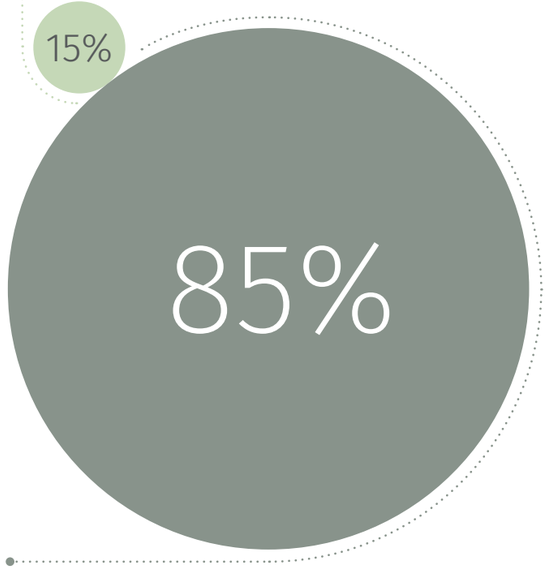


Activity (40%)
Band 2 and 3 treatments
Urgent care, referrals and charge exempt treatments for non-capitated patients

Capitation (60%)
Band 1 treatments
Urgent and charge exempt treatments for capitated patients

Blend B

Activity (15%)
Band 3 treatments
Urgent care, referrals and charge exempt treatments for non-capitated patients



Capitation (85%)
Band 1 and 2 treatments
Urgent and charge exempt treatments for capitated patients

The major challenge to full implementation has been finding a payment model that balances the financial risk to the NHS of removing the link between payment and activity. As the provider of last resort, ultimately the NHS will still be responsible for providing dental care.

On the other hand, dentists have been concerned that tying budgets to patient waiting lists risks unforeseen income declines, particularly if successful prevention leads to patients reducing their visits to the dentists.

In March 2021, NHS England and the British Dental Association announced that they will be working to bring reform to dental contract arrangements, and that a progress report will be delivered within the next year. In Wales, delays to the contract reforms have been announced to last until April 2022.

Dentists Engagement with Contract Reform is Low – but Covid-19 May Lead to a Change in Perspective

In 2019, 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.

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 since 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.

Nonetheless, an impact of the current pandemic may be a revival of dental contract reforms. Whilst many dentists distrust the motivations for a new contract, the advantages of a capitated system with its guaranteed per-patient income may seem more appealing now that practices have experienced first-hand the consequences of when dental activity stops.

This will be a critical question 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.

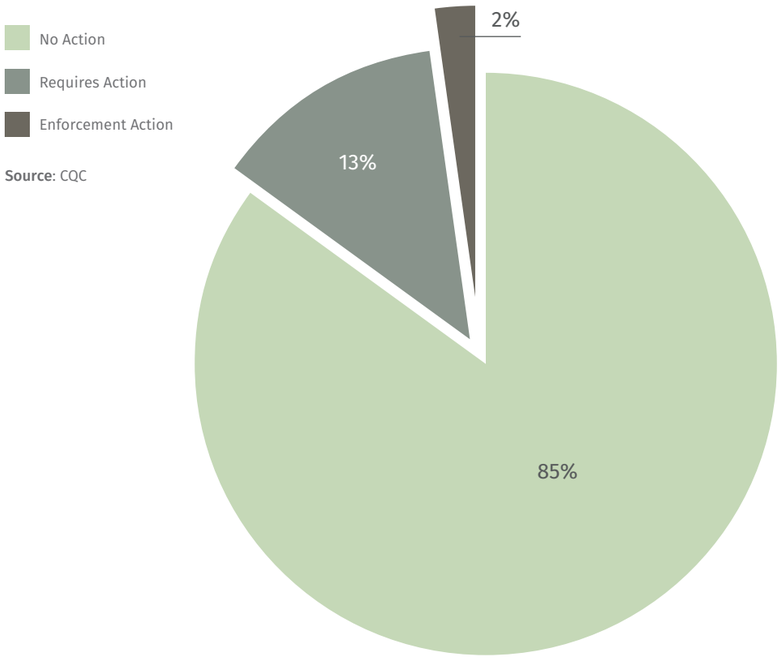
Regulation

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 2018/19 State of Care report confirmed that dental practices deliver high quality services. 85% of services inspected in 2018/2019 (1,201 practices) were considered safe and required no action, which is a decline by 5% from the previous year, whereas 13% of services needed to improve in specific areas and were rated as 'requiring action'. Enforcement actions were taken for 2% of the services inspected, meaning that they needed to significantly improve the quality of their services. Consequently, the proportion of inspections requiring regulatory action has risen from 10% in 2018 to 15% in 2019.

Routine dental inspections were halted in March 2020 by CQC due to the pandemic, and ratings were not published in CQC's 2019/20 State of Care report.

CQC Ratings of Dental Practices (2017/18)



Source: CQC

Spotlight on Fertility Services

Over the 20th century scientific progress has revolutionised our understanding of fertility – and the UK has often been at the forefront of these developments. The in-vitro fertilisation (IVF) technique was developed in Britain, with the first IVF baby born in England in 1978.

Fast forward more than forty years and the range of fertility solutions offered by clinics has expanded to the point that – although still the commonly used term when talking about assisted conception – IVF is no longer the primary method used. Intracytoplasmic sperm injection (ICSI) now makes up nearly half of all fertility cycles performed in Europe, excluding artificial insemination.

The variety of fertility treatment options available to intended parents is substantial. They can range from relatively simple procedures to highly innovative medical treatments. Gamete donations, collection and preservation (freezing) services are critical to enable fertilisation processes downstream, where donors are required. This is of particular importance for lesbian couples, or couples where one of the partners has a fertility issue.

However, fertility treatment is an area where scientific advancement clashes with national policy decisions, as frameworks regulating fertility differ widely country to country. This leads to significant differences in exactly who can access treatment, and the services available to them, depending on where they live.

Universal public-pay entitlement does not necessarily mean universal access

The UK has one of the most liberal fertility frameworks in the world. There is almost universal availability of fertility treatments, with few legal limits on who can access fertility services. Single women and same-sex couples have free access and there is a wide range of ancillary services available.

If you can afford it then private pay fertility services in the UK are the equal of any in Europe – and at a far lower price point than you would expect to pay in the NHS. The major barriers align with broader European trends – commercial surrogacy and sex-selection techniques being blocked across private and public pay services.

LEGALLY AVAILABLE FERTILITY SERVICES

Eligible Populations	Max IP Age F	IVF/ ICSI/IUI	Embryo Cryo-preservation	Gamete Donation	Donor Anonymity	Donor Compensation*	Genetic Tests	Surrogacy
• Hetrosexual • Lesbian couples • Single women	42	✓	• Medical • Social	✓	✗	✗ Expenses only	• PGD • PGS	• Altruistic

However, the UK also has the NHS – where healthcare is free at the point of use. This should surely extend to fertility services as well?

The answer to that is more complicated. It is yes, in theory, but many intended parents will tell you it is no in reality.

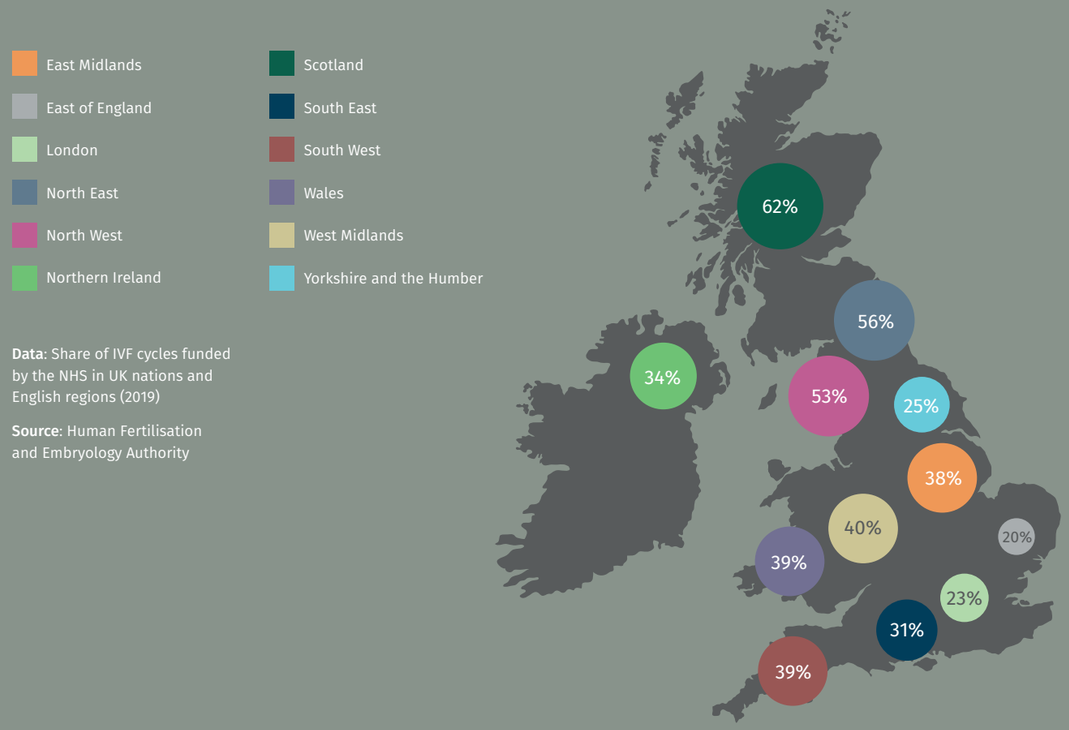
FERTILITY SERVICES COVERED BY THE PUBLIC PAYOR (NHS)

Eligible Populations	Max IP Age F	IVF/ ICSI/IUI	Cryo-preservation	Embryo Freezing	Genetic Tests	Reimbursement Levels
• Hetrosexual, married • Hetrosexual, unmarried • Single women • Same sex couples	40	✓	✗	✓	• PGS	• Regional variation ranging from 0 to 3 cycles of IVF • Local areas may limit cycles, impose age, BMI and/or childlessness criteria for treatments

There is considerable regional variation in access to fertility services via the public pay system. This is because many local areas restrict the availability or limit the number of reproductive cycles that are funded by the NHS. Navigation of complex reimbursement and access issues make understanding the sector difficult for both investors and those who intend to use services.

These restrictions have resulted in negative media attention for cash-strapped CCGs, but whilst limiting fertility services is against clinical guidelines it is not a contravention of commissioning rules. As a result, there is an increasingly active private pay market for fertility services, which presents unique opportunities for investors and operators to expand.

There is Significant Regional Variation in Fertility Services Access Levels in the UK



Data: Share of IVF cycles funded by the NHS in UK nations and English regions (2019)

Source: Human Fertilisation and Embryology Authority

Clinics need to be aware that market regulators are looking closely at how fertility services are being marketed

Regulation is always challenged by innovation. Scientific progress can often outstrip regulators – as it expands into areas outside the legislated scope of regulation. Fertility services have benefitted from a range of new techniques that are advertised as boosting success rates.

For those desperate to have children, it is hardly surprising that they can be deemed as vulnerable – and easy prey for more unscrupulous operators who will add thousands onto the cost of treatment, even if it adds very little to the chances of success in reality.

In recent years both the Competition and Markets Authority (CMA) and the Human Fertilisation and Embryology Authority (HFEA) have looked increasingly closely at the sector – working together to ensure fair and transparent pricing of private fertility services.

In 2020, HFEA adjusted the traffic-light rating system that it used to improve transparency on the likely success of add-on fertility services. This is a recent addition and follow concerns that consumers were being sold services with minimal transparency regarding the evidence-base on the likely efficacy of the added-on fertility service.

Due to concerns over fair pricing of fertility services, the CMA released final guidance on fair and transparent pricing of fertility services in June 2021. As the CMA is responsible for consumer protection in the fertility industry, the guidance aims to help providers of fertility services comply and understand their legal obligations under consumer law. This guidance addresses concerns expressed by the CMA regarding private fertility clinics' practices, such as a lack of price transparency and misleading claims about success rates.

In December 2021, the CMA is expected to begin its review of the sector's compliance with the updated consumer law, enforcing regulatory action and possibly penalties where necessary.

Keeping the UK as a world leader in innovation in fertility services

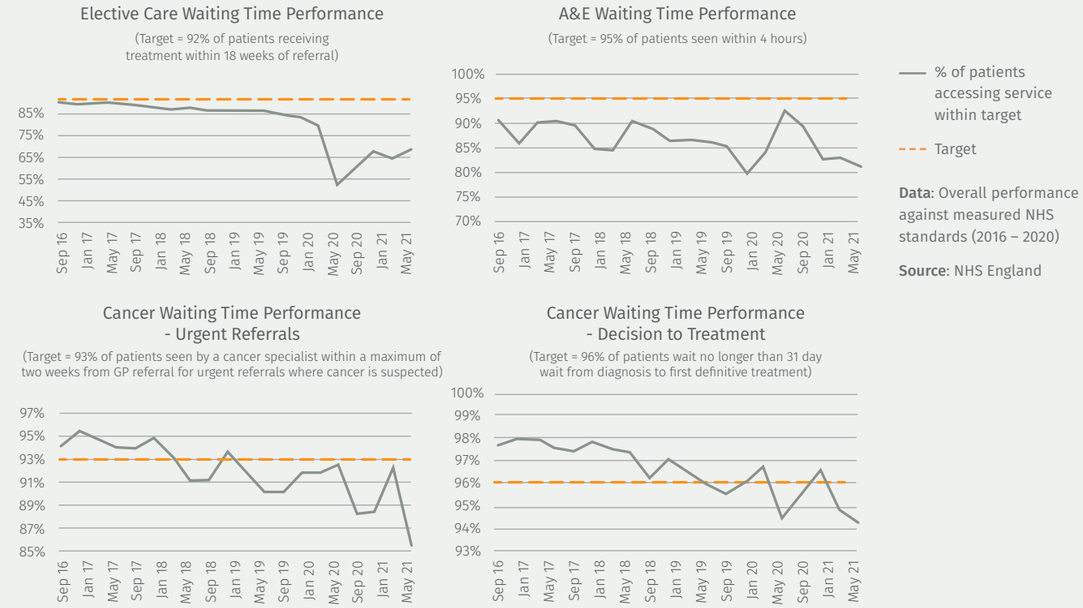
While the UK has one of the most liberal fertility service frameworks, extensions to the statutory limits on egg and gamete storage are under discussion. Under current law, the storage period is limited to a maximum of 10 years and only those stored for medical reasons, such as cancer treatment, and premature infertility can be preserved for a longer period of up to 55 years in total.

In 2020, the UK government consulted on whether the law to store frozen eggs, sperm and embryos for 10 years should change. The potential impact of the pandemic led the government to create a two year interim extension to the storage limit. However, recent announcements have suggested they intend to introduce a right for prospective parents to be asked every 10 years whether they would like the storage limit extended – up to a maximum of 55 years. The extension is backed by the HFEA but would require legislative change, and it is not yet clear when parliamentary time can be found to introduce it – so further change may have to wait until the next parliament.

Key Messages for Acute Hospital Care

- Over the course of 2020 and 2021, Covid-19 pandemic has dramatically changed the face of acute hospital care. Hospital admissions for routine elective work were paused and systems reconfigured to focus on containing the spread of the virus
- Before the pandemic, the elective care waiting list had grown to its highest ever level – 4.4 million people were waiting longer than 18 weeks for treatment. With waiting lists now at over 5 million, and this number expected to rise, returning to routine elective care is a core priority of the 2021-22 NHS operational plan
- The pandemic led to system transformation proposals that had been discussed for years to be embedded in a matter of months. This includes enabling video consultations for outpatient appointments, unblocking transfer of care pathways to reduce historic discharge delays, and consolidating diagnostic work into pathology hubs
- Funding to meet pandemic-related expenditure has not come out of core NHS budgets, and have been met directly by the Treasury. The Government appears committed to the agreed five-year plan that guarantees NHS funding to 2024. However, once centralised Covid-support is withdrawn, additional costs to support a return to normal is likely to put the health service under renewed pressure
- In May 2021, an additional £160 million was announced to target the backlog of care in light of the disruption Covid-19 caused, and to develop concrete plans for delivering elective care in innovative ways
- The private sector is likely to have a major role in improving the performance of the system – following new ways of working established during 2020 and 2021. The use of a national framework may make it easier for local commissioners, under considerable pressures, to make use of available local independent sector capacity and may also lead to greater price transparency
- Capital spending on estates and digital infrastructure is set to increase in the 2020-21 to 2024-25 plan following years of under-investment. This is likely to improve the quality of the hospital estate, increase diagnostic imaging capacity, and embed further changes outlined in the NHSX Tech Plan

NHS Performance Against Key Indicators Has Been Declining for Years – and was Accelerated as a Result of the Pandemic



Data: Overall performance against measured NHS standards (2016 – 2020)

Source: NHS England

Payers

Acute Trusts' deficits

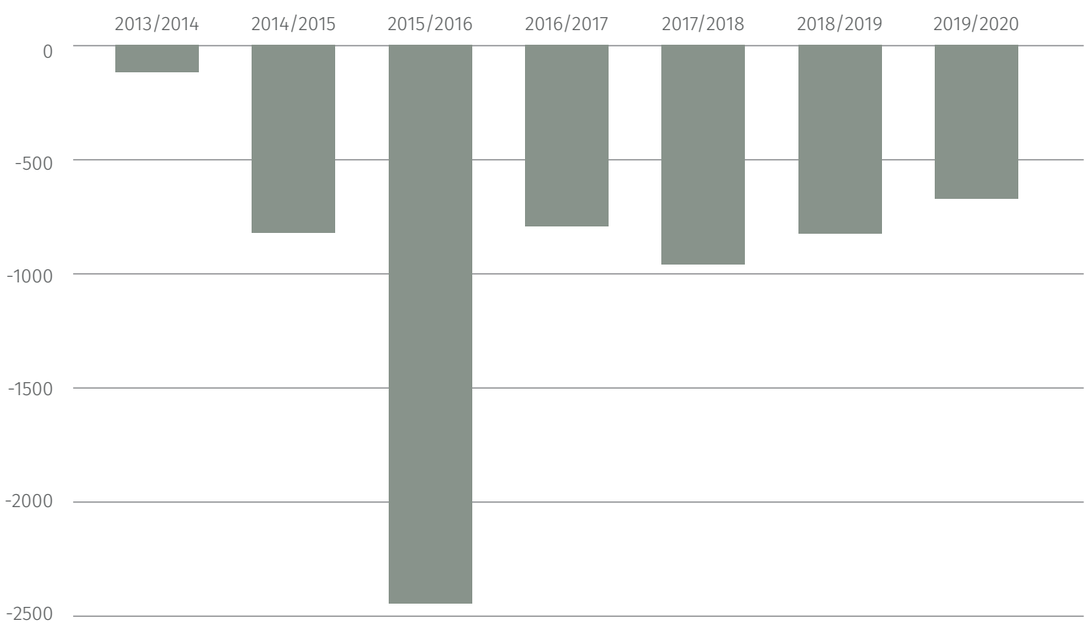
In recent years, the NHS acute sector experienced financial pressure as NHS funding growth did not keep pace with increasing service demand. Despite emergency cash injections and social care funding targeted towards relieving some of the pressure on hospitals caused by delayed transfers of care, significant deficits were routinely recorded between 2014/15 and 2019/20.

However, in 2019/20, many trusts demonstrated results that were better than projected, given the difficult circumstances. This highlights an improvement in financial management of many NHS trusts, with the deficit shrinking from £827 million in 2018/9, to £669 million in 2019/20.

To provide greater long-term sustainability, the government announced that from April 2020, £13.4 billion of NHS debt will be scrapped. This is debt accumulated by NHS Trusts as they struggled to balance the books in recent years and have relied on bail-out loans from the Treasury. It has long been noted within the sector that there was no practical expectation that these debts would ever be repaid. Whilst the proposal is positive, it should be noted that the debt is not technically written-off but repackaged into a Public Dividend Capital. This will attract a charge, but one substantially lower than current rates of interest.

NHS Trusts' Overall Deficit (2013/14 – 2019/20) (£, m)

Source: King's Fund



Health spending

Payment system and tariff reform

NHS acute services were historically commissioned locally by CCGs. However this is due to change with the introduction of Integrated Care Systems (ICSs), which will have an overarching NHS body responsible for services. Providers are paid for activity delivered via a National Tariff system - a catalogue of activity-based prices for different acute services – which are classified under diagnosis-related groups (DRGs). This payment model is also known as 'payment by results' (PbR) and gradually replaced block contracts in the 2000s. With ICSs, the NHS may well see a return to a variation of block contracts for NHS acute services, as all parts of the NHS within a local system will work together to balance the books and deliver services to their population.

The LTP confirmed that the Tariff will be amended over the next few years, and a new National Tariff Payment System is proposed for 2021/2022. Commissioners and providers will be expected to agree blended payments for outpatients that include advice and guidance and virtual consultations. The 'blended payment' would comprise of a fixed element based on locally agreed planned activity levels and any agreed advice and guidance services, as well as a quality-based element aligned to the successful delivery of those advice and guidance services. There will also be a variable element to the payment, which will support elective activity and reflect the achievement of best practice.

These reforms reflect NHS England's long-term ambition to develop new payment approaches that enable more integrated care services, and move towards population-based capitated budgets.

Some local areas have been trailing these approaches, which removes 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.

NHS England published the Integrated Care Provider (ICP) contract in August 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 reached £20 billion, 17% of the total NHS budget, and it is expected to grow to £25 billion by 2025. All specialist services are seeing reductions in activity due to Covid-19, but the impact varies widely across the different specialisms.

There are 146 specialised service areas in total. This includes directly commissioned mental health services, but in the acute sector they are primarily for rare conditions that often have low patient numbers and high-cost treatments. It can also include funding patients to access treatments overseas that are not available in the UK.

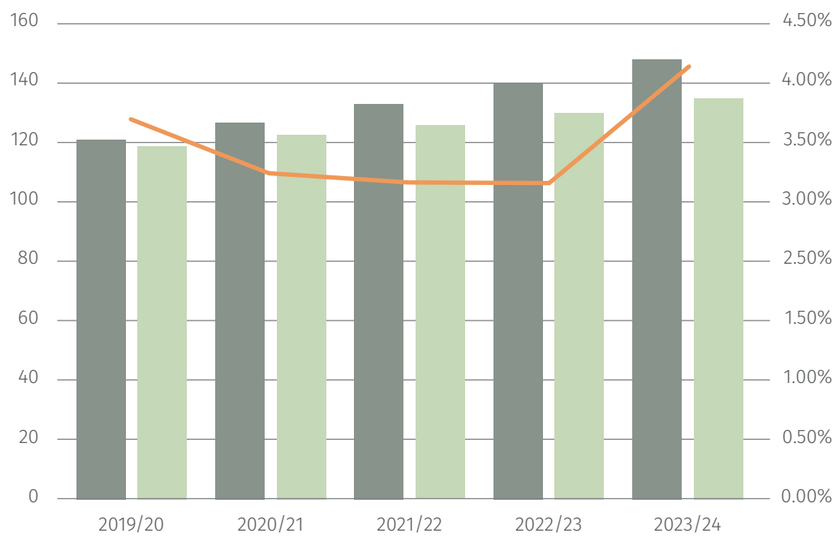
Capital spending

Increasing infrastructure in the NHS was a core part of Boris Johnson's electoral campaign and capital expenditure should reach £9.4 billion in 2021-22, up from £8 billion in 2020-21. This will seek to reverse historic under-investment, as since 2009, the UK invested less year-on-year than the OECD average on capital spending in healthcare.

Overall, £5.4 billion will be spent over the next five years building 40 new hospitals, as set out in Johnson's manifesto, and upgrading 70 more hospitals. Of the total amount, £1.3 billion will be spent in 2021-22.

This is in line with the capital strategy for health for 2020-2025, which was published in November 2020. Although delayed due to the pandemic, this strategy demonstrates the government's commitment to develop infrastructure. A key area of focus in the review was allocating extra money to health, and £500 million of the total £3 billion allocated to the NHS will be distributed to mental health services as a result. This is particularly key as many NHS Trusts have seen large increases in the number of patients looking to access mental health services as a result of the pandemic.

Projected NHS Revenue Funding Allocations in England (2019/20 - 2023/24)



Source: Department for Health and Social Care

Note: Data denotes total health spending. As NHS Acute hospital budgets receive income from multiple sources, it is difficult to accurately ascribe spend. Acute care is estimated to take up approximately 1/3 of the total NHS England revenue budget, and a further 16% is spent on specialist services – some of which would take place in acute locations

Policy and legislation

Efficiency and productivity

Despite a long-term funding settlement that secures year-on-year increases above the rate of inflation, the growing demand for services alongside the need to clear a backlog of cases that have risen during the pandemic, means that the efficiency challenge in the acute sector will likely continue in the years ahead.

The NHS 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 Five Year Forward View (2014) but remains slightly higher than historic efficiencies of 0.8%. The LTP outlines how it intends to improve efficiency and save £1.1billion 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 £5 billion of efficiencies. Progress towards achieving efficiency has been relatively slow and subject to local variation. Reports from the National Audit Office and from a House of Lords inquiry detail the need for more coordination and clear plans to achieve greater efficiency and minimise performance variation. In 2018/19, the NHS continued to deliver increasing activity, but performance against key access standards for acute services declined further.

Returning to Normal: How Covid-19 May Shape Opportunities for the Private Sector

As of August 2021, Boris Johnson has allowed for the easing of all Covid-19 restrictions, with nearly 65% of all adults fully vaccinated. It remains a fluid situation, and the impact of a return from holidays/return to schools may lead to an Autumn spike. However, it remains a return to a form of normality, and health system planners have moved into the next stage of operational planning – setting out plans that will see hospitals move towards business-as-usual activity as we learn to live with Covid-19.

