THE WHITEHALL REPORT 2022

MARWOOD GROUP

Contents

Introduction

As the UK emerges from Covid-19 it is clear that the delivery of health and social care will never be the same. Providers, payers, and patients alike have little desire to return to the same operational, financial, and delivery model that existed pre-pandemic. The crisis gave way to the rapid adoption and implementation of technology, allowed for more nimbleness, simplified decision-making, and created a flexible work and care environment – all of which have unequivocally changed the perspective on how, when, where, and who can deliver health and social care services. While so much was lost during the pandemic, we can now reflect back and see that much was also gained. Of course, many questions remain on how these gains are translated into a sustainable future model of care, but the UK is moving in the right direction.

With a 'future forward' mentality and a litany of health and social care priorities to be addressed in the health and social care system, our latest Whitehall report covers the key policy, funding, and regulatory developments from August 2021 through to August 2022. In doing so, it covers the key areas the UK government and national bodies have actioned to ensure that they are supportive of the exploration and innovation required to define new models of care during this transitionary period. From the outsized elective care backlog, out-of-pocket spending on care homes, greater scrutiny of children's social care services and special education providers, and the creation and adoption of post-Brexit UK policies and procedures in the Pharma, Biotech, and MedTech sectors, there have been numerous reports, and White Papers of interest to the sector. Chief amongst these developments, the Health and Care Act came into play in 2022, providing guidance and leadership to help commissioners and providers plot a course for a more sustainable future health care system.

Practically every sector of care has been touched across the past 12 months to help steer towards a different path of care delivery, as focus has now returned to the provision of health and social care. However, as with all healthcare initiatives, innovation and advancement must be balanced with the maintenance of high-quality standards, elevating access, and delivering services within a defined financial envelope.

In the health care sector, the Health and Care Act of 2022, the largest piece of legislation introduced this year, formalizes Integrated Care Systems (ICSs) which restructure the way health and care is commissioned and delivered and will have a far-reaching impact across healthcare services.

As part of this Act, a new Provider Selection Regime has been introduced which gives NHS commissioners freedom in determining when a competitive tender is needed. Due to be implemented in December 2022, this may streamline some service arrangements, but also allows ICSs to continue to run competitive tenders. This means that relationships with NHS commissioners are likely to remain a key dynamic for the sector, and that understanding asset spread across different ICSs will continue to be an important factor for private providers and investors.

ICSs have emerged at a particularly unsettled time within the NHS. Across the system, the policy focus shifted to recovering the elective care backlog, with the expectation that ICSs deliver increased elective activity compared to 2019/20 levels, and with dedicated funds in place to support this. Crucially, policymakers have recognised that the NHS lacks the staff and capacity necessary so the policy explicitly encourages systems to make use of private sector providers to optimise activity levels. Financial envelopes will guide what systems can afford to do themselves, and what they choose to outsource to the private sector, but ICSs remain sensitive to the growing pressure to increase activity levels and ensure recovery of the elective care backlog.

In social care, as the reliance on the private sector grows stronger, so does the scrutiny of the sector, from both a quality and financial perspective. The spring of 2022 saw the publication of a large number of national policy reports and independent reviews. In March 2022, the keenly awaited SEND Green Paper was published, setting out a set of ambitious reforms to the special education sector in the hope of achieving financial stabilisation and more consistent outcomes for children with special education needs across the country. In May, the Independent Review of Children's Social Care reported its findings, having been delayed while looking into the child abuse deaths of Star and Arthur. The Independent Review's recommendations demonstrated close alignment to the Consumer and Market Authority's (CMA) ideas for change, but it remains to be seen how the Government will respond.

Equity and access have also continued playing a larger role in policy development and this year we have seen England increase the coverage of fertility services to new parent groups. Driven by the Government's Women's Health Strategy, the NHS has expanded access to public-pay fertility services and improved the ability of Intended Parents to compare the performance of clinics. This is expected to lead to improved awareness of fertility treatment options and a growing pool of parent groups across England who may attempt to access NHS fertility services. However, without additional earmarked funding, and an insufficient donor supply, it is unclear how the NHS will cope, potentially resulting in an increase in the demand for private-pay fertility services.

The importance of government decision-making in healthcare is apparent and a point that Marwood Group drives home in every client interaction, recognizing that the importance is paramount when investing in health and social care. While the public funding of healthcare services can make healthcare assets an attractive investment, it is the interpretation and implementation at the regional and sometimes local level of national policies and recommendations that can determine the level of success or failure of an investment.

As the 2022 calendar year comes to a close, all eyes will be on our new government and the stance they take to support, or revise, key agenda items in the health and social care space across England. In an inflationary environment, they will no doubt feel pressure to ease the burden without making longer-term commitments. Historically, governments have been reluctant to raise tariffs and reimbursement rates for perceivably transient inflationary pressures, unless they become embedded, and in the short term may resort to one-off cash injections to bail out struggling providers rather than commit to long-term reimbursement/tariff uplift. We anticipate providers, payers and investors alike will be monitoring the situation closely across the coming months as continued CPI and wage inflation may force the issue to be addressed in 2023.

Our annual Whitehall Report acts as an important reference document to decode the complexity of health and care in England. We hope our insights into key and ongoing developments affecting the regulatory, funding, and policy levers impacting the health and social care markets in England help support decision-making for investors in the sector.
We hope you enjoy our Whitehall Report and look forward to further discussing the topics that we have covered.

Heather Pfeiffer

Director, UK and European Healthcare Advisory
Marwood Group UK
HPfeiffer@marwoodgroup.com

Key Policy Developments In Health And Social Care 1

NHS Reforms: The NHS Gets Its Biggest Shake Up For A Decade

Since the introduction of the Health and Social Care Act (2012), clinicians, commissioners, local authorities, and wider stakeholders have been united in their desire to significantly reform the health system. Due to this broad consensus, the direction of travel embodied by the recent reforms has been set iteratively, building on new ways of working and coalescing around the need for better integrated services, reduce bureaucracy and support improved working between parts of the NHS, and between the NHS and social care.

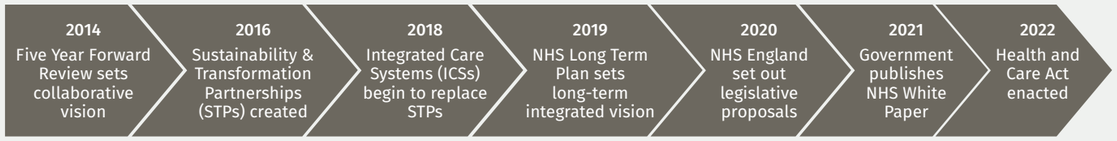
Recognising that 2020 and 2021 have been amongst the most challenging in the NHS's 72-year history, the government finally published a White Paper in 2021 framing the legislative basis to support system reform.

This acknowledged a need to bring together NHS organisations, local government and other partners at system level in order to deliver joined up approaches to improve health and care.

An eight-year journey for the health system

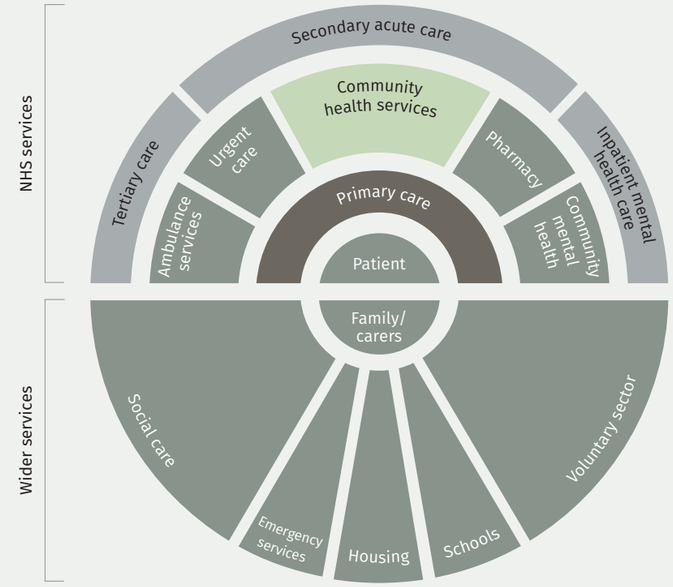
In many ways, local systems were already working to these goals via Sustainability and Transformation Partnerships (STPs). In this sense the Health and Care Act of 2022 represents the culmination of changes that have been expected since the publication of the NHS Long Term Plan in 2019. However, the new organisational structures and current focus on population health builds on work the system as a whole has been focused on even before that since the Five Year Forward View was published in 2014.

An eight-year journey of reform for the health system



Integrated care systems: new local commissioners on the scene

Perhaps the most defining feature of the Health and Care Act is the introduction of Integrated Care Systems (ICSs). From 01 July 2022, 42 ICSs have taken over from Clinical Commissioning Groups (CCGs) of which, following a series of mergers, there were approximately 106 as of April 2021, down from over 200 previously.



Whilst this restructure may seem like a move towards greater centralisation in the NHS, ICSs are in themselves composed of an Integrated Care Partnership (ICP), and an Integrated Care Board (ICB). The ICS will also have various geographical footprints, known as places and neighbourhoods. In many ways the ICBs will be most like CCGs, as they will merge some of the functions previously 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 ICPs 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 or social care needs - much like STPs were responsible for before.

- Integrated Care Board (ICB) – will hold NHS bodies within the ICS to account, allocate budget and commission services

- Integrated Care Partnership Committee (ICP) – will produce the integrated care strategy for their local area, which ICBs and local authorities will need to adhere to when making decisions, commissioning, and delivering services

These organisational forms will shape how public sector services are delivered and will impact demand in specific services areas. Overall, the changes are intended to support integration and innovation by enabling different parts of the health system to work together, reducing bureaucracy across the system, and providing more streamlined accountability. This mirrors the three key pillars presented in the NHS White Paper back in 2021.

Integration and innovation: three key pillars

Working together and supporting integration	Enabling different parts of the health and care system to work together effectively, in a way that will improve outcomes and address inequalities
Reducing bureaucracy	Turning effective innovations and bureaucracy busting into meaningful improvements for everyone, learning from innovations during Covid-19
Enhancing public confidence and accountability	Ensuring that there is the right framework for national oversight of our health system, that national bodies are streamlined, with clear roles and responsibilities and that the public and Parliament can hold decision makers to account

A new provider selection regime

The Health and Care Act, 2022 has also made changes to competition and procurement rules, especially the Public Contracts Regulations. It has done this by removing aspects of competition and procurement in order to remove barriers to integration. In practice this will mean that from December 2022, local areas – in keeping with guidance from 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.

Guidance on the new Provider Selection Regimes provided by NHS England is expected to work its way into contracting language over the next few years as it is integrated into local commissioning across England. Providers 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 who are able to demonstrate ongoing investment in innovative and integrated services may be well-placed to benefit from these changes.

The new Provider Selection Regime enables commissioners to avoid externally tendering if they wish, and to design provider selection for local need. This will provide clear opportunities for the private 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.

SELECTION TYPE	WHEN IT CAN BE EMPLOYED	IMPACT ON PROVIDERS
Continue 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 and service delivery • The private sector may benefit from having existing contracts extended, but strongly performing competitors may alter dynamics
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

Post-Covid-19: A Growing Elective Care Backlog

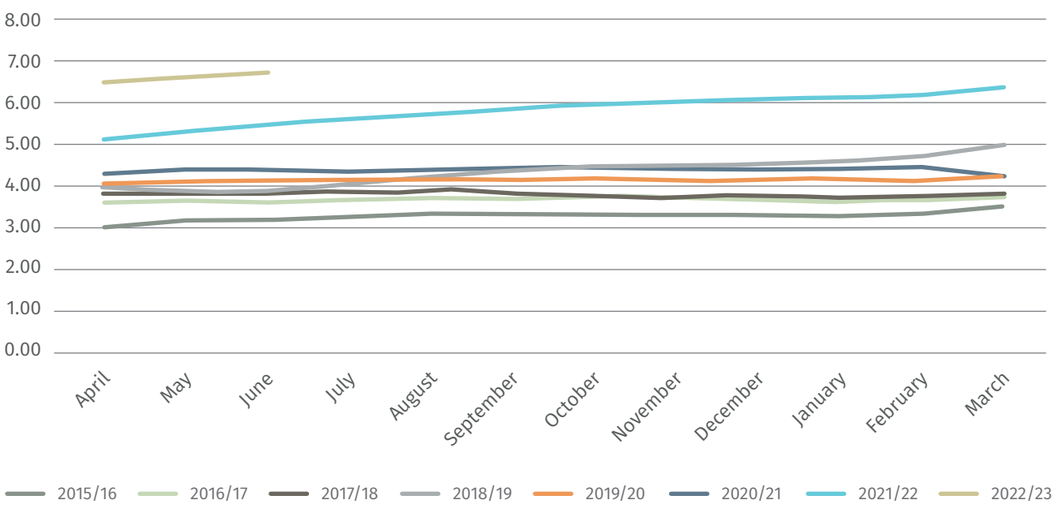
Nowhere is the changing NHS landscape in the post-pandemic era more apparent than the increasing large backlog of elective care waiting lists. Covid-19 had a devastating impact on waiting times that were already at high levels – increasing to 6.6 million people in March 2022 - up from 4.4 million shortly before the start of the pandemic.

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. Additionally, many of the challenges impacting the elective care waiting list have been exacerbated due to workforce insufficiencies and inadequate funding across the NHS.

The emergence of Covid-19 created a total stop to all elective activity in the initial phases of the crisis, so initially the waiting list actually shrunk in line with higher barriers to referrals to secondary care, falling by over 580,000 between February and May 2020. But as these barriers to referrals were lifted with successful roll-out of the Covid-19 vaccination program, the waiting list has grown to more than 6 million in November 2021. This clearly illustrates the magnitude of the backlog facing the NHS and the pressure on the health service to recover it.

The growing waiting list shows the private sector will likely continue to play a vital role within the system

Number of people waiting for elective care treatment, all specialities (mn)



Data: Number of patients waiting to start treatment at the end of the month, in millions (2015-2022)
Source: National Statistics RTT data

Elective care initiatives: a supportive landscape for increased outsourcing

The pandemic has demonstrated the extent to which the government is prepared to protect elective care delivery and ramp up capacity. In 2022, the system's policy focus shifted firmly to recovering the elective care backlog. This was accompanied by clear expectations that ICSs deliver increased elective activity compared to 2019/20 levels and was supported by dedicated funds to deliver additional capacity.

However, as hospitals are operating at the edge of their capacity, additional funding has been the only lever available to support waiting list reductions. In most areas, innovative pathway redesign had already been attempted, so the real opportunity for commissioners to make inroads on the waiting list is by looking to outsource more elective care to private providers over the next 3-5 years. Over the last two years, many private providers have created stronger relationships with their local systems.

As these evolve into formal ICSs, providers who proactively engage may find themselves well-placed to provide essential overflow capacity to the NHS. This may provide unique opportunities for private providers to deliver capacity across newly formed ICSs and help 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 help the NHS manage the waiting list by providing diagnostic activity which helps the NHS take stock of clinical risk on the waiting list and make key treatment decisions.

In 2021, the Elective Recovery Fund was announced specifically to target increased capacity for elective care delivery. This was followed in 2022 with more announcements of other elective care initiatives to reduce the backlog.

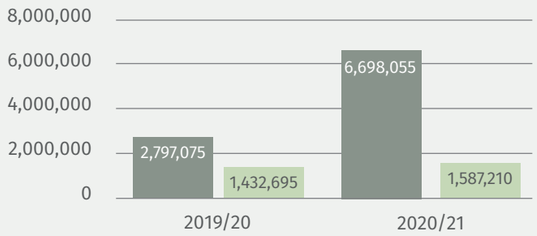
The Government has introduced several elective care initiatives to reduce the backlog since the start of the Covid-19 pandemic

INITIATIVE	DESCRIPTION	FUNDING
Elective Recovery Fund (ERF)	Announced in March 2021 to incentivise ICSs to tackle elective backlogs in their area. ICSs had to deliver elective care at a level greater than 95% (from July 2021) of their 2019/20 baseline level in order to receive funding	£2 billion for 2021/22
Elective accelerators programme	12 ICSs (and a joint paediatric provider group) received funding to implement and evaluate new ways of increasing elective care activity to 120% of the 2019/20 baseline	£160 million for 2021/22
Targeted Investment Fund	Funding available to ICSs and individual NHS trusts to support investments in elective reforms (i.e. use of technology), including in systems and for trusts facing the greatest challenges in elective activity	£700 million for the last 6 months of 2021/22 only, of which £500 million to be spent on capital
Increasing Capacity Framework (ICF)	Framework agreement set up by NHSE from April 2021. ICSs can use procure elective services from pre-approved private providers using the framework	Spend is estimated to be up to £10 billion between 2021/22 and 2024/25
Waiting list validation and management	Since 2020/21, NHSE&I has required ICSs to carry out a clinically led review of their waiting list on an ongoing basis, to ensure the effective prioritisation and management of clinical risk	Unknown, but costs vary locally
Elective Recovery Plan – additional activity	Approximately £2.66bn per year for delivering additional activity up to March 2025. An element of this will be invested in staff – both in terms of capacity and skills	£8 billion between 2022/23 and 2024/25
Elective Recovery Plan – capital investment	For spend on new beds, equipment, and technology to support elective recovery	£5.9 billion (capital)

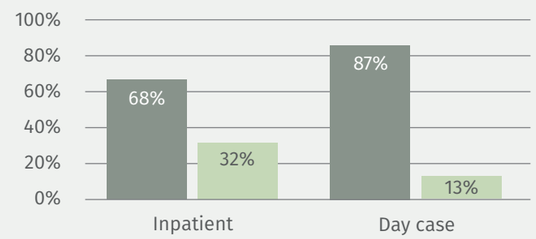
Source: National Audit Office; DHSC

The private sector has more than doubled its undertaking of NHS-funded procedures in 2020/21. They are mostly day cases

Total private-pay vs. NHS funded procedures delivered in the private sector (£, mn)



Percentage of private-pay vs. NHS funded care delivered in the private sector, by length of stay (£, mn , 2020/21)



Data: Number of pure private vs. NHS procedures delivered by the private sector in 2019/20 and 2020/21.
Note this is not nationally collected data and only includes data from providers who have submitted to PHIN.
Source: Private Healthcare Information Network (PHIN) Hospital Volume and Length of Stay

New paradigms for private hospital providers

Despite this special funding, policymakers have recognised that the NHS lacks the staff and capacity necessary to recover the backlog. Because of this, the policy explicitly encourages systems to make use of private sector providers to optimise activity levels. Although financial envelopes will guide what systems can afford to do themselves, and what they choose to outsource to the private sector, ICSs remain sensitive to the pressure to increase activity levels and activity levels show that the private sector has become a key player in ensuring recovery of the elective care backlog.

Under Pressure: Workforce Challenges In Health And Social Care

It is perhaps unsurprising that workforce is the key issue keeping NHS and local authority leaders awake at night. At the end of July 2022, the Health and Social Care Committee reported that the health and social care sectors are facing the greatest workforce crisis in their history. Despite this, the workforce plan which had been promised in Spring 2022 has not yet been published and the Government rejected the recommendation of undertaking an independent analysis of the health care shortages, voting it down three times during the development of the Health and Care Bill.

During 2022 reports of nurses quitting in droves and other workforce pressures across the system has plagued the media. The data also suggests there is a problem. At the request of the Health and Social Care Committee, the Nuffield Trust provided estimates for the number of vacancies in the NHS. This showed approximately 105,855 vacant posts as of March 2022, around half of which were nursing or medical posts.

Vacancies are only part of the problem. Across a large range of healthcare providers there are also concerns around staff absences from work through sickness, stress and burn-out. These all contribute to day-to-day staffing shortages.

As the NHS attempts to cope with continued shortages, the elective care backlog continues to grow, with estimates that by around 2030, the growing demand in health and social care will require an additional 475,000 jobs in health and an additional 490,000 jobs in social care.

Falling short of nurses: the domestic recruitment challenge

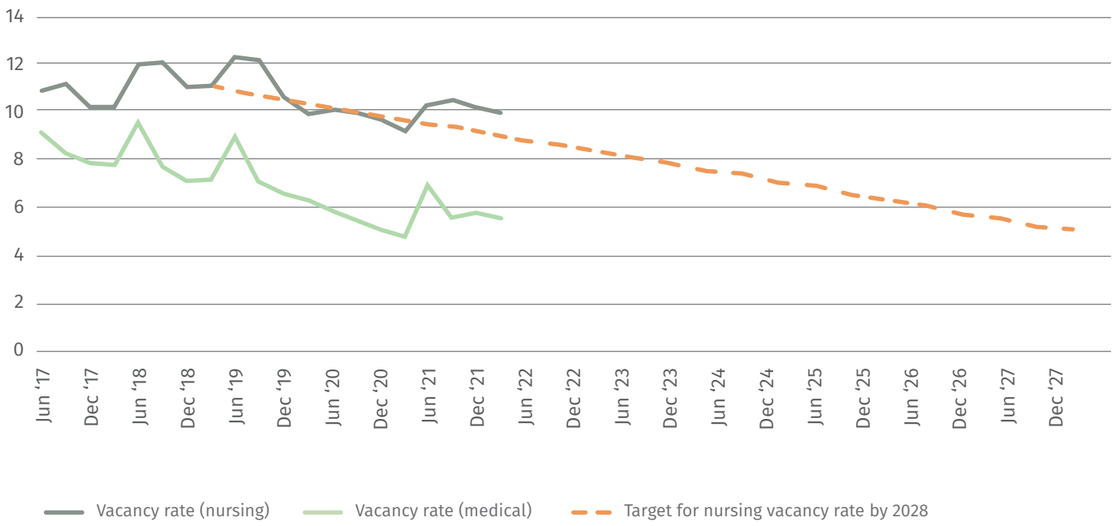
For the nursing workforce - a group where some of the biggest concerns lay – responsibility for training, recruitment, and retention is spread across the system. Local NHS trusts, foundation trusts and GPs employ nursing staff, and are responsible for their recruitment, retention, and day-to-day management.

Overall policy for the NHS and social care workforces sits with the Department of Health & Social Care (DHSC). But depending on the staffing group in question, a number of national and local NHS bodies are responsible for workforce planning and supply. For example, NHS England and NHS Improvement (NHSE&I) support and oversee the performance of NHS trusts in relation to workforce retention and other workforce responsibilities. During 2022, Health Education England (HEE) which previously oversaw NHS workforce planning, education, and training, was merged with NHSE&I to create a single organisation with responsibility for workforce.

Over the last decade, the NHS has lacked a national workforce plan, reflecting these dispersed responsibilities. However, in 2019, the NHS Long Term Plan (LTP) set out future service commitments and acknowledged the need to increase staff numbers, noting that the biggest shortfalls were in nursing.

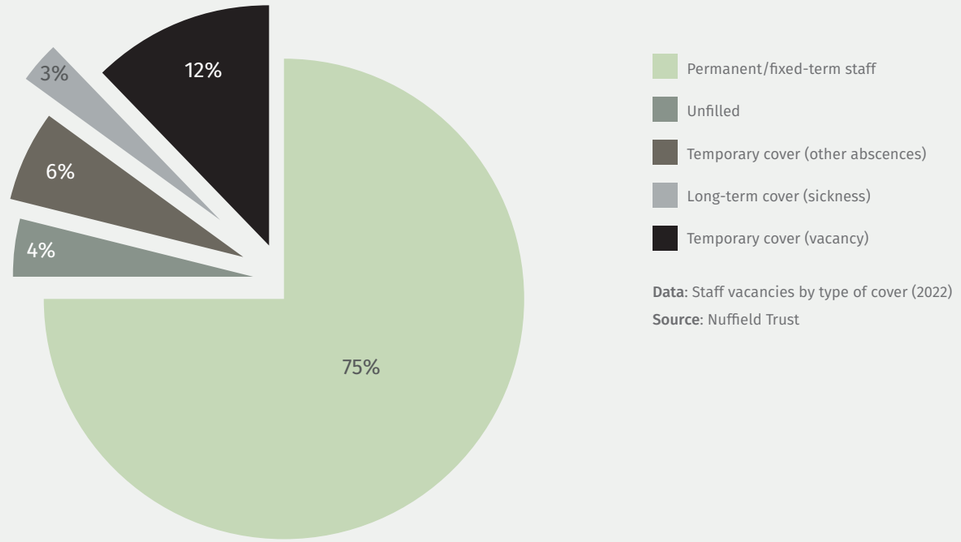
By the start of 2020, the nursing vacancy rate was at almost 11%, reflecting nearly 40,000 nursing vacancies in the NHS. During 2021, the vacancy rate increased before stabilising a bit over 2022. However, it still significantly off the target rate which the NHS would need to hit to achieve the Long Term Plan (LTP) goal of reducing the nursing vacancy rate to 5% by 2028.

Vacancy rate (%) for nurses and doctors in the UK



Data: NHS nursing and medical staff vacancy rates, in percentages (2017-2028)
Source: Nuffield Trust; NHS Digital

Staff vacancies by type of cover (2022)



Data: Staff vacancies by type of cover (2022)
Source: Nuffield Trust

One of the Conservative manifesto pledges in relation to the NHS was to deliver 50,000 more nurses by 2024 – which would be achieved by retaining existing workers, as well as hiring more nurses domestically and internationally. During 2022, the government has reported on the half-way mark towards achieving this target and flagged domestic recruitment as a key risk. This is because in 2022, approximately 21,130 students were accepted on to nursing courses, representing a fall of 1,560 (or 7%) from 2021. The report states that if this drop in new students continues next year and beyond, the 50,000 nurses target will be difficult to meet. Perhaps for this reason, national efforts continue to focus on recruiting overseas nurses to work in the NHS.

Social care: make or break?

Social care providers continue to face an equally, if not more challenging staffing environment. The workforce was struggling even before the pandemic but was hit hard through Covid-19. In July 2022, the Health and Social Care Committee reported that one in three care workers left their job in 2020/21. In the post-pandemic landscape of high costs of living, competition with other industries continues to create regional pressures.

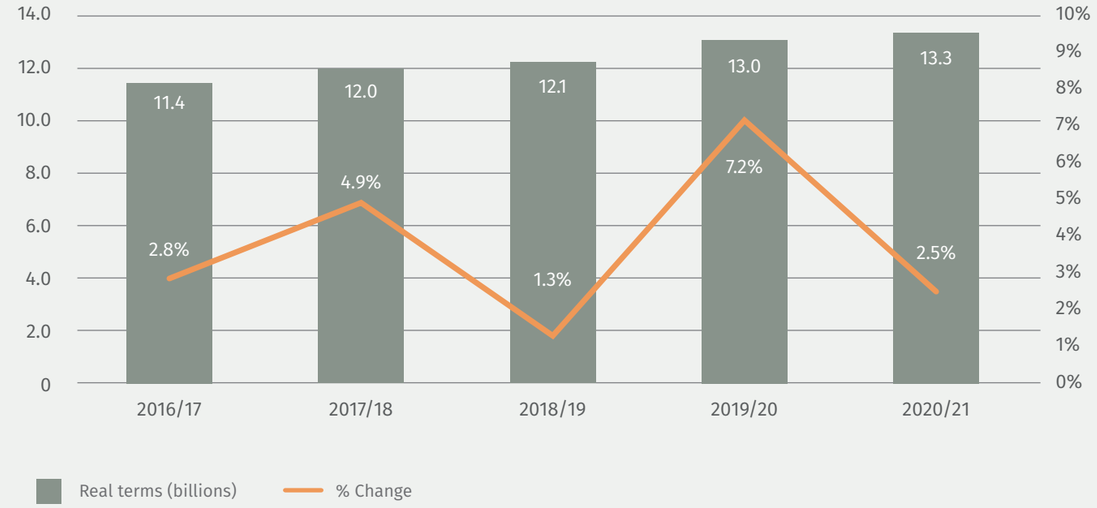
As a result, it is expected that social care providers will continue to struggle to recruit adequately into 2023. This will mean that most care providers may face challenges in retaining existing staff and recruiting new staff, adding to the existing skill shortages and compounding pressure on the social care workforce. While policy has devolved social care workforce planning to the local level, there is recognition that many of the drivers of recruitment and retention are in the national sphere, such as training places in university or industry. Without meaningful professional development structures, and better contracts with improved pay and training, social care will remain a career of limited attraction even while demand for social care grows.