The need to return to usual levels of delivery as quickly as possible is due to over 5 million people being on waiting lists at the end of the first quarter of 2021, with estimates showing a further rise of up to 13 million according to the new Health Secretary Sajid Javid. In addition, a renewed Covid-19 peak during traditional winter pressures would have a significant impact on services.

Tackling the elective backlog is a key political priority and will shape the direction of local health planning. The Government has made an additional £1 billion available if NHS Trusts are able to meet stretch targets on elective activity. This acts as significant financial incentive to ramp up delivery – although it has faced criticism for only making a dent in what will be required to clear the backlog.

The independent sector is key to the response with their ability to negotiate services under the national framework. From March 2021, local commissioners will agree capacity in accordance with local plans, and will buy from the national framework. This framework to increase capacity is set to last until November 2022, with a 24-month extension option available to contracting authorities

Many of the activities outlined by NHS England will have an impact on the independent sector, and providers should engage closely with their key local partners, as plans are increasingly taken forward at Trust and local system level. This is likely to be achieved under the new ICS model that is set to be fully functioning by April 2022.

NHS PRIORITIES	IMPACT ON THE PRIVATE SECTOR
A full resumption of all cancer services, with Cancer Alliances drawing up delivery plans covering April 2021 to September 2021, addressing all shortfalls by March 2022	The planning explicitly calls on ensuring sufficient diagnostic capacity is in place and that independent sector facilities are used where required
Return to elective care delivery, taking advantage of transformation opportunities, such as fast-tracking patients for high volume, low complexity care, and utilise new diagnostic networks	With NHS hospitals required to meet local Covid-19 demands, it will not be practical to deliver all care within the public sector. The private sector may be required to provide overflow capacity
Avoid outpatient attendances of low clinical value, shifting capacity to where it is needed, which can be done by having at least 25% of visits held virtually via telephone or video consultation	This has already proved to be a transformative moment for the roll-out of remote working tools in the NHS. Digital service providers may benefit from rapid take-up and volume expansion as the changes embed further

Waiting times

Covid-19 has had a devastating impact on waiting times that were already at the highest level in over a decade. It has been estimated that the overall waiting list could balloon up to 13 million people as the NHS begins to return to routine elective care, with waiting lists reaching record highs of 5.6 million in July 2021. This is up from 4.4 million shortly before the start of the pandemic.

However performance against key waiting time targets had been progressively slipping for years ahead of the pandemic. This had resulted in a national clinical review of waiting times standards across the NHS, including elective care, accident and emergency (A&E), cancer and mental health target.

Under the NHS Constitution, patients have the right to access certain services commissioned by NHS bodies within maximum wait times. There have historically been three high-profile targets which impact on the demand for both urgent and routine diagnostic imaging. They are the 4-hour A&E target, the 2-week wait for referral to cancer specialists, and the 18-week wait for elective care.

In June 2020, it was formally announced that the '4-hour A&E target' would be dropped. This is significant, as it was always seen as a totemic standard that performance in the NHS was judged around. The limited media or political backlash is a reflection of how much Covid-19 may have changed the debate around the NHS.

In practical terms, it will be replaced with an average wait time target. The reality may mean that little will change in operational behaviour as the new target is will be aligned quite closely to current performance – as the old target drove admission behaviours to such an extent that the current mean waiting time stands at 4 hours.

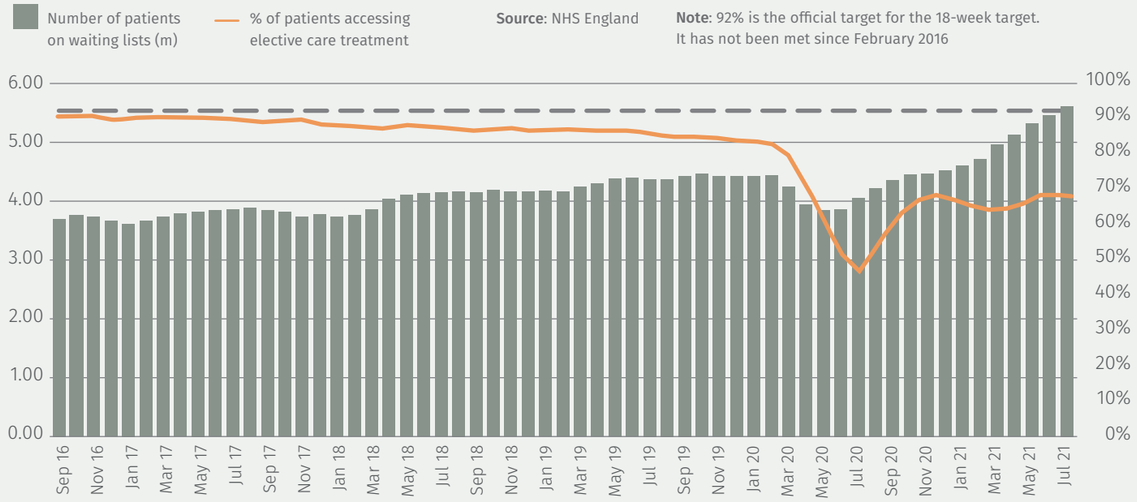
Elective care

The total number of patients waiting for elective care treatment has increased almost continuously in recent years, reaching 5.6 million in July 2021 – surpassing the previous record high last reached in September 2007.

Under the NHS Constitution, patients diagnosed with a non-urgent condition have a right to commence treatment within 18 weeks of referral. This is known as referral-to-treatment (RTT) time. However, the NHS has failed to hit this target since February 2016, and has been on a downward trajectory ever since. Even before the emergence of Covid-19, achievement had slumped to below 85%.

There has also been growth in very long waiters despite an NHS LTP ambition to eradicate waits of 52 weeks or over, that has been reinforced in the 2020/2021 NHS Planning Guidance, there were 2.4 million waiting over 52 weeks in March 2021. Providers were expected to monitor and manage these long waiting patients very closely and to submit timely and accurate data via weekly Patient Tracking Lists. Financial sanctions on providers remain in place and continue to be applied for any patient who breaches 52 weeks.

Number of Patients on Waiting Lists (m) and % of Patients Accessing Elective Care Treatment Within 18-Week Target Since September 2016



Covid-19 and the Impact on Waiting Lists

In January 2020, more than one in six patients were waiting more than 18 weeks for routine treatment. When Covid-19 hit in March 2020, non-urgent planned care was postponed until July 2020. This was to allow for greater NHS capacity for prioritising Covid-19 care, but ultimately led to significant backlogs of patients waiting to start treatment. Even after care was resumed in July 2020, many patients were still hesitant to visit their GPs for initial referral, compounding the backlog of care. In July 2021, a record number of patients were waiting to start elective treatment, totalling over 5.6 million people.

Despite the high numbers of people waiting as of present, In the immediate months following the first wave of the pandemic, the NHS had actually improved its performance against some key measures. The reduction of people coming to A&E overall meant it was easier to meet the 4hr target of those who did attend – whilst overall inpatient volumes for non-Covid-19 related visits were reduced, so treatment could be focussed in specific priority areas such as cancer.

Prior to April 2020, there was a 2-week wait for referral in cases where cancer was suspected. This was replaced by the requirement that patients with suspected cancer receive a definitive diagnosis within 28 days of referral. In April 2021, the NHS's chief medical director Stephen Powis reported that 19 out of 20 people have started their cancer treatments within one month of referral, and that mental health services are back at their pre-pandemic levels.

However, as activity has returned to normal, and people feel more comfortable re-attending hospitals, waiting lists have expanded. Meeting demand for elective care within the NHS's current capacity is viewed as unrealistic by many, and the Health Foundation estimates that spending growth would need to increase by a further £560 million a year to meet the 18-week standard by 2024. A £160 million initiative was introduced in May 2021 to help tackle the high numbers of patients on waiting lists, with additional non-financial support given to hospitals to implement innovative ways of managing the backlog.

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.

In April 2020, it was announced that a 28-faster day diagnosis standard would be implemented in full. This meant that 75% of patients referred for suspected cancer should be told of their diagnosis within 28 days of referral.

This standard has been outlined further in the NHS's 2021/2022 priorities, and an additional £1 billion of funding has been allocated to assist with the faster diagnosis objective.

In addition to the £1 billion, to support the development of Rapid Diagnostic Centres across England, £1.16 billion in funding was distributed through the Cancer Alliances, working closely with NHS England and NHS Improvement to support the delivery of cancer care.

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.

Electronic Prescription Service

The Electronic Prescription Service (EPS) was started to enable the replacement of paper prescriptions in general practice by electronic methods. It allows for prescribers to send prescriptions electronically to the patient's preferred pharmacy, which allows for more efficient and convenient prescribing. Currently EPS is in Phase 4 rollout which allows patients without a nominated pharmacy to benefit from e-prescriptions thereby expanding coverage to over 95% of all prescriptions.

Most Trusts can only prescribe electronically to their inpatients, however, with EPS, there is the possibility that out-patient prescribing may also become electronic. Most of the inpatient prescribing from Trusts is managed through the Electronic Patient Record (EPR), but some Trusts have purchased specialist software to aid e-prescribing, especially in complex treatment areas like chemotherapy. It is believed that including Trusts on Electronic Prescription Services will allow for the enhancement of the overall e-prescription market, which is beneficial for both Trusts and patients.

Workforce

The acute sector continues to face significant recruitment and retention issues. There have been particular difficulties recruiting to a permanent workforce, with a vacancy rate of around 9% across the NHS.

In July 2021, it was announced that NHS staff would receive a 3% pay rise. Although this has been welcomed across the NHS, tensions remain as it is below what was hoped for after the pressures of the previous 18 months. It follows renewed sector tensions, as the Government had previously only offered a 1% pay raise for nurses before backtracking.

International recruitment remains a focus area. Increasing numbers of medical professionals are arriving from non-EEA countries. This marks a change from the pre-Brexit environment, where greater numbers of EEA nationals were travelling to work in the UK. From 01 January 2021, EEA and non-EEA nationals are subject to the same immigration rules. These apply to healthcare workers as well.

In addition, the registration process for doctors who have non-UK qualifications has changed. EEA nationals are no longer able to benefit from the automatic recognition of their qualifications.

NHS people plan

The long-awaited NHS people plan was part published in July 2020. This followed an interim plan published in June 2019 – itself significantly delayed. The 2020 plan set out a series of well-intentioned measures, such as funding an additional 26,000 staff until 2023/24 through the Additional Roles Reimbursement Scheme and allocating £10 million to increase placement opportunities for nurses and midwives.

Although it retains focus on boosting recruitment, retention, and staff wellbeing, it has clearly been adapted as a result of Covid-19 to recognise the new challenges that the pandemic has brought. In the wake of Covid-19, a trial of a Digital Staff Passport was run to support the rapid movement of staff across NHS organisations. This showed beneficial properties, paving the way for its long-term use.

The plan follows through with the intention to devolve workforce planning to a local level, specifying that all systems should develop their own local People Plan in response to the document. These plans should be aligned with service and financial plans and are developed alongside partners – including in social care and public health. The focus is ensuring on increasing rationality of workforce plan across local organisations. It is unclear how the independent sector may fit into these conversations, but forward-thinking health systems should look to all sector providers in health and social care to get a holistic view on local workforce needs.

In July 2021, the Department of Health and Social Care asked Health Education England (HEE) to review their strategic framework for the health and social care workforce due to the shortage of workers in the sector. The updated framework is not expected until the start of 2022 at the earliest, but HEE has announced that the framework will include regulated professionals working in social care, like nurses and occupational therapists, for the first time. The new strategic direction will ensure that the workforce is adequate, and has the appropriate skills, values and behaviours to deliver high quality, world leading clinical services.

Regulation

Quality regulation and financial oversight

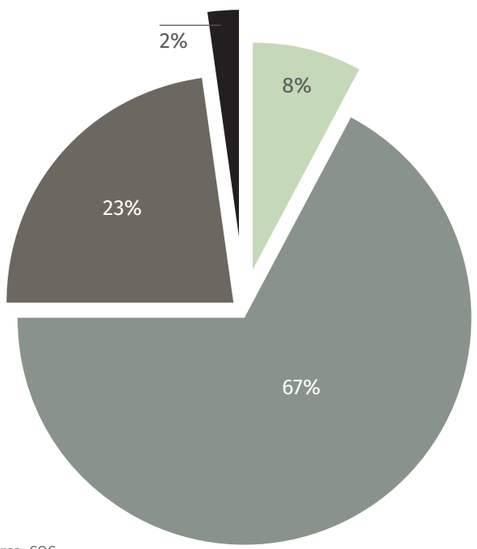
NHS Acute Trusts (and independent acute providers delivering NHS services) are regulated by the CQC. NHS Improvement has separate financial regulatory powers over NHS Trusts. Since 2019, NHS improvement has integrated closely with NHS England, but retains its status as an independent financial regulator.

Care Quality Commission

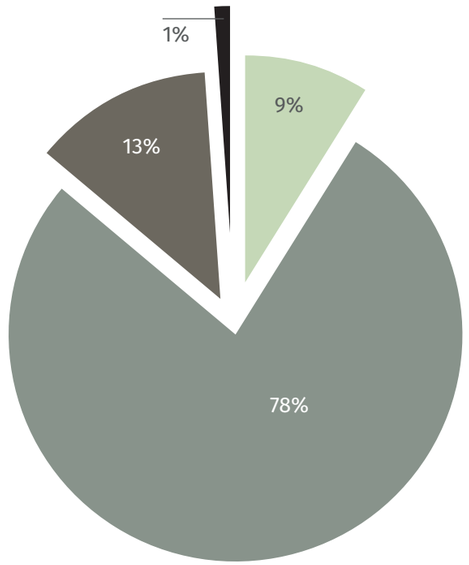
In 2019/2020, CQC inspections of NHS acute trusts showed overall improvement in the quality of care. 75% of NHS acute hospitals were rated good or outstanding, compared to 72% in the previous year. However, quality varies across the type of acute services provided. Services for children and young people perform the best, with 84% rated good or outstanding, while only 49% of A&E services were rated good or outstanding. This reflects the pressure A&E services are facing.

CQC also outlined that improvement is needed especially in community sexual health services, urgent care services and inpatient services, with around 30% of all these services rated as requires improvement. While safety was previously outlined in as a primary concern during inspections, there have since been improvements, with only 3% of core NHS trusts rating inadequate to CQC's 'Safe' key question in 2019, an improvement from 10% in 2016.

CQC Ratings of NHS Acute Trusts' Core Services



CQC Ratings of Independent Acute Trusts' Core Services



Source: CQC

Outstanding | Requires Improvement | Good | Inadequate

CQC's new strategy means regulating the NHS acute sector has shifted, with inspections occurring on the basis of need, focusing on risk and where care is poor. With the increased use of data and other tools, in-person inspections will be prioritised for worse performing trusts.

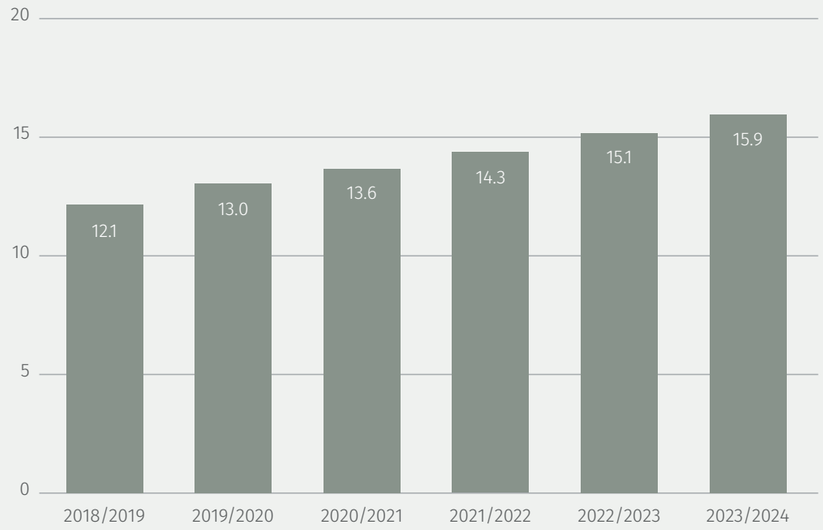
In addition, the way services work together in local systems will be assessed as a key feature of CQC's new strategy, with the aim that organisations will be held more accountable for people's care. The new strategy means that not all core services are liable to be inspected, and there may be targeted inspections around areas of interest. Safe and Well-Led remain key parts of CQC's new strategy for inspections – as they are seen as essential 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 87% 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).

Key Messages for Mental Health

- The overall NHS mental health budget is expected to increase from around £13.6 billion in 2020/21 to £15.9 billion in 2023/24
- The NHS Long Term Plan committed to increasing investment in mental health services at a faster rate than the wider NHS budget. This will deliver an additional real-term spend of £2.3 billion annually by 2023/24 – equivalent to 4.6% per year on average
- Specialised commissioning – previously the remit of NHS England – is set to be devolved to the local level. NHS-led Provider Collaboratives are likely to take the lead on future commissioning; these bodies may well provide a local forum for independent sector participation in strategic decision-making on mental health service planning
- Mental health priorities focus on early intervention, effectively supporting people in crisis, and improving community-based care. Covid-19 has increased the profile of mental health, due to the additional demand it has driven for mental health services. Children and young people's services are a primary focus, with clear KPIs measuring access and waiting times
- In April 2021, the government proposed key changes to the Mental Health Act of 1983, in response to the Independent Review of the act in 2017. They highlighted changes based on 4 key principles of: choice and autonomy, least restriction, therapeutic benefit, and putting the individual at the centre of care. These principles may indicate the direction of travel for future mental health reforms
- Traditionally, private providers have 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 a potential reduction in inpatient volumes
- Regulation in the mental health sector has come under increased scrutiny as a result of the care failings at Whorlton Hall. Reminiscent of the problems at Winterbourne View, it has placed a particular focus on the care provided to people with learning disabilities; some of the most vulnerable and isolated groups in mental health settings

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 independent providers, both for-profit and not-for-profit. 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 2019/20, the NHS spent nearly £13 billion on all mental health services, or about 14% of the total CCG budget. In 2021/22, the estimated total NHS spend on mental health is over £14 billion. The majority of NHS community and acute mental health services are funded locally by CCGs. NHS England funds specialised services, including secure services, high acuity children and adolescent 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 positive.

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

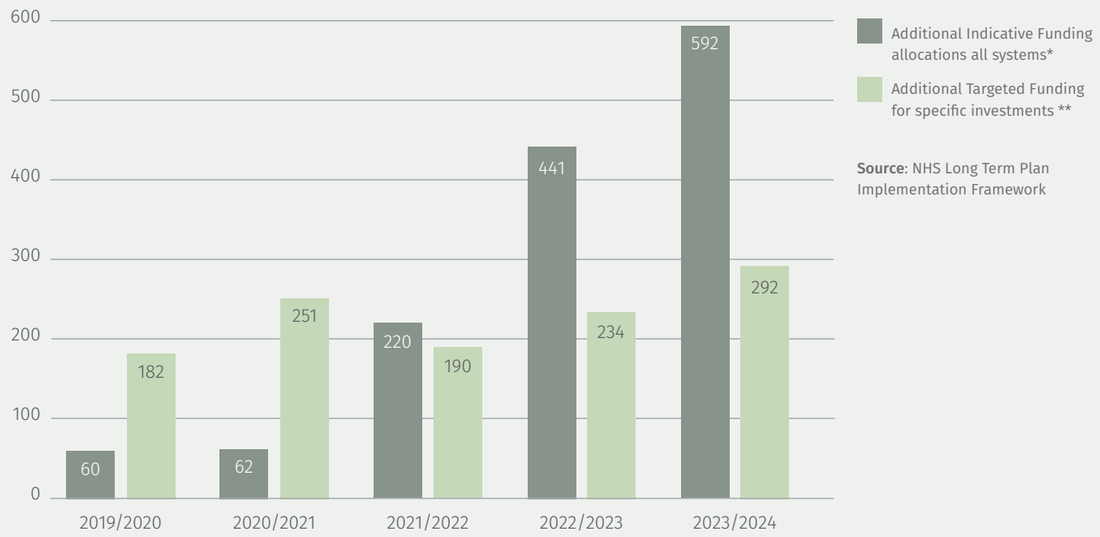
The NHS LTP confirmed spending on mental health services will increase by an additional £2.3 billion in real-terms between 2019/2020 and 2023/24 - leading to nearly £16 billion in annual spending by the end of the funding period. This is viewed by NHS England as the minimum investment level. CCGs and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

Historically, there had been difficulty in ensuring local commissioners funded mental health services appropriately, with money often diverted to under pressure acute services. As a result, NHS England instructed CCGs 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 reported meeting the Investment Standard for the first time. However, in response to concerns about whether this funding was actually materialising, NHS England independently audited expenditure. In July 2020, NHS England announced that 16 CCGs had not actually met the standard as previously claimed. In the 2019/20 period, just 10 CCGs did not meet the Mental Health Investment Standard. It is expected that all but 2 CCGs will meet the standard in 2020/21. Under the new ICS model, all ICSs will be expected to meet the mental health investment standard, and they may invest above this level if they wish.

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 access private services) and some services that do not offer regulated activities (such as self-styled

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.

Mental health payments

As set out in the National Tariff Payment System, mental health support will be paid for via a blended payment model, with the prior payment model for mental health being block contracts. The blended payment model involves trusts being paid a fixed amount based on the expected activity level and then a volume-related amount to reflect actual activity.

Other important elements included in the blended payment are quality outcome measures, the delivery of access and wait times, and an optional risk sharing agreement that provides and commissioners can utilise. However, providers can also decide to implement an alternative payment model, as long as it complies with local principles and the procedure from departing from a local currency. This change is an important way to ensure mental health services can reach the goals set out in the NHS LTP, as it will ensure mental health services will be informed by better quality and activity data.

Mental health providers will also continue to be eligible for a higher CQUIN allocation compared to other acute providers of specialised services, up to 1.25%. However, the complexity of commissioning and funding arrangements for mental health services continues to be flagged as an issue by CQC. It recognises that disjointed local commissioning arrangements can lead to fragmented, confusing pathways. The attempt to develop NHS-led Provider Collaboratives is seen as an attempt to improve commissioning arrangements.

Working Together Locally – the Changing Face of Mental Health Commissioning

NHS England is seeking to devolve significant amounts of its specialised commissioning function to the local level. The creation of NHS-led Provider Collaboratives established to manage specialised mental health services 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.

The Collaboratives will play an increasing strategic role in commissioning whole pathways of care. Integrated Care Systems must have developed plans that recognise these collaboratives by 2023/24.

The lead provider (who must be an NHS body) will be responsible for distributing the budget across partners to deliver services. It is not expected they will deliver all services in-house, and the model itself has little to address existing capacity issues currently within NHS-provided care. As a result, there will continue to be a role for the independent sector in mental health provision.

The level of independent sector involvement is likely to vary. In pilots, some providers reported being a full member of the Collaborative, whilst others were limited to working through issues on a case-by-case basis. However, the NHS England planning guidance is quite explicit that it should be "a collective of mental health, learning disability and autism providers from a range of backgrounds led by an NHS lead provider and working in partnership".

However, the independent sector is involved, reflecting the continuing shift from competition to collaboration in healthcare, and an increasing understanding that collaboration applies to all sector providers and not just those within the NHS.

Policy and legislation

Mental health in the NHS Long Term Plan

Mental health has been a priority within wider healthcare policy for many years and the NHS LTP confirms that this remains the case. 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.

There has already been some improvement in accessing certain services. For example, 80,000 more people started treatment under the Improving Access to Psychological Therapies Programme in 2019/20 compared with the previous year, an increase of 6.7%. Other improvements include the establishment of a specialist perinatal mental health community services in every STP, and standards related to children and young people's mental health services are being achieved or on track for delivery in 2020/21.

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. The shift towards more local health systems will help support responses to reduce health inequalities. 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	
ADULT MENTAL HEALTH SERVICES	**CHILDREN AND YOUNG PEOPLE MENTAL HEALTH SERVICES**
• New models of primary and community care will give 370,000 adults greater control and choice over the support they receive by 2023/24 • An additional 380,000 people per year will be able to access NICE-approved IAPT services by 2023/24 • Crisis pathways will improve, and more non-mental health staff will be trained to provide mental health support • Mental health liaison services will be available in all acute hospital A&E departments	• Funding for children and young people's mental health services will grow faster than both overall NHS funding and total NHS spending • 70,000 more children and young people will access treatment by 2020/21 • 345,000 additional children and young people will be able to access NHS funded support and school-based teams by 2023/24 • Mental health support will be embedded in schools and colleges • Funding will be made available for upstream preventative support

Recognising the impact of Covid-19 on mental health

In March 2021, the 'COVID-19 mental health and wellbeing recovery action plan' was published, which outlines the governments aims to prevent, mitigate, and respond to the mental health impacts of the pandemic during 2021/22. The paper outlines three core objectives for the COVID-19 recovery:

- To support the general population to take action and look after their mental wellbeing
- To prevent the onset of mental health difficulties, by taking action to address the factors which play a crucial role in shaping mental health and wellbeing outcomes for adults and children
- To support services to continue to expand and transform to meet the needs of people who require specialist support

The NHS will continue to monitor the pandemic's impact on mental health and the impacts of government action to improve this situation, particularly on targeted groups. This monitoring will be based on trends in self-reported mental health and wellbeing outcomes, demand and referrals for mental health services, prevalence (particularly among key at-risk groups), trends in suicide and self-harm.