Reforms to the Health and Care visa scheme may also be a way the government could bolster international recruitment to social care – by waiving the cost of sponsorship certificates and licences for one year and other similar measures. 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.

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 2019 NHS Long-Term Plan (LTP). This funding has driven major changes in the primary care landscape, and created opportunities for healthcare operators
- Primary Care Networks (PCNs), groups of GP practices with a combined patient population of between 30,000 and 50,000, are changing the way in-person care is delivered. This is an attempt by the NHS to scale primary care and offer a broad range of integrated services using multi-disciplinary teams of healthcare professionals. This is expected to continue to gain momentum driven by the new Health and Social Care Act, 2022
- Covid-19 has shown that a large volume of primary care can be delivered remotely. 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
- 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

Investment in General Practice in England (£, bn)



Data: Real Terms Government investment in General Practice services and the reimbursement for drugs dispensed in General Practices, excluding Covid-19 costs, in £ billions (2016/17 to 2020/21)

Source: NHS England

Payers

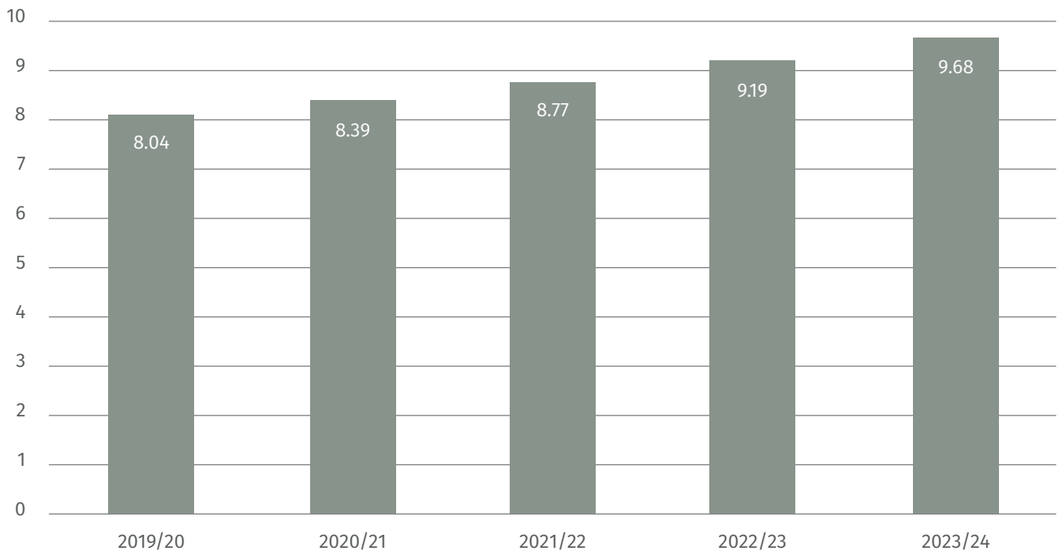
NHS funding for general practice

The Long Term Plan (2019) set out the vision for the NHS to 2029 and 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.

This overall increase in real-terms spending reverses a trend over the previous decade, where GP funding rose more slowly than other parts of the health service. This also gives local areas longer-term certainty in financial planning – with a five-year allocation set from 2019/20 to 2023/24. This will support long-term service transformations and enable a funding shift towards more preventative service options that may release savings for the NHS over time. ICBs 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.

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, through allocation by ICBs.

CCG allocations for Primary Medical Care (£, bn)



Data: Clinical Commissioning Groups (CCGs) allocations for primary medical care from NHS England, in £ billions (2019/20 to 2023/24)
Source: NHS England

GP contract reform to support the delivery of new care models

GPs 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 PCNs as part of Integrated Care Systems has required amendments to be made to existing contracts, but the core GP contracts remain the standard templates, with most GPs holding 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 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 51% of appointments were with non-GP staff in April 2022, up from 44% in 2021.

In December 2021, NHS England published a report detailing the GP contract for 2022/23. The changes outlined in this report were met with significant disagreement from both the BMA and GPs. The most notable change in the new contract is a requirement for PCNs to extend their services to 6:30PM-8PM on weekdays and 9AM-5PM on Saturdays, starting from October 2022. During these additional hours, a full MDT must be present to meet the health needs of the local population.

This specification in the new contract proved very unpopular amongst GPs, with many believing that the contract amendments were unrealistic due to a lack of resources and increasing workload pressures. Consequently, a ballot by the BMA found that over half of GP practices were prepared to withdraw from the PCN DES they were linked to, as they are unable to extend their hours without additional funding and staff. The BMA has called to significantly reform the 2023/24 GP contract to reduce GP workload and ensure patient safety.

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 enhance 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, and to introduce new IT systems that enable sharing patient records between various care professionals.

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 their products will be able to communicate with each other across organisational boundaries.

ICBs 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. This will enable primary care providers to meet the goal set out in the NHS LTP, five-year framework for GP reform and the Digital, Data and Technology Vision to provide quality patient care in a safe digital environment.

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 mere 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 is being distributed through PCNs - over £1.4 billion by 2023/24. However, considering the recent dissatisfaction regarding the 2022/23 GP contract, the future of GPs and their role within PCNs may be uncertain. This is supported by recent research, which found that 31% of practices experience no benefits from being part of a PCN and 42% of practices report an adverse increase in workload since joining a PCN.

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 access options for patients.

Regulation

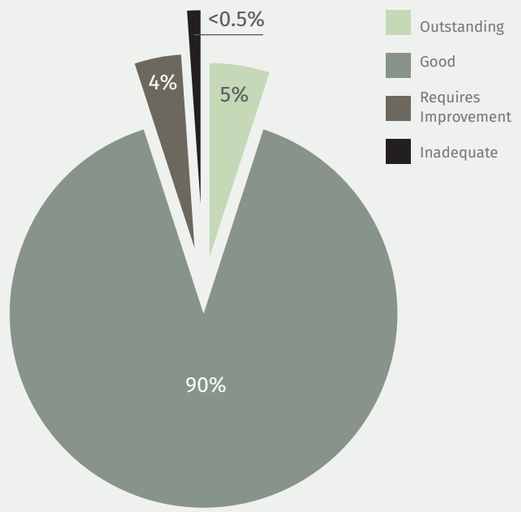
GP practices are inspected and regulated by the CQC, which employs a risk-based approach to care quality control. Using this approach, GP practices that have been rated good or outstanding by CQC's inspection teams are inspected less frequently, with gaps of up to five years between inspections. The 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 its State of Care report 2020/21, CQC notes that general practice face pressures from workforce recruitment and growing demand, with the number of GPs decreasing annually. A major issue is the lack of same day appointments, as only 45.4% of appointments taking place the same day they were booked. This can lead people to attend A&E with non-urgent conditions, putting a 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 95% of GP practices rated as good or outstanding in 2021. Public satisfaction with GPs was high in 2021, with 83% of the population stating they had a good experience with their GP.

In June 2022, an undercover investigation by BBC Panorama reported that one of the UK's biggest private primary care providers was contracting less qualified healthcare staff to carry out tasks that normally fall within a GP's responsibility. This incident sparked discussion regarding patient safety in practices, and the CQC initiated an investigation into the case.

CQC ratings of GP practices (2021)



Data: CQC overall rating of GP practices in England (July 2021)
Source: Care Quality Commission (CQC)

Regulating digital providers

The emergence of private 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. 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 and the focus on digital health within the LTP. 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 of healthcare services located outside of England. There are several 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.

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 a key aspect of assessing risks with a potential asset.

Spotlight on digital health: bringing care closer to home in England

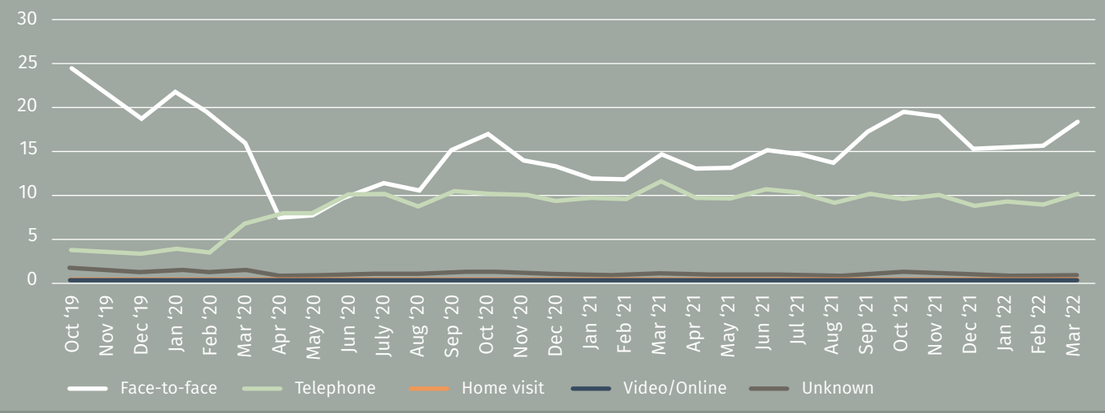
The 2019 NHS Long Term Plan (LTP) set out to provide all patients with digital-first primary care by 2023/24. Through this commitment, there has already been a noticeable increase in the use of telemedicine and remote prescription services, further accelerated by the Covid-19 pandemic and the use of teleconsultations.

In 2022, the NHS Data Strategy set out the ambition of connecting patients with healthcare services by registering 75% of the adult population with the NHS app over the next two years. The hope is that in doing so, patients will be able to access virtual consultations, manage hospital appointments, and book Covid-19 vaccines through the NHS app by March 2023. From September 2024, the ambition is for this app to also allow patients to complete hospital pre-assessment checks from home. Digital health could significantly contribute to meeting the goals set out in the LTP. Online consultations offer increased access to care, digital health can enable clinicians to access patients records more rapidly, and clinicians can communicate with other specialists, supporting best practice decisions, and improving patient safety. However, these goals also require supporting infrastructure and investment.

Over 2021, the DHSC announced a £2.1 billion funding pot to radically modernise the way in which healthcare is provided. This budget has specifically included allocations to improve IT services and further develop digital technology.

Bringing the government's ambitious plan to fruition and changing the way healthcare is delivered is a broad agenda. Over the last two years, the digital healthcare sector has gained significant momentum and is expected to further develop and grow over the next years, making it an interesting market for investors.

NHS appointments in General Practice by mode of appointment (mn)

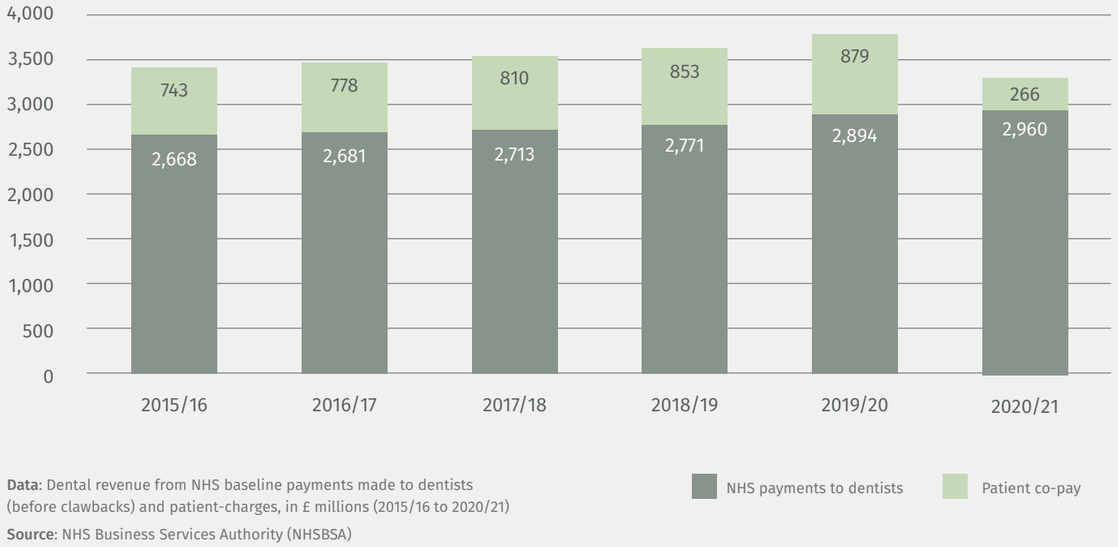


Data: NHS appointments in General Practice by mode of appointment, in millions (2019-2022) **Source**: NHS Digital

Key Messages For Primary Care: Dentistry

- Dental service provision in England primarily consists of independent 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
- 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. In 2020, a 5% increase in the patient charge was delayed due to Covid-19. This would have been the last year of the 5% increase announced in the 2015 spending review
- The freeze to patient co-pays has maintained the price difference between NHS and private services. This is expected to change from 2023 with the patient charge rise resuming to drive further price convergence between NHS and private care
- Private-pay dentistry was buoyant ahead of the emergence of Covid-19 and pent-up demand and continued access pressures in NHS-provided care may enable some defensibility in the wake of a period of economic downturn
- There is no expectation of a significant funding increase for the dental sector, even if wider NHS funding is set to be increased. This is due to the sector's relatively low priority status compared to other healthcare services
- Rising patient co-pays combined with the long waiting times in NHS dentistry may incentivise a segment of patients to switch to private services, most likely on a service-by-service basis in order to reduce waiting time
- In 2022, the General Dental Contract Reforms were withdrawn. These had been entirely focused on reforming contract for NHS provision, but wide-spread dissatisfaction with the Units of Dental Activity (UDA) system is likely to continue to drive dentists towards private provision

Dental revenue from NHS and patient charges, 2015/16 to 2020/21 (£, mn)



Data: Dental revenue from NHS baseline payments made to dentists (before clawbacks) and patient-charges, in £ millions (2015/16 to 2020/21)

Source: NHS Business Services Authority (NHSBSA)

Payers

In 2022, the UK has over 42,000 dentists, the majority of whom historically provided some NHS-funded services alongside private-pay services. NHS dentists who did this 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 patients pay for NHS services is an example of this model. Smaller revenue streams come via dental insurance and capitation plans like Denplan.

Shifting commissioning responsibilities from NHS England to ICBs

As part of the 2022 Health and Care Act nine ICBs have taken on delegated responsibility for dental services (primary, secondary and community) from 1st of July 2022. The expectation is that from 1st of April 2023, NHS England will delegate responsibility to all ICBs for all dental services.

NHS funding trends

Unlike most 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 the two revenue streams for NHS dental practices.

Direct NHS payments

The NHS contributes to dentistry funding through payments from NHS England and NHS Improvement. NHS England invests around £2.3 billion into dentistry services per annum. The exact amount paid directly by the NHS varies year-on-year but has gradually been declining in real-terms in recent years. In January 2022, NHS England allocated an additional £50 million towards urgent dental services, which had been delayed as a result of the Covid-19 pandemic. However, this allocation failed to meet its intended aims, as uptake remained low and only a fraction of the allocated budget was utilised. It is unlikely the Department of Health and Social Care will increase the annual dentistry budget over the coming years.

Patient charge (co-payment)

In dentistry, individuals are expected to contribute financially to the cost of the care they receive. This patient charge has increased at a faster rate than direct NHS payments over the last years. 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 24%. This growth in the patient contribution to overall dental practice income was expected to continue in the future, however as a result of the Covid-19 pandemic, the patient charge was frozen. As of yet, it is uncertain how the patient charge will develop over the coming years. It may increase; however, it is not expected to increase above the rate of inflation.

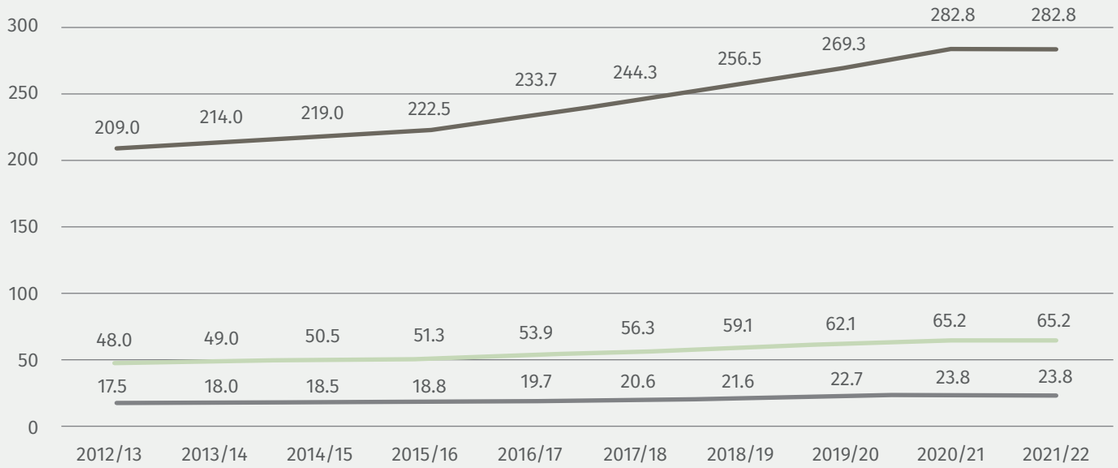
Within the dentistry payment system, there are four different levels of charge (known as 'bands'), depending on the type of treatment the patient receives. In recent years, patient charges increased by about 5% per annum across all bands, an increase notably higher than levels of inflation. In 2020, a 5% increase in the patient charge was delayed until December 2020 due to Covid-19. In 2021/22, for the first time since 2010, there was no increase in patient charge. However, data suggests one in five people delay their dental services due to the costs attached to it.

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
Band 4	Urgent treatment	£23.80

Some individuals are exempt from the patient charge – ordinarily due to age or income – 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.

During the height of the pandemic, Band 1 treatment fell from 60% of all services to 41%. Instead, the focus shifted towards urgent procedures, with 30% of procedures being classified as urgent. This was up 20% from 10% in 2019/20. As the UK has emerged from the pandemic, Band 1 treatments have gone up to 53% in 2021/22, and urgent treatments have decreased to 15%. Since 2017/18, there seems to be an increase in Band 3 treatments, which now make up 27% of all services.

Change in patient charge per treatment band (£)



Data: Dental patient charge per treatment band 1-3, in £ (2012/13 to 2021/22)
Source: NHS

The private pay dental sector

The dental sector is one of the few sectors within the healthcare system that has a clear and distinct private sector operating in parallel with the public sector. The size of the market has historically been minimal compared to NHS delivery, providing services that are not offered through the public health system. However, following the Covid-19 pandemic, the private pay market has grown, fuelled by patients experiencing difficulty in accessing NHS dental care. 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 sector has developed to offer services to consumers at varying price points - increasingly offering a direct low-cost model to compete with NHS services.

Over the past decade, 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.

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 impact on the private sector

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.

In the post-pandemic landscape, private dental practices have experienced an influx of patients and revenue. The limited accessibility to dental care during and following the pandemic has led to many patients reporting they were unable to get an appointment on the NHS for over 12 months. The British Dental Association (BDA) estimated that over 3,000 dentists stopped providing any NHS treatment over course of the Covid-19 pandemic. Additionally, many dentists decreased the percentage of NHS services they provided.

As accessibility of dental care decreased, willingness of people to invest in private dental care increased. In 2021, private practices experienced an unprecedented rise in the demand for cosmetic dentistry and expensive care – such as clear aligners and implants. As the cost-of-living crisis continues in 2022, this unprecedented rise is expected to plateau. Private dental care providers may have a unique opportunity in the post-pandemic landscape to meet the rising demand and increase accessibility to dental services.

In the face of the cost-of-living crisis, there is a longer-term risk for private providers as some consumers may forego private-pay options. 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 remaining, or switching down to save money whilst remaining within the private segment.

Policy And Legislation

General dental contract reform

Dental policy rarely garners much political attention compared to other NHS policy areas. However, it has become a politically hot topic over the course of 2021 and 2022. Decreasing access to NHS dental services - driven by dentists choosing to reduce their NHS commitments or handing back their NHS contracts altogether - has been met with political scrutiny. Three parliamentary debates took place on the topic in the first six months of 2022 alone, and several Healthwatch England organisations have reported widespread difficulties in obtaining NHS dental appointments. Waiting lists in some areas have now stretched to 2 years and beyond. Currently, no simple option has presented itself to ameliorate the pressing dental care situation, despite increasing pressure on the government and a demand for a contract reform.

Issues with the 2006 General Dental Contract

The 2006 NHS General Dental Service contract, which dental practices currently operate under, has been highly unpopular with the dental profession since its introduction, and is 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.

Historic attempts to reform the dental contract: pilots and prototypes

General dental contract reform has been under discussion for over 16 years, 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 focused on prevention has been developed, with pilot areas testing different capitated payment models. Three pilot studies testing three variants of a model contract ran until April 2022, spanning 201 practices participating in the Dental Prototype Agreement Scheme, which consisted of a form of capitation rate whereby dentists were rewarded for retaining patients on their practice lists and engaging them in preventive care.

There were three different remuneration methods 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.

On 1st of April 2022, all pilot studies ended. Since then, the 102 participating practices have returned to the 2006 NHS General Dental Service contract. None of the pilot studies yielded significant results regarding value for money or improvement in oral health. Ultimately, it is considered unlikely that any of the trialled contracts will be implemented moving forward, however official guidance is expected to be published later in 2022. The British Dental Association continues to advocate for the abolishment of the Units of Dental Activity (UDA) model in favour of a capitation-based contractual model.

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 aims to ensure that dentists do not under-deliver to NHS patients by over-committing to private provision, but also allows the NHS to manage the cost by not rewarding over-delivery. When practices miss their UDA volumes for three consecutive years, the NHS 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.

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 policy objectives is partly dependent on funding, which has been constrained, and efforts have prioritised 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. In conjunction with changes to consumer behaviour, this may eventually alter the type of work dentists do, both through NHS services and privately, and may require a different skill mix to respond to shifting demand and needs.

Regulation

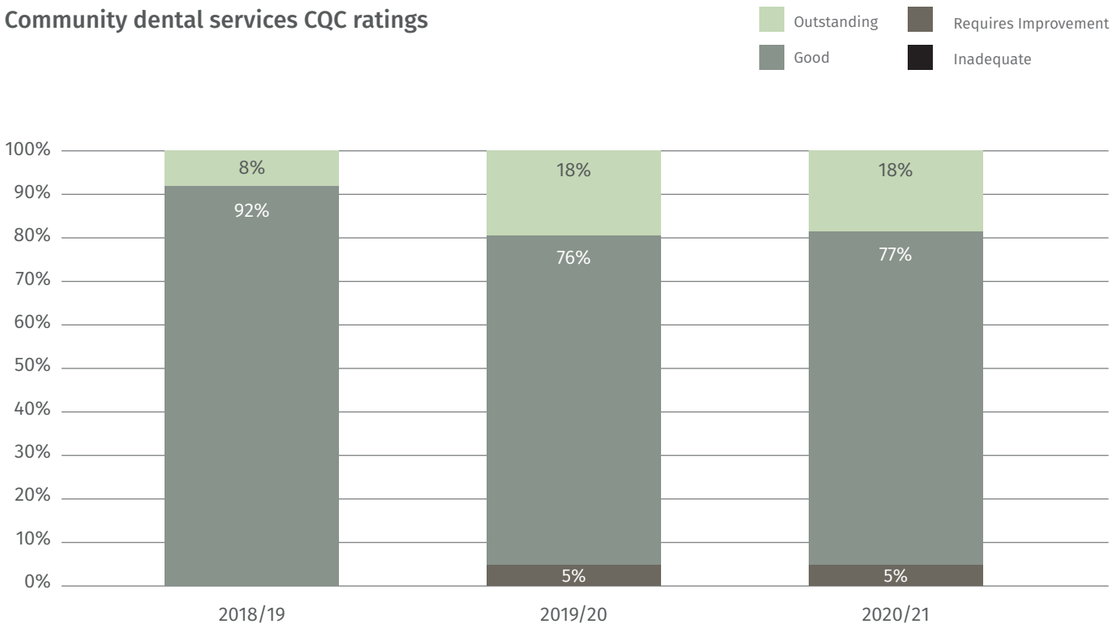
Compared to most healthcare services, the regulatory regime governing dentistry is light touch. This is because CQC considers that dental services represent a low risk to patient safety. Since 2015, CQC has carried out comprehensive inspections of 10% of dental practices each year.

Routine dental inspections were halted in March 2020 by CQC due to the pandemic, but the CQC's 2020/21 State of Care report has confirmed that access to NHS dentistry is a growing concern. In particular, the CQC has noted specific problems with children and young people accessing routine dental care during the pandemic.

The report also states that the public's perspective of dental care has fallen in recent years. According to the 2021 GP patient survey, which includes a section on NHS dentistry, the percentage of people who described their experience of NHS dentistry as 'good' fell from 84% in 2020 to 77% in 2021.

The CQC highlights accessibility as one of the major problems the dental care industry currently faces, with seven out of ten people struggling to access dental care during the pandemic. Furthermore, in 2021 only 48% of dental practices accepted new patients, both private and NHS-funded. Delays in care caused by the pandemic were more prevalent for NHS patients, of which 55% faced additional waiting times. In contrast, less than 50% of private patients experienced an increase in waiting times to receive dental care.

Community dental services CQC ratings



Data: CQC ratings of community dental services (2018/19 to 2020/21)
Source: Care Quality Commission (CQC)
Note: Percentages may not add up to 100% due to rounding

Spotlight on fertility

The range of fertility solutions offered by clinics has expanded to the point that 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. Intended parents (IPs) can access services which range from relatively simple procedures to highly innovative medical treatments. Gamete donation, 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, national policy decisions can lead to significant differences in which groups can access treatment, and the services available to them, depending on where they live. In July 2022, the UK Government published its first ever Women's Health Strategy which included landmark changes providing for more equal access to fertility services. Crucially, the Strategy removes the requirement for lesbian couples and single women to pay for artificial insemination privately to prove their fertility status. The policy change means that these groups will be eligible for 6 NHS-funded cycles of artificial insemination, prior to accessing IVF services if necessary. The new Strategy also pledges to tackle the 'postcode lottery' in access to IVF treatment by improving transparency on provision and availability of IVF regionally.

Without any new additional funding announcements or measures to increase provision of services to meet increased demand, the move may exacerbate already long waiting lists and continue to drive reliance on private providers, domestic and abroad. Given the numbers of IPs accessing fertility services privately, it is of little surprise that the UK's Consumer and Markets Authority (CMA) has taken an active interest. In late 2021, the CMA began a compliance review of the sector. Although this has yet to conclude, during 2022 the CMA also published guidance for fertility clinics and a guide for patients in the UK to increase awareness of obligations and rights under consumer law.