Out of Area Placements

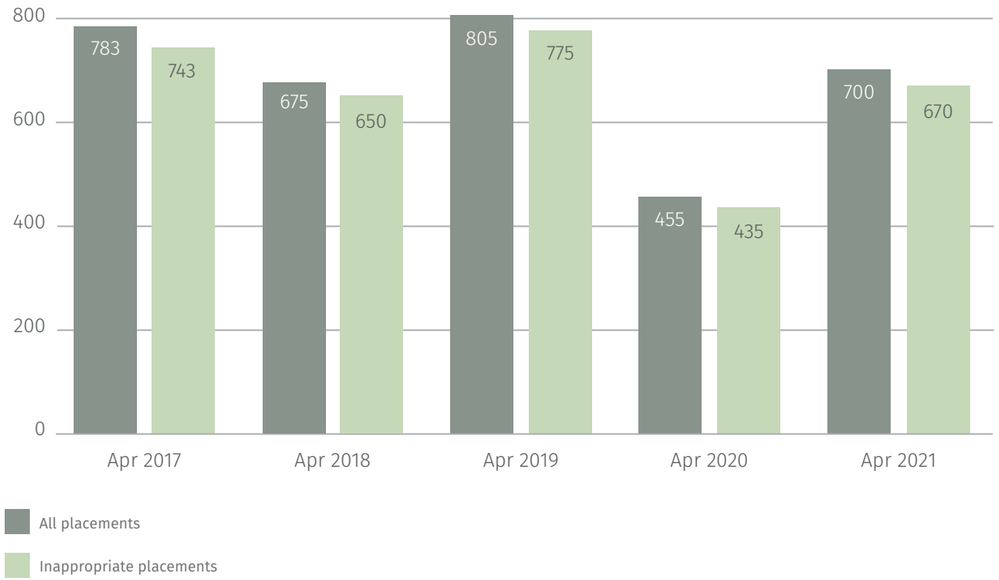
Reducing the number of out-of-area placements (OAPs) has been a policy objective in recent years. OAPs came into focus as a result of concern over the ability to provide appropriate oversight of care placements. More recently, it re-entered the public consciousness due to the media expose into care failings at Whorlton Hall.

OAPs have developed due to a long-term decline in bed availability in the NHS – in part in response to policy objectives to increase community care. The total number of NHS mental health beds fell 3% from 2019/20 to 2020/21, (18,182 beds to 17,610 beds). This has meant that local commissioners do not always have a local bed available to them, or which is suitable to the needs of the patients, and become reliant on using private provision to meet their statutory duties under the Mental Health Act.

In 2016, the FYFVMH aimed to eliminate inappropriate OAPs in adult acute inpatient care by 2020/21. This deadline was not met, but had managed to reduce out-of-area placements by 41% by April 2020.

However further progress was then impacted by the pandemic, which placed significant barriers on transitioning individuals to new locations. As a result out of area placements returned to levels only 10% below April 2017 levels.

Number of Placements Located Out of Area in Mental Health Services (2017-2021)



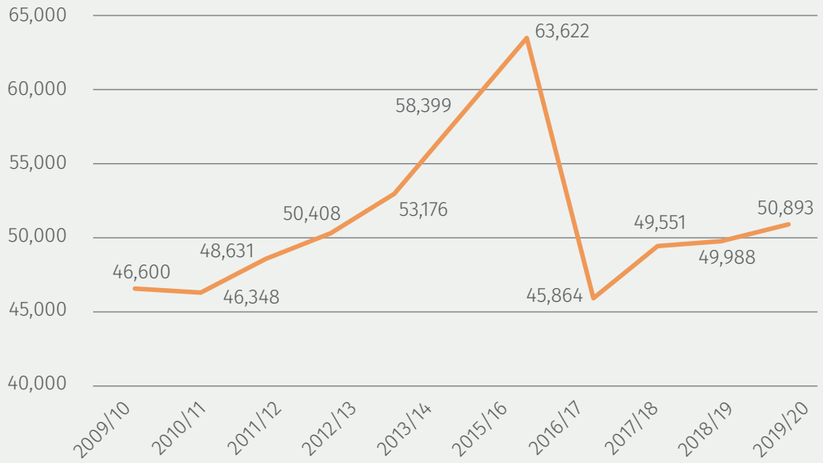
Source: NHS Digital

Mental Health Act review

The *Mental Health Act* 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. There has been an increase of nearly 10% over the last decade of people being detained.

Number of Detentions Under the Mental Health Act 1983 in NHS Facilities and Independent Hospitals (2012-2020)



Source: NHS Digital (KP90 data up to 2015/16, MHMSDS from 2016/17)

National data suggests there has been a sharp decline in mental health act detentions since 2015/16. These figures should be approached with caution due to issues in the data quality and a chance in recording methodology. NHS Digital estimated a 2% rise in inpatient admissions in 2016/17 even though it was recording a lower number. As a result, it is not viewed as directly comparable data.

The continuing increase in detentions over time has led to calls for reform of the mental health act. The Conservative Party pledged to replace it with new legislation and commissioned an independent review to form reform recommendations. Despite reporting its findings in December 2018, it took until April 2021 for the Government to publish how it intends to take forward legislative reform.

It has proposed key areas for reform regarding legislation and patient experience. The four main guiding principles that have been proposed to shape legislation and policies under the Mental Health Act are:

- Choice and autonomy – making sure people's views and choices are respected
- Least restriction – ensuring the powers of the Act are used in a less restrictive way
- Therapeutic benefit – making sure patients are better supported so they can be discharged as quickly as possible
- Treating the person as an individual – ensuring patients receive holistic and individualised treatment pathways

The Coronavirus Act 2020 was introduced to help mitigate potential shortfalls in the provision of mental health and allowed for short-term amendments to the Mental Health Act. Some changes included decisions for detainment being able to be made by one doctor rather than two, and the length of holding powers for clinicians increasing from 72 hours to 120 hours. However, the emergency provisions within the Coronavirus Act were never enforced, and the act has now expired.

Use of force

In November 2018 the *Mental Health (Use of Force) Act* was passed which provides clarity and accountability on 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, with the total number of restrictive interventions increasing from 104,931 in 2018/19 to 131,338 in 2019/20. 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. The interim report, published in May 2019, stated that the current system of care is "not fit for purpose". The full report on a Restrictive Interventions Reduction Programme is expected towards the end of 2021.

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, with updated guidance published in April 2021. The updated guidance highlighted more in-depth Mental Health Act visits will be carried out to protect vulnerable people, as well as more well-led inspections of mental health trusts and independent providers.

Data quality has been an ongoing concern within the mental health sector, and to improve regulatory oversight, CQC introduced a requirement for private providers of inpatient mental health services to report on agreed indicators from Q4 2018/19. CQC Insight – already a staple of CQC's NHS Acute Hospital monitoring – requires providers to collect and share information on a range of quality indicators. Inpatient mental health providers are expected to provide specific information on substance misuse and services for people with a learning disability.

During Covid-19, CQC has been able to make use of data collected through this process to provide national findings on the quality of care for vulnerable groups, and carried out remote "visits" to over 350 mental health wards. It has not involved singling out specific providers for poor quality care but provides trends that allow for learning across the sector.

In line with CQC's new strategy for 2021, 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 providers that 'require improvement' or are 'inadequate'. CQC can also 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.

CQC review of segregation, seclusion and restraint

CQC published a report on their findings on the use of restrictive practices on people with a mental health condition in October 2020. The focus of the report was the use of segregation and seclusion 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, the lack of a care plan to support patients returning to an open ward, and the lack of training and support for staff to allow them to best care for individuals.

CQC and concern over the quality of mental health services

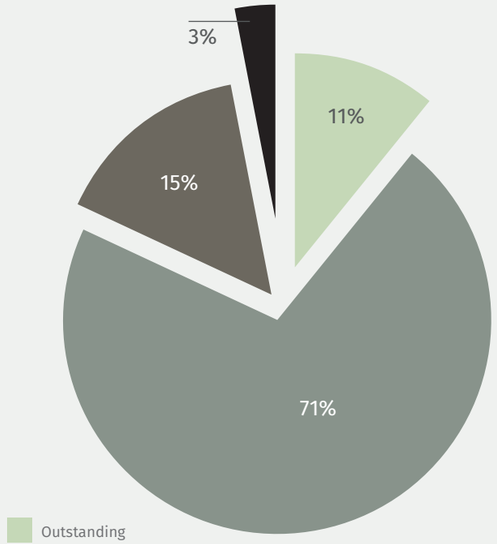
CQC's State of Care 2020 highlighted mental health as a key concern. The report acknowledges concerns about the safety of both NHS and independent services, with more than a third of services rated as requiring improvement or inadequate due to safety reasons. Exacerbating this is the lack of qualified, skilled staff which are unable to support patient with complex needs. The total number of mental health nurses has also continued to fall, with 10.6% fewer mental health nurses since 2009, a figure that may have worsened with Covid-19.

Overall NHS core services have improved from previous years where in 2017/2018, 22% of services were rated as either inadequate or requiring improvement. This year, this figure has reduced to 18%. However, independent core services have declined in quality, where in 2017/2018, 22% were rated as inadequate or requiring improvement compared to this year, where the figure has risen to 23%.

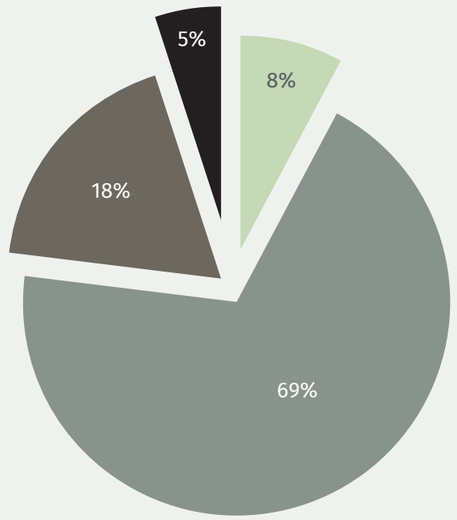
There has been a general improvement in the quality of community mental health services, while the quality of inpatient services has largely worsened, particularly in acute wards. In March 2020, 6% of these services were rated as inadequate compared with 2% in 2018, with 36% of these services rated as requiring improvement.

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. In the November 2020 Spending review, it was announced that £165 million would be ring-fenced for 2021/22 to replace dormitory wards with single en-suite rooms, but this is only a small amount of the total funding required to upgrade many buildings. A report released by NHS Providers in 2020 highlighted that there are 350 dormitory wards still in use across England which need to be replaced, and it is unlikely that the £165 million in funding will be able to sufficient for all wards.

CQC Ratings of NHS Mental Health Trusts' Core Services



CQC Ratings of Independent Mental Health Providers' Core Services 2019



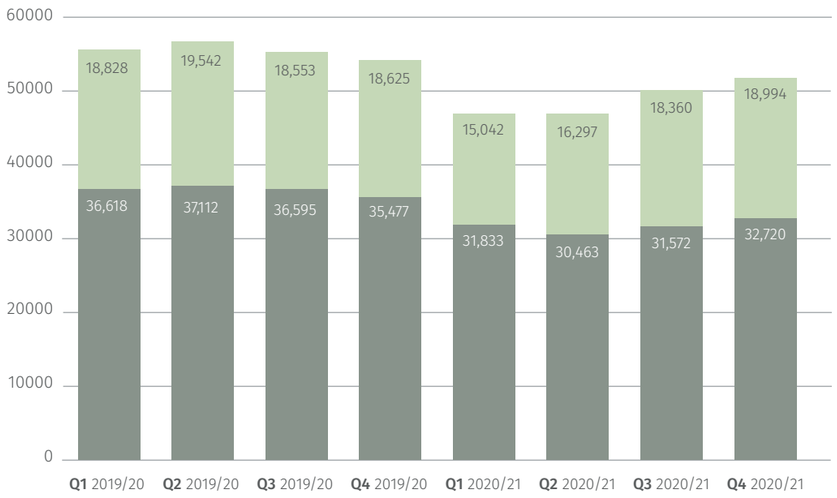
Note: Data does not take into CQC's reinspection's of providers in 2019. This will be reflected in the State of Care Report 2020, published in November 2020

Source: CQC

Key Messages for Complex Care

- In healthcare, complex care describes services that cover a wide range of conditions which 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 settings including highly specialised care in acute hospitals, ongoing therapy in community rehabilitation centres, or intensive at-home support
- The National Framework for Continuing Healthcare (CHC) and NHS-funded Nursing Care (FNC) was updated in October 2018. Changes clarified the assessments process and gave explicit guidance to CCGs and local authorities. These aimed to reduce unwarranted variation in local funding decisions across the country
- There has been a shift in the type of care package provided. Fast Track Continuing Healthcare packages (CHC) increased by nearly 90,000 in the last year, and standard CHC packages have risen by nearly 50,000 since 2019/20. Overall growth in the number of CHC packages was 135,243 in the last year, with this number having increased in the pandemic due to previously unassessed periods of care
- Pre-pandemic, the NHS spend over £4.7 billion on specialist care in the homecare (2018/19). Growth has been estimated at 3.9% and could reach £5.5 billion by 2022/23. However, this could've ramped up as a result of the pandemic as discharge plans were put in place with light-touch oversight
- CHC assessments were paused during the Covid-19 pandemic and were resumed in September 2020. From September 2020, a new national hospital discharge procedure was introduced, which highlighted that a patient's discharge would happen as soon as it was clinically appropriate to do so. This meant for a lot of patients, the assessment and organisation of continued care would take place at home, and CHC and social care assessments would take place in the community

Over the Last Two Years, There has Been a Slight Decline in the Overall Number of People Eligible for a Continuing Healthcare Package



Data: Number of people eligible for an NHS funding Continuing Healthcare (CHC) package by type (2018/19 – 2019/20)

Source: NHS England

Payers

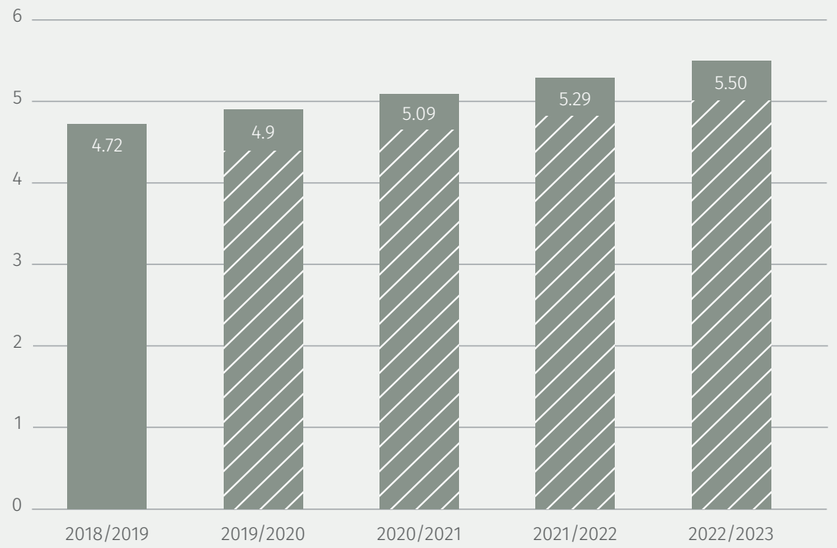
NHS continuing healthcare funding

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 in the community with high and complex needs arising from a primary healthcare need. CHC 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 as eligibility is determined through a needs assessment.

Funding CHC is currently the responsibility of local healthcare commissioners (CCGs). Once the ICS structure is fully implemented in the NHS, CHC will be the responsibility of the ICS NHS body in each region of England. Providers may also receive further funding support for individuals as a result of identified social care needs – these will be funded through local authority budgets. In some areas these may be delivered via joint budgets held between the CCG and the local authority (known as Section 75 budgets).

Spending on CHC accounts for 4.9% of the total NHS budget. In 2018/19, CCGs spent £4.72 billion on CHC across England. This is expected to increase by an average of 3.9% a year between 2018/19 and 2020/21. If this growth trajectory continues then spend could reach £5.5 billion by 2022/23.

By 2022/23, CHC Spend Could Reach £5.5bn if it Continues to Increase at an Expected 3.9% Per Year



Data: Estimated Total Expenditure on Continuing Healthcare in 2018/19 (£, bn), Marwood Analysis

Source: Kings Fund

CHC expenditure is a source of budgetary pressure for CCGs. Individuals 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 CHC 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 CCGs 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. The introduction of ICSs should reduce some inconsistencies across funding of care packages, as there may be less variation across

local areas with the overarching ICS NHS body responsible for the day-to-day running of the system. However, as high intensity providers are not uniformly located across England, it is likely that variation in service availability may still drive some differences in prices for CHC across a single ICS.

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. CCGs frequently develop local guidance in line with national guidance. A decision about eligibility for a full assessment for NHS continuing healthcare should be made within 28 days of an initial assessment or request for a full assessment.

Given the wider funding pressure on healthcare, NHS England requires CCGs to make savings on CHC spending. In 2015/16, NHS CHC cost CCGs £3.6 billion, and by 2020/21, CHC was expected to cost £5.2 billion. in 2018/19, savings were made from CHC, and CHC only cost around £3.7 billion, lower than the expected £4.72 billion. Some of these savings are expected to have come from improvements to the way data and benchmarking information is used, in addition to changes in the way services were commissioned.

However, there is no cap on NHS CHC funding, meaning all eligible patients should receive public-pay funded services. This means CHC is likely to remain an area in which there is considerable tension between CCGs' statutory obligation to provide CHC funding to those eligible and centrally driven saving targets. Nonetheless, the risk of legal challenges to decisions perceived as too restrictive is likely to induce CCGs to take a careful approach to funding decisions.

NHS-funded nursing care

Those who are not eligible for CHC funding and live in a nursing home may be eligible for NHS-funded nursing care. All CCGs are required to pay a weekly standard rate, which was set at £187.60 from April 2021. This is a 2% increase on 2020/21, when the rate was £183.92. ICSs will similarly be responsible for maintaining this weekly standard rate. Payments are made directly to providers and are intended to cover some of the individual's nursing care costs.

Policy and legislation

Wider complex care policy

Complex care does not attract 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 different strategies, such as mental health or learning disability. This can reduce national visibility on key issues affecting those with complex needs.

Updates to national eligibility frameworks for complex care

The Department of Health and Social Care published an updated national framework for both CHC and for NHS Funded Nursing Care (FNC) in October 2018. This followed a Public Accounts Committee inquiry which recommended changes to reduce variation in how care was assessed and delivered locally.

The National CHC framework further refines 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 reduce the variation between different areas.

ICSs will soon be responsible for determining an individual's eligibility for CHC and for commissioning appropriate services.

Key changes under the 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 should develop their own dispute resolution processes to deal with disagreements at a local level, and as quickly as possible

After the publication of the Integrated Care Services, it was highlighted that for continuing healthcare, NHS nursing care assessments, and for Care Act assessments, updates to hospital discharges will be brought forward. A legal framework called the "Discharge to Assess" model will allow for assessments to take place after an individual has been discharged from acute care. The Discharge to Assess model will not change the thresholds of eligibility for CHC or support through the Care Act.

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 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.

Complex care during Covid-19

During the early stages of the pandemic, there was a great focus on ensuring that people were discharged as swiftly from acute settings as possible. This was to free up as much bed capacity as possible in advance of a surge in Covid-19-related admissions.

As a result, the government enacted emergency legislation that allowed the NHS to discharge people out of hospitals without undergoing the routine discharge assessment process, leaving many thousands of patients nationally who have been provided with care packages without assessment.

From 01 September 2020, CHC assessments resumed and there was a change of process implemented to assess approaches in line with the hospital discharge service. The key priority was to ensure that NHS CHC and Care Act assessments were carried out and that eligibility decisions were confirmed within 6 weeks following a patient's discharge from hospital. In addition, there was a commitment to undertake NHS CHC referrals that were received after 19 March 2020 (which was when patients were discharged under the emergency legislation) and 31 August 2020. During the emergency period, the NHS paid for extensions of existing care packages and support for patients who were discharged from the hospital, or who otherwise may have been admitted to hospital. However, after 01 September 2020, this emergency funding budget would not fund new packages of support for patients but will continue to provide care package support to patients it funded between 19 March and 31 August 2020.

Social Care in England

Social care provision in England is primarily the responsibility of local authorities. However, national government exerts a high degree of control over both levers which affect local authority decision-making. Health and social care are split between two different funders:

- A health need will be funded through the NHS, and ultimately by the Department of Health & Social Care
- A social care need – if a person meets both the needs and eligibility thresholds – will be paid for by a local authority. For children who require a high level of support (a EHC plan), their support costs should be split between two different internal local authority budgets – and local health service may also be required to contribute

Central government is responsible for setting a local authority's budget, but social care is not directly ring-fenced so local authorities can choose to spend money how they wish. However, they will be required to meet their statutory responsibilities. Growing demand has meant that increasingly local authorities are reducing non-statutory services to ensure funding is available for statutory needs:

- Statutory responsibilities for adult social care are set out in the Care Act 2014
- Statutory responsibilities towards children and young people care needs are set out in the Children and Families Act 2014

Increasingly government has been exerting indirect centralised control by establishing ring-fenced conditions for funding. The improved Better Care Fund (iBCF), which compels money to be spent on clearly defined priorities, and the establishment of the Social Care precept, both force local authority revenue to be directed towards social care objectives. There is also standalone legislative power that will continue to support the Better Care Fund (BCF) and separate it from the mandate setting process for control over social care. The BCF will be £6.9 billion in 2021 to 2022, including £4.3 billion of NHS funding and £2.1 billion from the iBCF grant to local authorities and £573 million from the Disabled Facilities Grant (DFG).

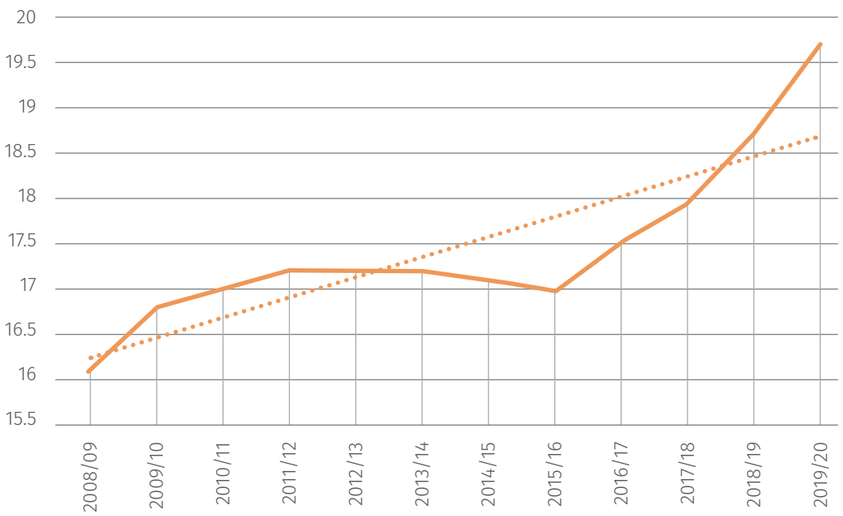
So long as they meet their statutory obligations, local authorities are currently free to set their own policy goals in relation to adult and children services. This can involve setting the overall strategic direction, balancing in-house versus outsourced care delivery, setting rates that providers are paid for services, and the level of need a person must experience before qualifying for care.

Greater oversight may come with the impeding Health and Care Bill. This is set to extend CQC's powers to give them a legal duty to assess local authorities' delivery of their adult social care duties. Furthermore, the Secretary of State will be granted a greater intervention power where the CQC reports failure in local authorities' duties. The Secretary of State will also be able to make direct payments to any direct providers of social care services in England.

The question of social care funding reform has come back into focus in recent months. High-level political discussions between the Prime Minister, the Treasury and the Health Secretary were derailed by the sudden resignation of Matt Hancock. However, he announcement in September 2021 of reforms to the social care system in England, show that the issue is being seriously considered.