Universal public-pay entitlement does not necessarily mean universal access

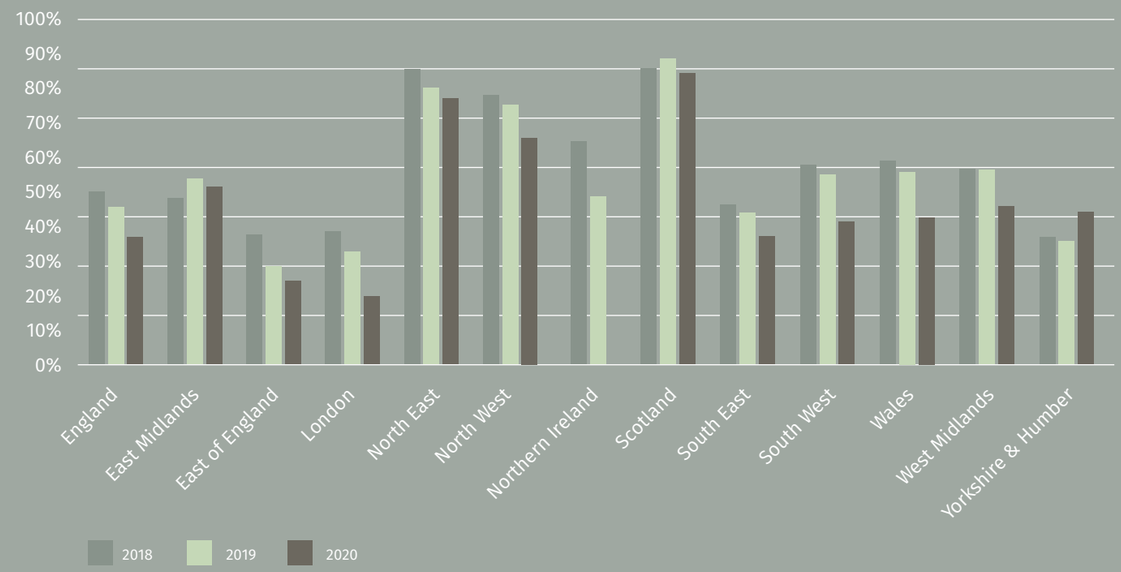
The UK has one of the most liberal fertility frameworks in the world. There is almost universal availability of fertility treatments, with few legal limits on who can access fertility services. Single women and same-sex couples have free access and there is a wide range of ancillary services available.

Despite the UK's National Healthcare System offering free care at the point of need, fertility services operate in a slightly different manner. This is because although some fertility services are publicly funded, there is considerable regional variation in access to fertility services via the NHS – with some local areas restricting the availability or limit the number of reproductive cycles that are funded by the NHS. Navigation of complex reimbursement and access issues can make understanding the sector difficult for intended parents and investors looking to grow fertility services across England.

As a result of the Covid-19 pandemic, access to NHS fertility services plummeted in 2021 compared to 2020. The proportion of NHS funded IVF cycles decreased in 11 out of 12 geographical regions, with the East of England reaching lows of 17%. The average percentage of NHS-funded IVF cycles in England fell from 32% to 26% over the same period. This has created space for private providers to provide services to intended parents and increase accessibility to fertility services.

With decreased access to NHS funded fertility services, there may be future opportunities for private providers to capitalise on an increasingly active private pay market for fertility services.

NHS funding of IVF cycles across UK and English regions

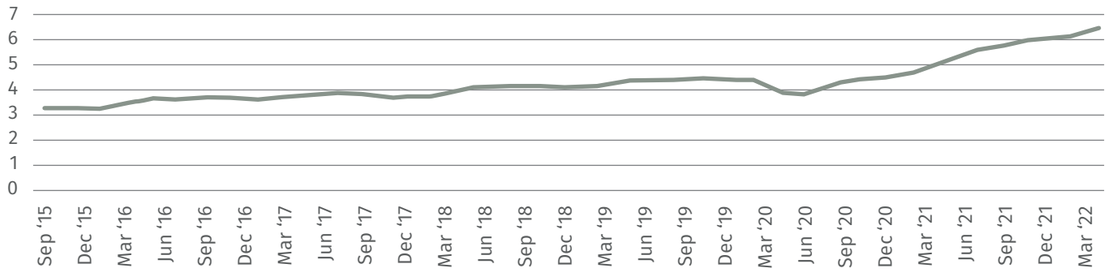


Data: Proportion of IVF cycles funded by the NHS in different UK nations and England regions (2018-2022)
Source: Human Fertilisation and Embryology Authority (HFEA)

Key Messages For Acute Hospital Care

- The Covid-19 pandemic has dramatically changed the face of the acute hospital care sector in England, with a focus on reducing the elective care backlog. This presents opportunities for private providers as commissioners seek to increase capacity across the system
- As of May 2022, the waiting lists stands at over 6.6 million, and is expected to continue to rise
- In February 2022, the government published a delivery plan for tackling the elective care backlog. This focused on reducing long waits as a key priority and to eliminate them completely by March 2025. The plan included ambitions to eliminate all two year waits by July 2022. A central support for these ambitions is diagnostic testing, with the ambition that 95% of patients requiring a diagnostic test receive it within 6 weeks by March 2025
- These expectations were set out alongside an Elective Recovery Fund intended to incentivise systems to treat more patients to tackle the elective backlog. For this £8 billion was allocated to the NHS, comprised of £5.9 billion for capital investment in beds, equipment and technology, and £2 billion for the Elective Recovery Fund to pay for consumables, overheads and overtime, and a £700 million Targeted Investment Fund to drive up and protect elective activity
- This funding was altogether intended to support the NHS to deliver 130% of pre-Covid activity levels by 2024-25. In the current financial year, £2.3bn was allocated to systems, which were asked to deliver 110% of pre-Covid levels as the first target on the way to that goal, but the vast majority of systems are falling well short of the threshold, with average activity levels across the NHS around 88% between April and mid-June 2022 due to Covid pressures, discharge problems, and capacity issues
- Overall, the NHS faces a continued challenging financial outlook, and guidance to Integrated Care Systems (ICSs) set out expectations that local systems balance budgets and break even in 2022/23
- The NHS National Tariff remains central to pricing for elective services and is expected to remain stable. However, future changes to the way NHS Trusts are reimbursed may have important knock-on effects for private providers, as the balance of reimbursed via block contract vs fee-for-service can influence outsourcing behaviours
- The 2022 Health and Care Act has changed the commissioning responsibility for acute care from Clinical Commissioning Groups (CCGs) to ICSs – in which NHS Trusts have a much more significant role

Number of people waiting for elective care treatment in England (mn)



Data: Number of patients on the elective care waiting list, in millions (2015-2022)
Source: NHS England

Payers

Historically, the NHS has commissioned private acute care providers to provide services. In 2020/21, the private acute sector delivered 5.2% of all NHS-funded elective activity, up from 0.02% in 2003/04. Hospitals are faced with increasing pressure to tackle the Covid-19 elective care backlog. In 2021, £2 billion was allocated to reduce the backlog under the Elective Recovery Fund (ERF). A further £8 billion was announced in October 2021, to be available for 3 years from 2022-2025. This creates a unique opportunity for the private sector to contribute towards the care of the millions waiting to receive elective care, as highlighted in the NHS Elective Recovery Plan in February of 2022.

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 2018/19, 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, which was set to be substantially lower than rates of interest.

With the introduction of Integrated Care Systems in 2022, ICSs will be required to break even at the end of every financial year. If this breakeven position cannot be attained, ICSs will need to demonstrate they will take serious steps in order to reduce their overall expenditure. Similarly, ICSs are expected to spend within the limits of their allocations, ensuring that underspending is avoided.

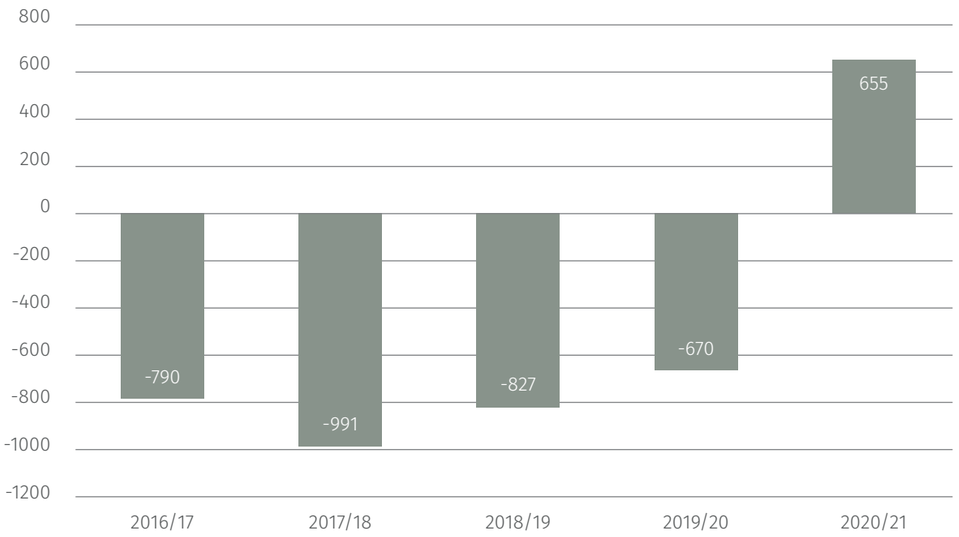
The Elective Recovery Fund – balancing elective requirements amid financial challenges

In the 2021 spending review, more than £8 billion was allocated to the NHS, alongside the goal for the health service to deliver 130% of pre-Covid activity levels by 2024-25. This was packaged up as the Elective Recovery Fund and intended to incentivise systems to treat more patients to tackle the elective backlog.

In the current financial year, £2.3bn was allocated to Integrated Care Systems, which were asked to deliver 110% of pre-Covid levels as the first target on the way achieving the 130% activity level objective. The 110% threshold, which measures the total volume of activity, equates to 104% in financial terms because of reforms to patient pathways that include an increase in avoided referrals. ICSs receive extra funding if they treat more patients over the 104% value threshold, but see money clawed back if they fall short.

This creates a need for local systems to increase elective activity but equally generates some pressure, as areas balance the need to make progress on key targets, against the system's overall financial position. However, the vast majority of systems are falling short of the threshold, due to Covid-19 pressures, discharge problems, and capacity issues. Between April and mid-June 2022, the average activity levels across the NHS were around 88%. This is understood to be driving an active discussion within NHS England about whether they should change the rules around the elective recovery fund as there is concern that the current activity levels will trigger widespread financial penalties across local systems.

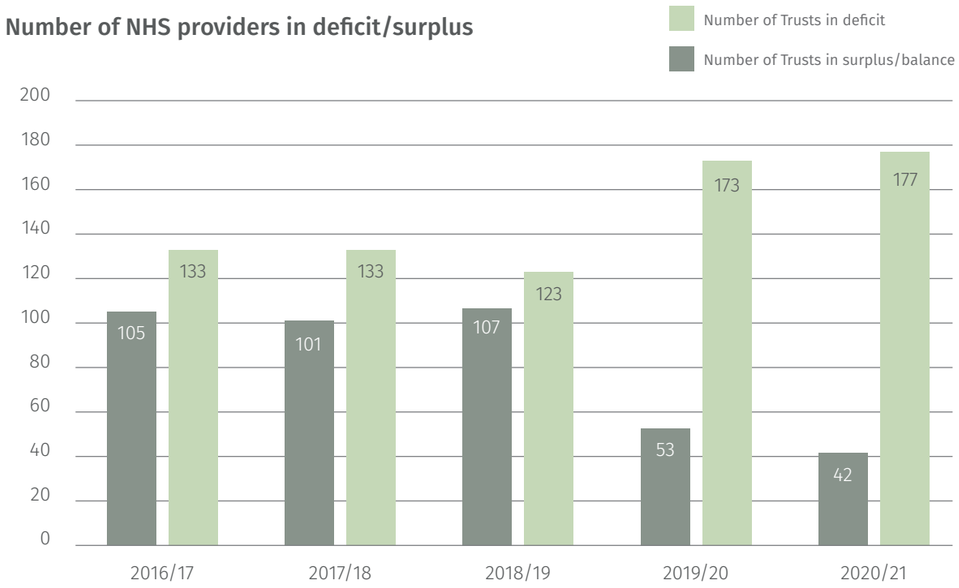
NHS providers net (deficit)/surplus (£, mn)



Data: NHS Trusts' overall deficit / surplus, in £ millions (2016/17 to 2020/21)

Source: DHSC Annual Reports and Accounts

Number of NHS providers in deficit/surplus



Data: Number of NHS Trusts in deficit or surplus (2016/17 to 2020/21)

Source: DHSC Annual Reports and Accounts Health Spending

Payment system and tariff reform

NHS acute services were historically commissioned locally by CCGs but changed with the introduction of the 2022 Heath and Care Act. This replaced CCGs with ICSs. Providers are paid for activity by ICSs using 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 is increasingly seeing 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 2019 LTP confirmed that the Tariff would be amended over the next few years, and a new National Tariff Payment System came into effect on 1st of April 2022. Within this new system, commissioners and providers are expected to agree on blended payments that include advice and guidance and virtual consultations for most secondary care services. 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 services recovering from the Covid-19 backlog and reflect the achievement of best practice.

This payment reform reflects NHS England's long-term ambition to develop new payment approaches that enable more integrated care services and move towards population-based capitated budgets. This follows on from previous plans. NHS England had published the Integrated Care Provider (ICP) contract in August 2019. This aimed to remove legal and funding barriers to integration and give a lead provider - usually an NHS Trust - responsibility for service integration in their local area.

Specialist services are funded by NHS England. Specialised commissioning is one of the fastest growing sectors in the NHS budget. The specialist services budget is projected to grow to £25 billion by 2025, up £5 billion from 2019/20. All specialist services have seen reductions in activity due to Covid-19, but the impact has varied widely across the different specialisms.

There are 146 specialised service areas in total. This includes directly commissioned mental health services and – more common in the acute sector – rare condition services, which 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.

Spotlight on: the changing perception of private healthcare

The number of people paying for private health insurance is on the rise. Major drivers behind this rise include difficulty in accessing NHS care, declined perception of quality on the NHS, and Covid-19 which has had a detrimental effect on elective care waiting lists. Although the private sector has been commissioned by the NHS for many years, there has been growing media criticism of its role within the healthcare over the last two years.

The NHS has commissioned services from the private sector since its origin in 1948, when GPs, dentists, pharmacists, and opticians all took on the role of private providers. In recent years, over 20% of the NHS budget has been allocated to organisations outside of the NHS.

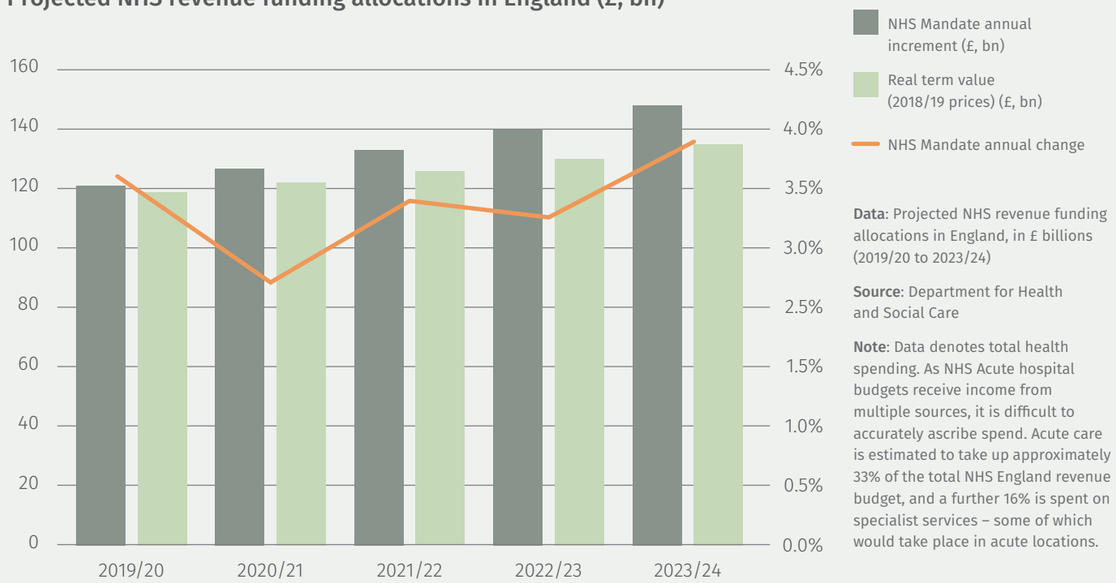
As a result of the Covid-19 pandemic, over 6 million people are currently waiting for elective care in England. The healthcare system is faced with immense pressure to deliver efficient care to tackle this backlog, which has made the NHS inaccessible to many. Recent surveys have shown that one in six people are prepared to pay for private healthcare to avoid the unprecedented waits NHS patients currently encounter. Private providers have continued to support the NHS in tackling the Covid-19 backlog by increasing capacity across the system.

Over the past year, private providers have had significant media attention, which often portrayed the private sector as inadequate and a risk to patient safety. In June 2022, a BBC Panorama investigation delved into operational matters within one of the biggest private primary care providers in England, the result of which was that the CQC launched an investigation into the case. Similarly, private healthcare made the headlines in January 2022. This was in relation the safety of mental health services provided by the private sector as studies found a potential correlation between avoidable deaths and private service delivery.

Like much of the NHS, the private sector is under constant scrutiny in relation to health care services. But it seems to be held to different quality standards by the public than the NHS, with every misstep emphasised. This skewed perception of the private sector is important for investors to be aware of, as it means that issues regarding regulatory standards, quality and compliance are essential to healthcare services.

The NHS has consistently relied on the private sector, and despite media attention, there is no indication that NHS commissioning of private providers will be downscaled in the future. In fact, the new Provider Selection Regime enables private providers to enjoy long-term contracts providing services to the NHS and making NHS services more accessible across England.

Projected NHS revenue funding allocations in England (£, bn)



Data: Projected NHS revenue funding allocations in England, in £ billions (2019/20 to 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 33% 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.

Capital spending

Improving infrastructure in the NHS was a core part of Boris Johnson's electoral campaign and capital expenditure reached £9.4 billion in 2021-22, up from £8 billion in 2020-21. Capital budget is projected to increase further over the coming years, with a total capital budget allocation of £10.6 billion in 2022/23. 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, £4.2 billion will be spent over the next five years building 40 new hospitals, as set out in the Johnson manifesto, and upgrading 70 more hospitals. Furthermore, the government has set out the improve diagnostic services, investing £2.3 billion to support diagnostic centres across the UK. During the course of the conversative leadership race, Rishi Sunak has campaigned on the promise of putting the NHS 'on a war footing' to tackle NHS waiting lists by increasing the number of Community Diagnostics Hubs to 200 by March 2024. This would be a significant development as there were only 40 Community Diagnostic Hubs in 2021.

This is also aligned with the NHS capital guidance for health for 2022-2025, published in April 2022, which demonstrates the government's commitment to invest in resources and increase capacity. Key areas of focus within the guidance are digital technology and mental health, with £2.1 billion allocated to digital health strategies and £450 to enhancing mental health facilities. This is particularly important as many NHS Trusts have seen large increases in the number of patients looking to access mental health services since the start of the pandemic.

Policy And Legislation

Efficiency and productivity

The Long Term Plan (2019) set out that in return for increased funding the NHS had to 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%. However, in March 2022 the government announced it would double its efficiency target to 2.2%. This new target

aims to free up £4.75 billion, which will be used to support vital services provided by the NHS.

The intention behind this revised target is that the increased efficiency target should be met by the digitisation of diagnostic and front-line services, and by restructuring surgical hubs, separating emergency and elective care. Furthermore, it seeks to reduce variability of quality between services. This increased efficiency is intended to ensure that taxpayer money is spent effectively, and that the funding settlement of £188.9 billion a year by 2024-25 will ensure best value for money.

As part of the plan set out in early 2022 to tackle the elective care backlog, the government announced a new platform to improve transparency on wait times and provide additional patient support. The 'My Planned Care' online platform would provide information and support to patients waiting for elective surgeries to incentivise patients to travel to NHS Trusts with shorter wait times. NHS providers would also be expected to upload supportive information to the platform to help patients manage their conditions while they wait for treatment.

Waiting times

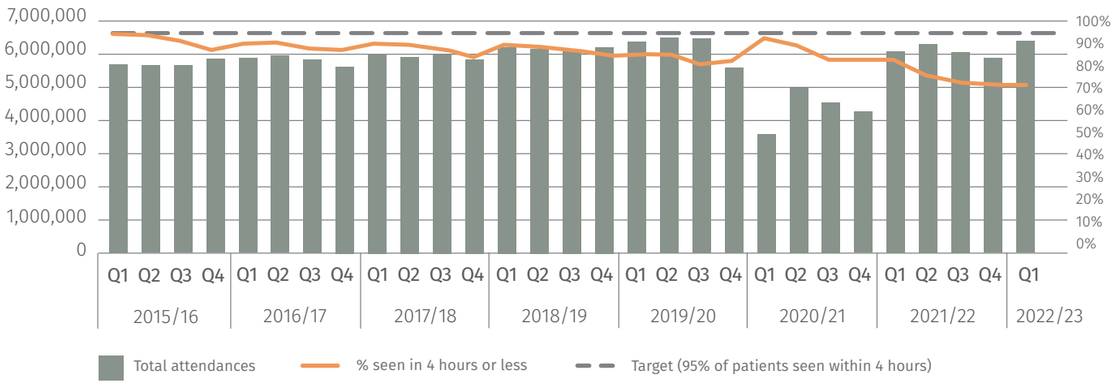
Covid-19 has had a devastating impact on waiting times that were already at the highest level in over a decade. It has been estimated that the overall waiting list could balloon up to 13 million people as the NHS begins to return to routine elective care, with waiting lists reaching record highs of 6.6 million in May 2022. This is up from 4.4 million shortly before the start of the pandemic and up from 5.6 million in July 2021.

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.

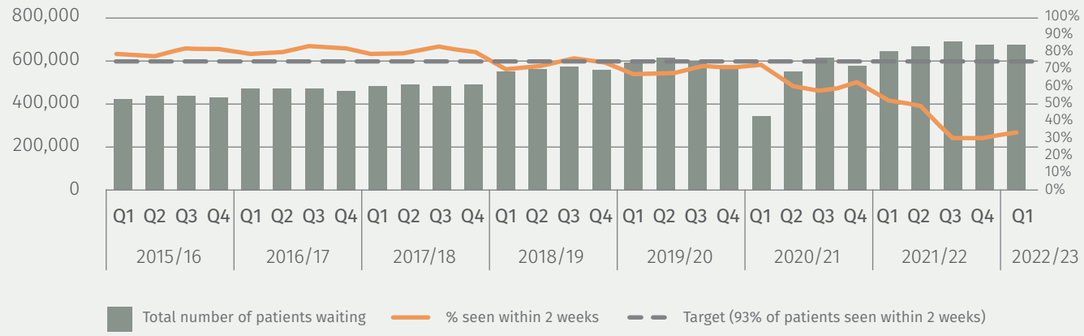
In practical terms, it will be replaced with an average wait time target. The reality may mean that little will change in operational behaviour as the new target will be aligned quite closely to current performance – as the old target drove admission behaviours to such an extent that the current mean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

A&E waiting time performance (Target = 95% of patients seen within 4 hours)



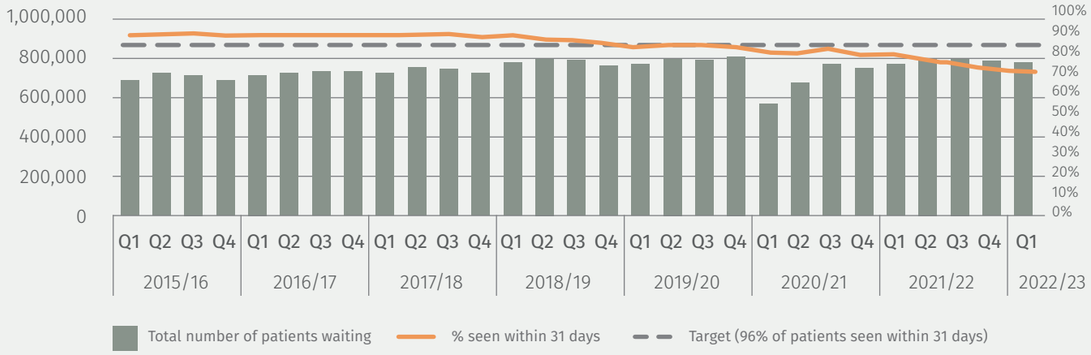
Data: Overall Accident & Emergency waiting time performance as % of patient seen measured against NHS standards for 95% of patients to be seen within 4 hours (2015/16 to 2022/23) **Source**: NHS England

Cancer waiting time performance (Target = 93% of patients seen referred to specialist with 2 weeks)



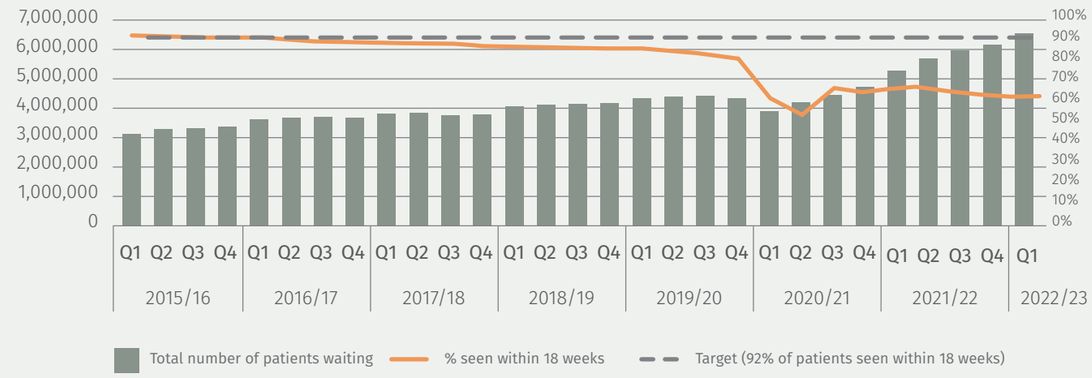
Data: Cancer waiting time performance as % of patients seen referred to first consultant appointment by GP urgent referral, measured against NHS standards for 93% of patients to be seen within 2 weeks (2015/16 to 2022/23) **Source**: NHS England

Cancer waiting time performance - decision to treatment (Target = 96% of patients wait no longer than 31 days from diagnosis to first definitive treatment)



Data: Cancer waiting time performance as % of patients upgraded to first treatment following a consultant decision, measured against NHS standards for 96% of patients to be seen within 31 days (2015/16 to 2022/23) **Source**: NHS England

Elective care waiting time performance (Target = 92% of patients seen within 18 weeks)



Data: Number of patients waiting for elective care and performance measured against NHS standards for 92% of patients to be seen within 18 weeks (2015/16 to 2022/23) **Source**: NHS England

Elective care

The total number of patients waiting for elective care treatment has increased almost continuously in recent years, reaching a record high of 6.6 million in May 2022. 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%. As of April 2022, RTT is 61.7%.

Due to the Covid-19 elective care backlog, the number of patients waiting over 52 weeks to receive secondary care has increased 300-fold, compared to pre-pandemic levels. In April 2022, over 340,000 patients were waiting over a year to receive care, down from 385,000 in 2021. The government has set out ambitious plans to completely eradicate the one-year wait by March 2025. To enable this, the government has allocated additional funding of more than £8 billion between 2022 and 2025, in addition to the original £2 billion Elective Recovery Fund.

Cancer care

The numbers of cancer patients facing delays in seeing a specialist for the first time and starting their treatment hit record highs during 2022 in England. As at March 2022, cancer care waiting times were the longest in recorded history. This prompted a flurry of media attention focused on cancer care in early 2022, with a re-announcement in February 2022 of new cancer targets to be introduced. There were also calls from the government for a call for evidence to inform a new 10-year plan to improve cancer care, speed up diagnosis and invest in innovative new treatments.

Cancer care was described as a major priority in the 2019 NHS LTP, and the LTP had already set out ambitious objectives to improve access to cancer services and survival rates – primarily by transforming care and diagnosing cancers at an earlier stage. By 2028, the NHS had set out to diagnosis 75% of cancers at an early stage, increasing survival significantly.

This had created a focus within the sector on ensuring swift access to early diagnostics. Waiting times for cancer are measured by the amount of time it takes for a patient to see a doctor – with nine different metrics measuring access. Cancer performance in 2022 failed to meet seven out of nine targets measuring its accessibility.

The targets re-announced in 2022 had previously been introduced in 2020. The first of these was a 28-day faster diagnosis standard which would mean that 75% of patients referred by their GP for suspected cancer should receive a definitive diagnosis within 28 days of referral by March 2024.