Social Care: An Overview 3

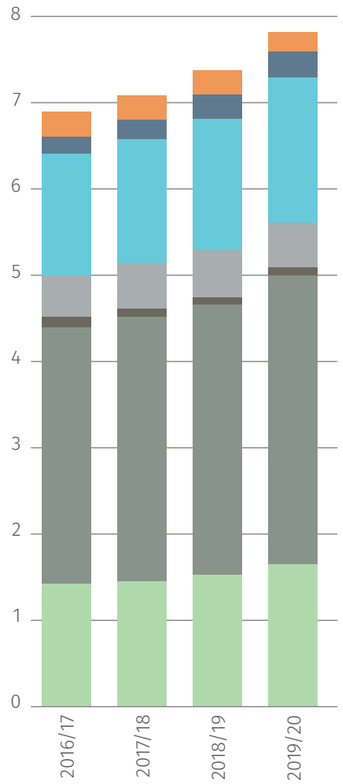
Overall Public Expenditure on Adult Social Care has Begun to Grow Since 2015/16, After Several Years of Funding Restraint



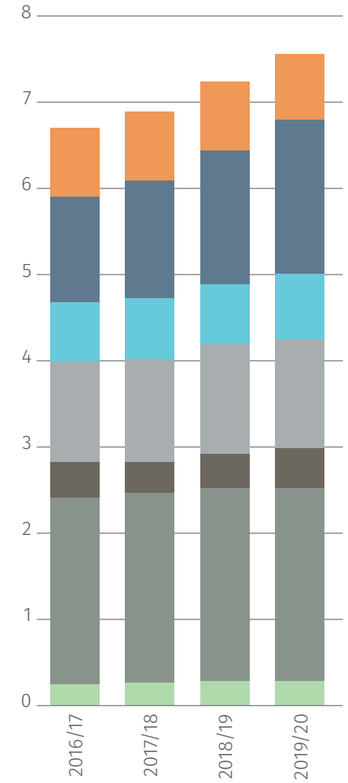
Data: Gross current expenditure on adult social care (£, bn)

Source: NHS Digital, Marwood Analysis

Spending on Older People Social Care by Support Setting (2016-2019)



Spending on Working Age Adult Social Care by Support Setting (2016-2019)

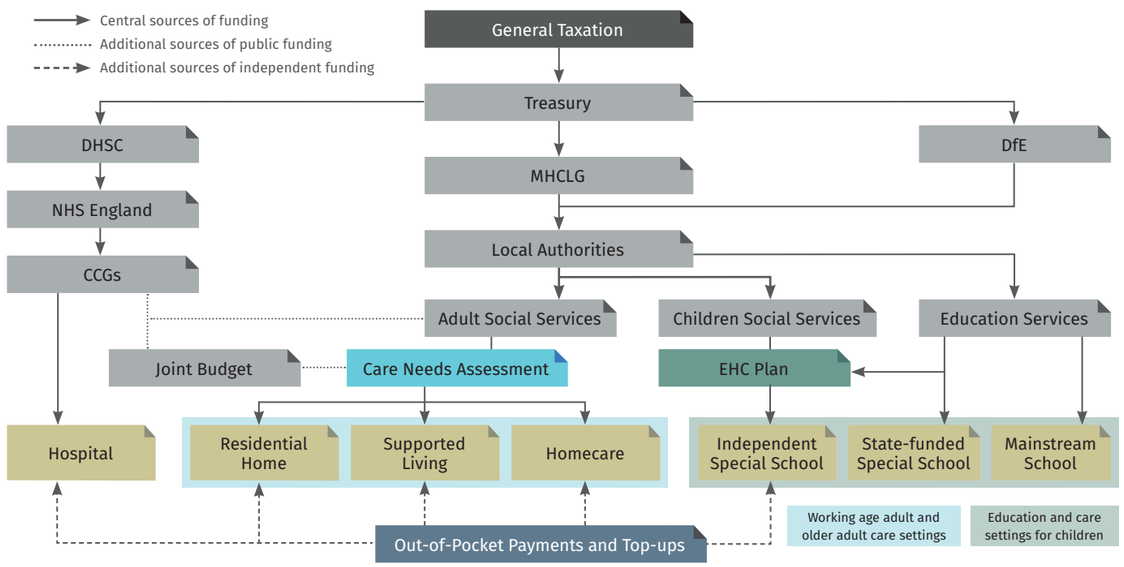


Data: Gross current expenditure on long-term care for clients aged 65 and over, by support setting (£, bn)

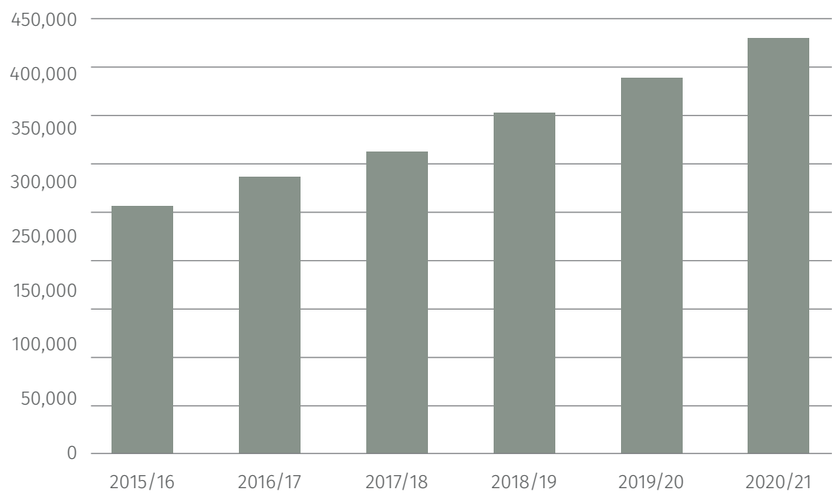
Source: NHS Digital, Marwood Analysis

- Other Long Term Care
- Supported Living
- Home Care
- Direct Payments
- Supported Accommodation
- Residential
- Nursing

Funding Flow into Social Care Providers



The number of children requiring SEND support



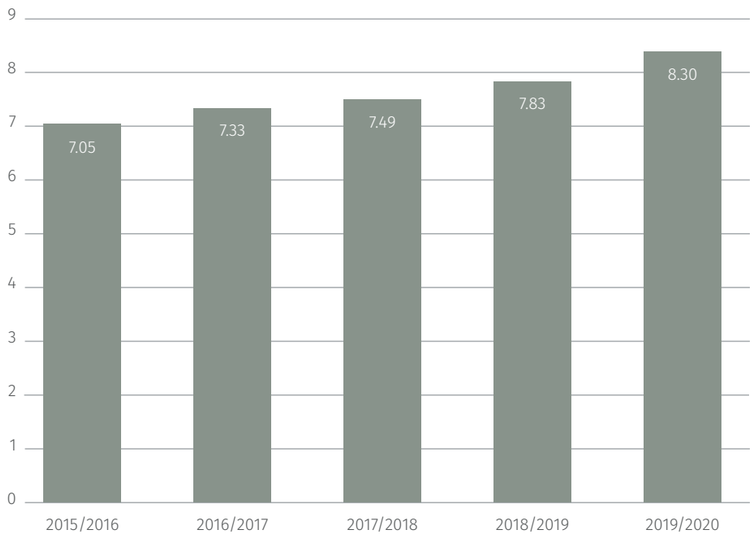
Data: Number of Children and Young People with EHC Plans or Statements of SEN

Source: Department for Education

Key Messages for Older People's Care

- Older people's care in England refer to services supporting individuals 65 years and older 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 18.7 million in 2045, with nearly 25% of the population being over 65
- Around £12 billion in social care funding comes from public payors. This includes local authorities spending more than £7 billion on older people's social care services. Increasingly top-up funding comes from other sources; with approximately £1.5 billion annually coming from the Improved Better Care Fund, up to £2.4 billion from a locally raised 'social care' precept, and the government promising an additional £1 billion each year ringfenced for social care
- Public pay users who most contribute towards their care account for a further £2.9 billion in funding. Pure private pay is estimated to make up more than 40% of the older people care market, drawing in over £11 billion in revenue annually
- The Covid-19 pandemic had a major impact on the social care sector. Occupancy rates in care homes plummeted, although the impact was not evenly distributed through the system. Whilst occupancy rates are returning, the pandemic may support the longer -term shift from care homes to homecare, as a result of residual concern from users and relatives about the safety of residential placements as anxieties over Covid-19 variants persist the near-term
- The pandemic has also forced the government to face the funding sustainability issue within social care. Proposals have yet to be clarified, but reforming social care is a key pledge made by Boris Johnson, and will no doubt be a key priority for the new Health Secretary Sajid Javid
- To support the policy direction towards more integrated health and social care, the use of digital technology is being expanded in older people's care. This has been supported with dedicated funding and a range of programmes to accelate the adoption of innovative programmes within the care sector

Direct Local Authority Expenditure on Older People's Care has Risen in Recent Years – and has Required Further Support from Central Government Budgets to Sustain Care Levels



Data: Gross Current Expenditure on long- and short-term care combined for over 65s, 2015/16 – 2019/20 (£, bn)

Source: NHS Digital

Note: Funding does not include additional money spent on public pay older people care through the Integrated Better Care Fund, or via locally raised revenue, such as the adult social care precept

Payers

Overview of social care funding for older people

Social care provision for older people is the responsibility of local authorities. The Care Act 2014 sets out statutory responsibilities 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. As a result, there are two main payers for older people's social care in England: local authorities and individuals. Many people find themselves responsible for either fully or part-funding the cost of their care in later life.

Eligibility for public funded support is via 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.

Multiple funding streams for older people's social care

Whilst adult social care providers will receive one payment for a public pay care package, it is important to be aware that social care funding can come from multiple sources. This leads to a great deal of complexity in local authority budgeting, and means that revenue sources are subject to different levels of protection.

Local authorities receive money to fund social care services as part of their core funding they receive from central government. This is not ringfenced, so they do not have to spend it on adult social care services. However, they do have statutory responsibilities, and so in reality, a large proportion of money will be used to deliver these services.

Alongside this, local authorities are also able to raise local revenue through the adult social care precept. As outlined below, the amount levied will vary according to local factors. In government funding assumptions, local authorities raise the maximum allowable under the precept, however local pressures may lead to a local authority waiving it, and therefore the local funding picture can vary from area to area.

In the 2020 Spending Review, it was announced that local authorities would be able to raise the maximum precept to 3% for adult social care, which was introduced alongside an additional £300 million grant for adult and children's social care, allowing for greater financing of social care across England. The maximum precept for adult social care in 2021 will also stay at 3%.

Funding also is delivered through direct government allocations. These come as ringfenced allocations for local authorities and must be spent on social care provision. In recent years, this has been a key element of spend with the Improved Better Care Fund delivering over £2.1 billion in 2020/21. This funding was combined with the £240 million winter pressures grant for 2020/21.

A final element is user contributions to their care. These are people who are receiving public-pay support but must also provide a top-up fee for their care. This is a significant additional revenue stream for providers – and totalled £3.1 billion in 2019/20.

Additional funding for social care

Whilst the funding environment remains under significant pressure, the sector has been sustained by ongoing additional allocations from central Government. This totalled nearly £4.5 billion between 2017/18 and 2019/20.

The direct allocations safeguarded funding for social care services but did not provide long-term sustainability, and were viewed as little more than a sticking plaster to prevent against possible provider withdrawal from the n the public-pay sector. The lack of sustainability can be seen in the Health and Social Care Committee's October 2020 report on adult social care and funding calling for an additional £3.9 billion to address the shortfalls of the sector.

In the 2019 and 2020 spending round, councils were granted an extra £1 billion for social care. This was through a further direct grant. The Government signposted an additional £500 million, although this money was raised through the adult social care precept, and so is directly generated by local authority revenue raising.

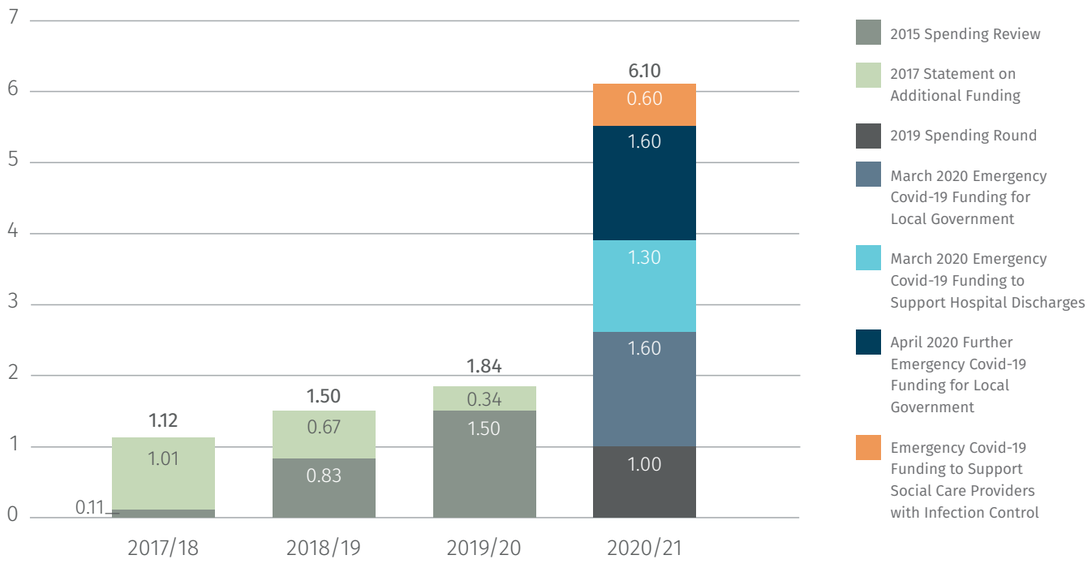
As the funding is allocated to local authorities directly, they are responsible for deciding how it should be spent. However, they must be able to demonstrate that spending is contributing to wider policy objectives. In particular, it should support reducing the length of hospital stays and help the 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.

The social care sector has received further emergency support as a result of the pandemic. While much of this financial support does not directly go to providers, commissioners have used it to meet costs related to Covid-19. This has included:

- £1.6 billion funding for local government in March 2020
- £1.3 billion to support hospital discharges in March 2020
- £1.6 billion further funding for local government in April 2020
- £0.6 billion to support social care providers with infection control

Provision of free PPE to health and social care workers has been extended until March 2022, and social care providers can access emergency supplies of PPE if needed through their local resilience forum (LRF).

Additional Non-recurrent Adult Social Care Funding from Central Government (£, bn)



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% and remained at this level until 2019/20. The majority of local authorities have made full or close to full use of this increased flexibility, and is estimated to have raised an additional £1.8 billion in 2019/20
- In 2019/20 and 2020/21, the social care precept maximum remained at 3%

Domiciliary care services

There has been growth in homecare provision over the last five years, with the number of registered homecare providers growing by 19%, and over 249 million hours of care delivered per year.

The overall market for older people homecare support is estimated to be over 630,000 – with over 580,000 receiving public pay support.

Prior to the pandemic, funding on community care began rising after long-term declines, with a 9.2% increase in 2017/18. However, community care is facing greatly increasing costs in the wake of Covid-19, and there are concerns that the local authority changes to care fee rates for the next year will not be sufficient.

Private providers delivering local authority contracts remain 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.

Covid-19 may have longer-term positive impacts on the homecare sector. Whilst there are challenges in delivering care – and provider costs will have increased – families and people who use services may view homecare as preferable to care home admission, with a perception that it is a less risky proposition.

Care home services

There has been a decrease in the number of registered care homes in recent years, with the number of residential homes decreasing from over 12,500 to 10,100 between April 2014 and April 2021. This represents a 19.2% decline. During the same period, registered nursing homes also fell – from 4,699 to 4,104.

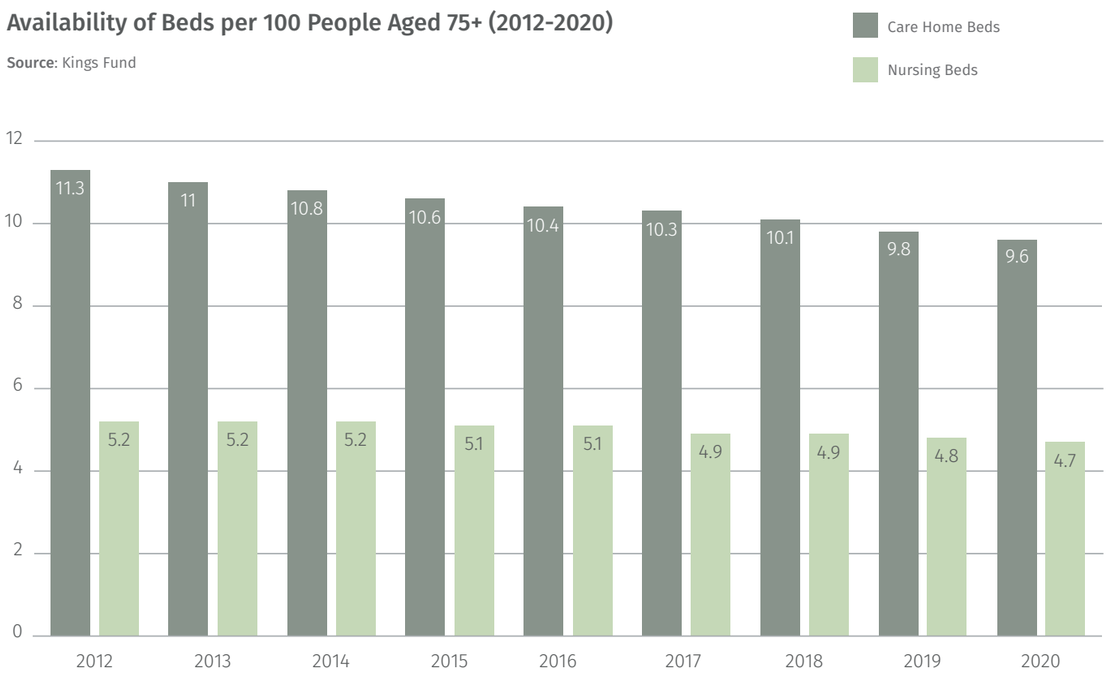
Since multiple care home locations may be registered by a single provider, and some providers chose to separate out the legal entities into separately registered locations, it is difficult to gauge the overall impact on the total number of providers.

The changes likely reflect some areas of greater consolidation in the sector, where smaller providers have been unable to remain competitive against a backdrop of rising cost pressures.

However, the declining number of care home beds per 100 over the last decade suggests the total capacity of the market is shrinking – if not through market contraction, then through growth in the total number of older people.

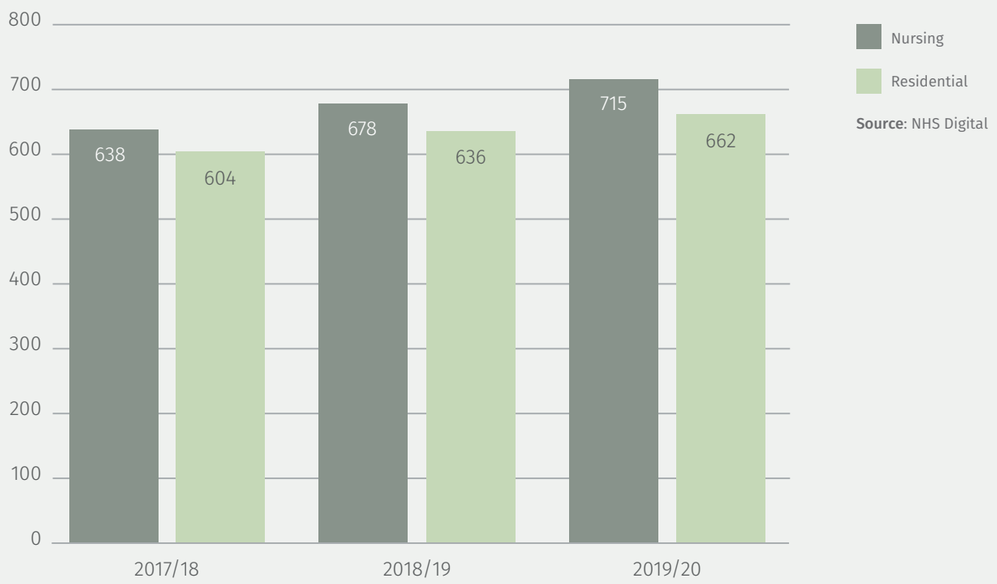
Availability of Beds per 100 People Aged 75+ (2012-2020)

Source: Kings Fund



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.

Average Weekly Unit Costs for Individuals Accessing Long Term Support in Nursing and Residential Care for Over 65s, 2017-18 to 2019-20 (£)



Source: NHS Digital

Policy and legislation

Boris Johnson has made consistent pledges to 'fix the social care system'. Prior to the emergence of Covid-19, it seemed that this was further empty rhetoric with the government showing little inclination of grasping the problem of providing a sustainable solution to older people's care. The proposed approach was to constitute a cross-party commission – something tried multiple times over the last twenty years with very little success in embedding long-term policy change.

In the 2019 conservative manifesto, Boris Johnson pledged to build a cross-party consensus to bring forward an answer that solves the problem long term and commands the widest possible support. They also promised £1 billion extra of funding every year for more social care staff and better infrastructure, technology and facilities.

However, in March 2021, Boris Johnson announced to the House of Commons liaison committee that social care reforms were under-way, and that a 10-year plan on social care reforms would be announced later in this year. In September 2021, changes to the social care sector in England were announced, as well as an additional £12bn a year for health and social care from a new hypothecated tax.

The key issue the government is looking to tackle is the high costs of care that some individuals face. Helen Whately, the Care Minister, emphasised the fact that individuals should not be forced to sell their homes to receive care provision. Boris Johnson will introduce a cap on care costs, meaning £86,000 will be the upper limit on the amount an individual can expect to pay for their care over their lifetime. Once the cap is reached on an individual's lifetime spend, their future care costs will be paid by the UK government.

This proposal is similar to the approach proposed by the Dilnot Commission in 2011, which emphasised the need for making means-testing for social care more generous.

This type of reform may be beneficial for individuals requiring social care, and for providers delivering services as it reduces concerns over finances for many individuals.

If the government does introduce this reform to social care, questions will be raised as to how much the government is willing to pay on the remaining lifetime spend for individuals.

Historically any reform attempts have been unpopular with the public – as it will require additional revenue to be generated from the tax base. The issue is viewed as being the reason why the Conservatives had such a poor election result in 2017 – ultimately leading to Theresa May position as PM becoming untenable and paving the way for Boris Johnson.

However, there is a growing understanding that the system is in crisis – and the increased visibility of the sector during the pandemic has created a window of opportunity where people may be more willing to pay if money was clearly ringfenced towards improving care services.

Improved Better Care Fund (iBCF)

The iBCF spans the NHS and local government and aims to join-up health and care services, so that people can live independently for as long as possible. Previously known as the Better Care Fund (BCF), it encourages integration by requiring CCGs and local authorities to enter into pooled budgets arrangements and agree an integrated spending plan.

In 2020/21, £6.7 billion was pooled in the BCF, comprising of £2.1 billion in the iBCF, £0.6 billion in the Disabled Facilities Grant, alongside the minimum contribution from CCGs of £4 billion. Funding levels have been maintained in 2021/22.

In 2019/20, over 90% of local authorities stated that they would be using the funding to increase the fees they pay to independent providers for homecare, as well as older peoples residential and nursing care. It was estimated that average homecare fee rates would increase by 4.3%, older people residential fee rates by 4.9%, and nursing home fee rates by 4.7% respectively when compared to the previous year. In 2020/21 much of the focus was on how local authorities could use the funding as extra support for the pandemic, particularly managing mental health post lockdown.

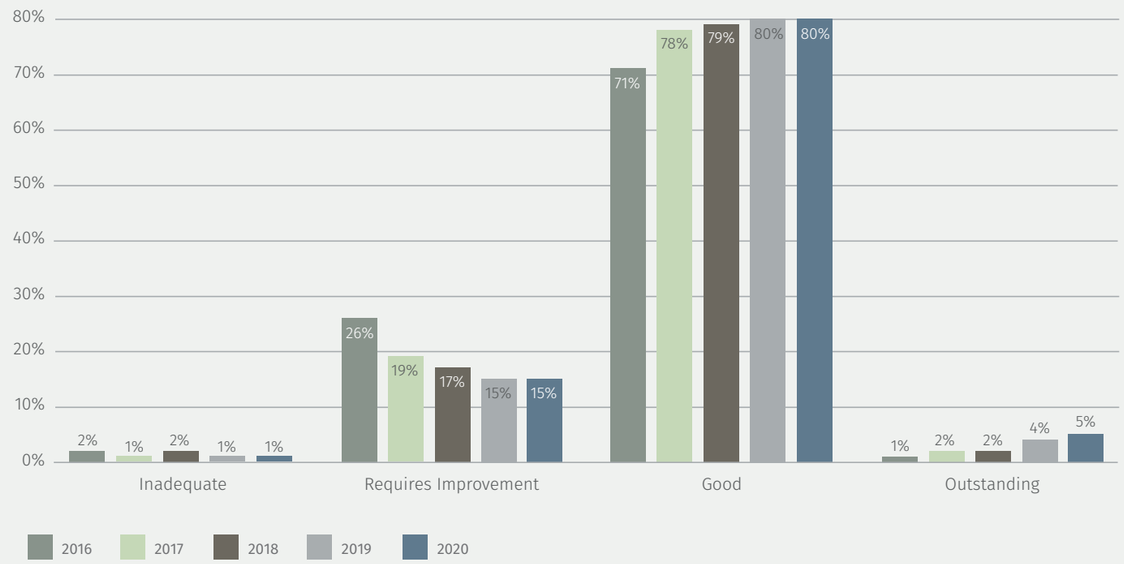
Regulation

CQC is responsible for regulating adult social care services. Its main function is to register, inspect and monitor providers. In line with CQC's new strategy for 2021, inspections will be carried out when there is a clear need to do so, meaning they will be increasingly targeted at poor 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.

Since 2016, CQC ratings have increased, with more providers receiving Good or Outstanding inspection ratings in recent years. This demonstrates a positive environment for social care, as standards have been increasing over the years. It is also positive for providers receiving Good and Outstanding inspection reports, and demonstrates the growing number of high-quality providers.

CQC Ratings of ASC Providers (2016-2020)

Source: CQC



CQC paused routine inspection activity during the pandemic. This reflected the challenge of inspectors being able to visit locations and the pressure on providers in managing infection control.

However, given the potential risk to individuals as a result of poor quality care, independent regulatory activity was maintained through the Emergency Support Framework (ESF). This risk-based tool aimed to highlight were safety red flags were emerging.

26% of issues flagged via this new tool related to lack of PPE or other infection control products, whilst 32% included concerns about how infection control or social distancing were being practiced at the service they worked in. However, only 4% referred to quality of care being impacted by Covid-19.

As of April 2021. CQC have resumed inspection activity where there were key safety concerns. Inspections focussed on infection, prevention and control (IPC) to ensure people received safe care. Additional capacity services were also reviewed when inspections resumed so that local authorities could be more supported as they navigate through the next stages of the pandemic.

CQC has taken this learning into account as it plans its future approach to inspection in line with its new strategy. It plans a more targeted approach that builds on its data gathered through its monitoring function. There is a concern from providers that CQC may adopt an approach that looks primarily at risk – and as a result makes it more difficult to highlight good and outstanding practice. However, high-performing providers may benefit from increased gaps between inspections.

Spotlight On Fixing Social Care In England

In September 2021, the Prime Minister announced reforms to the social care system in England, alongside funds of £12bn a year for health and social care from a new hypothecated tax. The funding will impact health and social care budgets from April 2022 and will initially be raised from an increase of 1.25% in National Insurance Contribution.

Successive governments have long recognised the need to fix the social care system, but most have avoided the issue due to the political risk involved. Although the government has badged the plans as a critical to ameliorating the social care sector, the funding announced will primarily be targeted towards recovering the NHS after the pandemic. An estimated £15bn to NHS England and a further £10bn for non-NHS 'health' budgets.

£6bn will also be distributed across Scotland, Wales and Northern Ireland, while approximately £5.4bn will be targeted towards social care services over the next three years. Over the longer-term horizon, it is expected that a greater proportion of funds will be directed towards social care in England. However, detail of how that will be achieved has not yet been made public and there is some skepticism in the sector about this.

The major changes in social care will involve the creation of a lifetime cap on care costs, so that no individual will ever have to pay over £86,000 for care in their lifetime. The eligibility threshold that determines how much an individual must contribute towards the cost of their care will also be adjusted. Currently anyone with assets over £23,250 must pay their care costs in full.

From October 2023 the system will change so that anyone with assets worth less than £20,000 will have their care costs fully covered by the government. Further, anyone with assets between £20,000 and £100,000 will be expected to contribute to the cost of care but will also be eligible for some means-tested support. It was also announced that the system will be made fairer, so that people who pay for their own care do not have to pay more than public-funded individuals for equivalent care. It is also anticipated that a White Paper on health and social care integration will be published in the next year.

Market oversight and preventing provider collapse

Since 2015, CQC have been responsible for monitoring the financial sustainability of social care providers which 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.

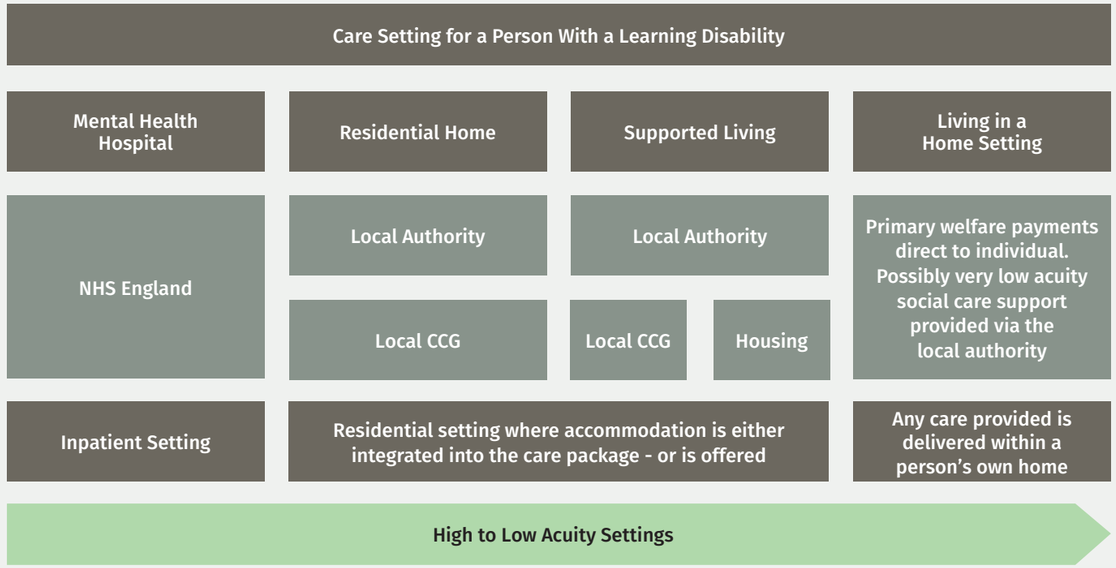
CQC's Market Oversight Team focuses on providers who either have a large national profile, or those that hold a large presence in a particular geographic region making them difficult to replace in case of failure and consequent service disruption. It includes both domiciliary care and care home providers.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

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.

Key Messages for Learning Disability Services

- There are estimated to be around 1.2 million people with a learning disability in England, over 950,000 of whom are aged 18 or older. This is projected to grow by 34% in 6 years in line with changing population demographics, as the number of older individuals will increase. In addition, an increased awareness of learning disabilities and changing diagnoses practices will lead to more individuals seeking support
- The policy landscape continues to seek to move all individuals out of inpatient care – viewing it as an inappropriate service model for people with learning disabilities. 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 with a learning disability, autism or both per million, will be cared for in an inpatient facility
- Spending on adult learning disability services has been relatively well protected during austerity compared to other elements of local authority spend and has been increasing year-on-year. In 2020, total local authority spend on learning disability was £6.1 billion, up from £5.8 billion in 2019. The majority of expenditure is on working age adults
- A wider lack of sufficient public capital investment in infrastructure – alongside a tough regulatory approval process for new buildings – has limited additional capacity for those transitioning out of inpatient environment
- Following a care failure scandal at a mental health hospital that provided inpatient support for people with a learning disability, there has been a renewed focus on time-limited placements and reducing the use of out-of-area placements

Adults With a Learning Disability May Receive Public Funded Care in a Variety of Settings; the Setting Location is Likely to Play a Role in Which Public Body is Primarily Responsible for Funding the Support Required



Payers

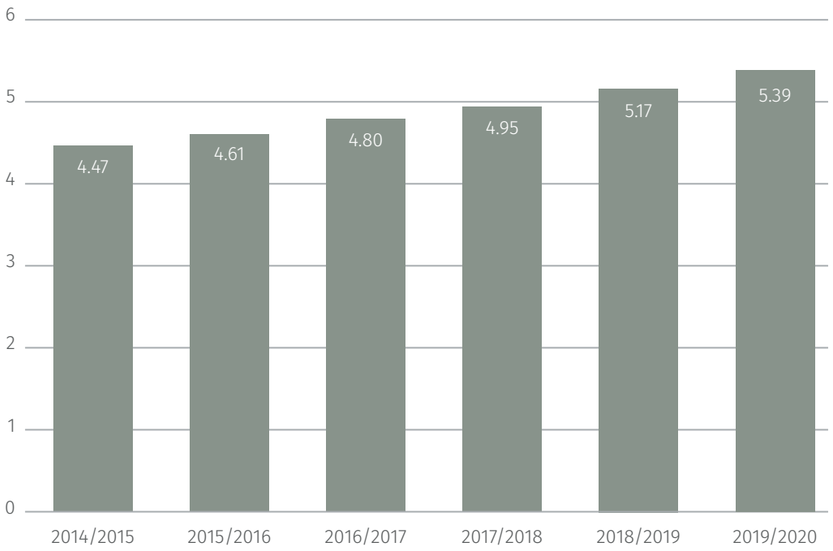
The three primary payers of learning disability services are NHS England, CCGs, and local authorities. NHS England and CCGs are responsible for funding most inpatient services, whilst local authorities finance community services. With national policy initiatives focussing on moving individuals with learning disabilities out of hospital into community settings, local authorities are increasingly responsible for a higher proportion of overall spend on learning disability provision. However, under ICSs, CCGs will be merged into new groups, and should assume the responsibility of former CCG commissioners. In practice, this will not affect the power local authorities and CCGs have over their spending on learning disability services, but it will allow for greater coordination and more consistent access to services.

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.

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.

Overall pressure on funding sustainability is 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 2019/20, local authorities spent over £5 billion on learning disability support for working age adults. Total spend, which includes NHS specialist care for people with a learning disability, and wider welfare support payments, is over £8 billion. The government has also confirmed that as part of the Improved Better Care Fund (iBCF), the Disabled Facilities Grant will continue in 2021/22, and will be worth £573 million.

Local Authority Expenditure on Learning Disability Support for Working Age Adults has Been Increasing Since 2014



Data: Gross Current Expenditure on long and short-term learning disability support for clients aged 18 to 64 in England (£, bn)

Source: NHS Digital

Policy and legislation

Funding incentives to shift payments towards community care options

The Transforming Care Programme was established in 2015 in order to support policy drivers in moving learning disability care into community settings. This did not require a major shift in budgetary allocations, and instead focussed on time-limited budgets. Initially, NHS England provided Transforming Care Partnerships (TCPs) with short-term support of £30 million over three years. The aim was to try and keep the overall sum of money that payers spend on learning disabilities the same but reallocate funding 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 was developed for particularly high-cost individuals. In these cases, the money would 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. It has been suggested that this has had limited utility given the strict criteria for use.

One of the major barriers has been the lack of appropriate community housing, and £100 million of capital investments over five years was made available for local authorities to invest in housing infrastructure. In many situations, this would have been funded through infrastructure built by private providers.

However, despite this extra support, it became clear that the planned objectives of the Transforming Care Programme were not going to be met. As a result, NHS England has maintained ad-hoc payments to maintain policy momentum. In 2017, an additional £76 million was provided to accelerate the development of community learning disability services and increase service capacity. However, this wasn't all 'new' funding, as it included £53 million released through the decommissioning of specialist inpatient services.

The 2020 March Budget unveiled further funding for the sector, promising £62 million for local councils and transforming care partnerships to help on costs associated with discharging people with learning disabilities or autism back io the community.

The NHS Long Term Plan

In recent years, learning disability policy has focussed on a shift from inpatient to community service provision. The NHS LTP outlines how the health service plans to build on 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. Whilst the NHS LTP focusses on positive achievements, it is important to note that many of the ambitions of the Transforming Care Programme were not achieved – with the attempt to move people out of inpatient facilities progressing more slowly than planned.

NHS England failed to meet their previous target of reducing the number of inpatient beds by 35-50% by 2019 for those with learning disabilities. The NHS LTP therefore acts as an unofficial reset of the target, by extending the deadline to 2023/24. The new ambition is to reduce inpatient provision for those with a learning disability or autism to less than half by March 2023/24. For every million adults, there will be no more than 30 people with a learning disability and/or autism cared for in an inpatient unit. For children and young people, there will be no more than 12 to 15 children with a learning disability, autism or both per million cared for in an inpatient facility.

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. The developing NHS-Led Provider Collaboratives are seen as a vehicle that may drive decisions over local spend. In addition, the LTP notes that, where possible, people with a learning disability or autism should be able to access a personal health budget, meaning that among lower-acuity adults with a learning disability, there may be a growth in user decision-making over their care.

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.

Out of area placements

The events exposed at Whorlton Hall have placed the issue of out of area placements (OAPs) 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 OAPs has 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 eliminate inappropriate OAPs in mental health services (including learning disabilities) for adults within acute inpatient care by 2021. Inappropriate OAPs are those in which patients are sent out of an area because no bed is available for them locally, which can delay their recovery.

OAPs cost more to the NHS and can also have a negative impact on the person receiving care as it separates them from friends and family. However, the failure to place an individual within their local area is usually the result of a lack of available appropriate local capacity rather than an ignorance of government policy objectives. Commissioners often must balance competing policy objectives: the requirement to provide timely and safe services to those in need against the objective of reducing OAPs. An OAP may be all that is available at that moment to meet an individual's immediate need.

An NHS Digital report on OAP s 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 675 in April 2018 to 845 in March 2019. However, in April 2020, OAPs fell to 455. The speed of this drop should be treated with caution, as it may have been related to poor data-keeping during the Covid-19 pandemic. The number of OAPs rose again after this point, and reached 700 in February 2021.

Remuneration of sleep-in shifts

In March 2021, the Supreme Court published its long-awaited decision on the liability of employers paying national minimum wage (NMW) for workers asleep on live-in shifts.

This case has rumbled through the courts for a number of years, and in 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 Supreme Court agreed with the Court of the Appeal. It dismissed the arguments that sleeping workers were entitled to NMW. This is line with recommendations from the Low Pay Commission.

Employers no longer face a potential sector-wide £400 million back-pay bill from HMRC, and can continue with existing practices. However, it is vital that they are aware – and have mechanisms for – ensuring employees on overnight shifts are paid NMW for the hours in which they are awake.

Regulation

Since the introduction of a new regulatory approach, CQC has inspected all providers of learning disability services. In October 2020, CQC updated its guidance to emphasise a stronger focus on outcomes for people, specifically their quality of life and the care they receive with their learning disabilities. The guidance highlighted three key factors for providers to consider if they are caring for individuals with learning disabilities, or looking to care for people with disabilities: right support, right care, and right culture.

Across NHS and private providers, nearly three-quarters of inpatient wards for people with a learning disability were rated as Good or Outstanding (73%). In adult social care, it has historically been the case that providers registered as having a learning disability specialism tended to outperform those that did not. However, since the emergence of care quality concerns at Whorlton Hall led to a closer focus on the care received by people with a learning disability, it may be the case that care ratings come under pressure across the sector.

Larger independent providers – often operating multiple locations which cut across health and social care – may find CQC's inspection process of learning disability providers frustratingly fragmented. 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.

Quality in Adult Social Care

Quality is a key aspect of any care service provision. It is also a parameter that varies depending on 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. 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 framework for inspections and ratings.

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.

Thematic review into the use of restraint and seclusion

Alongside their regular inspection regime, CQC 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. A thematic inspection exploring the use of restrictive practices on people with learning disabilities or autism in mental health settings, and adult social care settings was published in October 2020, slightly delayed due to the pandemic.

The report examined whether restraint and seclusion are being used as de facto tools to manage challenging behaviour rather than using more appropriate de-escalation techniques, and found that people were not getting the care they needed when they needed it. The report recommended that individuals are placed more at the centre of their care, and that tailored care packages are given to de-escalate challenging behaviour and to prevent subsequent hospital admission.

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

In October 2020, updated guidance on CQC's approach to registering services for people with learning disabilities or autism was published, in the wake of calls to place patients at the centre of their care. The "Right support, right care, right culture" guidance comes after contention with providers who have had their registration applications rejected.

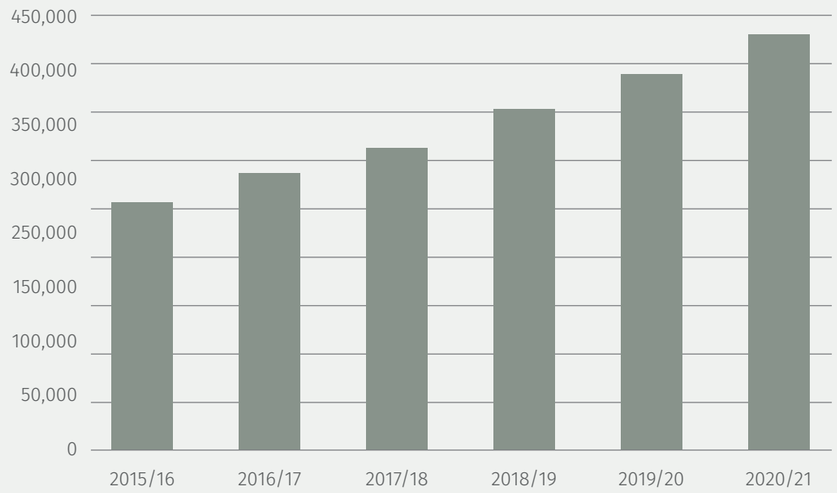
The most common reasons for rejection given are that providers do not meet the 'six-bed rule' set out in the national service model, or that their proposals would create a congregate setting of care. This has also increased pressure on commissioners, as it has placed an additional barrier on supply entering the market. The changes to the "six-bed rule" are yet to be seen after the updated guidance in October 2020, with criticisms that it continues to take too prescriptive an approach, and fails to clarify whether references to best practice meant that is the only practice allowable.

The October 2020 guidance follows on from Registering the right support published in June 2017, and the Building the right support October 2015 guidance, which initially set out the national service model for learning disability services. These policies also reinforced prior objectives of moving people out of institutional care models into more appropriate accommodation and they included specifications for new buildings that NHS England would be prepared to fund out of capital budgets.

Key Messages for Special Educational Needs and Disabilities Services

- The number of children and young 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 – reaching 430,697 individuals by January 2021
- Nearly 100,000 children receive support in Independent Special Schools. Of these, 19,000 are in receipt of an Education, Health & Care (EHC) Plan, which places a statutory obligation to pay for their care
- 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. As a result, the Government committed £7.8 billion for High Needs Funding in 2021/22, with a separate three-year spending commitment made from 2019/20
- 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. In 2020, there were 6,720 cases heard in mediation – and 3,700 were then appealed to a tribunal, with only 5% of cases being won by local authorities
- Since 2016, regulators have taken an increased interest in whether local authorities are meeting their statutory requirements – with CQC and Ofsted carrying out joint inspections in local areas

The Number of People that Require SEND Support has Grown Year-on-Year – a 68% Increase in Volume Between 2015 and 2021



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. Since 2014/5, High Needs funding as a percentage of the overall DSG has been increasing.

If a child is identified with a SEND requirement and is educated in a mainstream school, the first £6,000 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's high needs block, and represents the assumed required level of per pupil funding.

When a child with SEN 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 complexity 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 SENDs to attend independent special schools. As a result of these high cost placements, 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.

Funding pressures

Recent reports suggest the sector is 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 75,951 requests for assessment in 2020, down from 82,300 in 2019. Of these new requests, over 60,000 were approved for EHC plans, which is up from 53,900 in 2019.

The LGA projects a £1.6 billion high needs funding shortfall across local authorities in 2021/22. 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 DfE has acknowledged this pressure and committed an extra £780 million towards SEND funding in 2020/2021. This followed a "Call for Evidence" review initiated by the DfE in May 2019, which 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. However, it avoided the question of whether the overall level of funding was adequate. The SEND review was expected to be published at the end of June 2021, but has yet to be released, with no estimates on publication.

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.

What is a Special School?

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

Private payers

Local authorities provide the majority of SEND funding, but there are rare instances where the parents also contribute towards costs. 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 from 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 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.

A review of the SEND report expected to be published in Summer 2021 has been delayed. Having been twice delayed previously due to the pandemic, and with now publication deadline given, there is a risk that it may not be published this year.

The review's work had been near completion and it had been expected to focus on an increase in provision for children on the threshold of SEN support in mainstream schools – to help ensure that EHC plans are reserved for those with the greatest need. It was also expected to focus on pupil placement outcomes, with a more robust mechanism for monitoring the high financial cost of support. Legislative change was not expected.

The further delay to publication will mean that there will be little active change to the existing system in the near future. It may be the case that the delay is to align publication with the concurrent review into children's care homes and adoption services – and could reflect a planned broader approach to the sector.

Education, health and care plans

Children and young people go through an established process to identify whether they have needs that require support. This is set out in the SEN Code of Practice. However, local authorities are responsible for establishing their own systems, which can lead to considerable variation at the local level.

SEN Support is available 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 replaced the previous 'Statements of SEN' system, however the criteria to receive support has remained unchanged.

The overall number of pupils who have EHC Plans in England is increasing. It reached 430,697 by January 2021– an increase of 40,588 (10%) from the previous year.

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

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 publish a 'Local Offer', which details the support available to people with SEND. This is to support parents to understand what their rights and entitlements are.

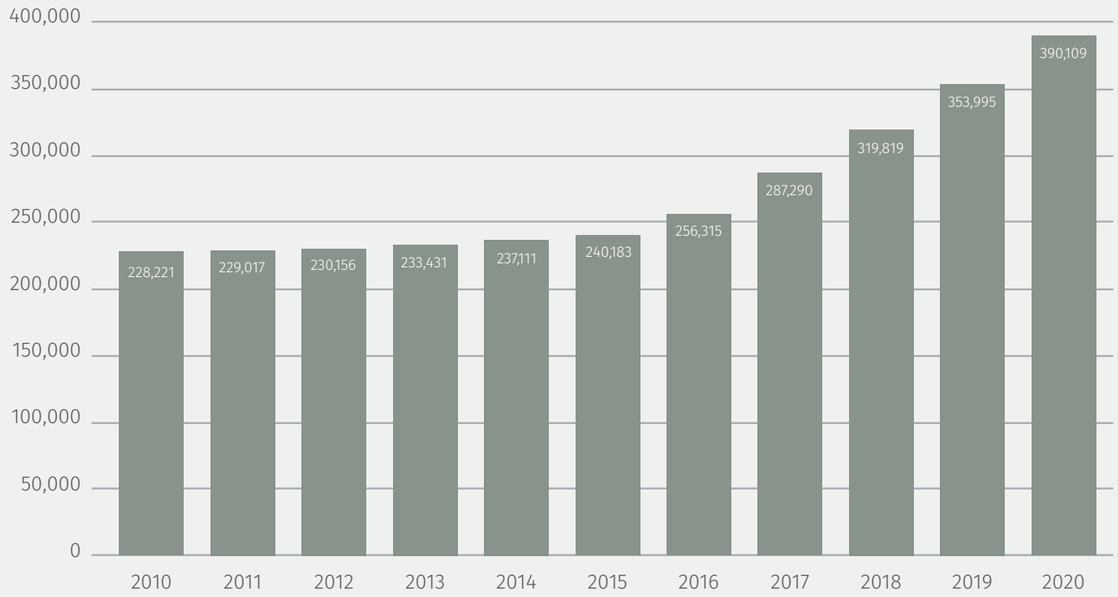
Whilst there is a presumption that a mainstream option will be given if available, this is made less transparent by the 'right to request', which enables the child (or their family/carer) to request a certain location. This can include private independent schools registered as available. Local authorities 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 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, 6.4% of pupils with an Education, Health & Care Plan, are taught in independent special schools. This remains unchanged from 2019/20, but this percentage and has been slowly increasing from its base level of 4.2% in 2010.

Number of Pupils with Statements and EHCPs Combined (2010-2020)

Source: Department for Education.



Percentage of Pupils with an EHC Plan by Type of Provision (2010 – 2020)

Source: Department for Education. **Note**: This data does not include pupils who are only in receipt of SEN support, and are not in receipt of an EHC Plan

SCHOOL TYPE	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Maintained Nursery	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.1	0.1	0.1
State-funded Primary	25.8	25.8	25.9	26.0	26.2	26.2	25.5	25.8	26.3	27.4	28.3
State-funded Secondary	28.8	28.4	27.7	26.9	26.2	26.2	25.5	25.8	26.3	20.4	20.4
State-funded Special	38.2	38.7	39.0	39.6	40.5	41.4	42.9	43.8	44.2	43.8	42.6
Pupil Referral Unit	0.9	0.8	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.8	0.9
Independent	4.2	4.3	4.7	4.9	5.1	5.3	5.7	5.8	6.1	6.4	6.4
Non-maintained Special	2.0	1.9	1.9	1.8	1.7	1.6	1.6	1.5	1.4	1.3	1.3

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.

The number of appeals registered with the SEND tribunal continues to rise each year, a total of 7,917 appeals were registered in 2019/20 - a 24% increase on the previous year, and the fourth successive yearly increase. In the last three years, appeals registered with the SEND tribunal are about 25% of those that go into mediation.

Although formal data is not reported, it has been recorded that the success rate of claimants on appeal at tribunals was 92% last year. This figure only represents tribunal cases, and does not include those settled outside of tribunals. 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. Out of £780 million committed to SEND education in 2020/21, £645 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 from September 2022 onwards. 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 March 2021, there were 260 schools on the list

School inspections

School inspections in England are undertaken by Ofsted, a non-party political government body. Although Ofsted is responsible for inspecting all government run schools, not all independent schools are overseen directly by Ofsted, which only inspects about half of the independent schools. Those which are not are instead inspected by either the Independent School's Inspectorate (ISI) or the Schools Inspection Service (SIS).

Despite this, Ofsted still plays a role in reviewing the quality of the ISI and SIS's inspections and following a recommendation from the Department of Education in 2018, has increased the number of unannounced visits to ISI and SIS inspections. This means that although independent schools are still inspected by ISI and SIS, Ofsted plays a greater role in monitoring these inspections.

In September 2019, Ofsted announced its new education inspection framework which sets out Ofsted's inspection principles and the main judgements that inspectors make. This was published following a four-month consultation on the framework in early 2019, with changes intended to change the focus of inspections, so that more time is spent looking at what is taught and how it is taught.

Following the disruption of Covid-19, Ofsted is now carrying out a phased return to inspection. In May, some on-site inspections resumed, with full inspections expected to resume in autumn 2021, but the exact timing is still under review. The May 2021 inspections were at providers who were considered "inadequate" and "require improvement", with other emergency monitoring visits carried out if necessary. The routine programme of inspections will be restarted in September in the last update of the timing.

Local area Special Educational Needs and disabilities provision

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 organising 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.

However, they are important as a poor inspection can lead to local authorities being required to create action plans that are monitored by Ofsted and the DfE. This can lead to local improvements that will make it easier for parents to access EHC channels and potentially boost placements in higher complexity providers.

In July 2020 it was announced that the Department of Education and the Department of Health and Social Care had formally commissioned Ofsted and CQC to develop a new area SEND inspection framework, with inspections beginning once the existing cycle finishes. The Ofsted and CQC inspection framework is expected to be up and running in 2022.

Key Issues in Pharmaceuticals: Community Pharmacy

- In England, there are around 11,600 pharmacies, responsible for dispensing over 1 billion prescription items annually
- For many people community pharmacies are at centre of their routine healthcare interactions – it is the place where they receive publicly reimbursed prescriptions and get advice from healthcare professionals
- Nearly 9 in 10 people live less than a 20 minutes' walk to the nearest location. These pharmacies receive 1.6 million visits a year
- Despite this, community pharmacies can seem isolated from the core of the UK healthcare landscape. It rarely is the centre of policy debates about the NHS and has traditionally had a limited function in service delivery
- The role and purpose of community pharmacy could change in the upcoming decade, as prescription dispensing increasingly shifts to remote provision, whilst broader policy options explore the opportunity of using the pharmacy as a focal point for low complexity care interactions
- Community pharmacies also function as the main entry point for non-reimbursed over-the-counter medicinal products. This is a critical revenue generator for many pharmacies

Payers

Community pharmacies are funded from a variety of payers. The NHS Drug Tariff is provided by NHS prescription services. It sets the reimbursed price and remuneration that pharmacies can receive from the NHS under the Community Pharmacy Contractual Framework (CPCF). In addition, many community pharmacies receive funding from other sources, such as under the Pharmacy Quality Scheme (PQS), which is a payment to financially reward pharmacies which demonstrate high quality provision of care, in addition to other payments for delivering certain core services, such as prescription dispensing.