The NHS outsources some cancer services to private cancer care providers. For example, Northumbria Healthcare FT outsources 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, the NHS aims to extend EPS services in out-patient secondary care from 2022 onwards. 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 in recruiting a permanent workforce, with a vacancy rate of around 9% across the NHS. Anecdotal evidence suggests huge numbers of nurses are leaving the NHS and working for agencies, where the rates are higher for doing the same job.

In July 2022, the Review Body on Doctors' and Dentists' Remuneration (DDRB) recommended a 4.5% pay rise for NHS staff, which has been accepted by the government in full. This falls short of the 30% pay rise over the coming five years which doctors have advocated for in 2022. This will be welcomed across the sector, as all NHS staff under the remit of this year's pay review will receive a pay rise.

This followed tensions, as the Government had previously only offered a 1% pay raise for nurses before backtracking. Due to the ever-increasing rise in inflation, doctors' take-home salaries have been decreasing since 2008. This creates an increasing risk that healthcare staff will take industrial action or continuing voting with their feet and leaving the NHS.

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. As a result of Brexit, EEA and non-EEA nationals are subject to the same immigration rules from 1 January 2021. These rules apply to healthcare workers as well.

NHS people plan

The long-awaited NHS people plan was first 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 private 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 was not expected until the start of 2022 at the earliest but has now been delayed until later in 2022. 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.

Spotlight on: healthcare professional regulation in the UK – potential future reform

Patient safety and wellbeing has always been at the heart of service delivery, but due to the immense pressure healthcare staff have been under during the pandemic, patient safety has been a more active concern. According to the General Medical Council (GMC), healthcare staff burnout rates have reached a record high since the council started recording the data in 2018. To improve patient safety, the DHSC proposed reforms in March 2022, which aimed to increase regulatory efficiency and improve patient safety, by creating new regulatory structures for fitness to practise processes. These proposals also incorporate learning from the pandemic to address the significant challenges faced by the current system.

The proposed reforms have been met with enthusiasm by many stakeholders across the NHS. If implemented as currently proposed, the reforms would simplify regulatory legislation, and facilitate a fair legal process for registrants and patients. Currently, 75% of fitness to practice claims are resolved without a formal hearing, which it perceived to reduce transparency. Under the new regulation, transparency would be considered a priority.

Encouraging a safe space for healthcare workers to express concerns and be supported is essential to creating well-functioning teams. Furthermore, implementing early warning systems using reliable data could prevent malpractice, and increase patient safety. Stakeholders have called for the CQC to alter its inspection of healthcare organisations, taking team culture and leadership into consideration. This may favour private providers with strong leadership teams and positive organisational cultures.

The government faces great challenges in the post-pandemic landscape. This may delay progress on regulatory reforms. However, as the proposed changes are considered a means to tackle the current challenges, the government may prioritise the reform programme. This may be overall beneficial for the sector, as both patients and healthcare professionals may be better safeguarded, with the system evolving to become more responsive.

Regulation

Quality regulation and financial oversight

NHS Acute Trusts (and private 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

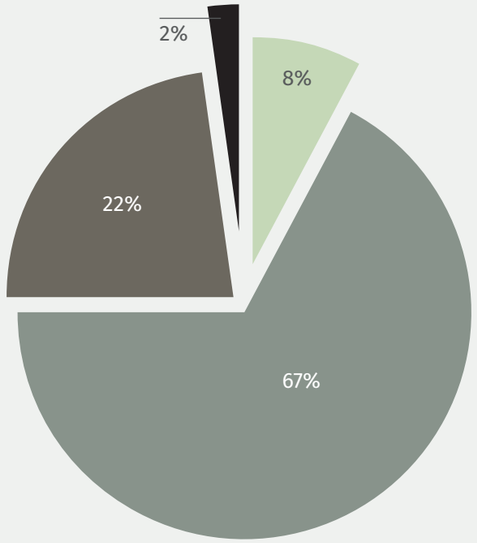
In 2020/21, CQC inspections of NHS Acute Trusts demonstrated the quality of care in the acute sector had maintained at a similar level compared to 2019/2020. 75% of NHS acute hospitals were rated good or outstanding, compared to 72% in 2018/2019, 2% of services proved to be inadequate. Quality in the acute sector was variable across different types of services. Services for end-of-life care perform the best, with 88% rated good or outstanding. These ratings are closely followed by critical care, which were found to be 87% good or outstanding. In contrast, only 47% A&E services were rated good or outstanding, down 2% from 2019/2020 – 47% of A&E services required improvement. This reflects the extreme pressure A&E services are facing currently.

CQC also outlined that improvement is needed especially in community end-of-life services, urgent care services and inpatient services, with around 14% 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 2020/21, down from 10% in 2016.

CQC's new strategy means regulation of 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 their ICS will be assessed as a key feature of CQC's new strategy, with the aim that organisations will be held 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.

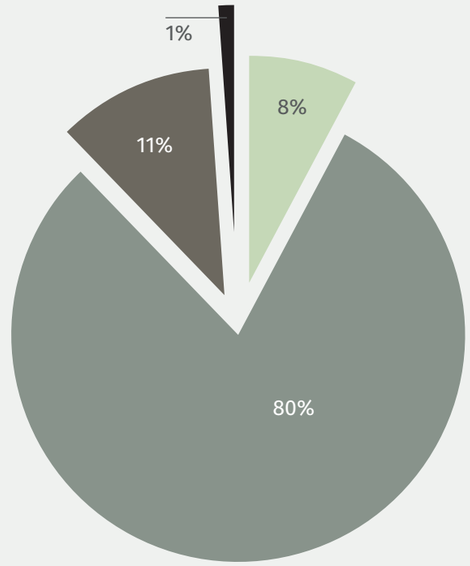
CQC also regulates private acute providers. Overall, the private sector performs better than the NHS sector, with 88% of private providers good or outstanding. However, it is complex to provide an equal comparison as NHS Trusts tend to offer a wider range of core services, including those that tend to receive poorer ratings, such as A&E.

CQC ratings of NHS acute core services



Data: CQC overall rating of NHS acute core services (July 2021
Source: Care Quality Commission (CQC)
Note: Percentages may not add up to 100% due to rounding

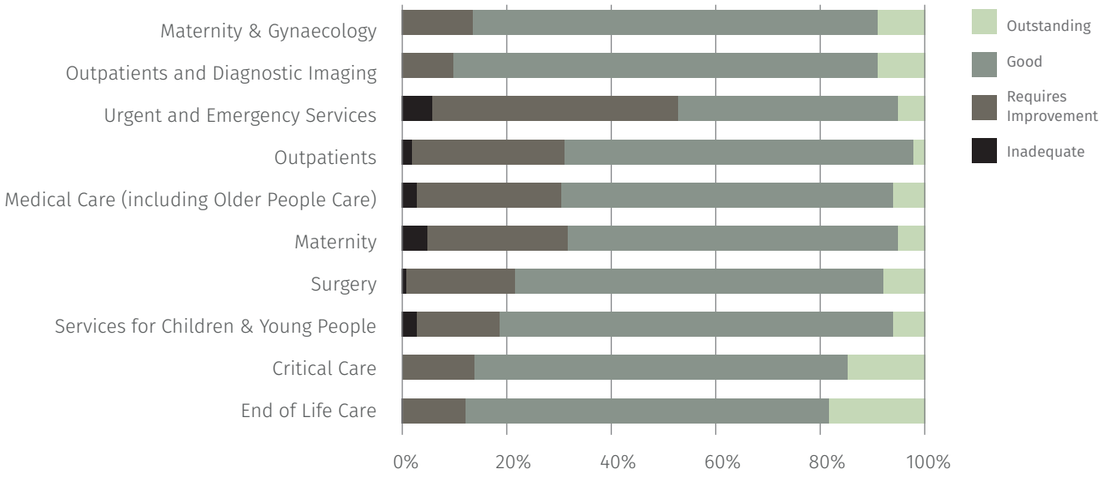
CQC ratings of independent health acute core services



Data: CQC overall rating of private health acute (non-specialist) core services (July 2021)
Source: Care Quality Commission (CQC)
Note: Percentages may not add up to 100% due to rounding

Outstanding Good Requires Improvement Inadequate

CQC ratings of NHS acute core services

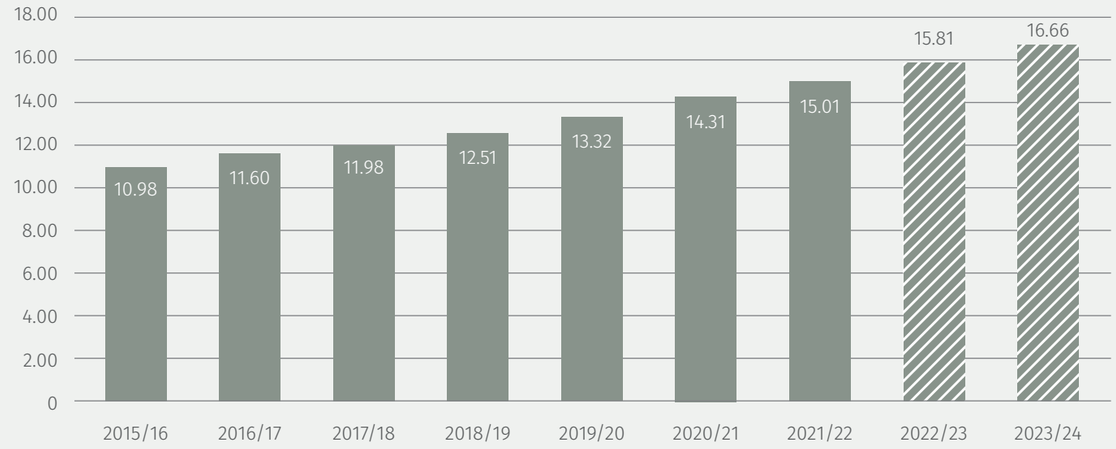


Data: CQC rating of acute core services, by type of service (July 2021)
Source: Care Quality Commission (CQC)

Key Messages For Mental Health

- The overall NHS mental health budget is expected to increase from £15 billion in 2021/22 to £16.7bn billion in 2023/24
- Mental health priorities remain focused on early intervention, effectively supporting people in crisis, and improving community-based care. Covid-19 has driven additional demand for mental health services and the NHS remains committed to increasing investment in mental health services at a faster rate than the wider NHS budget
- NHS-led Provider Collaboratives are expected to take the lead on future commissioning of mental health services; and may provide local forum for independent sector participation in strategic decisions on service planning
- A draft Mental Health Bill was published in June 2022. This follows extensive consultation to the government's proposed changes (announced April 2021) to the Mental Health Act of 1983. The government's ambition is to introduce the Bill in 2023
- 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 reduction in inpatient volumes
- Regulation in the mental health sector has remained under scrutiny and has placed a particular focus on the care provided to people with learning disabilities and children and young people; some of the most vulnerable groups in mental health settings

NHS actual and projected spend on mental health (£, bn)



Data: Projected Overall Expenditure on Mental Health Services in England, in £ billions (2018/19 to 2023/24). Projections using historic growth rate (5.3% CAGR)
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 NHS community and acute mental health services are funded locally by ICBs. 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. 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, this budget was increased to £14.3 billion, a 7.4% increase. The funding for mental health services has increased at a faster rate than the overall budget for the NHS, excluding Covid-19-related expenses, and is projected to increase over the coming years.

The Long Term Plan (LTP) set out to increase spending on mental health services by an additional £2.3 billion per year, in real-terms by 2023/24. This is viewed by NHS England as the minimum investment level, as ICBs and local authorities may choose to provide additional financing. To reduce waiting times for those for those in need of mental health services, the DHSC has pledged an additional 500 million for 2022/2023. This budget aims to support the NHS workforce and reduce the pressures caused by the pandemic. However, due to the high levels of inflation, this real-term budget could fall short of what is expected of the NHS. Specifically, the £450 million allocated to increase patient safety in A&E, upgrade acute mental health facilities and replace in-patient dormitories could prove insufficient.

Historically, there have been difficulties in ensuring local commissioners funded mental health services appropriately, with money often diverted to under pressure acute services. As a result, NHS England instructed ICBs 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 (MHIS).

In 2018/19, all CCGs (previously responsible organisations) 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, only 10 CCGs did not meet the Mental Health Investment Standard. During 2020/2021, all CCGs stated they met the MHIS standards, and 100% of CCGs are projected to meet the MHIS in 2021/2022. Under the Health and Care Act, all ICSs will be expected to meet the Mental Health Investment Standard and may invest above this level if they wish.

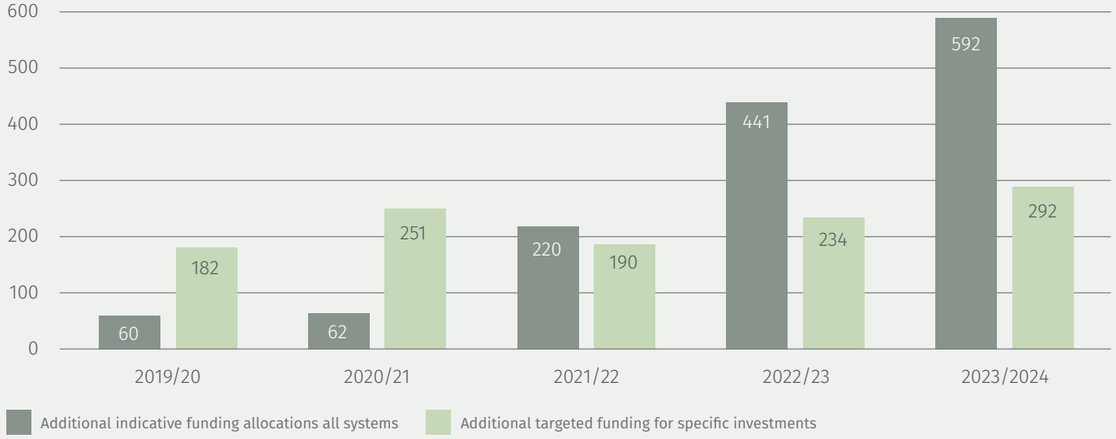
Currently, 85% of mental health funding is allocated to local commissioners - this ratio has remained static over the last five years. However, as part of the New Care Model (NCM) initiative to improve a range of specialist mental health services, mental health trusts will soon begin to take commissioning responsibilities away from NHS England. This is underway with plans that by the end of 2023/24 provider collaboratives will cover the whole country with their scope expanded to include all specialised mental health, learning disability and autism services.

This may mean that, private providers offering inpatient services are likely to see a greater proportion of the revenue come from local funding pots, as NHS England moves away from funding higher acuity inpatient services. Local ICBs will continue to fund all community mental health services – and may provide revenue streams to private providers through commissioning of acute inpatient beds, and rehabilitation/step-down services.

Projected mental health funding (2019/20 – 2023/24)

	2019/20	2020/21	2021/22	2022/23	2023/24	5-YEAR HISTORIC CAGR
Overall Actual MH Spend (£, bn)	13.3	14.3	15	TBD	TBD	+5.3%
Overall Projected MH Budget (£, bn)	13.0	13.6	14.3	15.8	16.7	
Total NHS Budget for all services (£, bn)	120.5	126.9	133.1	139.8	147.8	+4.9%

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



Data: Additional and targeted funding for mental health to support elements of the Long Term Plan
Source: NHS Long Term Plan Implementation Framework

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 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 providers 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 intended to ensure mental health services can reach the goals set out in the LTP, by making sure mental health service decisions are informed by better quality and activity data.

Mental health providers will also continue to be eligible for a higher Commissioning for Quality and Innovation (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 development of NHS-led Provider Collaboratives is as an attempt to improve commissioning arrangements.

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 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 and intended 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 inpatient settings, but these should be focused on individuals with the highest acuity needs. By 2023/2024, NHS England aims to improve mental health services to support 1,880,000 people per annum, an 80% increase compared to 2020/2021.

The LTP builds on earlier policies, 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 related to this was the need to establish Mental Health Support Teams that could be accessed through educational settings.

Mental health in the Health and Care Act

Under the new Integrated Care Model, mental health funding will be safeguarded, as the Health and Care Act places a duty on the Secretary of State to report annual mental health spending. This supports a continued positive funding outlook for mental health services, as it may increasingly be difficult for the government to fail to meet set budgetary standards. Mental health commissioning has shifted to Provider Collaboratives which will provide mental health services for their local populations. As per the Health and Care Act, private providers may be able to join local Provider Collaboratives discussions, and to be commissioned for services.

Out of Area Placements

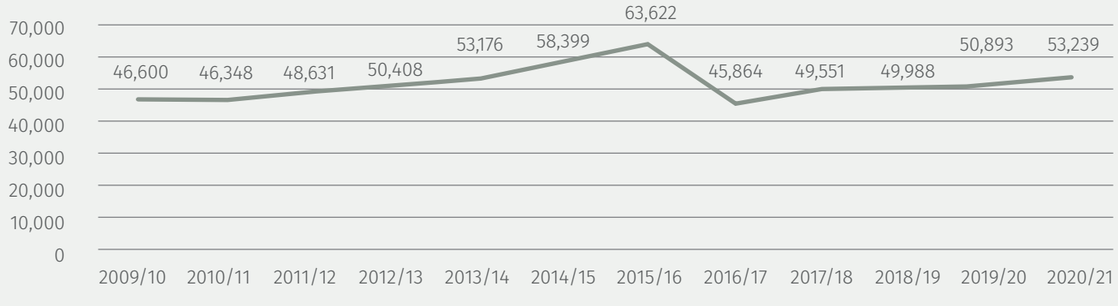
Reducing the number of out-of-area placements (OAPs) has been a policy objective in recent years. OAPs came into focus as a result of concern over the ability to provide appropriate oversight of care placements. More recently, it re-entered the public consciousness due to the media exposure into care 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). Of this total, 10,123 beds are owned by private providers, with 90% of beds being occupied by NHS patients. To fund the commissioning of private beds, 13.5% - or about £2 billion - of the NHS mental healthcare budget is allocated to private providers. The decrease in total bed availability 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 out-of-area placements were reduced by 41% by April 2020 compared to April 2017 levels.

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 approximately 10% below April 2017 levels. Indeed, between April 2021 and April 2020, the number of OAPs increased by 54%, from 455 to 700, although this still represents an 11-13% decrease on 2017 levels.

Number of detentions under the Mental Health Act 1983 in NHS facilities and independent hospitals



Data: Number of detentions under the Mental Health Act 1983 in NHS facilities and independent hospitals (2009/10 to 2020/21)
Source: NHS Digital Mental Health Act Statistics

The draft Mental Health Bill

The Mental Health Act (1983), last amended in 2007, determines how someone with mental health problems can be sectioned (i.e., detained in hospital without consent for assessment or treatment) and their rights under section. Over the past ten years, the number of people sectioned under the Mental Health (MH) Act has increased steadily. This has drawn increasing policy attention towards a need to modernise the MH Act.

The Conservative Party pledged to replace it with new legislation and commissioned an independent review to form 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.

In June 2022, Sajid Javid, then Health Secretary, introduced the draft Mental Health Bill in parliament. There is now a legislative process of review before it becomes an Act, but this is expected to pass in 2023.

FOUR MAIN GUIDING PRINCIPLES SHAPING PROPOSED KEY AREAS FOR REFORM

- 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 draft Bill contains a number of amendments to the MH Act (1983) which may result in the following changes:

- Autism and learning disability would not be considered to be conditions for which a person could be subject to compulsory treatment under section 3
- Changes to the criteria for detention by setting out two new tests with a higher risk threshold
- A new definition of "appropriate medical treatment" to require that the treatment must have a reasonable prospect of alleviating, or preventing the worsening of, the patient's mental disorder
- A new duty on the clinician in charge of the patient's treatment to consider certain matters and take steps when deciding whether to give treatment to a patient under the Act
- Quicker expiry of the initial detention period under the Act and more frequent review and renewal of the detention
- Extend the amount of time patients can apply to the Mental Health Tribunal and make automatic referrals more frequent
- A new power of 'supervised discharge' and a statutory 28-day time limit for the transfer of a person from prison to hospital for treatment under the MH Act
- Expand access to an Independent Mental Health Advocate (IMHA) from only those detained under the Act, to voluntary (or 'informal') patients and a statutory duty on hospital managers to supply information on complaints procedures to detained patients and their Nominated Person (new statutory role)
- Powers to allow Mental Health Tribunals to make recommendations to the "responsible after-care body" to make plans for the discharge of a patient at a future date
- Reforms to the identification of which particular NHS body and local authority is responsible for arranging the after-care
- Reversal of the burden of proof, so that the local authority responsible for the guardianship must prove that the patient continues to meet the guardianship criteria in Mental Health Tribunals
- Removal of prisons and police cells from places of safety
- Prevention of the remand of a person for their own protection when the concerns arise from their mental health needs
- Transfer of patients from Crown Dependencies into England and Wales for reports and treatment

Regulation

Use of segregation, seclusion and force

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. In the updated March 2022 report, mental health facilities had failed to improve their services significantly, and many shortcomings remained unresolved. Other issues the CQC identified included problems with staff and management – including poor leadership styles and insufficient workforce - and lack of external oversight.

Regulation of independent mental health providers

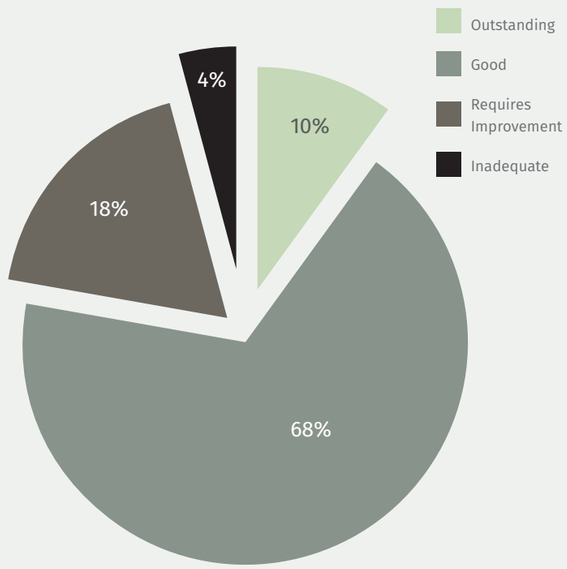
CQC regulation of private providers mirrors the regulation of NHS providers in the most part, although there is some slight variation in relation to specific requirements relevant to NHS organisations. CQC guidance on monitoring, inspection and regulation for independent healthcare providers (2018) clarified the regulatory approach for independent mental health services, and updated guidance was published in April 2021. This 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 key indicators from Q4 2018/19. CQC Insight requires providers to collect and share information on a range of quality indicators.

During Covid-19, the CQC was 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 announced in 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 – which will generally be 48 hours.

CQC ratings of NHS and private mental health services



Data: CQC Ratings of NHS and Private Mental Health Services (July 2021)
Source: Care Quality Commission (CQC)

CQC and concern over the quality of mental health services

CQC's State of Care 2021 highlighted the increasing need for mental health services, especially to support vulnerable groups. The report acknowledges concerns regarding the rising severity of mental illness, with people more commonly presenting to A&E in desperate need of help. Similar to other healthcare sectors, mental health saw a steep increase in the use of digital technology to provide care. Despite the positive impact this increased accessibility had for some, others were unable to access digital services, highlighting the need for continued face-to-face appointments.

In the 2021 State of Care report, the CQC does not distinguish between private and public providers. Overall, 22% of mental health services were rated as either inadequate or requiring improvement. 68% of services were rated good, and 10% received an outstanding rating. In 2020, NHS services performed marginally better than private mental health services. However, independent providers tend to focus on inpatient services – an area where ratings are generally lower.

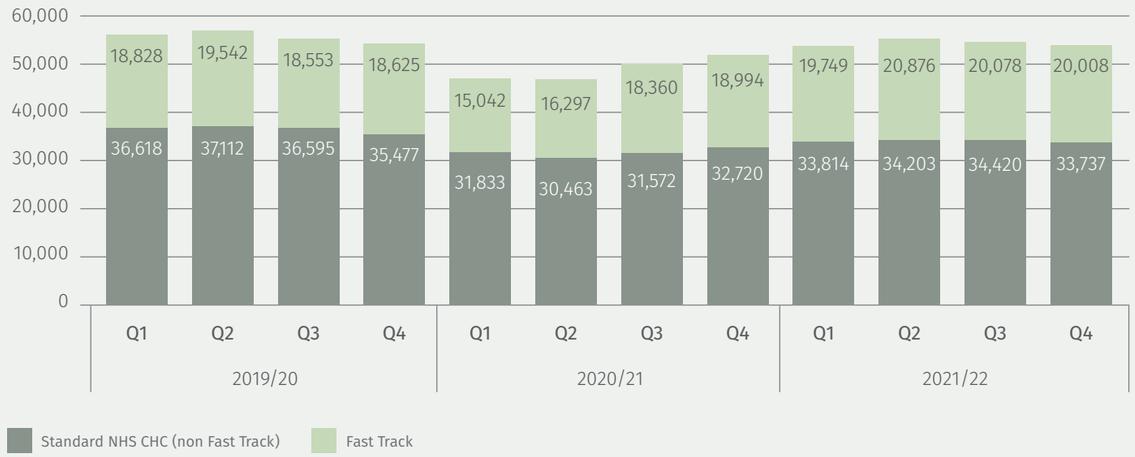
There has been a general improvement in the quality of community mental health services, however inpatient facilities tend to not perform as well. In July 2021, 42% of acute wards for adults and psychiatric intensive care units were considered inadequate or required improvement. This is comparable to March 2020. Forensic inpatient wards, on the other hand, do perform well - 84% of facilities being rated good or outstanding.

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. The BMA's response to the 2022 Spring budget expressed concerns over the mental healthcare funding, especially in light of the rising inflation and rising demand for mental health support.

Key Messages For Complex Care

- Complex care describes services that cover a wide range of conditions which require high levels of ongoing support, such as 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
- Continuing Healthcare (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
- Those who are not eligible for CHC funding and live in a nursing home may be eligible for NHS-funded Nursing Care (FNC)
- Overall, the number of CHC packages and FNC packages has continued to grow. Spend on NHS CHC has grown over the last 3 years, from £3.15 billion in 2017/18 to £4.54 in 2020/21. However, spend in 2020/21 was impacted by the Covid-19 pandemic and the resulting changes to the NHS financial framework and operational policies, in particular, publication of guidance in respect of the Hospital Discharge Service. Therefore, the 2020/21 data is not comparable with earlier financial periods
- 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. This has meant that a patient's discharge occurs as soon as it is clinically appropriate to do so, meaning the assessment and organisation of CHC care may take place at home, or in the community
- The National Framework for CHC and FNC last updated in July 2022, has revised the assessment process and provided explicit guidance to local health systems and local authorities
- Over the last few years, the Consumer and Markets Authority (CMA) has been actively investigating concerns that some care home providers may be breaching consumer law by charging additional fees from CHC funded residents for essential care

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 (2019/20 to 2021/22)
Source: NHS England

Payers

NHS continuing healthcare funding

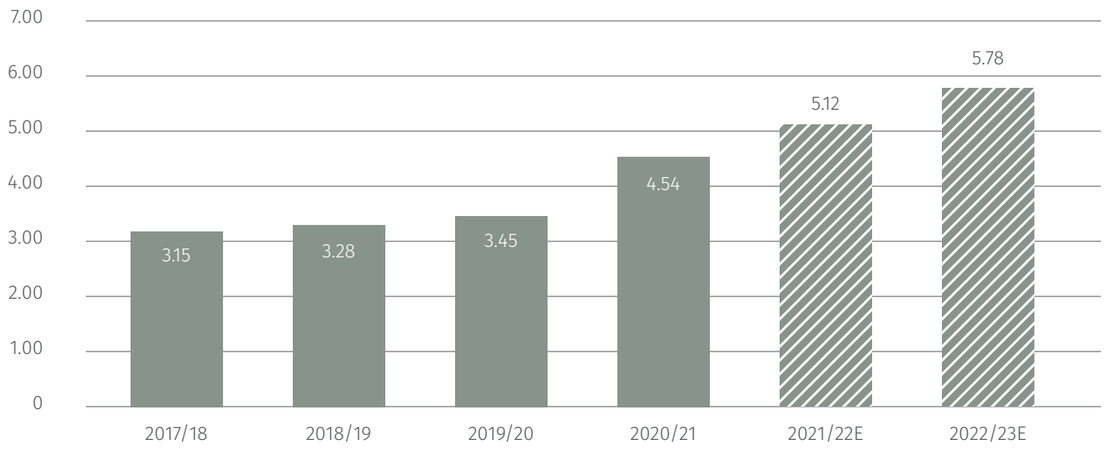
The majority of long-term complex care is funded through the NHS CHC budget. CHC is a comprehensive package of NHS-funded care intended to support individuals in the community with high and complex needs arising from a primary healthcare need. CHC often supports individuals suffering from neurodegenerative 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.