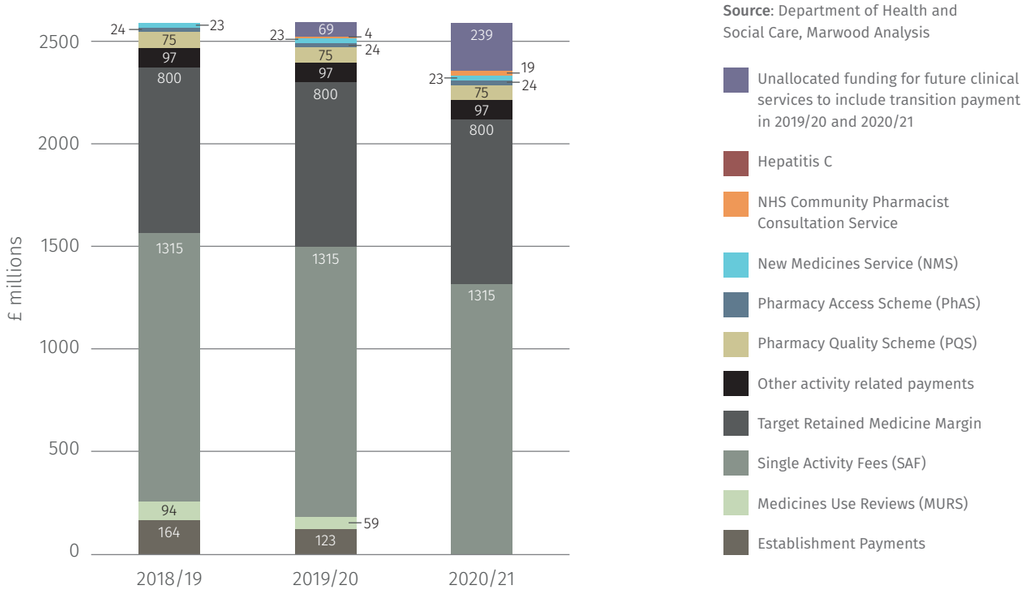
Community pharmacies can also receive payments for other commissioned services, with this payment coming from local authorities or CCGs. Retail activities also supplement community pharmacy funding, as the sale of over-the-counter medicine. In 2018/19, a five-year funding agreement was reached for community pharmacies in England, which provided long-term stability to the sector.

Over the five years, community pharmacy funding will remain constant, maintaining a total of £2.592 billion each year. This will ultimately be a real term decrease given inflation but may be balanced out due to significant technological efficiencies which may help drive reductions in the cost of doing business. Within the mix of funding for community pharmacies, unallocated funds for future clinical services will grow substantially, with increases also expected in the NHS Community Pharmacist Consultation Service.

Within the landscape of community pharmacy, several key players contribute to significant lobbying. The Pharmacy Services Negotiating Committee (PSNC) actively promotes the interests of all community pharmacies in England with NHS contracts and works closely with Local Pharmaceutical Committees (LPCs) in their role as the local NHS representative organisations. PSNC keep funding levels under constant review to ensure that fees and allowance components remain stable at £1.792 billion.

To ensure full delivery of this component as agreed under the Community Pharmacy contractual Framework, the PSNC achieved an agreement with the government to increase the Single Activity Fee to £1.29 from August 2021. This represents a 1.5% increase over the previous levels and signals a continued commitment to maintaining funding levels.

Overall, Community Pharmacy Funding will Remain Static Over the Next Five Years – at £2.592 Billion per Year



Data: Community Pharmacy Five Year Funding Settlement broken down by segment

Source: Department of Health and Social Care, Marwood Analysis

- Unallocated funding for future clinical services to include transition payment in 2019/20 and 2020/21
- Hepatitis C
- NHS Community Pharmacist Consultation Service
- New Medicines Service (NMS)
- Pharmacy Access Scheme (PhAS)
- Pharmacy Quality Scheme (PQS)
- Other activity related payments
- Target Retained Medicine Margin
- Single Activity Fees (SAF)
- Medicines Use Reviews (MURS)
- Establishment Payments

Additional funding during Covid-19

During the Covid-19 pandemic, advance emergency loans of £370 million were agreed by PSNC and DHSC. These were delivered to pharmacies between 01 April and 01 July 2020 in recognition of the significant cashflow pressures that community pharmacies were facing. While these loans were beneficial to the sector during the first peak of the pandemic, it is important to note that the loans will need to be repaid.

In addition to these loans, the PSNC and the DHSC have arranged reimbursements for community pharmacies from March 2020 to March 2021, due to the increased costs pharmacies faced during the pandemic. Some of the key areas for which pharmacy contractors were allowed to be reimbursed included for extra staffing costs during the pandemic, additional costs for Covid-19—safe facilities, and extra assistance for IT set-up costs for virtual pharmacy activities.

Policy and legislation

Pharmaceutical Needs Assessments (PNA) were first required by the Health Act of 2009, where Primary Care Trusts were required to publish and prepare PNAs. These are important in identifying where pharmacies are needed and are a vital part of commissioning – alongside healthcare needs which are identified in local Joint Strategic Needs Assessments.

As local system priorities become increasingly shaped by local population health needs, community pharmacies may see objectives orientated to their specific location and populations. However, this does not mean a totally fragmented service, as the funding settlement sets out some expectations around what community pharmacists need to provide.

The five-year funding settlement was an opportunity for the Government to reaffirm its support to the sector, whilst recognising that the role of the physical pharmacy is changing. The settlement also signals that the government anticipates remote providers to deliver cost savings in the future.

The vision for community pharmacy is as a hub in a local community and an important part of the high street – particularly in more rural locations. Their presence is more than just the dispensing of prescription medicines. Alongside changes in service delivery, the Government has also committed to reviewing regulations that may provide more flexibility in how operators build their business.

This includes potential legislative and policy changes to:

- Enable a 'hub+spoke' dispensing model to pharmacies that are not part of the same legal entity
- Enable efficiencies within the skill mix of pharmacy teams and support greater clinical integration
- Support consolidation within the sector
- Examine the funding model to ensure that it is fit for purpose as the sector changes shape

Regulation

In 2013, the NHS Pharmaceutical and Local Pharmaceutical Services regulations were published. These set out the requirements for PNAs to be published by health and wellbeing boards. It also outlined which pharmaceutical inclusion list applications are maintained, and what the provision of certain pharmaceutical and dispensing services are in the community.

Under the CPCF for 2019/20 to 2023/24 pharmacies are seen as essential to supporting the NHS Long Term Plan and pharmacies which are included on the pharmaceutical lists must provide a list of their essential services and engage in an appropriate system of clinical governance and healthy living. Pharmacies can also choose to provide enhanced services for identified patient need, through commission from NHS England. All of these services together make up the CPCF.

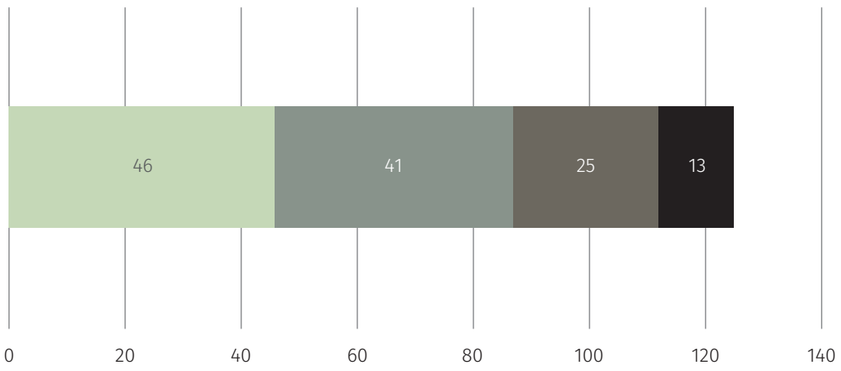
In line with the updates to the CPCF, and due to Covid-19 having a huge impact on community pharmacies, a revised NHS Pharmaceutical and Local Pharmaceutical Services Regulations was released in October 2020. Many of the changes in these regulations were agreed in the five-year CPCF plan but were delayed due to Covid-19. The key additions published in the 2020 NHS Pharmacy Regulations are summarised in the table below:

SUBJECT AREA	DESCRIPTION OF REGULATION
Pandemic Treatment Protocol	Part of the new Essential Service Dispensing provisions, this protocol may be used to supply medicines for the treatment or prevention of a disease related to a current or anticipated pandemic
Flexible of pandemic vaccinations	Allows for the flexible provision of immunisation services (e.g., flu or coronavirus vaccination) in the case of a declared pandemic emergency. This allows NHS England to agree the limiting or stopping of other pharmaceutical services at specified times during core or supplementary hours, and to prioritise the administration of such vaccinations
Remote access to services	Contractors must facilitate remote access to their services if patients wish to access these services in that way – e.g., a patient who usually has their prescription delivered by the pharmacy may request the contractor to provide necessary advice and other services via the phone or using a video consultation
Discharge Medicines Services (DMS)	Implemented in February 2021 - under this service, NHS Trusts can refer patients who they believe would benefit from extra guidance around new prescribed medicines
Electronic Prescription Services	Access to the platform must remain constant and reliable in all pharmacies. Should the services become momentarily unavailable, then an item should be prescribed to a patient within a reasonable timeframe and the PSNC will provide further guidance
Health Living Pharmacy (HLP) status	All pharmacies are required to meet the Healthy Living Pharmacy level 1 quality criteria

Key Messages for Branded and Innovative Drugs

- The UK continues to be an attractive location for pharmaceutical developers and manufacturers, supported by a positive policy and regulatory environment
- In 2020, the biotech sector was worth £2.8 billion, up more than 115% from 2019 when the sector was worth £1.3 billion. Despite expectations that the pandemic would severely affect investments, 2020 was the best year on record for the sector, with 2021 expected to break the record again. More than £830 million was raised in the first three months of 2021, almost comparable to the £894 million that was raised in the first six months of 2020
- 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 improving access to and use of the NHS's unique patient dataset
- The NHS spent approximately £8.6 billion on branded drugs between Q1 2020 and Q3 2020 – if spending continues on this trajectory, £11.5 billion will be spent in 2020 in total
- NHS spend on specialised medicines has risen sharply because of a wave of new treatment options, and NHS England's pricing agreements on CAR-T therapies reflect a more flexible approach to funding access to advanced therapies. However, the near four-year battle over Orkambi, Vertex's cystic fibrosis drug, shows that NHS England continue to take a firm line on value for money pricing
- 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

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: Catapult, Cell and Gene Therapy, 2020

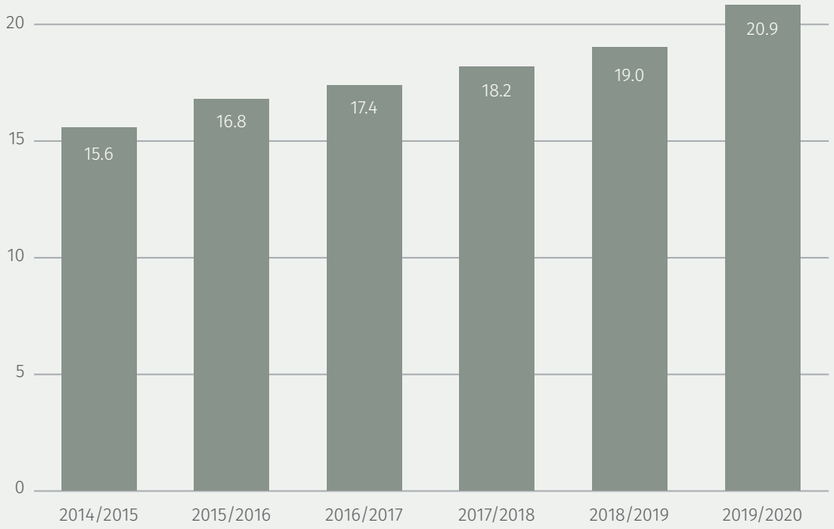
Payers

Overall spend on pharmaceutical products across the NHS has been increasing in recent years – and reached £20.9 billion in 2019/20, an increase of nearly 10% from 2019. This total spend covers both hospital and community settings, and all types of pharmaceutical expenditure (branded and innovative, and generics and biosimilars).

Hospital expenditure has been accounting for an increasing proportion of the overall spend - reaching 55.9% in 2019/20. Primary care expenditure on pharmaceuticals also increased in 2019/20, after a previous three-year decline in spending.

The total amount reported on pharmaceutical expenditure is the list price for the products and so does not include any agreed commercial discounting arrangements.

NHS Overall Expenditure on Pharmaceuticals has Risen 33% Between 2014/15 and 2019/20



Note: This represents the reported public pay spend in hospital and community settings for all types of pharmaceutical products. It does not take into account discount agreements or rebates.

Data: Prescribing Costs in Hospitals and the Community 2014/15 to 2019/20 (£, bn)

Source: NHS Digital

Spending controls

The NHS spent approximately £8.6 billion on branded drugs between Q1 2020 and Q3 2020 – suggesting an annual spend in the region of £11.5 billion. This covers products sold via the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) or statutory pricing schemes, or via parallel imports. In reality, this spend is mitigated by discounting against the list price, and other price agreements that may lead to rebates.

Voluntary Scheme for Branded Medicines Pricing and Access (VPAS)

In January 2019, the VPAS replaced the Pharmaceutical Pricing Regulation Scheme (PPRS). VPAS outlines an 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.

Containing pharmaceutical spend remains a key policy objective for the NHS, and the VPAS attempts to do this whilst ensuring access to medicines for patients. A key element 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 he predecessor PPRS between 2014 and 2018.

NHS ALLOCATED GROWTH WITHIN THE BRANDED DRUGS BUDGET	2015	2016	2017	2018	2019	2020	2021
	0%	1.8%	1.8%	1.9%	2%	2%	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 2021, this equated to 5.1%. This is a reduction on the 5.9% that was due to be repaid in 2020, and the 9.6% that was due to be repaid in 2019. The amount a specific company would have to pay back in 2021 would be worked out as follows:

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

VPAS does differ from the 2014 PPRS in one significant way, the requirement for companies to offer the same deal – whether agreed in England, Scotland, Wales or Northern Ireland – across all. This could present opportunities for the industry, as companies could focus on striking one deal in England and then leverage that across all nations to support faster uptake. At the same time, this creates risks as companies may have to give bigger discounts to all, instead of just to some.

As under PPRS, there are a number of exemptions. For example, 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 England and Wales and provides recommendations for whether they should be reimbursed by the NHS in these geographies. 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.

These changes have enabled highly innovative products with very small patient populations to fall under NICE recommendations. The high-cost gene therapy product, Strimvelis, was a beneficiary of this methodological change. It has a particularly unusual status as patients access the treatment in Italy, rather than on-site in an NHS facility. This is due to the six hour shelf life of the product, and the only approved manufacturing site being in Italy.

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 £20 million 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 £20 million 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 currently underway, with the findings expected to be published in December 2021. 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 as NICE hopes to speed up patient access to new and promising health technologies, increase market access for appraised products, and allow for a simpler evaluation process of health technologies.

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.

Preferably a drug will be priced in line with NICE's QALY assessment and drug pricing can be easily agreed. However, with new innovative drugs coming to the market, even with adjustments to QALY thresholds it can be difficult to reach agreement with a manufacturer. The protracted discussions over Orkambi reflect this. To avoid the potential reputational harm, and a delay in providing access to a drug of therapeutic value, the NHS's preference is for agreeing a simple confidential discount.

The development of the VPAS continues with an evolution towards more bespoke commercial arrangements that can apply to individual drugs.

The UK government has also historically provided additional funding for specific diseases or conditions for particular groups. In 2011, the Cancer Drugs Fund was set-up to provide dedicated funding to give patients access to expensive new cancer drugs that had been rejected by NICE as they did not meet the cost-effectiveness threshold.

In 2016, the Cancer Drugs Fund was reformed as a managed access fund for cancer drug. This managed access fund allowed innovative cancer drugs to be funded for up to two years while additional data was being collected on their effectiveness, after which point NICE made a final decision on whether they should be made available through the NHS.

In July 2021, the government announced plans to reform the Cancer Drugs Fund with an additional Innovative Medicines Fund (IMF) with £680 million. The IMF will support the existing £340 million Cancer Drugs Fund with a matching funding pot to deliver innovative treatments through the NHS.

NHS England's expanded role

Pricing of branded drugs is agreed on an individual product 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 DHSC has traditionally been the key price 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 DHSC 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.

As NHS England have a broader remit than NICE, it has an ability to look at the impact of drugs within the wider healthcare environment. This can provide opportunities to find reimbursement even without NICE approval. For instance, in May 2019 NHS England reached an agreement on reimbursing Ocrevus, a new drug that can slow the evolution of multiple sclerosis, in spite of a previous NICE rejection. The new deal was secured on the back of a commercial discount that brought the product QALY into a range that NICE could then approve.

Policy and legislation

The UK policy landscape is overall favourable to the development of new drugs. Increasingly, this is focused on 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 would be used from 2019 to deliver highly personalised diagnostics to children with cancer, and adults suffering from certain rare conditions or specified cancers. This 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 that the NHS is preparing to fast-track tumour agnostic cancer drugs similar to its fast-tracking of CAR-T therapies.

Support for the development of novel antibiotics

In 2019 the UK launched a five-year national action plan to tackle antimicrobial resistance, with the aim that it be contained and controlled by 2040. As part of this, the NHS is promoting the development of new antimicrobials and is offering two contracts for research in this area to pharmaceutical companies. New drugs would be paid for by the world's first 'subscription-style' payment model for antibiotics and made available to UK patients as early as 2022.

Two treatments, Cefiderocol (Fetcroja), developed by Shionogi, and ceftazidime with avibactam (Zavicefta), manufactured by Pfizer, have been chosen to be evaluated in an innovative health technology process. The outcome of these evaluations over the next 12 months will help develop the subscription price of each product, and will inform future subscription prices for other innovative medicines.

While the world continues to experience the Covid-19 pandemic, the UK remains committed to supporting the development, testing and evaluation of innovative drugs to stimulate the global antimicrobial pipeline.

Life Sciences industrial strategy

Wider policy objectives relevant to the development of branded and innovative drugs are outlined in the Life Sciences Industrial Strategy 2017. Partly developed in anticipation of Brexit and its impact on the life sciences 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 £14 billion
- 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
- Continuing 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.

Life Sciences vision

In July 2021, building on the Life Sciences industrial strategy, the UK set out a 10-year strategy for the Life Sciences sector. It aims to embed the UK as a global leader in life sciences as part of a post-Brexit vision.

The document sets out seven key aims for stakeholders to achieve over the next decade including improving the understanding of mental health conditions and diagnostic solutions, and accelerating studies into dementia treatment.

Following from the success of the AstraZeneca-Oxford University Covid-19 vaccine, the Life Sciences Vision is focused on the continued discovery and development of leading vaccines, with the aim of developing a formalised Vaccine Registry.

It announced £1 billion of funding into the Life Sciences Investment Programme, which the government envisions will help attract further investment and growth into the UK's life sciences sector. The funding is aimed at helping companies scale up operations and create new high-skilled jobs in the UK.

The NHS Provides Unique Opportunities to Conduct Rapid Clinical Trials

The UK has one of the most integrated research systems in the world and now has the third highest number of clinical trials in the world after the US and Germany. Supported by investments of £300 million a year from the National Institute for Health Research into the infrastructure for clinical trials – particularly research nurses and other trials staff – the NHS has the ideal conditions for important trials to be run across the country.

One key aspect facilitating this is that the NHS is a single integrated health system in which patients can be tracked from birth through their NHS number. Another advantage is the UK's diverse population. Although Scandinavian countries have similar health systems to the NHS, their relatively smaller populations are far less diverse than the UK's, making them less suitable for clinical trials.

The £300 million annual investment in this area has an estimated £2.4 billion financial return for the UK economy, attracting international research organisations and pharmaceutical and medical device companies to conduct trials. This brings new therapeutics such as innovative cancer drugs into the NHS, and benefits patients by providing broad access through the NHS.

In a post-Brexit landscape, and the ability to evolve regulation out-of-step with European competitors, the Life Science industry is likely to maintain a position of importance to the wider economy, as highlighted in the Life Sciences Vision 2021. As a result, the UK research and clinical trials will continue to be an important source of investment, innovation and excellence over the next decade.

Regulation

Marketing authorisations

New drug approval under the MHRA post-Brexit

When Britain formally exited from the EU, it marked a major shift in regulatory responsibility for pharmaceuticals. Previously, marketing authorisations for new drugs in the UK and in the EU market were regulated by EU law and could be delivered centrally by the European Medicines Agency (EMA) or at national level by competent authorities. From the beginning of 2021, pharmaceutical regulation in the UK is no longer overseen by the EMA. The Medicines and Healthcare products Regulatory Agency (MHRA) has become the sole regulator for drug authorisation in the UK. However, in order to ensure regulatory alignment and minimise disruption for manufacturers and distributors, many of the EU rules laid out under the EMA have been transferred across to the MHRA, so much of their functions are identical.

The benefits of the EMA being able to approve therapies across countries in the EU has been transferred over in the new trade deal, with the UK and EU states recognising each other's good practice in medicine manufacturing. However, this does not apply for regulatory checks, meaning that both the MHRA and the EMA will have to regulate any products that are to be sold in their respective territories. To that effect, any manufacturers that are selling medicines or medical devices in the UK must obtain a licence from the MHRA instead of the EMA. If they are looking to sell in both territories, then licences must be obtained from both the MHRA and the EMA.

The MHRA has historically played a key role in shaping EU pharmaceutical regulation. Post-Brexit, its legacy is likely to endure for some time as EU regulation is complex and will take many years to amend. With the MHRA's approval process aligning closely with the EU regulatory framework, manufacturers and developers are hoping to expect similar timelines and approaches to marketing authorisation as with the EMA. However, there have been concern that there may be a duplication of efforts for manufacturers to submit the approval paperwork across both jurisdictions, which may lead to an increase in costs.

Health leaders have also expressed concern that any additional regulatory burden could lead to manufacturers de-prioritising the UK as a country to introduce new medicines and devices in favour of a broader launch strategy across EU member states.

To mitigate this, the MHRA has indicated that it will offer faster assessment routes for certain medicines, like biologics. Its established Innovation Office will 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.

Manufacturers will also be aware that the UK has traditionally been a leader in regulatory science and were a major driver in streamlining the EMAs more bureaucratic processes. This attitude is likely to mean Britain remains a favourable territory for regulatory approval.

In July 2021, the MHRA released their Delivery Plan 2021-2023, which sets out their role in developing and supporting the life sciences sector in the UK. Specific focus is on the accelerating of new therapies and innovative treatments to market, improving patient outcomes, and ensuring the continued safety, quality and efficacy of medicines and medical devices. At the core of their delivery plan is a continued focus on a "patients first" approach.

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. All existing centrally authorised products (CAPs) were automatically converted into UK marketing authorisation on 01 January 2021, but manufacturers could opt out of this process within 21 days of the withdrawal of the EU. This means that manufacturers based in the EU will be able to continue selling their products in the UK, and the EU has signalled they will be offering a similar deal to UK based manufacturers.

Clinical trials regulation

Before gaining a marketing authorisation, all therapies must complete the clinical trial process. Within the EU, the framework regulating clinical trials is set at EU level, with a new Clinical Trial Regulation (CTR) confirmed in April 2021, with full implementation in 2022. However, in the UK, the regulation of clinical trials is now in the jurisdiction of the MHRA.

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 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, the UK is not given automatic access to the proposed clinical trial portal and database. With negotiations ongoing and the new system to be fully implemented in 2022, the UK's direct access to the clinical trial portal and database remains uncertain.

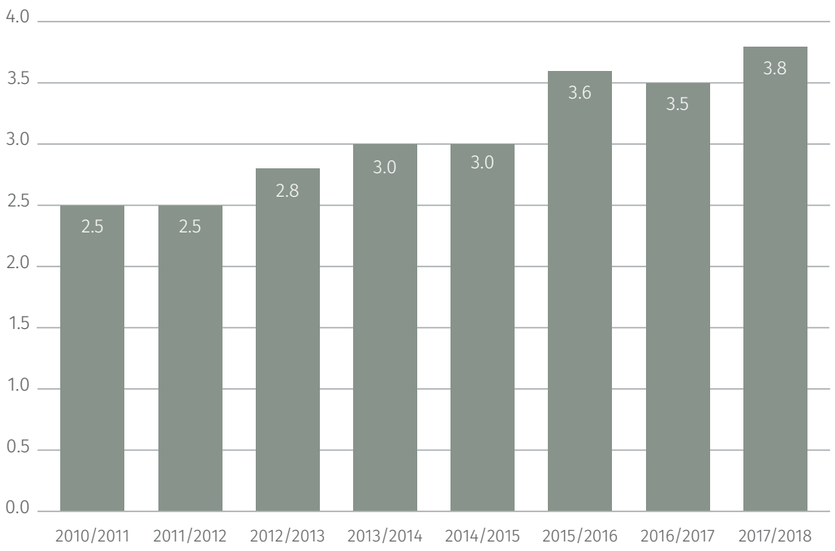
Getting access to the portal and database would facilitate UK-based developers' participation in cross-border cooperation and access to wider patient pools across Europe. However, it could increase timelines for clinical trial authorisations. Therefore, there may be advantages for the UK to not fully 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.

In the MHRA's Delivery Plan 2021-2023, great focus was placed on clinical trials, specifically, ensuring a more innovative and pragmatic approach to trials. The plan announced a new service due to be launched towards the second half of 2021 that will speed up recruitment of patients into clinical trials. The MHRA hopes to have 25% of UK GP practices signing up for clinical practice research data. By the end of the fourth quarter of 2021/22, it is also hoped that UK legislation will be adapted to increase the use of real-world data in clinical trials. Two NIHR funded real world trials will also be initiated through the MHRA's innovative data-enabled clinical trial platform.