If an individual is determined to be eligible for CHC, they are allocated a Personal Health Budget, which gives the individual more autonomy over the services and care they choose to receive. Personal Health Budgets can be provided in one of three ways: budget can be held by the commissioner; a direct payment can be made to the individual; a third party can manage the budget. The budget itself is set in agreement between the individual – or a third party representing them – and the local ICB.

Funding CHC falls within the responsibility of ICBs, introduced in July 2022 by the Health and Care Act. ICBs will allocate budget for providers, based on the needs of the population within the ICS. 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.

Spending on CHC, over the last years, accounted for 4.9% of the total NHS budget. In 2018/19, CCGs spent £3.3 billion on CHC across England. This expenditure was expected to increase by an average of 3.9% a year between 2018/19 and 2020/21. This would mean CHC Spend could Reach £3.82 billion by 2022/23. However, spending has in fact grown at a much faster rate during Covid-19, potentially due to stronger drives to discharge patients from in patient settings. Although no recent data is available on the current CHC budget, following historic growth recent trajectory, spending is instead more likely to reach £5.8 billion by 2022/23.

Total NHS England CHC expenditure (£, bn)



Data: Total NHS expenditure on Continuing Healthcare (CHC), in £ billions (2018/19 to 2022/23). Projections using historic 3-year CAGR (+13%).

Source: NHS FOI; Marwood Analysis

CHC expenditure was a source of immense budgetary pressure for CCGs and will continue to financially burden ICBs. Individuals eligible for a Personal Health Budget often have high acuity needs leading to expensive care packages. 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 local decision-making around funding packages of care, and access varies across local areas. CCGs used to spend around 4% of their total budget on CHC on average, however this masked a variation of between 1% and 10% of budget across individual CCGs. The introduction of ICSs should reduce some inconsistencies across funding, as there may be less variation across local areas with the overarching ICS 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.

Currently, there is no cap on NHS CHC funding, meaning all eligible patients receive public-pay funded services that they are assessed as needing. This is slightly different to the newly introduced cap on social care costs, which was set at £86,000 and means that individuals will not have to spend more than this amount on their care. As there is no cap for CHC, and 'top up' fees are not permitted, CHC is likely to remain an area in which there is considerable tension between ICBs 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 incentivise ICBs to take a careful approach to funding decisions.

CMA action over concerns that some private care homes are charging CHC residents top-up fees

The UK's CMA has actively investigated concerns that some private care home providers may be breaching consumer law. During 2020, the CMA secured more than £1 million in refunds for NHS funded CHC residents at a private provider's care homes who it deemed paid an unfair additional fee towards essential care. A number of private providers have formally committed to stop charging the additional fee to current and future CHC residents at their homes. Consumer guidance from the CMA has been updated to increase awareness amongst the public.

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. Historically, CCGs were required to pay a weekly standard rate, which was set at £187.60 from April 2021. This is a 2% increase from 2020/21, when the rate was £183.92. ICBs will be responsible for maintaining this weekly standard rate, which was increased to £209.19 per week in April 2022, up 11.5% compared to 2021/2022. Payments are made directly to providers and are intended to cover 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 – partly as a result of the ageing population - 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 July 2022. The framework aims to guide those providing care to patients with complex care needs, and was a collaborative effort between NHS England, DHSC and local authorities. The framework reflects current CHC legislation and provides greater clarity around issues of eligibility and funding.

The 2022 National CHC framework further refines the definition of a primary health need to reduce national variation, whilst leaving local ICBs responsible for determining individual eligibility. The framework does not introduce 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.

Individual eligibility for NHS-funded complex care is heavily reliant on four main domains: nature of the condition(s), the intensity, the complexity, the unpredictability. These characteristics, either separately or on the whole, may identify a 'primary health need', which would deem an individual eligible for CHC funding and a Personal Health Budget.

The 2022 National CHC framework sets out that the NHS should meet an individual's assessed healthcare and social care needs. However, an individual is free to purchase additional private services to support the care they are receiving, and this privately provided care should not affect the publicly funded care they are eligible to receive. Ultimately, an individual may wish to pay to receive additional care to meet their needs, and private providers have the opportunity to take up a share of the complex care market.

Key changes under the 2022 National CHC framework include:

1. Incorporates changes stemming from the 2022 Health and Care Act, such as redefining key players in CHC – ICS and ICBs - which now operate under the Act. Previous requirements for local authorities to assess an individual's care needs before being discharged from hospital were revoked. However, NHS bodies and local authorities still have a legal obligation to meet individuals' health needs, and to assess and monitor care needs appropriately
2. The provision of care will shift towards an increasingly 'patient-centred' approach. A major part of planning and delivering care will now be influenced by an individual's views and/or those of their representative, providing care which meets an individual's personal care needs and preferences
3. Strengthens guidance on major topics within CHC provision and aims to eliminate any ambiguity present in prior editions. Revised topics include location of care assessment, determining capacity and consent, and best interest decision-making

Regulation

Regulation of independent complex care providers

The CQC aims to inspect and monitor public and private providers equally. The May 2022 CQC guidance on monitoring, inspection and regulation for independent healthcare providers updated 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. The CQC published a statement in May 2022 highlighting GPs' unique role in ensuring patients have early access to palliative care. By putting GPs at the centre of palliative care, care needs can be identified at an early stage, and plans can be put in place to ensure medical and emotional needs are met.

Social Care In England

Social care provision in England is primarily the responsibility of local authorities. However, the national government exerts a high degree of control over both health care and social care. This affects local authority decision-making which is 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 will be funded by a local authority if a person meets both the needs and eligibility thresholds. For children who have an Education, Health, and Care plan (EHC) and require a high level of support, their support costs should be split between different internal local authority budgets – and local health services may also be required to contribute

Central government is responsible for setting a local authority's budget, but social care funding is not directly ring-fenced - local authorities can choose to spend money how they wish. However, they are required to meet their statutory responsibilities, providing adequate social care to those who meet the eligibility criteria. Growing demand for statutory social care services has meant that local authorities are increasingly reducing non-statutory services (such as library 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

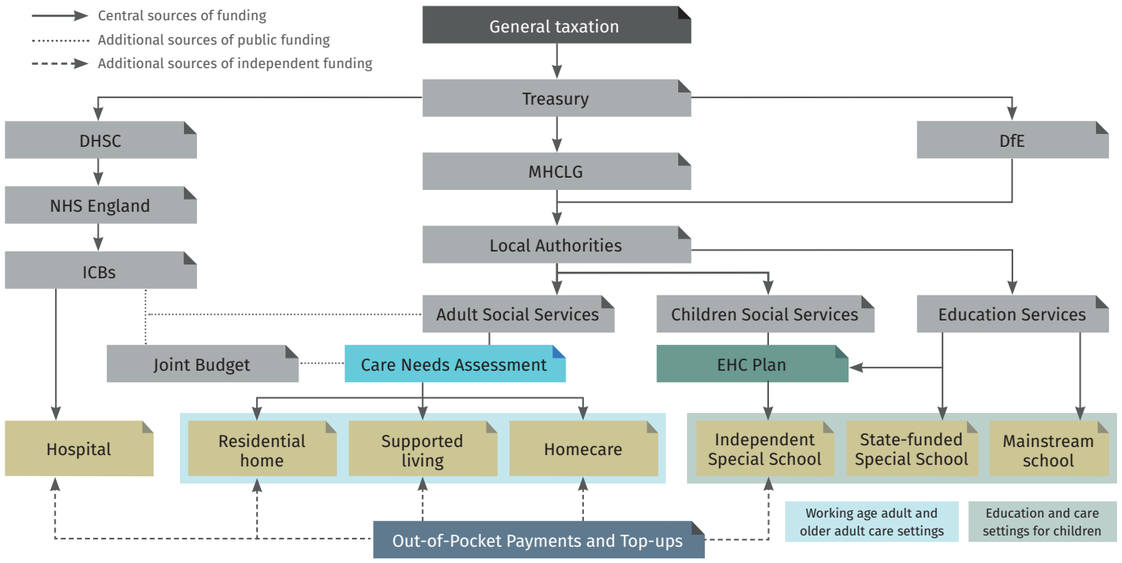
Increasingly, the government has been exerting indirect centralised control by establishing ring-fenced conditions for funding. The improved Better Care Fund (iBCF), which compels money to be spent on clearly defined priorities, and the establishment of the Social Care precept, both force local authority 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 total BCF was £6.9 billion in 2021/22, 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). In 2022/23, ICB funding will be increased to £4.5 billion, in line with the 5.66% uplift that has been applied nationally to all Health and Wellbeing Boards. The DFG is projected to remain at £573 million until 2024/25. The iBCF will enjoy a £63 million inflationary uplift on 2021/22 allocations. Altogether, the BCF will be £7.2 billion in 2022/23.

As long as local authorities meet their statutory obligations and operate according to national guidelines, they are 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.

The 2022 Health and Care Act has brought greater regulatory oversight to the social care sector. The Act has extended CQC's powers, by giving the regulatory body a legal duty to assess local authorities' delivery of their adult social care services. Furthermore, the Secretary of State has been granted greater intervention power where the CQC reports failure in local authorities' duties.

Additionally, £5.4 billion will be allocated to adult social care through the Health and Social Care Levy, including £3.6 billion to reform the current social care payment system. However, this is expected to fall short. A report by the Levelling Up, Housing and Communities Committee in August 2022 stated that adult social care needs at least £7bn a year to meet the cost of reforms, rising costs and unmet care needs.

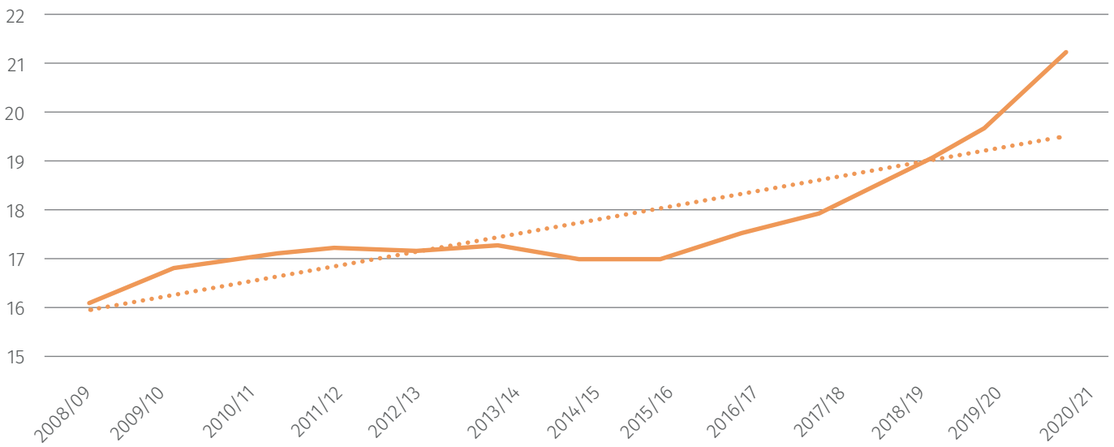
Funding flow into social care providers



Source: Marwood Analysis

Overall public expenditure on adult social care has continued to grow since 2015/16 after several years of funding cuts

Gross adult social care expenditure (£, bn)

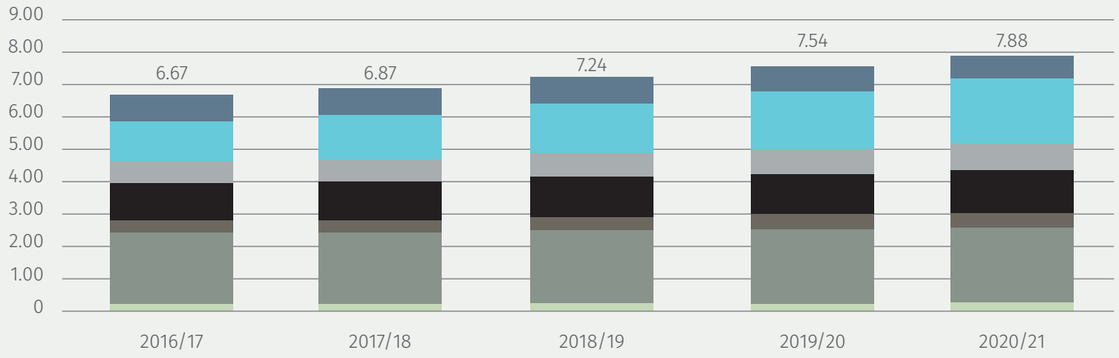


Data: Gross current expenditure on adult social care, in £ billions (2008/09 t0 2020/21)

Source: NHS Digital, Marwood Analysis

Social care spending is increasing for both working age adults and older people - although growth in type of settings differs

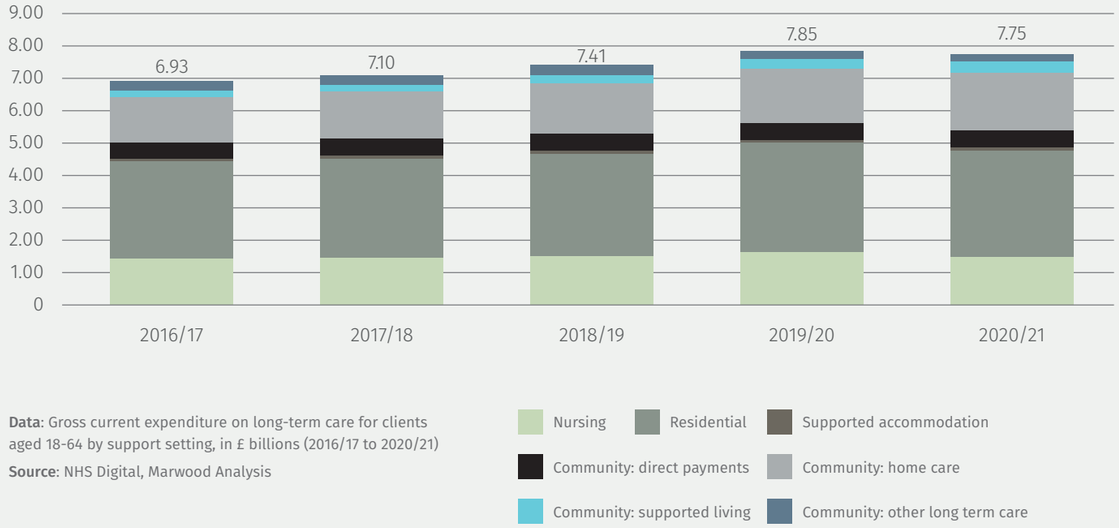
Spend on working age adult social care by support setting (£, bn)



Data: Gross current expenditure on long-term care for clients aged 18-64 by support setting, in £ billions (2016/17 to 2020/21)

Source: NHS Digital, Marwood Analysis

Spend on older people social care by support setting (£, bn)



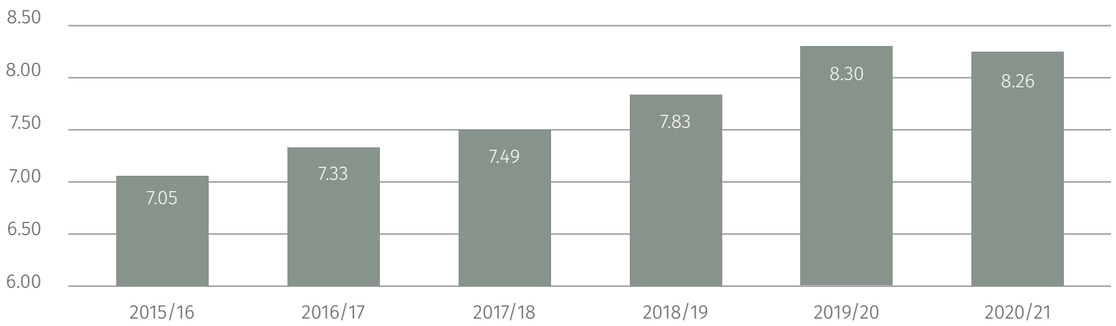
Data: Gross current expenditure on long-term care for clients aged 18-64 by support setting, in £ billions (2016/17 to 2020/21)

Source: NHS Digital, Marwood Analysis

Key Messages For Older People's Care

- The Covid-19 pandemic had a major impact on the social care sector and forced the government to face the funding sustainability issue within social care. Reforming social care was a key pledge made by Boris Johnson, and remained a key priority Sajid Javid while he was Health Secretary
- The Health and Social Care Levy was introduced as a temporary 1.25% increase to both the main and additional rates of Class 1, Class 1A, Class 1B and Class 4 National Insurance contributions for the 2022 to 2023 tax year. Revenue raised will go directly to support the NHS and equivalent bodies across the UK
- From April 2023 onwards, the National Insurance contributions rates will decrease back to 2021/22 tax year levels and be replaced by a new standalone 1.25% Health and Social Care Levy whose revenue will be ringfenced to support UK health and social care bodies
- 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 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
- Older people's care refers 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
- 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

Local authority spend on older people's care has risen since 2015/16 (+3.2% CAGR), dipping slightly in 2020/21 due to the Covid-19 pandemic



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.

Data: Gross Current Expenditure on long- and short-term care combined for over 65s, in £ billions (2015/16 to 2020/21)

Source: NHS Digital

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.

Unlike most NHS services, older people's 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.

Currently, a needs and means test is carried out by local authorities to determine an individual's eligibility for state-funded social care. 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.

In September 2021, the government announced a reform of the current needs test by introducing an £86,000 social care cap as part of the Build Back Better plan. This plan, which will go into effect in October 2023, ensures that individuals will never pay over £86,000 for their personal care over a lifetime. It is important to note is that the cost of living in residential care are not included in the cap. Furthermore, the threshold at which people receive public funding support will increase to £100,000, up from £23,250.

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 through local taxation and the Department for Levelling Up, Housing and Communities (DLUHC) to fund social care services. This is not ringfenced and local authorities 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 statutory social care services.

Alongside local taxation and the DLUHC, local authorities are also able to raise local revenue through the adult social care precept. As outlined below, the amount levied varies according to local factors. In national 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.

Funding is also delivered through direct government allocations. These come as ringfenced allocations for local authorities and must be spent on social care provision. In recent years, the Improved Better Care Fund has been an essential element in this, with a budget of £2.14 billion for 2022/23.

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, however, it is uncertain how this will change in the coming years under the new Health and Care Act.

In 2020/2021, the total gross expenditure on social care was £21.2 billion. Of this, local authorities spent £7.8 billion on long-term support for older people: £4.8 billion was allocated to nursing or residential care, £2.9 billion was spent on community support, £115 million was allocated to supported accommodation, and £507 million went to short-term support for older people.

The Autumn 2021 Budget and Spending Review revealed that the Health and Social Care Levy will allow £5.4 billion to be spent on reforming adult social care funding, as well as wider improvements of the social care system, over the coming years. Furthermore, it specified that local authorities will be authorised to increase the Social Care Precept by 1% per year.

Additional funding and funding pressures

Whilst the funding environment remains under significant pressure, the sector has been sustained by ongoing additional allocations from central Government. This funding totaled nearly £4.5 billion between 2017/18 and 2019/20, with an additional £6.1 billion during 2020/2021 for infection control and emergency Covid-19 funding.

Several factors have led to greater funding pressures over the last several years. The greying population means that increasingly more adults require care – with 1 in 7 people in the UK being aged over 65, there is a risk care needs are not being met. Furthermore, almost 15% of this population will be faced with catastrophic care costs over £100,000. Despite the growing number of adults requiring care, workforce has not increased.

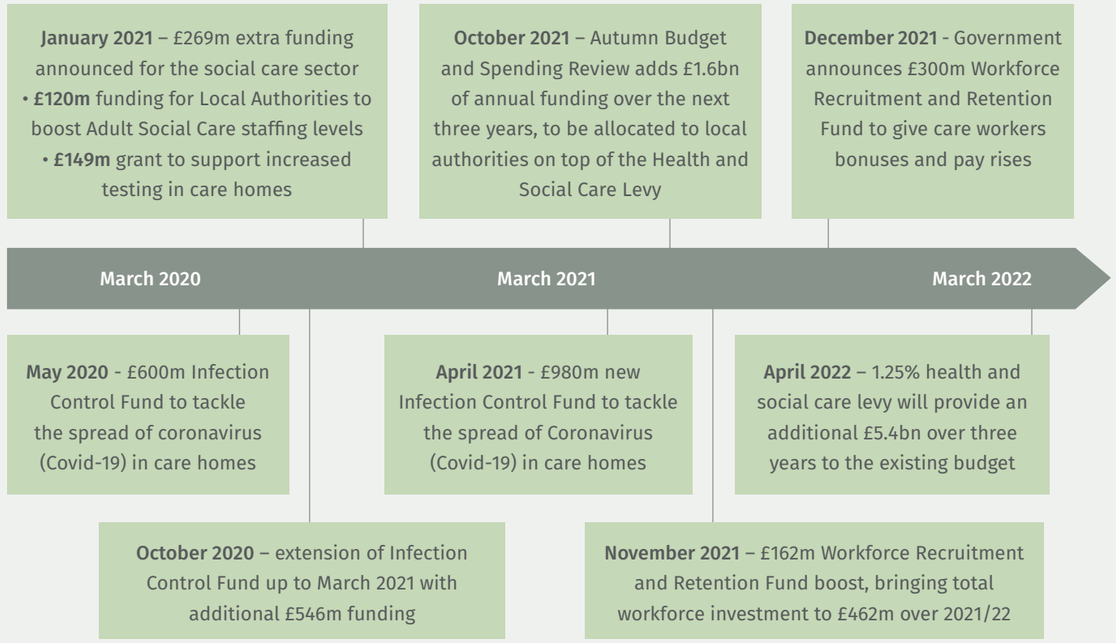
In 2020/21, staff turnover rate was recorded to be 34%, and over 100,000 care staff vacancies were advertised per day. Many social care workers have expressed concerns over the financial compensation they receive. Wages have increased in real terms; however this increase is incomparable to the increase in wages other sectors have experienced. In December 2021, the government announced £300 million – on top of the already allocated £162.5 million – for the recruitment and training of social care workers. Despite additional funding, over 70% of local authorities have expressed serious concerns regarding the financial sustainability of the care they provide through care homes.

The lack of financial sustainability was emphasised in the Health and Social Care Committee's October 2020 report on adult social care, stating that an additional £7bn per year was required by 2023/24 to close the 'funding gap'. This additional funding would be utilised to cover raising National Minimum Wage, demographic changes and support those who face catastrophic social care costs.

Direct allocations safeguard funding for social care services in a particular year, however they do not provide long-term sustainability. To significantly increase funding for social care, the government introduced the Health and Social Care Levy in April 2022. The Levy aims to support adult social care over the next three years by providing an additional £5.4 billion to the existing budget. Of this, £1.7 billion will be used for a wider reform of adult social care and £3.6 billion will be used to reform the social care payment system.

In the Autumn Budget and Spending Review 2021, the Government announced an additional £1.6 billion of annual funding over the next three years, which would be allocated to local authorities on top of the Health and Social Care Levy. As the funding is allocated to local authorities directly, they are responsible for deciding how it should be spent. The Secretary of State announced an additional £636 million through the social care grant in 2022/23. Together with the increase in improved BCF and adult social care precept flexibilities this is a significant source of additional funding, with a total worth of over £1 billion.

Additional funding boosts delivered to the social care sector (2020-2022)



In March 2022, the then Health and Social Care Secretary Sajid Javid announced new guidance on how £1.36 billion in funding would help local authorities to pay a fairer rate of care. The Market Sustainability and Fair Cost of Care Fund increases the support available for the care sector as part of the government's 10-year vision for reform set out in the People at the Heart of Care White Paper. The new guidance sets out how local authorities must:

- Carry out cost of care exercises to improve understanding of how much it costs to provide care in their specific area, including assessing the various costs care providers face in the area
- Ensure the care market in the area is sustainable and identify and increase rates where a fairer cost of care is needed
- Spend no more than 25% of funding in year one towards implementation costs to ensure remaining funding goes towards genuine increases in fee rates

Domiciliary care services

In the coming decade, homecare needs are projected to increase significantly. In the last five years alone growth in the sector has seen the number of UK registered homecare providers grow by 19% to over 10,000. These providers have delivered over 249 million hours of care per year, to more than 950,000 people.

Prior to the pandemic, funding of community care began rising after long-term declines, with a 9.2% increase in 2017/18. However, community care is facing increasingly greater costs in the wake of Covid-19, and there are concerns that local authority changes to care fee rates over the coming years will not be sufficient to meet the growing need or keep up with inflationary pressures.

Private providers who deliver local authority community care contracts are remain under pressure due to the constrained funding environment. However, with domiciliary care remaining an essential service for local authorities and the wider health and social care system, local services

may be increasingly commissioned in a joined-up way, with funding split between health and social care. This may help to keep up with national living wage uplifts and to meet the needs of clients with higher acuity needs. 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. This may be a longer-term positive impact of Covid-19 on the sector.

Care home services

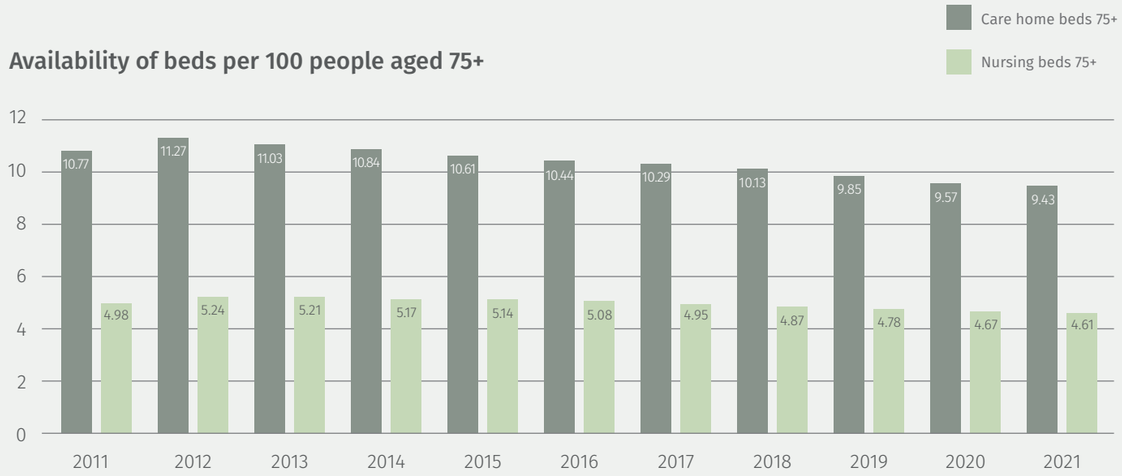
Between 2014 and 2021, the number of nursing home beds decreased gradually from 5.2 to 4.6 per 100 people aged over 75. Similarly, the number of residential care home beds has fallen from 11.3 in 2012 to 9.4 per 100 people aged 75 or older in 2021. This decrease can partially be accounted for by the government's commitment to providing home care to patients, allowing individuals to live independently at home longer.

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. As of 2019, over 75% of all care and residential beds were owned by private providers, with the number of publicly owned declining annually.

Recruiting and retaining workforce was a struggle across both domiciliary care services and care home services even before the Covid-19 pandemic

- The staff turnover rate of permanent and temporarily employed staff working in the adult social care sector was 30.4% in 2019/20
- Turnover rates have increased steadily, by 10.2% points, between 2012/13 and 2019/20
- Data shows that those that travel further for work were more likely to leave their role. Average turnover rate for care workers in the private sector was 7.3% points higher for those that travel more than 20km (32.3%) to work compared to those that travel less than 1km (25.0%)
- Turnover rates amongst under 20s was 46.9%, compared to 22.4% for those 60 and above, revealing that the social care sector struggles to retain younger workers
- Data also shows that new recruits are particularly difficult to retain. The average turnover rate for those with less than one year of experience in sector was 43.8%. This decreased to just 21.0% for those with 20 years or more experience
- Finally, there was a slightly higher turnover rate for those on zero-hours contracts – they had an average turnover rate of 33.2% compared to 26.7% for those not on zero-hours contracts

Availability of beds per 100 people aged 75+

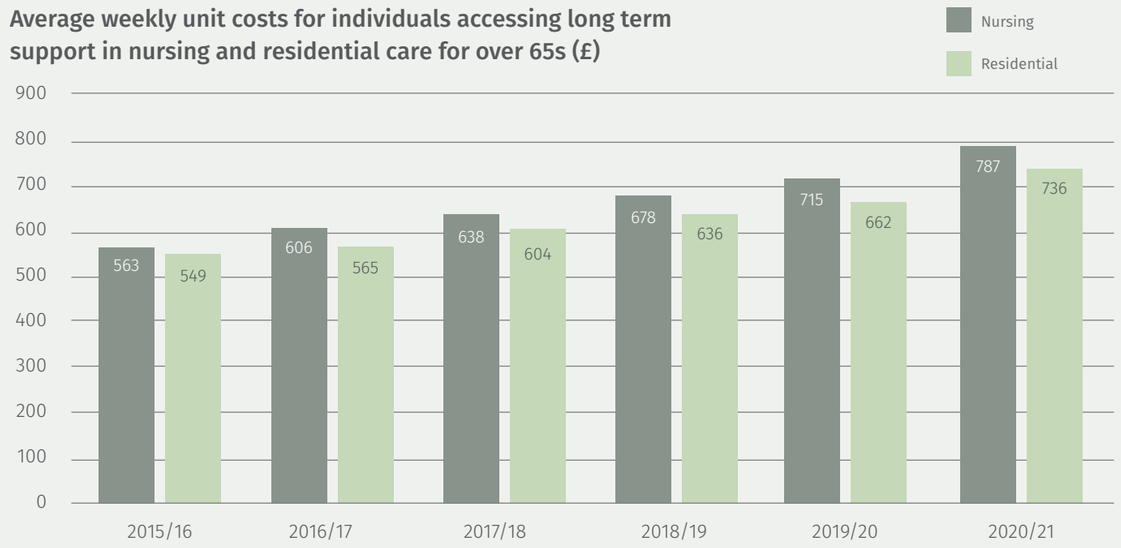


Data: Number of beds available per 100 people aged 75+ (2012-2021)
Source: Kings Fund

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.

In 2021/22, approximately 35% of the care home market consisted of those who pay for their own care (self-funders). This was down from approximately 37% in 2019/2020. However, this is subject to regional variation with more self-funders in the south of England, where around 44.1% of care home residents are self-funders. 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 (£)



Data: Average weekly unit costs for individuals accessing long-term support in nursing and residential care for over 65s, in £ (2017/18 to 2020/21)
Source: NHS Digital

Policy And Legislation

The Government 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 the year. In September 2021, changes to the social care sector in England were announced through the Health and Care Act, as well as an additional £12bn a year for health and social care from a new hypothecated tax. The 2022 Health and Care Act paved the way for two major changes in the social care system.

First, it aimed to tackle the high cost of care that some individuals face. Helen Whately, former Care Minister, emphasised the fact that individuals should not be forced to sell their homes to receive care provision. In response, the government introduced a cap on care costs - GBP86,000 identified as 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. Second, the Health and Care Act aimed to support a wider system reform, by supporting and recruiting a highly skilled social care workforce and adopting a more integrated approach to care, one that works seamlessly with healthcare services to meet complex health and social care needs.

Historically reform attempts had been unpopular with the public – as it would require additional revenue to be generated from the tax base. This is viewed as the reason why the Conservatives had such a poor election result in 2017 – ultimately leading to Theresa May's position as PM becoming untenable and paving the way for a new PM. However, the increased visibility of the sector during the pandemic created a window of opportunity where people increasingly understand that the system is in crisis – and may be more willing to pay towards improving care services. It remains to be seen whether the change in Prime Minister in September 2022 will impact this issue, as Conservative leadership hopeful Liz Truss stated that she would give £13bn to the adults' social care sector if elected.

Spotlight on: a new cap on eligible care costs

Successive governments have long recognised the need to fix the social care system, yet major reforms were never achieved. In March 2022, the government voted to reform the way adult social care is funded. The lifetime cap on care costs aims to offer people a deeper insight into their care costs and will prevent people from selling valuables and property to pay for care.

The current care funding system employs a needs and means test to determine an individual's eligibility for state-funded care. Only when someone's needs are deemed significant enough - whilst having minimal assets - will an individual receive state-funded care. Public funding support covers the cost of a 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. Under the current system, there is no cap on the maximum amount one person can spend on their social care needs.

The current system has been scrutinised for many years and is widely considered to be unfair – both the public and politicians have expressed the need for a system reform. Despite this political attention the system has received by the past governments, no significant change was ever implemented.

In 2011, Sir Andrew Dilnot proposed a cap on care costs by introducing a new, fair adult social care funding system. The proposition was approved in the Care Act 2014, however was delayed and ultimately shelved by the 2015 Conservative government. The proposed adult social care reform discussed since September 2021 is based on this model of social care funding.

The new social care cap and an extended means test will be implemented in October 2023 and is highly reminiscent of the 2011 proposed reform. Under the new system, social care costs are capped at £86,000 – no individual will face costs beyond this cap in their lifetime. Furthermore, the system will change so that anyone with assets worth less than £20,000 will have their care costs fully covered by the government. 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 – in practice this means 90,000 care users will be supported by the government.

It is essential to note that only self-funded care counts towards the lifetime care cap – means-tested council funding for those with the least wealth will not count towards this cap. This means that some people still face catastrophic care costs, and risk losing their home to pay for care.

Though adult social care reforms will financially support those who require care later in life, it fails to truly create a fair care system for all. Specifically, people in North East, Yorkshire and the Humber and the Midlands risk spending 70% of their assets on adult social care, whereas those in the South East may be less affected by the reforms.

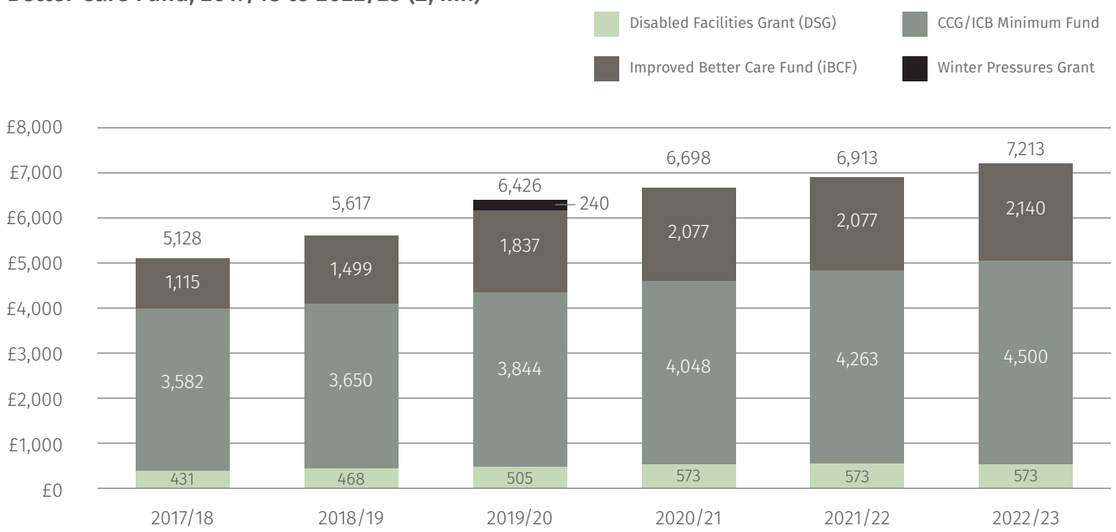
The government has been transparent regarding the financial sustainability of the new system: it could save up to £900 million a year by 2027/2028. The new care system leaves something to be desired in terms of fixing a broken system and meeting the needs of those with the least wealth.

Improved Better Care Fund (iBCF)

The iBCF spans the NHS and local government and aims to join up health and social care services – aiding people to live independently for as long as possible. Previously known as the Better Care Fund (BCF), it encourages integration by requiring ICBs and local authorities to enter into pooled budget arrangements and agree an integrated spending plan. In 2018, the government conducted a review of the performance and efficacy of the BCF and concluded that 93% of all areas found that the BCF improved collaboration and integration of local services.

In 2021/22, £6.9 billion was pooled in the BCF, comprised of £2.08 billion in the iBCF, £0.57 billion in the Disabled Facilities Grant, alongside the minimum contribution from CCGs of £4.26 billion. The minimum ICB contribution, which replaces CCG contribution, to BCF is set to increase slightly in 2022/23, from £4.26 to £4.50 billion.

Better Care Fund, 2017/18 to 2022/23 (£, mn)



Data: Growth in Better Care Fund funding, including the Disabilities Facilities Grant (DSG), CCG/ICB funding, Improved Better Care Fund (iBCF) and Winter Pressures Grant, in £ millions (2017/18 to 2022/23)

Source: NHS England

Regulation

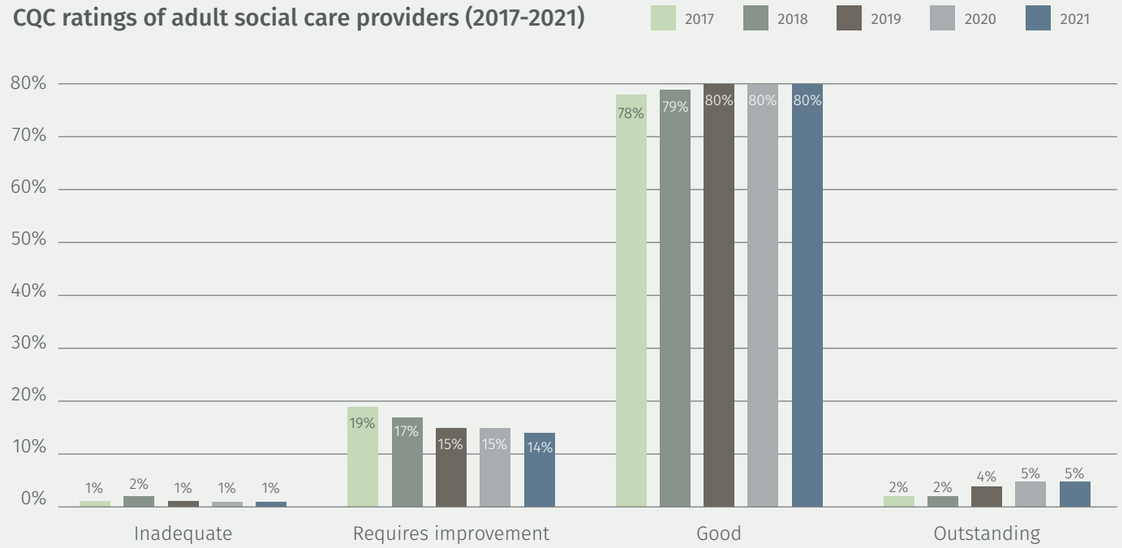
The CQC is responsible for regulating adult social care services in the UK. Its main function is to register, inspect and monitor providers. In line with CQC's new strategy published in 2021, inspections will be carried out when there is a clear need to do so - meaning they will be increasingly targeted 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. In 2020/21, 80% of adult social care services were rated good, and 5% of services were considered outstanding. Only 1% of all adult care services were considered to be inadequate. 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.

Overall, community social care services perform best, with 92% of services being rated good or outstanding. In contrast, nursing homes have significantly lower ratings, as 22% are considered to need improvement or are inadequate.

CQC resumed inspection activity in April 2021 after pausing its regulatory services due to the pandemic, focusing on areas where there were key safety concerns. Inspections focused 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 navigated through the next stages of the pandemic.

CQC ratings of adult social care providers (2017-2021)



Data: CQC Ratings of Adult Social Care Providers (2016-2020)

Source: CQC

CQC has taken this learning into account as it plans its future approach to inspection in line with its new strategy: the transitional monitoring approach. It plans a more targeted approach that builds on the 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 practices. However, high-performing providers may benefit from increased gaps between inspections.

Market oversight and preventing provider collapse

Since 2015, CQC has 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 from 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 work closely with providers and local areas in the event of any concerns over a provider's status.

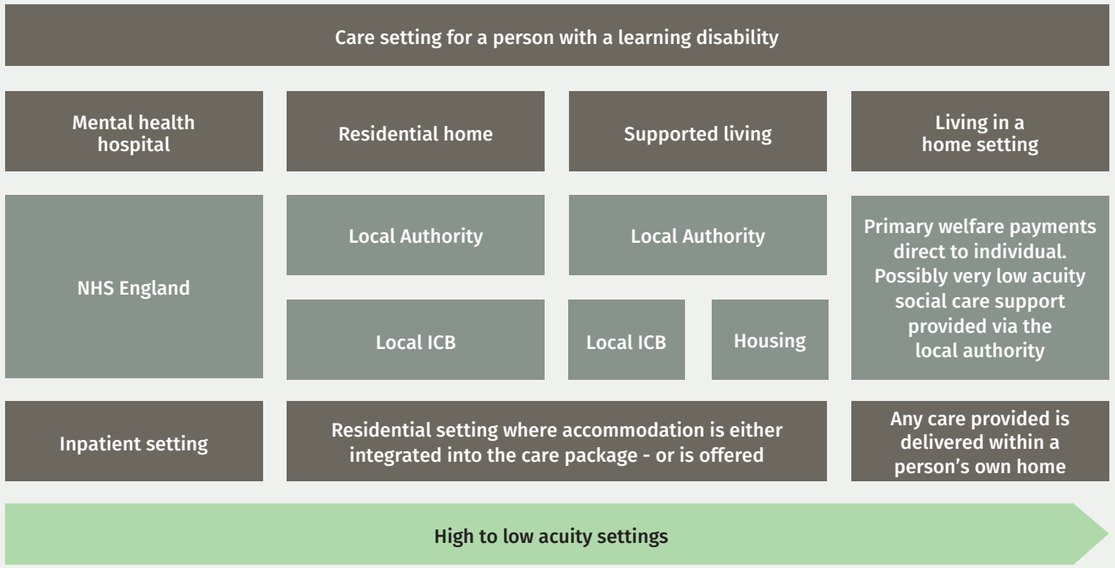
It should be noted that the CQC cannot intervene in case of concerns over the stability of providers they are monitoring, their role is limited to warning the relevant local authorities about their concerns so they can make arrangements to deal with potential service disruption in case of catastrophic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

In May 2022, the CQC updated their Market Oversight Scheme to both clarify and introduce activities and actions the CQC might take. Closer monitoring will take place where there are serious concerns regarding a provider's financial stability. The CQC also holds the power to contact local authorities to address concerns.

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
- The policy landscape continues to seek to move individuals out of inpatient care – viewing it as an inappropriate service model for people with learning disabilities. The LTP has set an 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, cared for in an inpatient facility
- Spending on adult learning disability services has been relatively well protected compared to other elements of local authority spend and has been increasing year-on-year
- In 2020/21, local authorities spent over £5.5 billion on learning disability support for working-age adults. This was slightly more than the £5.39 billion spent in 2019/20
- 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

Adults with a learning disability may receive publicly funded care in a variety of settings; the setting is likely to determine which public body is primarily responsible for funding



Payers

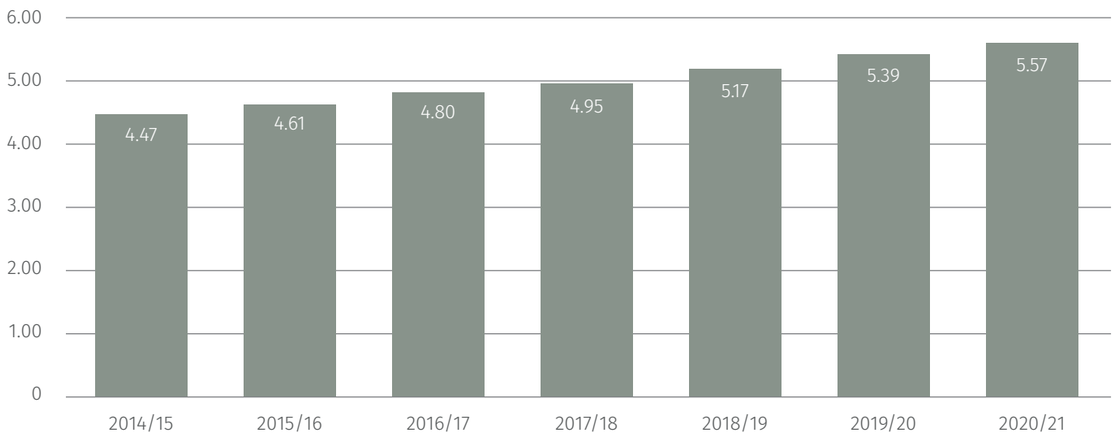
The three primary payers of learning disability services are NHS England, ICBs, and local authorities. NHS England and ICBs are responsible for funding most inpatient services, whilst local authorities finance community services. With national policy initiatives focusing on moving individuals with learning disabilities out of the hospital into community settings, local authorities are increasingly responsible for a higher proportion of overall spend on learning disability provision. With the introduction of ICSs in 2022, fewer organisations across England will be responsible for larger populations, which will allow for greater coordination and more consistent access to services.

The number of adults identified with a learning disability has risen substantially over the last decade. As providing appropriate learning disability services is a statutory responsibility, this has placed additional pressure on local authority budgets compounded by the impact of 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, which may vary between ICBs. 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 disabilities receiving social care is projected to rise by 72.5% between 2015 and 2040. In 2020/21, local authorities spent over £5.5 billion on learning disability support for working-age adults. Total spending, which includes NHS specialist care for people with a learning disability, and wider welfare support payments, is over £8 billion. The government also included a £573 million Disabled Facilities Grant in the Improved Better Care Fund (iBCF) in 2021/22.

Local authority expenditure on learning disability support for working age adults (£, bn)



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 to support policy drivers in moving learning disability care into community settings. This did not require a major shift in budgetary allocations, and instead focused 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. The guidance for local commissioners on supporting people with learning disabilities in the community will be revised in 2022/23.

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 was the lack of appropriate community housing, and £100 million of capital investments was made available for local authorities to invest in housing infrastructure between 2016 and 2021.

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. 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 with costs associated with discharging people with learning disabilities or autism back into the community. In 2021, the Autumn Budget and Spending Review allocated £500 million to the recruitment and training of the social care workforce.

The NHS Long Term Plan

In recent years, learning disability policy has focused on a shift from inpatient to community service provision. The 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 LTP focuses 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. In March 2022, there were 2,010 learning disabilities or autism inpatients, this had remained stable for approximately six months. The LTP acted as an unofficial reset of the target, by extending the deadline for bed reduction 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. NHS-Led Provider Collaboratives are seen as a vehicle that may drive decisions over local spending. 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 ICSs will implement national standards over the next five years, applicable 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 in 2019 at Whorlton Hall have kept the issue of out of area placements (OAPs) in the public eye. It highlighted the potential risks of placing highly vulnerable people in inpatient settings a long way from commissioner oversight.

Whilst reduction of OAPs has been a policy objective for some time, 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. However, as of 2022, the government has been unable to eliminate all OAPs.

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 lack of knowledge 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 OAPs for mental health in England published in June 2022 showed that current initiatives are failing to significantly reduce the number of OAPs. The number of OAPs in England remained relatively stable between April 2018 and March 2022, totalling 675 and 670, respectively. During the Covid-19 pandemic, there were rapid drops and rises in the number of OAPs, but ultimately the government failed to meet its own targets.

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 Appeal. It dismissed the arguments that sleeping workers were entitled to NMW. This is in 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 with learning disabilities, specifically their quality of life and the care they receive for their learning disabilities. The guidance highlighted three key factors for providers to consider if they are caring for individuals with learning disabilities: right support, right care, and right culture.

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.

During 2022, CQC undertook a review focused on services that provide care for people with learning disabilities and challenging behaviours. CQC inspectors carried out 145 unannounced inspections that looked at two national standards:

- care and welfare
- safeguarding (protecting people's health and wellbeing, and enabling them to live free from harm)

Across the 145 inspections, 69 (47.5%) failed to meet one or both standards. The provision inspected included NHS Trusts, private services and care homes. Larger private 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.

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 an 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 prevent subsequent hospital admission.

In December 2021, a progress report on restraint and seclusion was published by the CQC. The regulatory body concluded that stakeholders had responded to the recommendations made in the initial report. Despite this response, the CQC found that there were still too many learning disabilities and autism inpatients in hospital wards. 2,000 of these inpatients were subjected to restrictive measures in August 2021 alone and discharge from inpatient wards was considered too slow. Based on these findings, the CQC urgently recommends further change to the system, including more housing facilities and a greater workforce. A full progress report is expected later in 2022.

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 came after contention with providers who had their registration applications rejected.

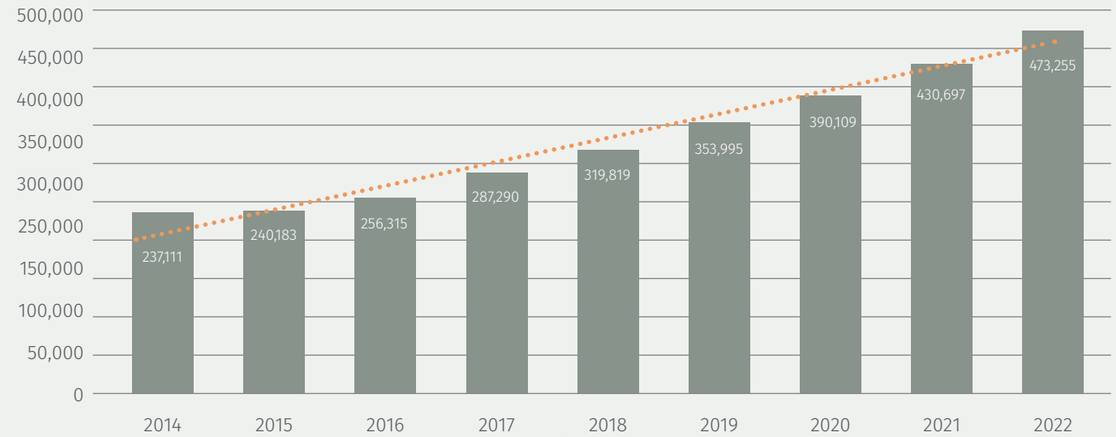
The October 2020 guidance follows on from Registering the Right Support published in June 2017, and the Building the Right Support October 2015 guidance, which initially set out the national service model for learning disability services. These policies also reinforced prior objectives of moving people 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.

There are two common reasons for rejection of new provider facilities: providers do not meet the 'six-bed rule' set out in the national service model – no facility with less than six beds can be registered, and providers' proposals would create a congregate setting of care. This has increased pressure on commissioners, as it has placed an additional barrier on supply entering the market. In a June 2022 progress report, the CQC acknowledged the criticisms it received regarding the "six-bed rule", however, the regulatory body continues to uphold the regulation to safeguard vulnerable patients and ensure best practice principles are adhered to.

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 473,255 individuals by May 2022
- Nearly 164,600 children with an Education, Health & Care (EHC) Plan, which places a statutory obligation to pay for their care, receive support in Special Schools. Of these, 20,300 are placed in Independent Special Schools
- There is also a growing number of children with SEND who have looked after status, meaning the local authority has corporate parenting responsibility for providing safe and secure housing and meeting the child's wider needs
- The policy landscape has remained stable since the introduction of the Children and Families Act. However, there have been a number of national policy reviews and reports published throughout 2022 which may lead to changes in the sector
- The SEND and alternative provision green paper, published in March 2022, confirms that meeting SEN should remain a core part of mainstream schools' role in future, and sets out proposals on how schools will be supported to fulfil that role. The green paper also points to changes to the notional SEN budget in future
- Over the last five years, 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 – when cases reach a tribunal, they are usually determined in favour of the parent. This contributes to pressure on local authorities to improve local services and manage demand for those whose needs can be met in less costly settings
- 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 area. Where regulators have issued concerns, data reveals this has driven system improvement at a local level

The number of people that require SEND support has grown by +10% CAGR between 2015 and 2022



Data: Number of children and young people with EHC Plans or Statements of SEN (2014-2022)

Source: Department for Education

Payers

Local authorities

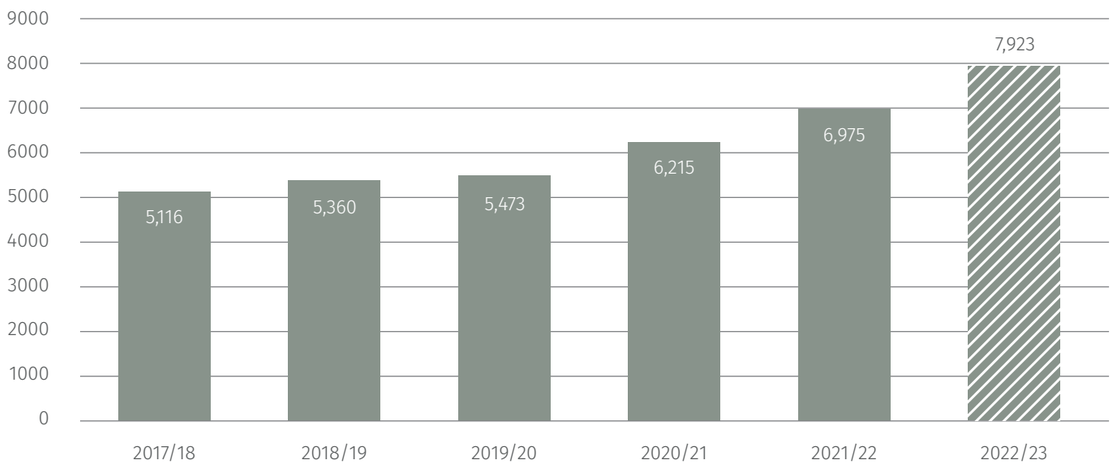
Local authorities are responsible for the vast majority of education funding for children and young people requiring SEND support. The annual budget comes from the Department for Education and is contained within the 'Dedicated Schools Grant' (DSG). The DSG is split into three blocks - the schools' block, 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 an 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. In July 2022, the government issued guidance to help local authorities comply with the requirement to identify for each mainstream school in their area a notional amount to guide schools in their spending to meet the costs of additional support for the school's pupils with SEN.

If a child with SEN is attending a state-funded special school, then their school receives 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 SEN 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.

High needs block allocations to local authorities (£, mn)



Data: DSG allocations, after deductions for academies recoupment and direct funding of high needs places by ESFA, in £ millions
Source: Education and Skills Funding Agency; Marwood Analysis

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. In 2021, there were 1.4 million students – or 16% of all pupils - who required SEN support, 326,000 pupils – or 3.7% - had EHC plans. These are the highest rates of SEN provision and EHC plans ever recorded.