Key Messages for Generic and Biosimilar Drugs

- 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
- NHS England planned to increase the uptake of biologic medicines with the aim of saving £400 to £500 million per year by 2020/21 as part of the LTP. Nearly £300 million was saved in 2018/19
- 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 LTP are likely to provide opportunities for oncology, arthritis, and diabetes biosimilars
- The UK generic drug market is mature, with policies and pricing mechanisms incentivising competition and quick market penetration expected to continue
- Generics can be freely priced – and this has traditionally worked well to keep prices low. However, drug pricing is closely monitored 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. From April 2022, reimbursement will be undertaken by the ICS, who will enable the provision of medicines in primary care. 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 £13.5 billion 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 £315 million 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 were three possible reasons for the increase: medicine shortages; currency fluctuations; and increases in wholesalers' margins. It had 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.

Over the last three years, some generic medicines have seen their prices skyrocket, with some examples shown in the following table.

PRODUCT	JULY 2018 PRICE	OCTOBER 2020 PRICE	PERCENTAGE INCREASE
Risperidone 6mg tablets – price for 28 tablets	£2.68	£49.21	+1,736%
Hydrocortisone 0.5% ointment – price for 15g	£5.71	£44.00	+671%
Phosphates enema (Formula B) – price for 128ml or 1 standard tube	£3.98	£27.93	+602%
Furosemide 20mg/2ml solution – price for an injection of ampoules 10 ampoule	£3.52	£21.19	+502%
Lormetazepam 1mg tablets – price for 30 tablets	£3.84	£17.77	+363%

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 £200-300 million 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. The use of biosimilars is believed to have saved the NHS £800 million a year, with clinicians able t o use these extra savings to treat a greater number of patients.

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 £400 million a year on Humira, making it the single most expensive hospital drug. The introduction of adalimumab biosimilars saved almost £110 million in 2018/19 after it came off patent, with future savings expected to be over £150 million annually. Total drug savings in 2018/19 were reported to be over £293 million.

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, arthritis 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 has led 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.

In October 2020, the CMA investigated Essential Pharma, and they alleged that lithium-based medicines, Priadel and Camcolit, were abusing their dominant position in the market as therapies for bipolar disorder. Essential Pharma were proposing to withdraw Priadel from the market, which caused concern among healthcare providers, as Priadel is the dominant drug for lithium-based bipolar treatments. The Department of Health and Social Care intervened and imposed temporary measures on Essential Pharma to halt their withdrawal of Priadel.

Another recent investigation by the CMA was into Advanz and its private equity owners, as it was alleged that they inflated the price of its thyroid tablets by up to 6,000%. The CMA fined Advanz £100 million for charging excessive prices for liothyronine tablets, which are used as a thyroid hormone deficiency treatment. The NHS spent nearly £30 million on liothyronine tablets by 2016 as a result of the unfair pricing, and the NHS placed the drugs on the "drop list" in July 2015 as a result of the extortionate costs. This led to many patients being unable to access the liothyronine treatment, and many patients had to switch to other treatment options for hypothyroidism, which was not as effective a treatment for many patients. The fines were issued in July 2021, and with these efforts, the CMA aims to make it easier for the NHS to seek compensation from firms charging excessive prices.

The CMA is continuing their investigation into anti-competitive agreements in the pharmaceutical sector, after pausing the investigation during the pandemic. The UK's departure from the EU has also signified a shift in the legislative proceedings of the CMA. This means for suspected infringements, only UK domestic competition law will apply. In March 2021, the CMA announced a partnership to collaborate with organisations in the US, Canada and Europe to investigate pharmaceutical mergers, and ensure that all concerns raised by the mergers and acquisitions were fully addressed.

Regulation

Biosimilar marketing authorisation

As biosimilars are similar, but not identical to a biological medicine that has already been approved, their regulatory approval differs to that of small molecule generic drugs. Prior to this year, the regulatory framework was set at EU level and the majority of new biosimilars were subject to EMA approval. From 2021 onwards, the MHRA is responsible for marketing authorisations for biosimilars.

The MHRA has announced that it will follow the same principles for biosimilars as the EMA currently does. It has also announced that for two years after Britain's withdrawal from the EU, Great Britain will adopt the decisions that the EMA have taken on the approval of new marketing authorisations, highlighting a promising environment for drugs approved in the EU that are looking to be sold in the UK.

In addition, the MHRA has also announced that it will introduce new assessment routes to support approval of new medicines in the UK. Two of these new routes target biosimilars specifically, reflecting the wider regulatory and policy interest in these drugs:

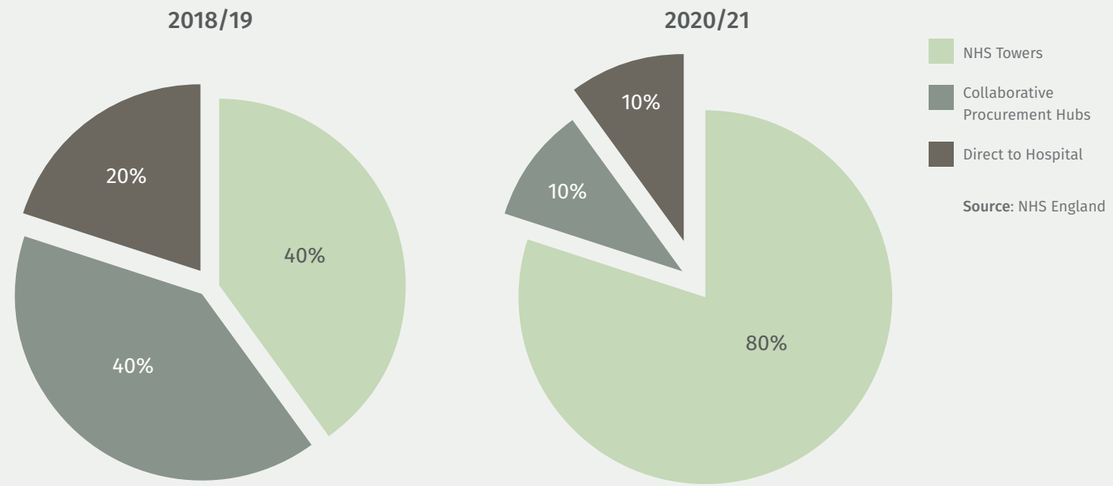
- Targeted assessment process: the MHRA will evaluate the marketing authorisation application together with the EMA's Committee for Medicinal products for Human Use (CHMP) assessment reports submitted by the applicants. An opinion will be reached within 67 days of submission of a valid application to 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

Key Messages for Medical Devices

- Overall, government policy is supportive of the medical device sector, with a focus on encouraging innovation and facilitating market access for new cost-effective devices
- In April 2021, the MedTech Funding Mandate was published, which identifies NICE-approved devices, diagnostics, or digital products that are effective and cost-saving for the NHS. This mandate has already outlined five key technologies in its first year that will be commissioned by CCGs
- NHS Trusts are the main purchasers of medical devices, spending £6 billion on devices from simple clinical consumables to highly innovative diagnostic equipment
- The NHS aims to shift 80% of its medical devices expenditure to a central procurement system by 2022 through the transition to the New Operating Model
- Efforts to centralise NHS medical device procurement are being led by the development of 11 NHS Procurement Towers that centralise products by category, with the aim of reducing localised price variation and enabling Trusts to procure more efficiently
- The 2020 NHSX Tech Plan outlines a number short and long-term technological innovations, presenting major opportunities for the medical device sector to engage with the NHS in a mutually beneficial manner
- The MHRA is now the main body responsible for regulating UK medical devices after Brexit. Much of the regulation is aligned with EU regulation for medical devices, minimising disruption for manufacturers despite some duplication of paperwork that will occur

Policy has Led to Operational Changes that Seek to Increasingly Channel Expenditure Through Centralised Procurement Processes



The NHS Future Operating Model has a target to double the proportion of Trust expenditure on medical consumables that is purchased through a central location. These are structured as series of eleven categories covering all types of products purchased by healthcare providers.

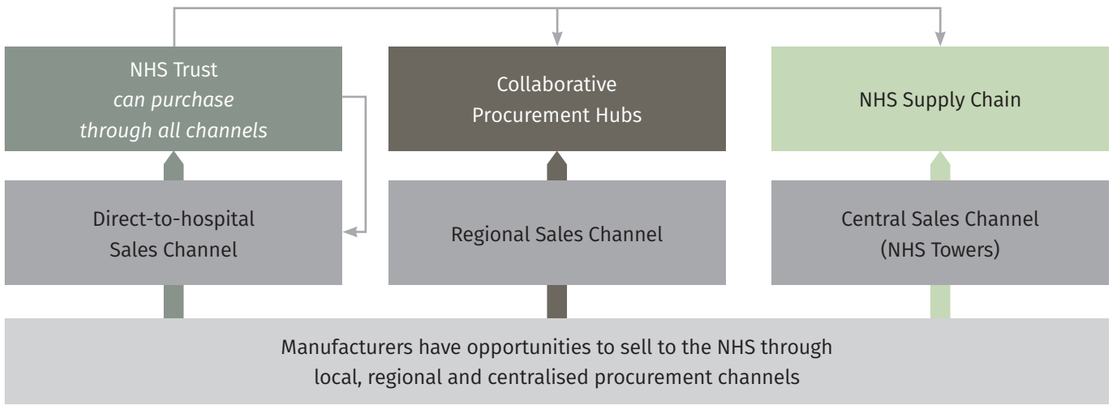
Payers

Centralising NHS Trust procurement

NHS Trusts are the main payer for medical devices. They spend £6 billion 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 – all Tower contracts have been awarded. 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 £700 million could be released through more efficient procurement processes for goods and services. To achieve this, the New 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 2022. 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, with many still opting for the old procurement model. However, they are required to financially contribute to the New Operating Model as a way to incentivise purchasing through the NHS Towers. Improving procurement efficiency continues to be a key objective under the NHS 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.

Spotlight on Reimbursment for Digital Therapeutics

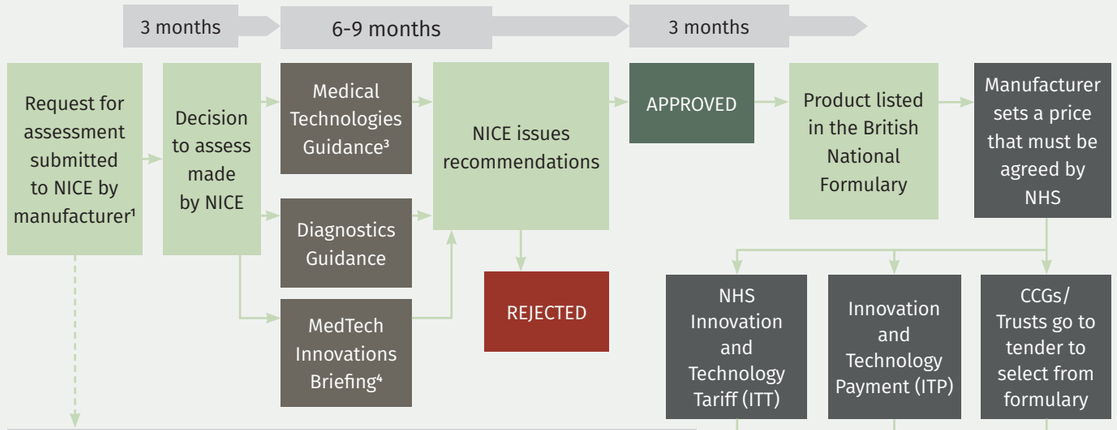
Digital health is rapidly becoming an established therapeutic modality alongside traditional medicines and medical devices. A recent example of this was seen during the pandemic, when many people self-monitored their oxygen saturation levels using pulse oximeters. These medical devices were used in conjunction with associated health apps to track their health. Whilst the rise of digital health tools holds great clinical promise, investors should be aware that in practice, the reimbursement process for digital therapeutics is decentralised in the UK, with CCGs ultimately the key decision-makers in purchasing digital health solutions for the NHS.

At present digital health technologies may only be included in care provision and treatment pathways following regulatory approval. This had been via a CE mark, but after June 2023 will require a UKCA marking. In addition, the technology must meet NICE's evidence standard framework for digital health solutions.

Despite these centralised processes, the actual decision around reimbursement/adoption is mostly made at a local level by CCGs. These can select among NHS-vetted service providers, using NICE guidance on clinical assessments to support their evaluations. However, the clinical assessment of value is still conducted at a local level, with the local budget and expected benefits taken into account.

Due to CCGs' financial circumstances, this mostly translates into commissioners looking for evidence on their expected return on investment, by way of financial savings opportunities or local pilot studies to collect evidence on the impact of the digital health solution. While this creates significant challenges for providers seeking to increase take-up of their digital health technologies across the UK, it also presents opportunities for those who understand local commissioning dynamics and priorities.

Market Access Flow Chart for Medical Devices with CE Mark



Notes

1. NICE conduct assessment if product offers substantial benefits to patients or healthcare system compared with current practice. Benefits must be clearly described and supported by evidence
2. NICE assessment is not mandatory for CCG adoption, but can be challenging without it
3. Medical Technologies Guidance process most commonly used for digital health products considered medical devices. The process is currently in draft, with the first wave of digital products undertaking the full NICE approval process.
4. The MedTech Innovation briefing route may prove to be an option if it is felt that the Company may not be meet the requirements for a full NICE approval. The Company may choose to approach that route themselves, or NICE may direct them towards it
5. The reimbursement route depends on the commissioner/provider of services for that patient population. If there are multiple target populations (e.g. some specialised and others not) reimbursement decisions may be required from different bodies for each population

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, 16 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 £500 million 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 – with the aim of generating annual savings of £60 million. By the end of 2018, £250 million 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 wheelchairs and other walking aids. Each CCG is responsible for deciding which medical devices are included in their formulary and funded in their local area. This includes the technologies covered by the MedTech Funding Mandate 2021/22.

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.

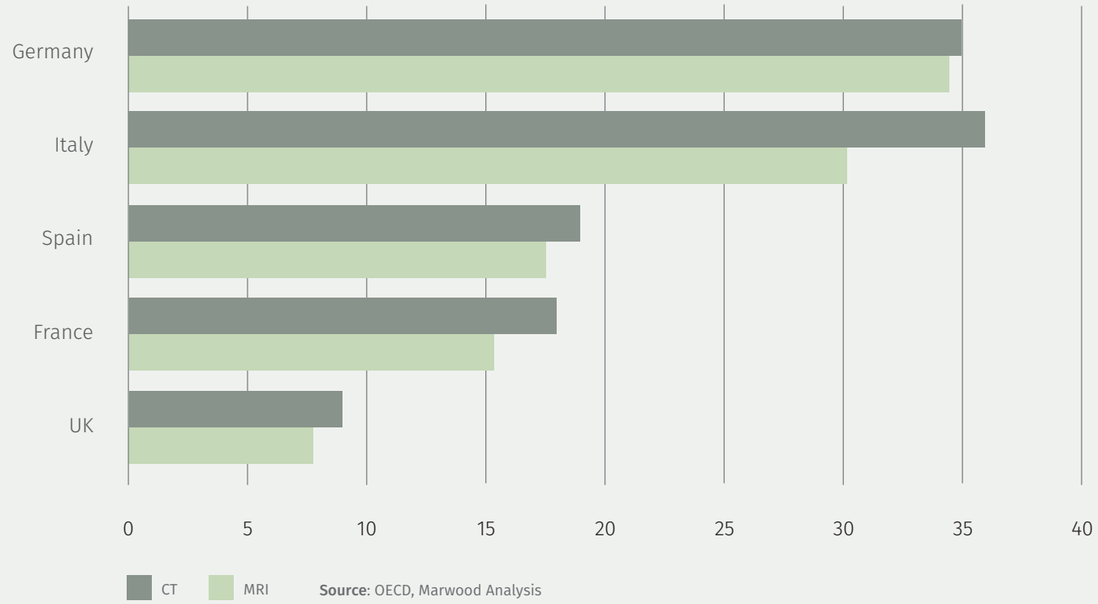
Policy and legislation

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.

The Prime Minister Boris Johnson has committed to upgrading cancer diagnostics across the NHS in England and pledged a £200 million budget for it over two years. The DHSC has confirmed that this funding is separate from the £2 billion pledged for upgrading 20 hospitals in England and for new equipment and AI research. The pledge to upgrade cancer diagnostics has also been reiterated in the Life Sciences Vision 2021, with a great focus on developing and utilising the most innovative technology for earlier detection.

The UK Lags Behind the Rest of the EU Big 5 in the Number of MRI / CT Machines per Million Population



Source: OECD, Marwood Analysis

The Independent Medicines and Medical Devices Safety Review Report

The report, also known as the Cumberlege report, was commissioned in 2018 to review how the health system in England responds to reports about the harmful side effects from medicines and medical devices. It was published in July 2020.

The report identified positive benefits, both financial and patient safety related, from the use of barcodes for medicines and medical devices. The benefits were endorsed by the Chair of NHS England, Lord David Prior who has called for the NHS to embrace barcodes widely. In addition, the report recommended the creation of two patient-oriented groups. The first of these is an independent Patient Safety Commissioner with a statutory responsibility to champion patients' voice and promote users' perspectives pertaining to medicines and medical device usage. The second is an independent national Redress Agency to help those harmed by medicines and medical devices.

At the end of July 2021, the government responded to the report with an update on actions that have been implemented following its publication. In January 2021, a Patient Reference Group was established, which allows for more patients' voices to be heard as it relates to medicines and medical devices. The government also issued apologies to patients and families of those who were affected by incidences with pelvic mesh, Primodos, and sodium valproate.

For adverse event reporting, the July 2021 response highlighted the MHRA's reflection on the issue and drew attention to the MHRA's Delivery Plan 2021-2023 of "Putting patients first". Furthermore, the response announced an £11 million package of funding for testing, scoping and assessing costs for a central patient-identifiable database for devices.

The MedTech Funding Mandate 2021/22

As part of the LTP, the MedTech Funding Mandate was published on 01 April 2021. This supports certain devices, diagnostics and digital products to be commissioned by CCGs. The policy supports technologies that are effective and can deliver savings to the NHS, notably over £1 million across the next 5 years to the English population. The mandate is also supportive of, technologies that are cost-saving, specifically in the first 12 months of their implementation. However, technologies must be affordable to the NHS, meaning the budget impact does not exceed £20 million in the first three years.

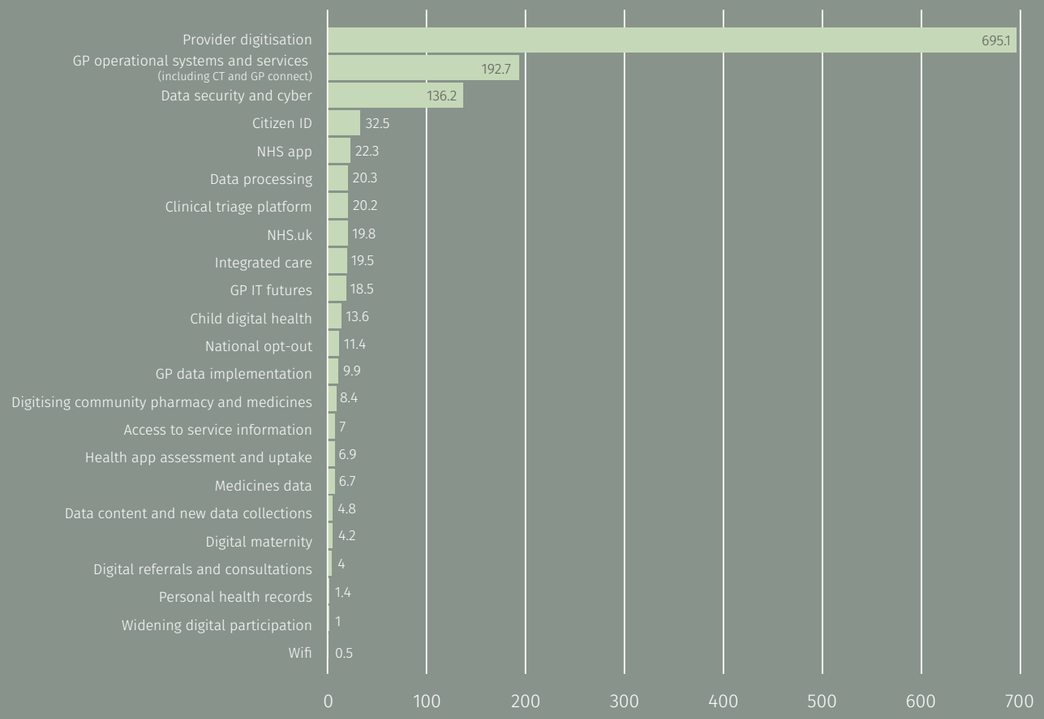
In the first year of the MedTech Funding mandate's implementation, it was agreed that four key technologies will be supported. These are:

- Placental growth factor-based testing, which is a blood test to assess pre-eclampsia in pregnant women
- SecurAcath, which secures percutaneous catheters
- HeartFlow, a device that creates a 3D model of coronary arteries and assesses whether there are any blockages
- gammaCore, a device that alleviates severe headache symptoms

After the first year of its implementation, the NHS's Accelerated Access Collaborative (AAC) will continue to monitor NICE guidance on particular medical devices and diagnostics to see if any more meet the MedTech Funding Mandate Criteria for future years.

The MedTech Funding Mandate does not directly fund the technologies listed above, but NHS-funded care providers can be reimbursed by their clinical commissioner if they wish to use these devices.

Funds Still Unspent from NHS Tech Allocation to April 2021 (£m)



NHSX Tech Plan – opportunities for the medical device sector

The NHS Tech Plan was published in February 2020 and lays down the missions of technological development in the NHS. It also elaborates the short- term and long-term activities required to achieve the missions. The plan presents several opportunities for the medical device sector to engage with the NHS in a mutually beneficial manner. The table below describes the key missions and their corresponding one-year and long-term activities across all work streams identified as priorities:

Whilst technology adoption is critical for ensuring the longer-term sustainability of the NHS, it remains to be seen how much the loss of Matt Hancock will impact on the visibility of tech solutions within central decision-makers. The former Health Secretary was a major proponent of the digital agenda and was instrumental in setting up NHSX – with his departure, NHSX risks slowly losing its purpose and being absorbed back into NHSE.

MISSION	ONE-YEAR ACTIVITIES	LONG-TERM ACTIVITIES
Reducing the burden on workforce	• Improving login – Single Sign On introduction • Enhancing clinical communication with integrated communication and workflow management software	• Digital staff identity and passporting • Supporting innovation to release staff time
Ensuring information about people's health can be safely accessed wherever needed	• Establish core standards for digital diagnostics including pathology • Medicines standards – initial standardised dataset on secondary care prescriptions and medicines administration	• Delivering solutions based on HSIB recommendations around communication of results to patients and registries of implantable devices • Next generation Electronic Prescription Service to cover all care settings and medicines types • Develop a process to recognise and act on digital issues reported from the Patient Safety Incident Management System
Improve health and care productivity using digital tech	• Digital first NHS reducing the need for face to face OP appointments • Streamlining bookings, referrals and advice management	• Improving efficiency in corporate functions • Ensuring interoperability in all community care providers including pharmacists, optometrists, dentists, ambulance, mental health and social care workforce
Giving people tools to access information and services directly	• NHS App – enable records viewing, appt. booking, prescriptions and reminders • NHS website functionality and syndicated content improvement • Interoperable digital maternity and child health records	• Enabling digital and proxy access to systems and services • Integration of digital products with NHS App infrastructure • Enabling people to set contact preferences to be used across health and care organizations and systems

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 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. In the 2019/20 AAC report, 14 products had been identified as rapid uptake products, with almost 500,000 patients at more than 200 sites accessing these products.

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. The AAC's funding strategy is also tied to the MedTech Funding Mandate.

Life Science industrial strategy and vision

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 encourages NHS use of innovative devices meeting NICE's cost-efficiency criteria.

NICE initiated a consultation on its evaluation method for medical technologies and diagnostics in Autumn 2020. The new programme of NICE's evaluation methodology is expected to be published in December 2021, with full implementation of the new processes in January 2022.

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.

The Life Sciences Vision of 2021 aims to promote the UK as a dominant market leader in life sciences after the success of the Covid-19 vaccine, and other treatments throughout the pandemic. 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

The UK Medicines and Medical Devices Bill 2021

As a result of Brexit, from May 2021, the regulation of medical devices in the UK is no longer under the realm of EU law. The UK government introduced the UK Medicines and Medical Devices Bill in February 2020, with the final bill passing through parliament a year later in February 2021. The bill enabled the creation of a regulatory framework in the UK after Brexit, and it mirrors most elements of current and upcoming EU regulations. It also stipulates the creation of a UK medical device register.

The UK regulations have been set out by the Medicines and Medical Devices Bill of this year, which supplement the 2002 Medical Devices Regulations. If a manufacturer or supplier of medical devices wants to sell or distribute their product in the UK, registration from the MHRA is required after January 2021. However, if a device was registered before this period, then there is a grace period until June 2023 where devices with a CE marking can be recognised in the UK. After this point, medical devices will need to receive a UKCA marking, and organisations will need to ensure they are fully compliant with MHRA guidance to continue selling in the UK.