High needs funding shortfall across local authorities was expected to reach £1.6 billion in 2021/22, as projected by the LGA. In the 2021 Autumn Budget and Spending Review, the government announced additional funding to support children with SEN. Despite this additional funding, the SEN funding gap was estimated to be £1.3 billion in March 2022, as a result 75% of all local authorities are now in an SEN funding deficit, 52% more than in 2021. This highlights the urgent need for funding to match the increased demand for SEN provision, and to acknowledge the increasingly complex needs of SEN children.

While not ring-fenced funding, local authorities have a statutory requirement to fund these services. Often the private sector acts as a provider of last resort – where other, less specialised placements, may have broken down. As a result, local authorities have limited negotiating power over the cost of placements.

The Department of Education has acknowledged this pressure and increased annual funding to over £9.1 billion for 2022/23 – a £1 billion increase compared to previous years. This unprecedented increase of 13% is significantly more than the government has invested in SEND services before. Furthermore, high-needs services received an additional £325 million in July 2021. In the coming years, funding will increase annually, with a 5% increase in 2023 to 2024, and 3% beyond that. Further funding may be announced in future Budget and Spending Reviews.
At a local level, there have been several judicial reviews against individual local authorities. These often relate to 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 was found in favour of Surrey County Council's planned savings against the SEND budget.

Private providers

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 therefore should provide coverage for all appropriate care needs.

A parent can always pay independently for a place at a specialist school if the local authority has rejected the application for a particular school. However, the cost of placements would make this unaffordable for many.
There is anecdotal evidence that local authorities are looking to use guidance in the SEND Code of Practice around the 'effective use of resources' to avoid placements 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 the local authority providing a description of the services for education, health, and social care services 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 vast majority of SEND education legislation was determined by 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 to achieve this 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 SEND was expected to be published in Summer 2021 but was delayed for a third time due to the Covid-19 pandemic. In March 2022, the report was finally published as a green paper and highlighted three major areas of concern facing the SEND and alternative provision system.

Firstly, the report found that the experiences of children and parents/carers in navigating the SEND system and alternative provision were increasingly negative. The quality of provided support was highly variable, and often depended on a child's geographical location or educational level, resulting in a child's needs often being neglected. As a result, the government has announced ambitious plans to deliver homogenous care across the UK, decreasing variability and attaining a high standard of care throughout the country.

Secondly, children with SEND or in alternative provision perform significantly worse than their peers across every measure. A new, more inclusive system should improve these outcomes and enable SEND-supported children to thrive. In 2022/23, the government has allocated an additional £1 billion to support those with the most complex needs. By 2030, schools should form a more collaborative network to share expertise and resources to significantly improve performance. Furthermore, the CQC and Ofsted should introduce a collaborative inspection framework to support excellence.

Lastly, despite continuous investments and additional funding, the current SEND and alternative provision system is not financially sustainable. The government has proposed a funding reform through the introduction of a new national framework of banding and price tariffs for funding. New funding agreements between local authorities and the Department for Education should aim to increase the financial sustainability of special educational needs schools.

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

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. In January 2021, 325,600 pupils were found to have EHC plans, this increased to 355,600 in January 2022 – a 9% annual increase.

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. EHC Plans 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.

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.

Local authorities must publish a 'Local Offer', which details the support available to people with SEND. This means information is now more readily available for parents, increasing their understanding of their rights and entitlements.

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.

Number of pupils with an EHC Plan by type of provision (2010 – 2022)

SCHOOL TYPE	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Alternative provision/pupil referral unit	1,707	1,667	1,625	1,451	1,467	1,549	1,489	2,209	2,330	2,731	3,181	3,239	3,596
Mainstream - Independent	1,946	2,178	2,076	2,334	2,486	2,885	2,979	3,261	3,228	3,618	3,970	4,555	5,033
Mainstream - LA maintained	105,194	102,376	89,902	81,340	75,652	70,408	64,871	62,515	62,234	64,450	67,924	74,331	79,804
Mainstream - LA maintained - resourced provision	8,763	8,924	7,966	8,096	8,667	8,083	7,414	7,032	6,440	6,214	5,810	6,566	6,436
Mainstream - LA maintained - SEN unit	6,937	6,564	6,027	5,323	4,932	5,046	5,529	3,808	3,227	3,486	3,509	3,674	3,251
Non-maintained early years	942	768	901	855	1,018	956	1,048	1,136	1,476	1,708	2,024	2,219	2,518
Special - Independent	7,347	7,661	7,858	8,262	8,653	9,284	10,137	11,083	11,785	13,744	15,854	17,839	20,324
Special - LA maintained	84,818	86,107	85,632	83,753	81,937	82,930	81,604	81,414	82,669	83,934	83,441	84,042	85,781
Special - Non-maintained	3,486	3,379	3,314	3,353	3,417	3,542	3,584	3,859	3,698	3,788	3,787	3,907	4,088

Note: This data does not include pupils who are only in receipt of SEN support, and who are not in receipt of an EHC Plan

Source: Department for Education

These conditions include: 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.

In 2022, 4.3% of pupils with an Education, Health & Care Plan, are taught in independent special schools. This percentage has been slowly increasing from its base level of 3.2% in 2010. The primary most common type of need is 'Autistic Spectrum Disorder', a gender bias can also be noted - 15.4% of boys received SEN support in contrast to 9.2% of girls.

Spotlight on: local authorities are adapting to the national policy direction signposted in the SEND Green Paper

The SEND Green Paper which had been the biggest unknown in the sector over the last three years has focused on preventing needs and on making wider improvements to the system. This centres on reducing local variation in local authority practice, putting earlier intervention in place and clarifying the support and services available for SEND. This may help local areas level up to best practice across England and increase the identification of needs in the short-term.

The government's vision is that improving the SEND system may reduce spend overall and protect funding for pupils with higher needs over the medium- to long-term. Local areas across England have seen a flurry of activity to refresh local strategies in line with this national policy direction. This has meant many local authorities have sharpened their policy focus on reducing out of area placements, and on increasing use of high-quality providers.

A key theme throughout most local authorities strategies and national policy is on making the whole system more sustainable by managing lower level demands with less intensive, less costly interventions to protect funding for those whose needs require more specialist interventions (i.e., specialist provision for SEND).

Government commitment to increase number of special schools

There has been a commitment by the Government to increase the number of specialist 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.

Out of £780 million committed to SEND education in 2020/21, £645 million was spent on 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. The government has also pledged to open 60 free special education schools by September 2025 – creating approximately 4,500 new places. In October 2021, the government announced a £2.6 billion funding pot of capital investment, to help create 30,000 "high-quality" school places for children with SEND to 2024, as well as fund the construction of new free schools, and improvements to the accessibility of existing buildings.

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, and – in certain cases - the CQC. 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.

Furthermore, Ofsted consults parents and pupils, and takes their experiences and views into consideration when publishing their final report.

Schools are re-inspected based on Ofsted's final report. Schools rated 'good' or 'outstanding' are ordinarily revisited in 4 years to confirm the school has retained a high standard of education and support. Schools that are deemed to require improvement are re-inspected within 30 months of Ofsted's initial inspection. If a school is considered 'inadequate', it will also be monitored and Ofsted will revisit the school within 30 months.

Local area Special Educational Needs and disabilities provision

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

These joint inspections are conducted 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 don't evaluate the quality of support provided to individuals.

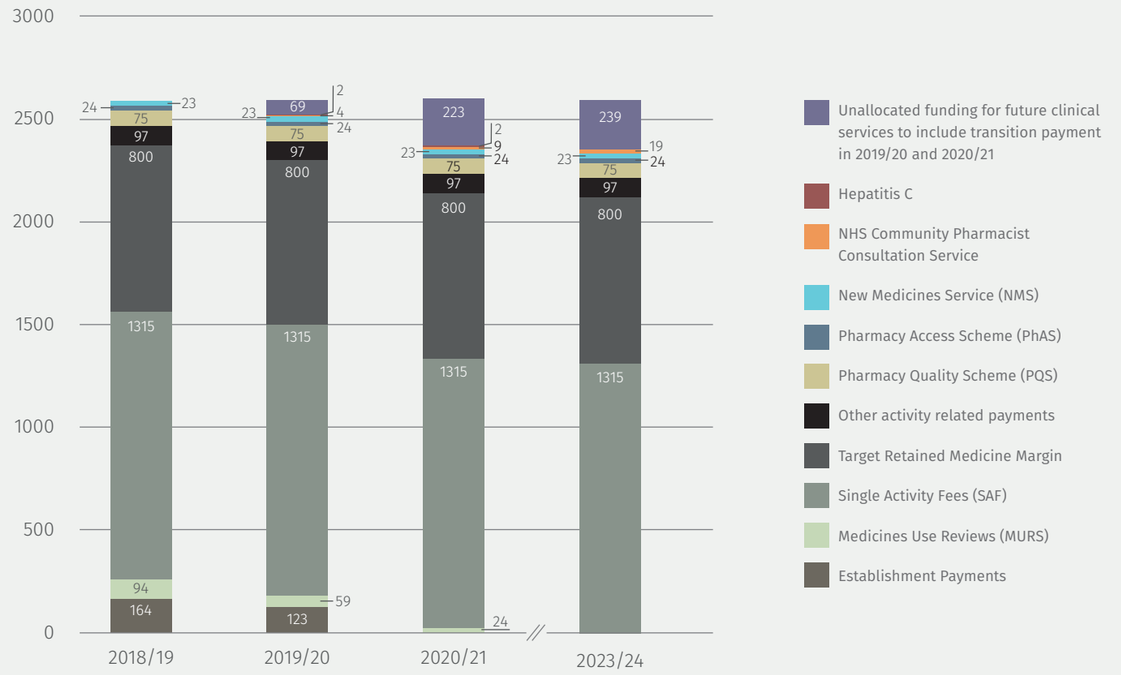
However, they are important as a poor inspection can lead to local authorities being required to create action plans that are monitored by Ofsted and the DfE. This can lead to local improvements that will make it easier for parents to access EHC channels and potentially boost placements in higher complexity 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 early 2023. Key areas of focus are on reducing out of area placements and supporting children with SEND to become prepared for adulthood. This is likely to increase a focus on outcomes of SEND placements.

Key Messages for Pharmaceuticals: Community Pharmacies

- In England there are around 11,600 pharmacies, receiving 1.6 million visits a year and dispensing over 1 billion prescription items annually
- Community pharmacies are at the centre of routine healthcare for many people as they are where people 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 pharmacy so it makes sense that policy has focused on integrating community pharmacies into the core of the NHS healthcare landscape, with a growing role in service delivery to reduce the demand on primary care
- The role and purpose of community pharmacies is in flux, as prescription dispensing is increasingly shifting to remote provision, and broader policies are placing pharmacies at the heart of the NHS for many patients with a range of health conditions
- For the last five years, much of the NHS' work with community pharmacies has also been focused on reducing unnecessary prescriptions. In 2022, the NHS announced new action to tackle unnecessary prescriptions, rolling out expert pharmacy teams who can give advice to patients, so that the NHS can make best use of resources while maximising other treatment options
- Community pharmacies also function as the main entry point for non-reimbursed (over the counter) pharmaceutical products. This is an essential revenue generator for many pharmacies

Overall, community pharmacy funding will remain static over the next 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

Payers

Community pharmacies are funded from various income streams. The NHS Drug Tariff is provided by NHS prescription services and sets the reimbursed price and remuneration that pharmacies can receive from the NHS under the Community Pharmacy Contractual Framework (CPCF). In addition to the Drug Tariff, community pharmacies may provide other NHS and non-NHS services that generate activity-based fees, payments for enhanced and advanced NHS services, and Pharmacy Quality Scheme (PQS) payments. The PQS is a payment to financially reward pharmacies that demonstrate high quality provision of care, in addition to other payments for delivering certain core services, such as prescription dispensing.

In 2021, a review led by the chief pharmaceutical officer for England, found that of the 1.1 billion prescription items dispensed in the community in England in 2020/21, as many as 110 million (10%) “need not have been issued”.

Over the last five years, much of the NHS’ work with community pharmacies has focused on reducing unnecessary prescriptions. Following the 2021 review into medicines overprescribing, the NHS has announced new action to tackle unnecessary prescriptions by rolling out expert pharmacy teams in 2022 to provide advice to patients, and ensure the NHS makes best use of resources.

Community pharmacies can also receive payments for other commissioned services, with this payment coming from local authorities or ICBs. Retail activities also supplement community pharmacy funding, such 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. In July 2022, an updated version of the agreement was published, revealing slight adjustments to the funding arrangements. The plan introduces new enhanced and advances services, such as the Smoking Cessation Service and the Hypertension Case-Finding Service. The Community Pharmacist Consultation Service (CPCS) was also expanded to GP practices, and the Discharge Medicines Service (DMS) was introduced to improve medicines safety on discharge from hospital.

Over the five years, community pharmacy funding will maintain a total of £2.592 billion each year. Due to high levels of inflation and the strain of the Covid-19 pandemic, this will ultimately be a real-term decrease. However, this may be balanced out through significant technological efficiencies which may help drive reductions in the cost of doing business. The Pharmaceutical Services Negotiating Committee (PSCN) released a statement in 2022 outlining the funding pressures community pharmacy currently faces, and how inflation will have a detrimental impact on the financial sustainability of many pharmacies. However, the Government has not announced plans to increase the community pharmacy budget to account for inflation.

Within the landscape of community pharmacy, several key players contribute to significant lobbying. The 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 to March 2022. This represented a 1.5% increase over the previous levels and signalled a continued commitment to maintaining funding levels. As of April 2022, the Single Activity Fee has been reduced back to £1.27 – the PSNC will continue to monitor fee levels throughout the year to ensure full funding is allocated.

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 cash flow pressures that community pharmacies were facing. While these loans were beneficial 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 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 introduced by the Health Act of 2009, in which 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 of April 2013, Health and Wellbeing Boards have a statutory duty to publish and update the local PNA, which reflects how pharmaceutical services aim to meet the changing needs of the local population. NHS England consider the PNAs when determining market entry to a pharmaceutical list, for example opening additional pharmacies to meet rising demand.

As local system priorities become increasingly shaped by 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. Pharmacies will be incentivised to meet certain healthcare needs of a local population, acting as the first point of contact for many health-related concerns, relieving pressure from other primary NHS services.
The five-year funding settlement was an opportunity for the Government to reaffirm its support to the pharmaceutical 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 the dispensing of prescription medicines. In 2022, pharmacies have introduced smoking cessation services, highlighting the evolving role of pharmacies. Alongside changes in service delivery, the Government has also committed to reviewing regulations that may provide more flexibility in how operators build their business.

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.

Community pharmacies are regulated through the Community Pharmacy Contractual Framework (CPCF), which spans the financial years 2019/20 to 2023/24. Under CPCF pharmacies are seen as essential to supporting the NHS Long Term Plan - pharmacies that are included on the pharmaceutical lists must provide a list of their essential services and engage in clinical governance and healthy living initiatives. Pharmacies can also choose to provide enhanced services for identified patient needs, through commissioning. The 2022 Health and Care Act, shifts responsibility over pharmaceutical services from NHS England to the newly formed ICBs.

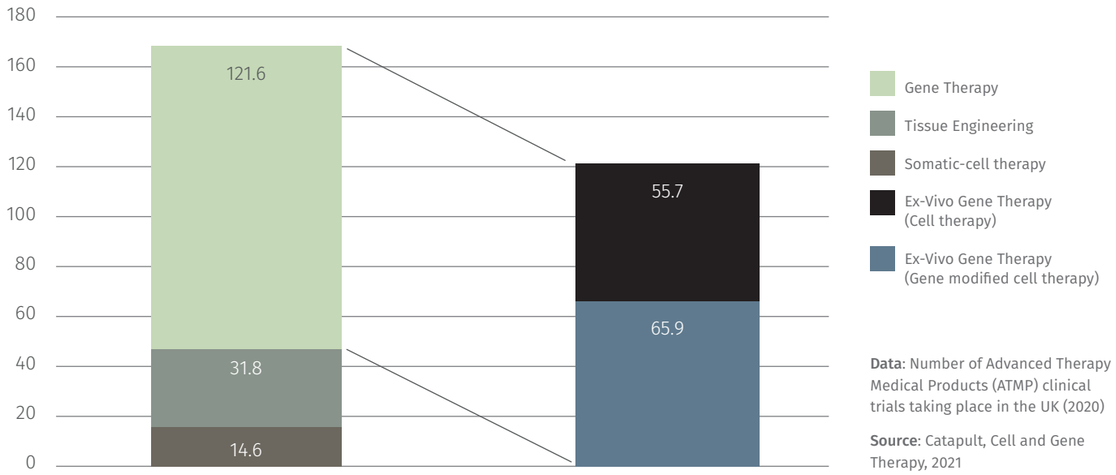
In July 2022, an updated version of the CPCF for 2022/2023 was released, outlining regulatory changes. Under this revised CPCF, additional pandemic requirements were included – pharmacies will be required to comply with recommendations from the government or NHS England & NHS Improvement (NHSE&I) to keep staff safe. Through the pandemic response programme, NHSE&I are allowed to conduct infection control risk assessments at pharmacies, as well as evaluate the pharmacy’s response to potential infection control risks.

Key Messages For Branded and Innovative Drugs

- The UK continues to be an attractive market for pharmaceutical developers and manufacturers, supported by a positive policy and regulatory environment with the government, keen to position the country as a biotechnology leader
- Government's policy focus remains firmly on innovation and strengthening the UK's position as a global leader in life sciences. This is supported by ongoing join-up between the NHS and industry to maximise use of the NHS's unique patient dataset
- The government spends significantly on research and development (R&D) grants and tax breaks for the biotech sector. R&D expenditure is anticipated to increase in 2022, due to greater funding from public organisations and private investors. This presents an opportunity for industry growth
- Funding on pharmaceutical products in the NHS remains constrained creating pricing pressures, but the multi-year spending control agreement continues to allow for annual spending growth of 2% on branded and innovative drugs
- NHS spend on specialised pharmaceutical products has continued growing in line with new treatment options. But the decision from the Consumer and Markets Authority (CMA) in July 2022 to fine pharmaceutical firms for overcharging the NHS for a life-saving epilepsy drugs, shows that the government and the NHS will continue to take a firm line on value for money pricing

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

Number of Advanced Therapy Medical Products Clinical Trials (ATMP) performed in the UK, by sub-sector



Data: Number of Advanced Therapy Medical Products (ATMP) clinical trials taking place in the UK (2020)

Source: Catapult, Cell and Gene Therapy, 2021

Payers

Overall spending on pharmaceutical products across the NHS in England has been rising in recent years – but declined slightly in 2020/21 due to the Covid-19 pandemic. In 2020/21 the total spend was £16.7 billion, covering both hospital and community settings, and all types of pharmaceutical expenditure (branded and innovative, generics, and biosimilars).

Primary care pharmaceutical expenditure is worth over half of the 2020/2021 budget, with £9.42 billion spent on pharmaceutical products across primary care services. In contrast, hospital expenditure makes up approximately 45% of the total budget, spending £7.59 billion on pharmaceutical products.

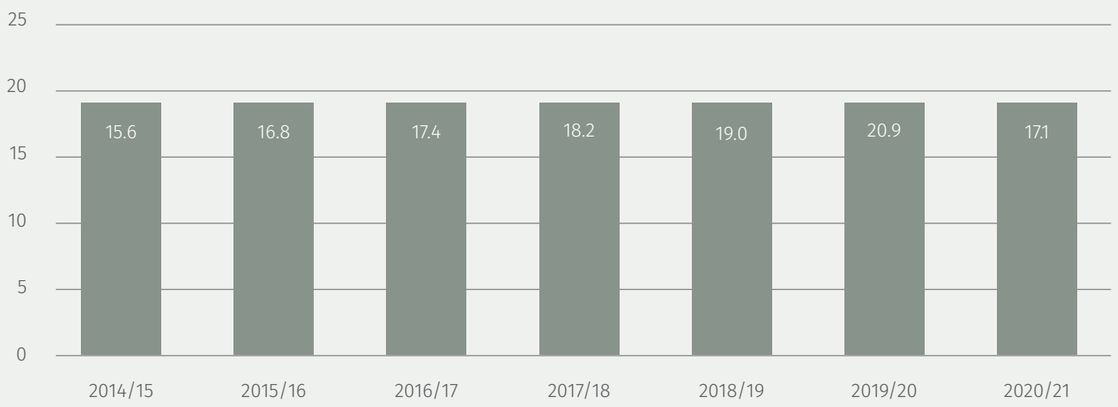
The total amount reported on pharmaceutical expenditure is the list price for the products and so does not include any agreed commercial discounting arrangements.

Spending controls

The NHS spent close to £13 billion on branded drugs in 2021. 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.

NHS overall expenditure on pharmaceuticals has risen by 10% between 2014/15 and 2020/21, down from 33% in 2019/20

NHS overall expenditure on pharmaceuticals (£, bn)



Data: Prescribing costs in hospitals and the community, in £ billions (2014/15 to 2020/21)

Source: NHS Digital

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.

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 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 the predecessor PPRS between 2014 and 2018.

NHS ALLOCATED GROWTH WITHIN THE BRANDED DRUGS BUDGET	2017	2018	2019	2020	2021	2022	2023
	1.8%	1.9%	2%	2%	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 payback 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 2022, this equated to 15%. This is a sharp increase from 5.1% and 5.9% that were due to be repaid in 2021 and 2020, respectively. This reflects the rapid growth in sales, partially explained by the Covid-19 pandemic. Apart from the increase in repayment, the VPAS remains otherwise unchanged for 2022/2023. 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 payback decisions are imposed on pharmaceutical companies.

NICE's cost-efficiency assessment and 2022 manual

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 reimbursed by 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 of life and can go up to £300,000 per QALY.

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 larger patient cohorts.

In January 2022, NICE announced an overhaul of its appraisal process of the cost-effectiveness of pharmaceutical products and health technologies. These changes came into effect in February 2022 and aimed to provide patients with expedited access to innovative and promising treatments. Though the core of the framework for determining cost-effectiveness will remain unchanged, the implemented changes are significant.

The newly introduced NICE 2022 manual will offer greater flexibility in the appraisal of pharmaceutical products for severe diseases which have a higher cost per QALY, exceeding the original £30,000 upper limit. In previous years, this financial flexibility was reserved for end-of-life treatments and has now been extended to include severe diseases and health inequalities – funding products up to a newly increased cap of £50,000.

NICE is committed to offering greater flexibility in the evidence it considers during the appraisal process by incorporating real-world evidence from the lived experiences of patients. This offers greater insights into areas that typically generate insufficient research for recommendations, such as paediatric conditions and rare diseases. This removes barriers to promising innovations in areas where research is currently limited yet extremely necessary.

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.

Ideally, a drug will be priced in line with NICE's QALY assessment. 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. To avoid the potential reputational harm and a delay in providing access to a drug of therapeutic value, the NHS will commonly negotiate drug deals confidentiality.

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 – funding potentially life-saving medication.

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, which 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.

NHS England holds a powerful negotiating position, as most negotiations take place behind closed doors – the NHS will commonly pay significantly lower prices than what a drug is advertised for. This was demonstrated in the first quarter of 2021, when the world's most expensive drug was approved by the NHS for use – a single dose of this drug, Zolgensma, added up to a total of £1.79 million.

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 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. Especially in the post-Brexit landscape as there is an increased focused on innovative therapies, which include cell and gene therapies and biologic drugs. Both updated policy guidelines and regulation provide an attractive landscape for investors looking to gain access to the pharmaceutical market.

NHS Long Term Plan

The 2019 LTP set out the goals, ambitions, and policy guidelines for pharmaceutical services, making 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 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 were further strengthened in the LTP, which announced that genome sequencing would be used to deliver highly personalised diagnostics to children with cancer, and adults suffering from certain rare conditions or specified cancers. The ambition to improve cancer services was further reflected in the Government's 2022 10-Year Cancer Plan consultation. This sets out to implement significant strategic changes to detect and treat cancer at an early stage, through innovative technology, increased workforce, and eliminating health disparities. The 10-Year Cancer Plan builds on the LTP and takes an even more ambitious stance to prevent cancer and improve outcomes significantly. An update on the consultation is expected in late 2022.

The 100,00 Genome Project was initiated in 2013 and placed the UK at the forefront of genetic medicine research by sequencing 100,000 genomes from around 70,000 people suffering from rare diseases or cancer. 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. Data from recent pilot studies suggest that those enrolled in the genome project have already experienced significant benefit from their participation – demonstrating how the project can transform the lives of many, providing fast accurate diagnoses and improving prognosis.

Support for the development of novel antibiotics

While the world continues to experience the Covid-19 pandemic in 2022, the UK remains committed to supporting the development, testing, and evaluation of innovative drugs to stimulate the global antimicrobial pipeline. 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 – incentivising companies to develop new antimicrobials and pushing back against overprescribing.

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. This strategy is a collaborative effort between NHS England, the government, medical charities, and science companies. 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 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.

Regulation

Marketing authorisations

New drug approval under the MHRA post-Brexit

When Britain formally exited from the EU in January 2021, it marked a major shift in regulatory responsibility for the pharmaceutical industry. 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 the national level by competent authorities. In the post-Brexit landscape, 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 to 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 has 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.

The MHRA has indicated that it will offer faster assessment routes for certain medicines, like biologics and biosimilars. 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.

In July 2021, the MHRA released their Delivery Plan 2021-2023, which sets out its 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.

In June 2022 MHRA announced work to help review and approve promising cancer drugs as part of Project Orbis, a programme coordinated by the US Food and Drug Administration (FDA), with the aim of helping patients access treatments faster. This provides a framework for concurrent submission and review of oncology products among international partners. The regulatory authorities of Australia, Canada, Singapore, Switzerland, and Brazil are also participating but each country remains fully independent in their final regulatory decision.

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 January 1st 2021, but manufacturers were able to opt-out of this process within 21 days after the withdrawal of the EU. In practice, this has a positive effect on the UK pharmaceuticals market as manufacturers based in the EU will be able to continue selling their products in the UK and vice versa.

Clinical trials regulation

Before gaining a marketing authorisation, all therapies must complete the clinical trial process. Historically, this process has been regulated by the EU through the Clinical Trial Regulation (CTR). After the UK's withdrawal from the EU, the regulation of clinical trials fell within 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.

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. This ambition was reflected in the 2021 Medicines and Medical Devices Act. Under the new Act, the UK can update its regulatory framework overseeing clinical trials, developing a leading regulatory environment in which innovative research is encouraged. The development of such a framework would enable the UK to retain its status of a leader at the forefront of life science innovation, fostering ground-breaking research and creating opportunities for skilled jobs in the UK.

The UK Government published a consultation on proposals for legislative changes to clinical trial regulation in early 2022. In this consultation, the Government expresses its ambition to create a thriving clinical research environment, supporting effective and promising clinical trials. In the post-Brexit landscape, the Government aims to involve the public and those with relevant lived experience in the design of clinical trials – this sends a strong message which puts participants at the centre of clinical trials. Furthermore, the proposal would expedite the appraisal of clinical trials by simplifying the application process. The consultation also sets out new legislative guidelines on research transparency and safety reporting. Ultimately, the proposal would make the UK a highly attractive country for clinical trials which focus on excellence, safety, and innovation.

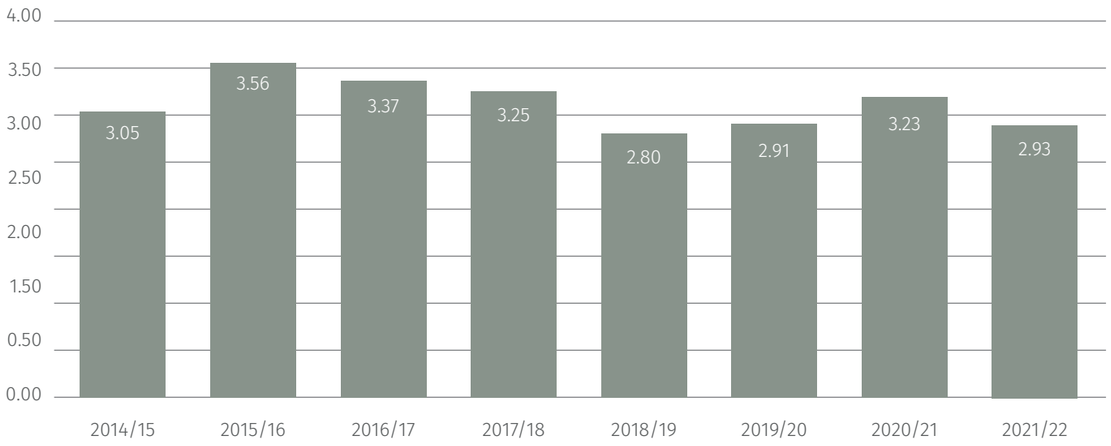
Through the input of trial participants, researchers, developers, and other stakeholders, the new regulatory framework will be considered. The results of the consultations are expected to be published in late 2022.