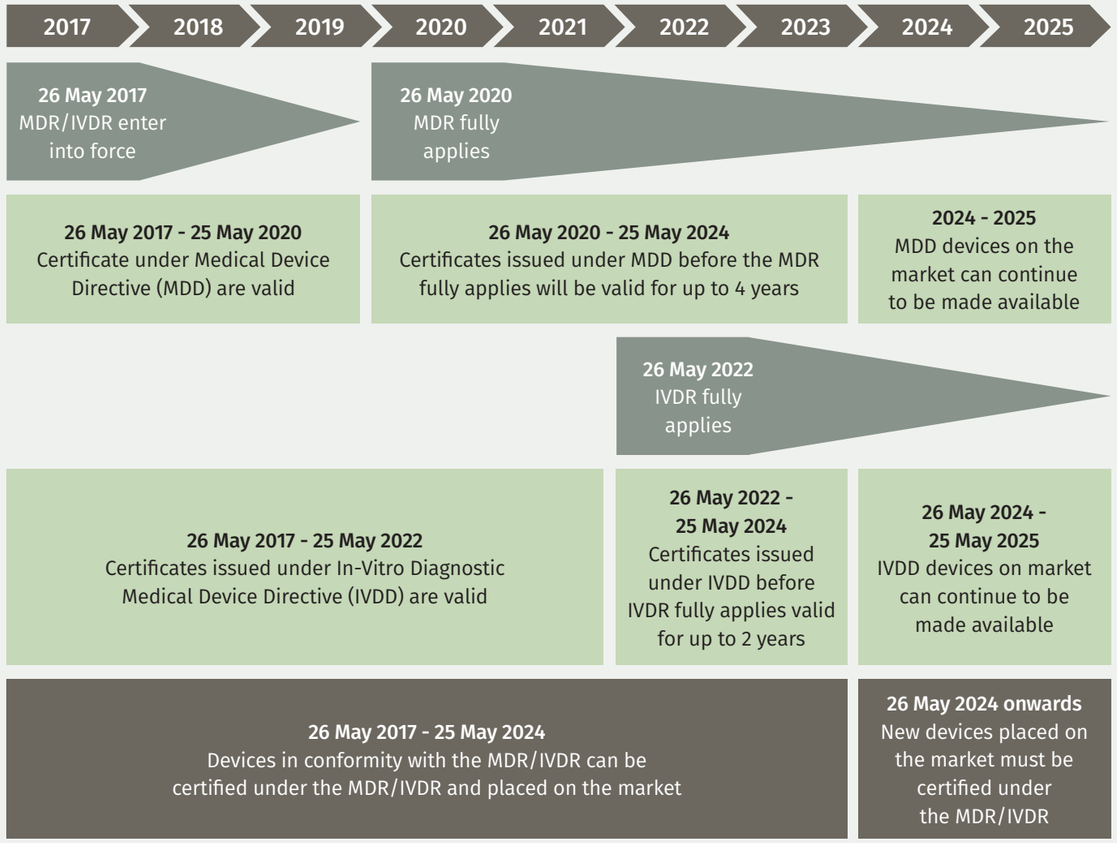
EU Medical Device Regulations

The EU Medical Device Regulation (MDR) was implemented in May 2021, and the In-vitro Medical Device Regulations (IVDR) is due to be implemented in May 2022, but these will not apply to the UK markets. 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 Regulation - Implementation Timelines



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 UK 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 UK MDR and be able to place a UKCA mark on their device.

Certification

Defining device classification is essential to any manufacturer as it will determine the regulatory pathway required in order to obtain a UKCA 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 UK Approved Body, an independent organisation which has been accredited to assess that medical devices are compliant with UK regulation through reviewing clinical and scientific data, manufacturing process, and the quality management system.

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 has left the EU, the timelines have been aligned with EU implementation. This means that manufacturers can expect a similar regulatory framework for medical device authorisation in the UK and in the EU. The MHRA has also issued guidance stating that it would continue to accept CE marked devices manufactured in the European Union until June 2023, but devices wanting to be sold in the UK are expected to apply for UKCA. All devices, both MDR and IVDRs, in the UK market need to be registered with the MHRA.

Classification under the Medical Device Regulation

Approval Process	Medical Devices		In-vitro Diagnostic Medical Devices	
Conformity Assessment via Notified Body	Class III	High Risk Examples: Pacemakers, Implanted cerebral simulators	Class D	High public health risk, high personal risk Examples: Hepatitis B blood-donor screening, ABO blood grouping
	Class IIb	Medium/High Risk Examples: Condoms, Lung ventilators	Class C	Moderate to low public health risk, high personal risk Examples: Blood glucose self-testing, PSA screening
	Class IIa	Medium Risk Examples: Surgical clamps, Dental fillings	Class B	Low public health risk, moderate to low personal health risk Examples: self-testing, Cholesterol self-testing
Self-certification	Class I	Low Risk Examples: Wheelchairs, Stethoscopes	Class A	Low public health risk, low personal risk Examples: Clinical chemistry analysers, Specimen receptacles

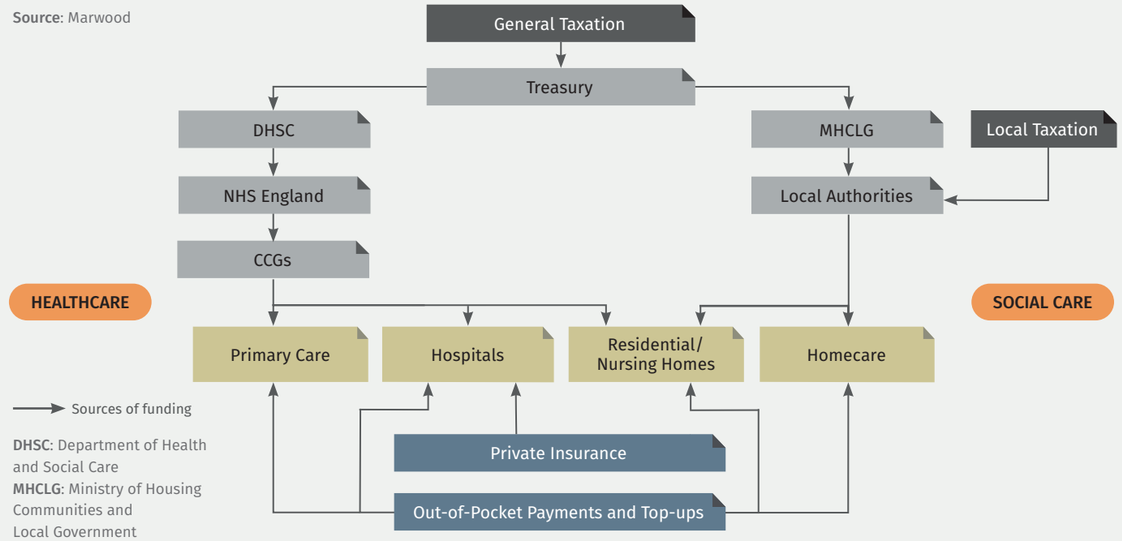
Overview Of Health & Social Care In England 5

Key Messages for Overview of Health & Social Care In England

- The NHS remains a major policy priority of the Conservative government under Boris Johnson – and as part of the general election pledges have committed substantial funding to it. It is set to receive an additional £20.5 billion funding in real terms between 2019/20 and 2023/24, including £2.3 billion for children and adult mental health services and £4.5 billion for community and primary care services
- The 2020 Budget announced additional capital funding, uplifting the total budget to £8.2 billion in 2020/21. There is also £854 million until 2025 to upgrade hospitals. However, longer-term funding remains to be clarified. The publication of a capital review has been delayed until the Spending Review, and the Government has suggested that it will contain a five-year investment plan
- Covid-19 has led to major system transformations adopted at pace across health and social care settings. The rapid roll-out of digital provision may lead to long-lasting change in health service delivery. The role of the private sector may also shift in the upcoming years as the NHS battles an elective care backlog that may hit 13 million as activity begins to resume after being paused through the pandemic
- System transformation objectives will see an increasingly strategic approach to commissioning across local health economies. Alongside the development of Integrated Care Systems, the emergence of NHS-Led Provider Collaboratives could radically reshape how mental health and higher-acuity learning disability services are commissioned, and the role of the private sector within them
- 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. Funding reform has become an increasing political priority since the emergence of Covid-19, and the Government has begun to develop options to secure long term funding sustainability for the sector
- Local authorities have protected social care funding at the expense of other services – in 2019/20, social care accounted for 57% of local authorities' budgets, up from 34% in 2009/10

Funding Flows

Source: Marwood



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

Population

Source: ONS (2017)

Total

66.8M

Life Expectancy

78.7 years 82.7 years

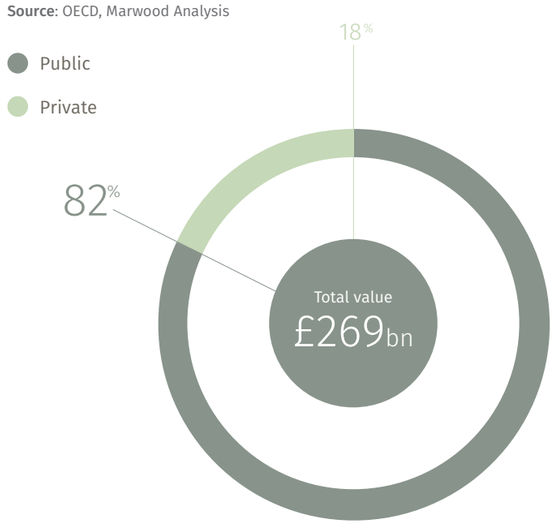
Population

- 29.6% are aged between 0 and 24
- 51.9% are aged between 25 and 64
- 18.5% are aged over 65

Selected Health and Social Care Data

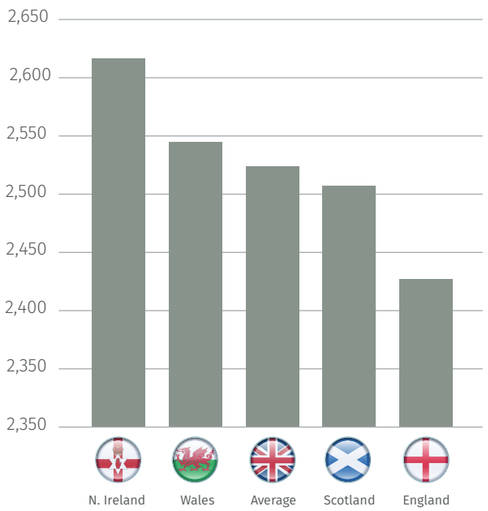
UK Healthcare Expenditure (2020)

Source: OECD, Marwood Analysis



Public Health Spending Per Capita (2020)

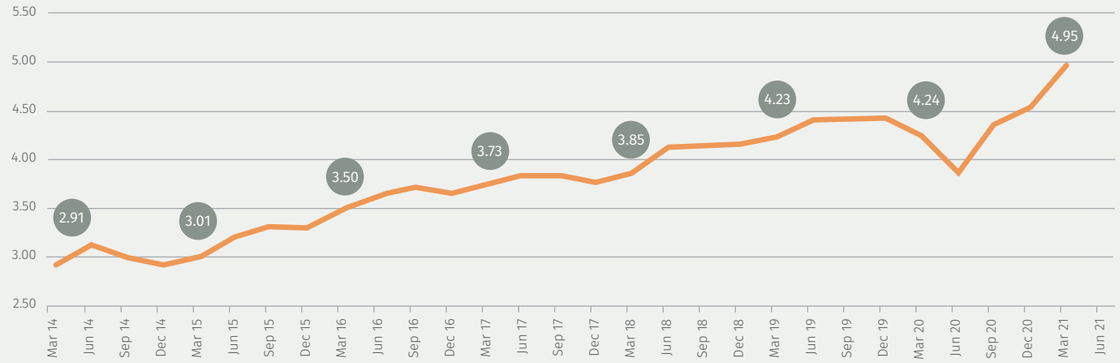
Source: ONS



Healthcare expenditure per capita in England is 3.8% lower than the UK average.

Number of People on Elective Care Waiting Lists (m)

Data: Number of people waiting to start treatment after referral from a consultant (m). **Source:** OECD, NHS Improvement



Implementation of the Long Term Plan for the NHS Supported by Additional Funding, Including Capital Funding

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 followed from the Summer 2018 announcement of £20.5 billion additional real-term funding for the health service, and provides a clear steer on where this new money is likely to be spent. Since coming to power as Prime Minister in July 2019, Boris Johnson continued to place the NHS as a top priority.

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

- Local children and adult mental health services funding will be ring-fenced and grow by an extra £2.3 billion in real-terms by 2023/24. The focus remains on early interventions, eliminating out-of-area placements, and improving crisis care
- £4.5 billion 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

The LTP does not represent a radical change. It broadly maintains the direction set by the Five Year Forward View (2014), but 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. NHS England have also proposed legislative changes that support integration but may impact on the ability of private providers to compete for NHS contracts. The Government has indicated that it would introduce these changes.

The LTP implementation will depend on the availability of capital funding. The Government announced that the total capital budget will increase to £8.2 billion in 2020/21. In addition, £854 million have been allocated to projects to upgrade hospitals in the next five years. However, longer-term funding remains to be clarified. The publication of a capital review has been delayed and is now expected by the Summer. The Government has suggested that it will contain a five-year investment plan.

A full chapter of the LTP is dedicated to healthcare digitisation. Priorities have been detailed in NHSX's Tech Plan, which outlines the vision for how technology will support the implementation on the LTP. They include: introducing digital staff identity, integration of digital products that support the NHS App, developing core record standards and supporting interoperability standards to ensure people's information can be safely accessed wherever it is needed.

Healthcare

Funding

Healthcare funding in England is primarily public and comes from general taxation. It is allocated to the DHSC by the Treasury.

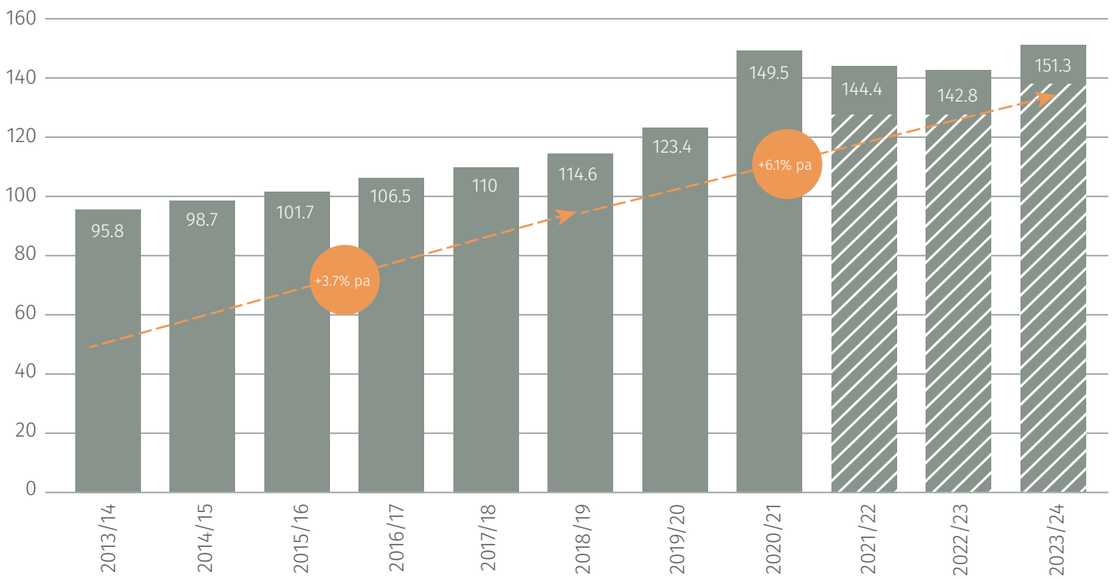
Healthcare funding is set to increase above the level of inflation until 2023/24. This will lead to average annual increases above the rate of inflation of 3.4% between 2019/20 and 2023/24. These funding increases follow a period of financial containment, which was most acute between 2010/11 and 2014/15 when healthcare funding increased by about 1% per year on average. In 2021/22, the NHS has been allocated £139 billion. This funding applies to the NHS revenue expenditure – money spent on healthcare services by NHS England and CCGs, and an additional £3 billion in funding for Covid-19 extra costs.

The total capital budget for 2021/22 will be increased to £9.4 billion, a 34% increase on the £7 billion allocated in 2019/20. £325 million for new diagnostic machines has been allocated, alongside £165 million to replace mental health dormitories with single en-suite rooms.

An extra £1 billion was set aside to tackle the backlog of elective care, with additional funding allocated to deal with the increased costs of the pandemic. Overall, these announcements will be welcome given the previous drop in NHS capital resources. However, longer term capital funding allocations remain unclear.

Total NHS Revenue Budget Allocations (£, bn - Nominal Terms)

Source: NHS Funding Settlement, Spring Budget 2020



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 partly 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 and fertility sectors. There is also some growth in out-of-pocket expenditure on services that provide faster, or virtual, access to GP appointments.

When first created, there were 211 CCGs. However, the number has reduced through a series of CCG mergers. After the ICS policy becomes fully implemented in April 2022, CCGs will be integrated across ICSs, with one commissioner covering each geographical area. As of May 2021, there are 42 ICSs across England.

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.

Since April 2021, ICSs are responsible for allocating funding to meet patient needs for local service provision across acute, secondary and the majority of mental health services, with the fundamental benefit of ICSs being easier coordination and collaboration across health and care 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.

For mental health services, the development of NHS-Led Provider Collaboratives, which can include the private sector, will take on commissioning responsibility for services across a wide range of mental health services that are not primarily commissioned through NHS England's specialist commissioning function. This could have large impacts for the way that the independent sector interacts with NHS-funded care in this area.

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 March 2021, there were over 41,000 GPs, including locums. However, the NHS is seeing a sustained decreased in the number of GP per population – from 52 per 100,000 in 2015, to 46 per 100,000 in 2021.

The secondary care provision landscape is primarily 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.

Private providers are authorised to deliver NHS services. Under the provisions outlined in section 75 of the Health and Social Care Act 2012, CCGs are required to launch competitive tenders for contracts whose total value is over £615,278.

The Government has indicated its intention to introduce primary legislation to relax NHS procurement rules. The decision to put contracts to tender would be left to CCGs. While this could reduce the number of tenders the private sector could bid for in the future, the impact would likely differ across sectors and depend on local commercial dynamics and existing relationships. Those sectors where NHS provision has been scaled back, such as high acuity mental health services, will continue to rely on private sector provision.

Regulation

The healthcare system in England is subject to significant regulatory oversight, and these can lead providers to face competing priorities. There have been efforts to align 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

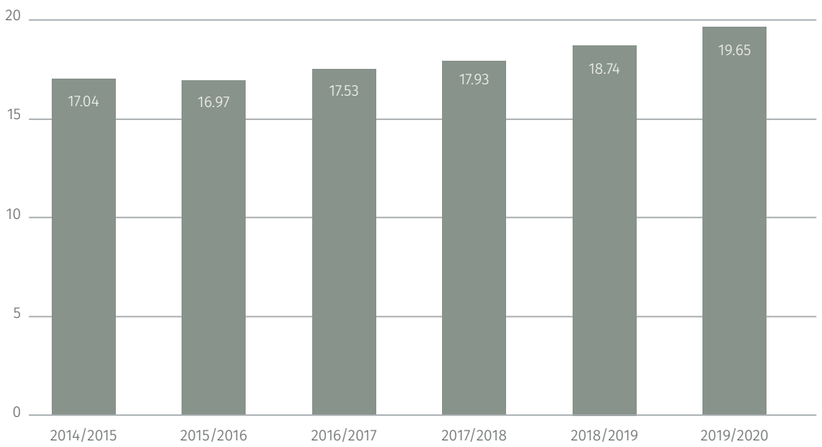
Funding

Publicly funded social care cover services for adults with physical or learning disabilities, and services for older people who are losing their independence. These services are funded by 152 local authorities, whose budgets are made up of a complex mix of national and local taxation.

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. Whilst there have been moves to offset the reduction of central funding for local authorities by giving them 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.

These changes have placed social care spending under pressure. Following a period of decline after 2010, expenditure has risen by 6% in real terms from 2015/16 to 2019/20. Since 2017/18, the Government has announced additional central ring-fenced funding for social care to be allocated to local authorities. This amounted to £3.5 billion between 2017/18 and 2019/20. The 2020 Spring Budget announced that the Treasury would provide an additional £1 billion funding for social care in 2020/21 and this will

Local Authority Adult Social Care Expenditure (All Age) (£, bn)



Data: Adult Social Care Gross Current Expenditure (£, bn)
Source: NHS Digital

continue every year of the current Parliament. However, the 2021 Budget did not mention any kind of long-term funding for social care, leaving much of the sector underfunded.

Payment system

Social care providers are exposed to a mix of public and private payments. This is because social care services are not free at the point of use. Local authority funding only provides a safety net and many people must pay for their own care privately. This is determined by needs and means tests.

Public funding support covers the cost of nursing 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 homeowners applying for financial support in a nursing home, the value of their property is included in assets. Those who do not qualify for local authority funding pay the full cost of nursing home services out-of-pocket. Some people may choose to pay 'top-up' fees to stay in a nursing 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 2019/20, the average weekly local authority fee was £660, while the average weekly fee charged to self-funders was £858.

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 2021/22, the UK Homecare Association set the minimum price of home care costs at £21.43 per hour, with rates varying greatly across local authorities, and according to the complexity of the care provided. However, the average hourly rate paid to providers is substantially below the level that local authority-delivered services cost per hour, and is a factor behind the boom in privately provided homecare provision, as cash-strapped local authorities looked to offset declining budgets by finding cheaper private sector alternatives. There are increasing calls from the private sector to uplift fees substantially – particularly in light of increases in the national minimum wage and difficulties in attracting workers to the sector.

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 nursing home beds across 16,392 locations. The 30 largest nursing 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.

In May 2021, CQC launched a new strategy. The focus of its new approach will be to drive regulation using high-quality data and feedback from people about their experiences of care. As before, the CQC's focus will remain on ensuring safe services which continuously learn and improve. However, a key difference will be a greater focus on encouraging services to work with their local systems to improve the quality of care.

Political environment

Boris Johnson has been Prime Minister since July 2019 following the resignation of his predecessor Theresa May. Having inherited a minority government and a Parliament highly divided over Brexit, Johnson called an early general election on 12 December 2019, which delivered the strongest Conservative majority for 40 years.

Subsequently, Parliament approved the Withdrawal Agreement with the European Union (EU), and the UK officially left the EU on 31 January 2020 and entered an 11-month transition period which ended on 31 December 2020. Johnson reached a trade deal with the EU at the last hour, just one week before the transition period officially ended. While many aspects of the deal are still to be fleshed out from the Conservative Party side, and the EU side, the agreement outlined the UK's departure from the EU, with this new political era commencing on the first day of 2021.

With a renewed and more than comfortable majority in Westminster, Johnson's Government has sought to move away from Brexit and turn to addressing internal policy issues. The NHS reforms are clearly a major priority, following the direction outlined in the LTP, and with the advent of the Integrated Care Systems. Social care is still awaiting reform, with reforms to the sector proposed in September 2021 by the government.

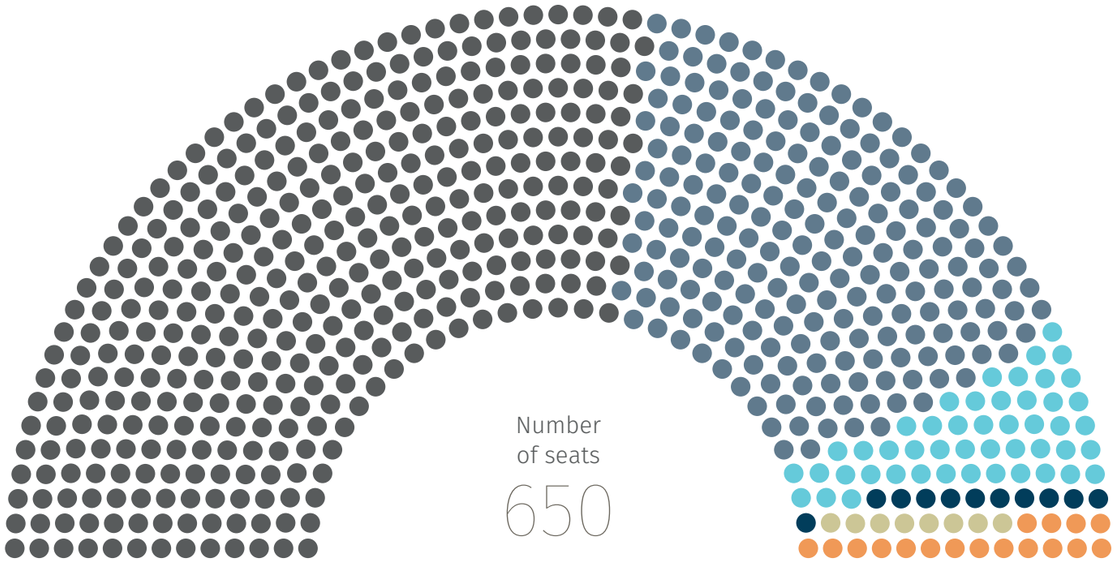
Composition of Parliament

Government

- Conservatives (364)

Opposition

- Labour (202)
- Scottish National Party (48)
- Liberal Democrats (11)
- Democratic Unionist Party (8)
- Others (17)



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

DCLG: Department of Community and Local Government

DHSC: Department of Health and Social Care

DRG: Diagnosis Related Groups

EMA: European Medicines Agency

EU: European Union

FNC: NHS Funded Nursing Care

FT: Foundation Trusts

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

IBCF: Improved Better Care Fund

ICS: Integrated Care System

LA: Local Authority

LGA: Local Government Authority

MDT: Multi-Disciplinary Team

MHRA: Medical and Healthcare Products Regulatory Agency

NAO: National Audit Office

NHS: National Health Service

NHS FT: NHS Foundation Trust

NHSI: NHS Improvement

NICE: National Institute for Health and Care Excellence

NMC: Nursing and Midwifery Council

NMW: National Minimum Wage

PAC: Public Accounts Committee (House of Commons)

PbR: Payment by Result

PHE: Public Health England

PHI: Private Health Insurance

PMS: Personal 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

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