Key Messages For Generic And Biosimilar Drugs

- With increasing numbers of biologic drugs approaching patent expiry in Europe, the NHS is keen to leverage savings from potentially cheaper biosimilar versions. This may make the UK an attractive launch market for biosimilar manufacturers
- NHS England continues pushing the uptake of biologic medicines with the aim of generating savings for the NHS and uptake has increased quickly over the past four years. This is expected to continue, supported by national policy and guidance to ICBs and NHS Trusts
- Priority clinical areas identified in the LTP continue to provide opportunities for oncology, arthritis, and diabetes biosimilars
- The UK generic drug market is mature, with stable policies and pricing mechanisms incentivising competition and quick market penetration expected to continue
- Generics can be freely priced, this has traditionally worked well to help keep prices low. However, drug pricing is closely monitored as there have been several high-profile cases of pharmaceutical companies finding ways to push through substantial price increases

Generic drug spending in primary care has fluctuated over time

Cost of items prescribed and dispensed generically (£, bn)



Data: Primary Care Spending on Generic Drugs, in £ billions (2014/15 to 2021/22)
Source: National Audit Office, Marwood Analysis

Payers

Generic drug price setting

Generic drugs are copies of originator branded drugs that 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.

In England, 81% of drugs prescribed in primary care are generic – this generates significant savings for the NHS. Four years after market entry, generic prices are found to be 70–90% lower than the original price.

Companies are able to set their own prices for the generic drugs they sell. 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 ICBs for 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 has 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 billions every year. However, in June 2018, the National Audit Office (NAO) outlined that a substantial increase in the number of 'concessionary' requests made by community pharmacies had resulted in £315 million of additional costs for CCGs in 2017/18.

Concessionary prices may be approved when pharmacies cannot purchase medicine at the Drug Tariff's price or below, and are often indicative of price increases of generics. 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.

Even though generic drug prices can increase in times of shortage, the British Generic Manufacturers Association (BGMA) has found that most prices restore within twelve months. This demonstrates that the UK generic drug market is a well-functioning system in which prices fluctuate with demand and supply.

Throughout 2022, drug shortages have become an increasingly common issue, leading to over 100 concessions being granted in some months. Ultimately, this shortage has had a significant impact on the pharmaceutical sector - 83% of pharmacies noted a notable increase in drug shortage over the last year, with two-thirds of pharmacies facing the consequences of this shortage on a daily basis. 97% of pharmacies reported that the shortage has caused significant frustration amongst patients.

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. 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. Biologic drugs tend to be used in hospitals and are primarily commissioned through NHS England's Commercial Medicines Unit.

In July 2022, it was announced that the NHS had saved £1.2 billion on medication over the last three years by using biosimilars and generic drugs. Over one-third of these savings were achieved through the introduction of cheaper adalimumab biosimilars, which is used to treat over 45,000 patients with rheumatoid arthritis, inflammatory bowel disease, and psoriasis. Adalimumab biosimilars are projected to continue to save the NHS £150 million annually.

Policy And Legislation

Biosimilar policy

Given their cost-saving potential, it is unsurprising that biosimilars have attracted policymakers' 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. Full guidance on the prescription of biosimilars can be found on the British National Formulary (BNF) website. Policy efforts are focussed on encouraging commissioners, clinicians, and patients to switch to biosimilars.

Guidance to ICBs 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 NHS guidance is not binding on ICBs: 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 on the NHS, and by extension the ICBs, it would be surprising if they did not use the guidance as a way to generate savings. This has led to products listed as second or third-line items or removed from individual ICBs' formularies.

If GPs want to issue a new prescription for a product that is not on their ICB'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.

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 ICBs 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 ICBs.

Following the launch of adalimumab biosimilars, NHS England also issues specific guidance to NHS Trusts. 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.

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 drug companies and the DHSC. Regulations implementing the provisions in the Act came into force in July 2018 and companies now have to provide pricing information on a quarterly basis.

In October 2020, the CMA investigated Essential Pharma as they alleged that lithium-based medicines, Priadel and Camcolit, were abusing their dominant position in the market as therapies for bipolar disorder. Essential Pharma was 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 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 having 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 its investigation into anti-competitive agreements in the pharmaceutical sector, after pausing investigations during the pandemic. The UK's withdrawal 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

Biosimilars resemble biological drugs that have previously been approved yet are not identical to them. Due to this slight dissimilarity, biosimilars' regulatory approval differs to that of small molecule generic drugs. Before Brexit agreements were finalised, the regulatory framework was set at the EU level and the majority of new biosimilars were subject to EMA approval. In the post-Brexit landscape, the MHRA is responsible for marketing authorisations for biosimilars.

When the MHRA adopted the responsibility for the regulation of medicines, the regulatory body announced that it would follow the same principles for biosimilars as the EMA followed. It was also announced that for two years following Britain's withdrawal from the EU – until January 1st, 2023 - Great Britain will shadow the decisions that the EMA takes on the approval of new marketing authorisations. This highlights a promising environment for drugs approved in the EU that are looking to be sold in the UK.

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

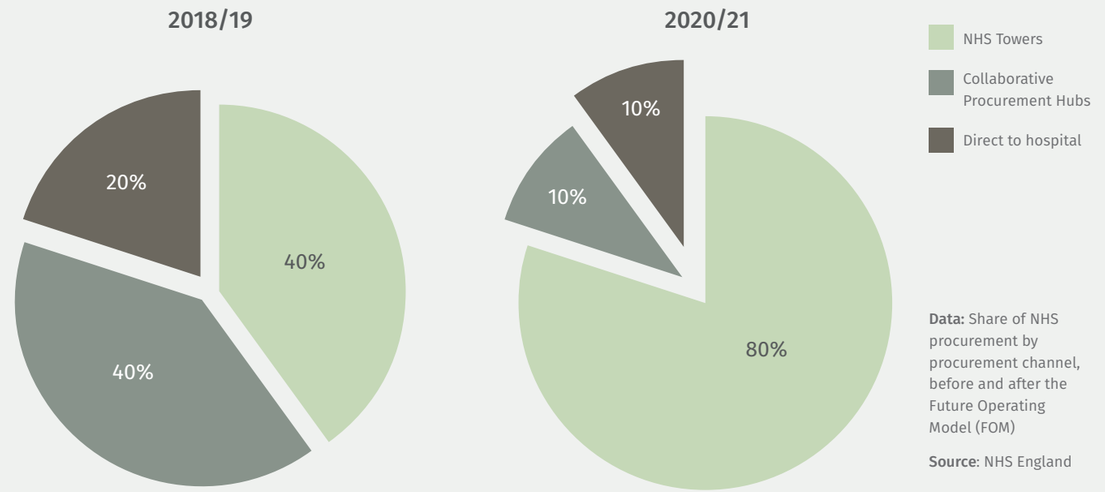
- Targeted assessment process: the MHRA will evaluate the marketing authorisation application together with the EMA's Committee for Medicinal Products for Human Use (CHMP) assessment reports submitted by the applicants. An opinion will be reached within 67 days of submission of a valid application to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

- Rolling review route: the MHRA will offer ongoing regulatory input and feedback to the applicant to help them get the development of their drug right and avoid regulatory approval delays

Key Messages For Medical Devices

- Government policy remains supportive of the medical devices sector, with ongoing focus on innovation and market access for new cost-effective devices
- In June 2022, the DHSC launched a new strategy which identifies the digitalisation of health and social care services as a top priority
- To support digital transformation, the DHSC has allocated over £2 billion to digitise the NHS
- The MedTech Funding Mandate, updated annually, identifies NICE-approved devices, diagnostics and digital products that are considered to be effective and cost-saving for the NHS
- NHS Trusts are the primary purchasers of medical devices, spending over £6 billion on devices ranging from simple clinical consumables to highly innovative diagnostic equipment
- The NHS is shifting up to 80% of its medical device expenditure to a central procurement system and new operating model
- NHS Supply Chain formally launched the procurement process for category management services in April 2022, with planned award dates in early 2023 and implementation by the end of 2023. These services form part of its Target Operating Model (TOM) programme as an evolution of the existing approach
- The MHRA remains the main body responsible for regulating UK medical devices. Much of the regulation is aligned with EU regulation for medical devices. This minimises disruption for manufacturers
- In January 2022, the EU voted to extend deadlines for In-vitro Medical Device Regulation (IVDR), with new deadlines now in effect for different classes of devices. The decision was taken because Covid-19 was deemed to have heavily impacted Member States abilities to meet the new regulation requirements and could lead to a significant disruption in the supply of a multitude of in-vitro diagnostic medical devices on the market
- In February 2022, it was announced that NHSX would be merged with NHS England

Policy has led to operational changes that seek to increasingly channel expenditure through centralised procurement processes



Data: Share of NHS procurement by procurement channel, before and after the Future Operating Model (FOM)

Source: NHS England

Payers

Centralising NHS Trust procurement

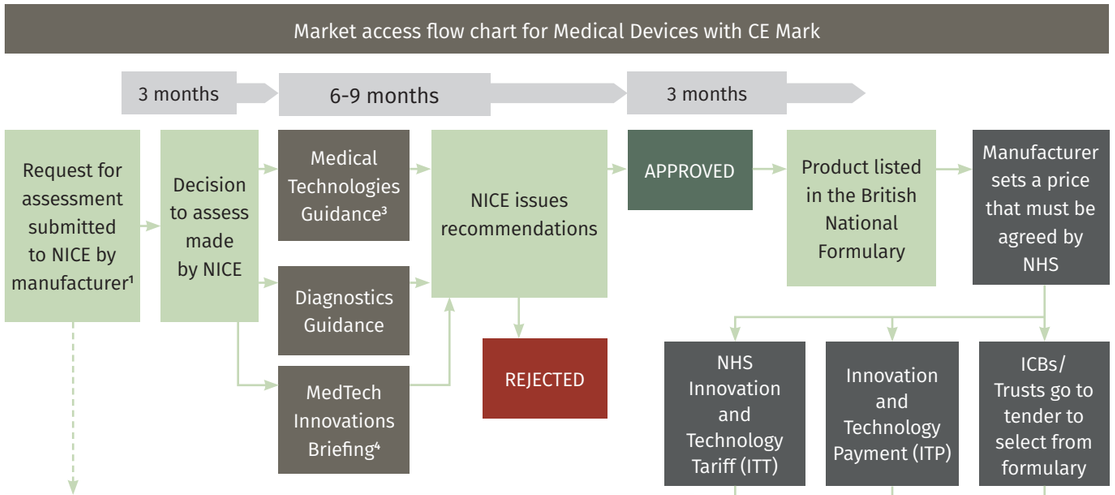
NHS Trusts are the main payer for medical devices. They spend over £6 billion each year purchasing a wide range of devices, ranging from small consumables like syringes to larger equipment, such as medical beds. The cost of the majority of medical devices used in hospitals is included in the calculation of the NHS tariff for the delivery of acute services.

NHS Trusts can purchase products directly from manufacturers or through regional hubs. However, they are now encouraged to purchase through the centralised NHS Towers, which replaced the NHS Supply Chain in 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.

The Carter Review estimated that £700 million could be released through more efficient procurement processes for goods and services. To achieve this, a new Operating Model has been established. This model 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 LTP.

NHS Supply Chain aims to deliver savings of £2.4 billion to the NHS by 2023/2024, by leveraging the buying power of the NHS to drive savings and provide a standardised range of clinically assured, quality products at the best value through a range of specialist buying functions.

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

Spotlight on digital health: developing Artificial Intelligence policy

Creating innovative AI policy has developed into an area of interest within the government's agenda. Whilst there is no specific legislation written to cover Artificial Intelligence (AI), efforts are being made to develop the UK's own version of the European Commission's proposed Artificial Intelligence Act. This would mean the current legal and regulatory requirements which govern AI –primarily built for other purposes – would be superseded.

In July 2022, Nadine Dorries, then Secretary of State for Digital, Culture, Media and Sport set out the government's preferred approach to legislation in this sector. Chief amongst the top priorities were to establish the core characteristics of AI across all sectors, and to use this to inform the scope of the regulatory framework. Within this, regulators would still be able to set out and evolve more detailed definitions of AI according to their specific domains. By not establishing a fixed definition of AI, the UK diverges from the EU and attempts to foster a flexible, pro-innovation approach to AI regulation.

The NHS Transformation Directorate has supported commissioners looking to implement AI in their hospitals. In previous years, there has been discussion surrounding the potential for reimbursement reforms to the NHS tariff and payment systems to incentivize the uptake of AI technologies across the health system. So far, this has not materialised, but much groundwork has been laid to make the UK a favourable environment for the adoption and development of AI-based technologies.

Specific funding streams have also been deployed. In 2020, the AI in Health and Care award began making £140 million available over four years to accelerate the development of AI technologies that meet the strategic aims set out in the NHS Long Term Plan. Funded by NHS England & NHS Improvement with the National Institute for Health and Care Research (NIHR), the dedicated funds have provided support for AI solutions seeking to address multimorbidity and to inequalities in health and care.

Specialised commissioning

Specialised devices are paid for 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 in the development of clinical device specifications, which will inform future HCTED procurement.

Integrated Care Boards

Some medical devices used outside of the hospital are primarily commissioned by ICBs. This includes wheelchairs and other walking aids. Each ICB 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 2022/23.

Decisions are based on NICE guidance on the cost-efficiency of devices. Devices recommended by NICE's Technology Appraisal Programme and used outside of the hospital must be funded by a patient's ICB within three months of the guidance being published.

ICBs 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 the hospital and preventing hospital admissions suggests that home-based and wearable monitoring devices may be needed so that patient's 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 former Prime Minister Boris Johnson 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 greater focus on developing and utilising the most innovative technology for earlier detection.

The Independent Medicines and Medical Devices Safety Review Report

The Safety Report was commissioned in 2018 and aimed to review how the health system in England responds to reports of harmful side effects from medicines and medical devices, specifically vaginal mesh, sodium valproate, and Primidos. The report was finalised and 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 patient-identifiable database for devices.

The MedTech Funding Mandate 2022/23

The MedTech Funding Mandate policy aims to advise the NHS regarding the effectiveness and financial sustainability of MedTech innovations. The mandate is updated annually to provide a revised vision that reflects current challenges and innovations.

The MedTech Funding Mandate 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 included:

- 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

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

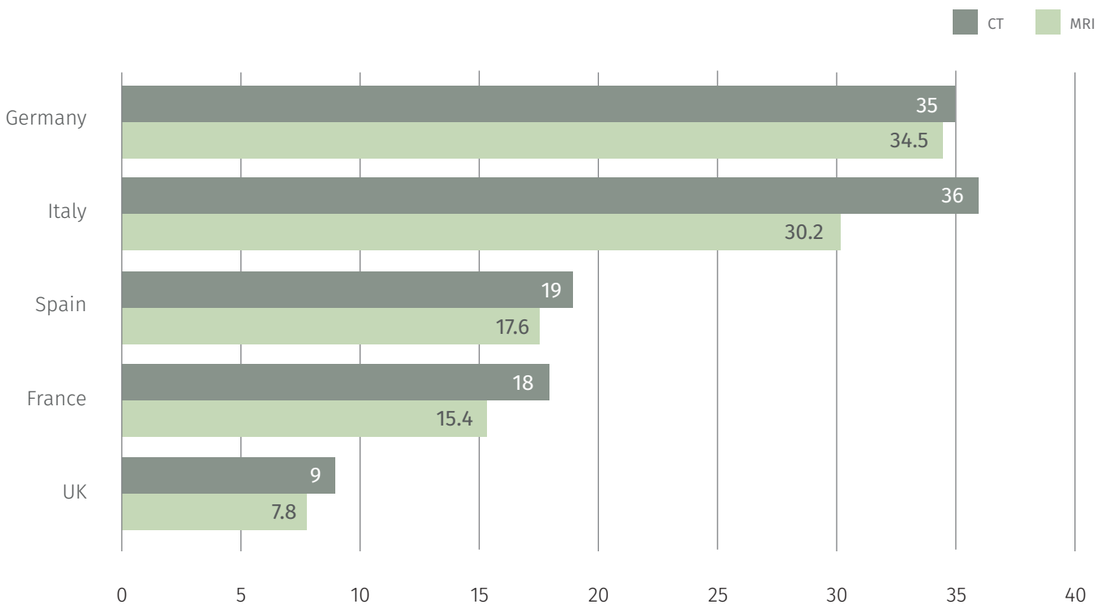
After the first year of its implementation, the NHS's Accelerated Access Collaborative (AAC) will continue to monitor NICE guidance on particular medical devices and diagnostics to see if any more meet the MedTech Funding Mandate Criteria for future years.

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 the 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 UK lags behind the rest of the EU Big 5 in the number of CT / MRI machines per million population



Data: Number of CT / MRI machines per million population
Source: OECD, Marwood Analysis

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 its 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.

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 benefit 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.
During 2022, it was announced that NICE would review how it could expand its review of digital technologies being used by the NHS. This followed recognition that the significant

increase in digital health technologies being adopted by the NHS was straining the regulators' ability to review them all, and to determine which offer value for money. This potential expansion could lead to significant opportunities for digital technologies to access the NHS market

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 mirrors most elements of current and upcoming EU regulations. It also stipulates the creation of a UK medical device register.

The UK regulations set out by the Medicines and Medical Devices Act (2021) supplement the 2002 Medical Devices Regulations (MDR). If a manufacturer or supplier of medical devices wants to sell or distribute their product in the UK, registration from the MHRA is required. However, if a device was registered before January 2021, there is a grace

Spotlight on: the rise and fall of NHSX

In November 2021, it was announced that NHSX would be retired and evolve into the strategy function in the Transformation directorate, a part of NHS England. In February 2022, further details on the merger were announced. NHSX was never a statutory body, with staff employed by either the Department of Health and Social Care (DHSC) or NHSE.

Similarly, NHS Digital would be merged with NHS England and NHS Improvement to become the CIO directorate. The merger represents an ambition to move forward as one united brand, creating organisational clarity and simplicity for the sector.

NHSX was short lived, having been set up in 2019, by former Health and Social Care Secretary Matt Hancock to form a bridge between information technology teams from the DHSC, NHS England, and NHS Improvement. As a budget-holder, NHSX commissioned services from NHS Digital and worked closely together with Government Digital Services.

Matt Hancock set out ambitious plans for NHSX, and over the course of 2019 to 2021, the organisation took on several major projects to realise these ambitions. NHSX took steps in the digitalisation of the provision of healthcare, encouraging clinicians and community care services to utilise video consultations. NHSX also aspired to transform the NHS into a paperless healthcare system – an ambition that soon proved to be unrealistic within the given timeframe. Though efforts to reduce paper waste continue within the NHS, a "paperless deadline" has repeatedly been pushed back.

During the Covid-19 pandemic, NHSX engaged in what may have been its downfall and commissioned a contact tracking app to track the transmission of the Covid-19 virus and prevent infection. The app played a major role in the government's infection control strategy during the height of the pandemic.

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.

In June 2022, the MHRA announced that the regulatory body would strengthen its regulation of medical devices, protecting patients and encouraging innovation. As the MHRA has gained autonomy after the UK's withdrawal from the EU, it seeks to reform its medical devices regulation and amend the 2002 MDR. New measures, which are expected in 2023, include increasing the scope and extent of regulation to safeguard all patients, addressing health disparities in medical device usage, and shaping the UK as a world-leading hub of innovation. Through the proposed changes, the UK may become a more attractive environment for manufacturers to develop and introduce innovative medical devices – and benefit those looking to invest in the development and innovation of medical devices 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) was implemented on May 26th, 2022. These will replace three directives – the Medical Device Directive (MDD), the Active Implantable Medical Device Directive, and the In-Vitro Medical Device Regulations, but will not apply to the UK markets.

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.

Classification under the Medical Device Regulation

Approval process	Medical devices		In-vitro diagnostic medical devices	
Conformity assessment	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

Implementation

Implementation periods were introduced from the beginning 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.

IVDR deadlines delayed

Plans to replace the European In Vitro Diagnostic Medical Devices Directive 98/79/EC (IVDD) with the IVDR have been set since 2017. The IVDR initial date of application was planned for 26 May 2022, following a five-year transition period.

However, in December 2021, the European Parliament voted by an overwhelming majority to adopt proposals by the European Commission to delay certification deadlines for the IVDR. While the IVDR date of application is still May 26, 2022, a regulation providing more time to certain categories of IVDs entered into force on in January 2022.
When the original date for IVDR was set, one of the biggest changes would be a change in risk classification, which would result in about 84% of the IVDs then available in the EU requiring Notified Body certification under the IVDR -12 times as many as the 7% under the IVDD.

The second major change in impact is related to the requirements for health institutions manufacturing "in-house" IVD tests. These entities must meet certain quality requirements and standards and need to justify using in-house tests instead of commercially available tests.

Key MDR dates

- 26 May 2024: certificates issued under MDD become void. This is the last date for placing medical devices on the market unless they meet MDR requirements
- 26 May 2025: the last date for end-users (i.e., hospitals) to put MDD products into service

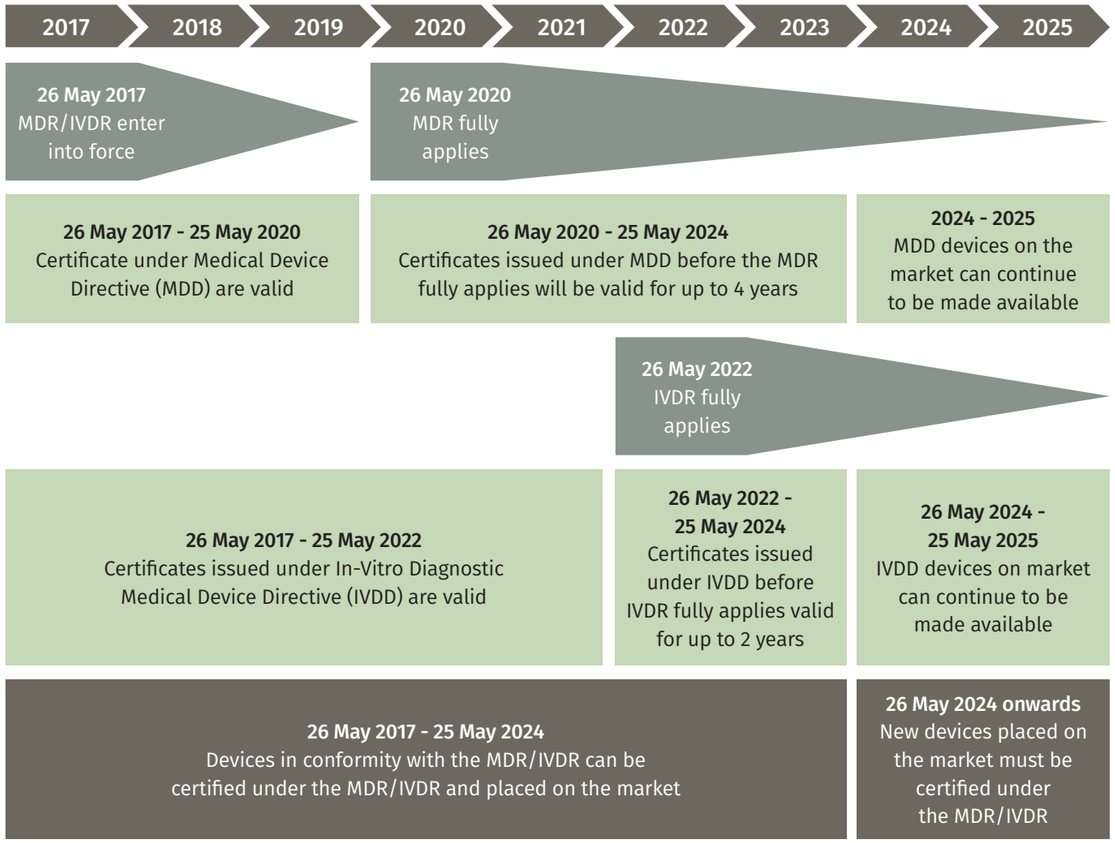
Implementation for label and packaging

- 26 May 2021: deadline for medical devices Class III and implantable
- 26 May 2023: deadline for Class IIa and IIb devices
- 26 May 2025: deadline for Class I

Implementation for direct marking and reusable devices

- 26 May 2023: for Class III and implantable
- 26 May 2025: for Class IIa and IIb
- 26 May 2027: for Class I

Medical device regulation - Implementation timelines



Spotlight on: a plan for digital health and social care

In June 2022, the Department of Health and Social Care launched a new strategy which identifies the digitalisation of health and social care services as one of the top priorities for the Department. The strategy outlines four different fronts, which will act as building blocks for the government to significantly improve its digital healthcare services.

The DHSC's first ambition is to lay down strong digital foundations to equip the digital system for better care. This will include digitising all health and social care records across the country and integrating records across different ICS' to give a comprehensive insight into a patient's health status. In social care settings, non-clinical staff will be able to view and contribute to the patient's records, providing a holistic perspective. Furthermore, digital diagnoses will become a major priority - innovative AI and image-sharing will enable clinicians to make best practice diagnosis decisions.

The government's second ambition includes supporting independent healthy living by increasing the accessibility of health and social care services. More resources will become available for individuals to meet personalized healthcare needs on demand.

To transform the NHS's services, the system needs to be equipped to rapidly adopt innovative technology. Innovators and frontline teams will, through collaborative efforts, help develop systems that allow swift adoption and utilisation of technological advances. NHS organisations will also continue commercial negotiations to develop digital products that are best suited to meet the individual needs of patients, whilst reducing workload and increasing system productivity. Novel technology will need to meet high standards of usability, clinical safety, cyber security, and sustainability – tech investors and sellers will be required to demonstrate that their products meet these standards.

A final major ambition set by the DHSC includes aligning oversight with accelerating digital transformation. The DHSC recognises the challenge of implementing digital transformation on a national scale. As such, the Department will embed digital transformation in oversight arrangements – ICSs will be required to take the necessary steps to comply with the non-negotiable standards of providing digital care. Changes in regulatory oversight are yet to be implemented; the DHSC will explore different options with NHS England and the CQC to create a robust regulatory framework.

To aid the digital transformation, the DHSC has allocated over £2 billion to digitise the NHS. This investment in digital care is unprecedented and reflects both the government's urgency and commitment to achieving the outlined ambitions. Furthermore, social care providers will be supported by £150 million to attain and maintain the right foundations to enable digital care provision – these foundations include high-speed connectivity, digital skills, and cyber security.

As of June 2022, the DHSC has pledged to digitally transform England by 2025 - digital technologies should be an intrinsic element of the way health and social care is provided nationally. This paves the way for a digital future for the NHS, setting the system up for long-term digital sustainability. However, in this politically tumultuous environment, it is uncertain if the new Prime Minister will be able to prioritise the digitalisation of the NHS sufficiently.

The strategy for digital health and social care provides an elaborate and ambitious plan to transform the healthcare system nationwide. It is hoped that the unprecedented investment in digitisation will drive a digital overhaul, equipping the NHS with the tools it needs to provide social care in the 21st century and beyond. The proposed digital system for social care is a promising initiative that could greatly improve access to care, offering continuous support to those in need.

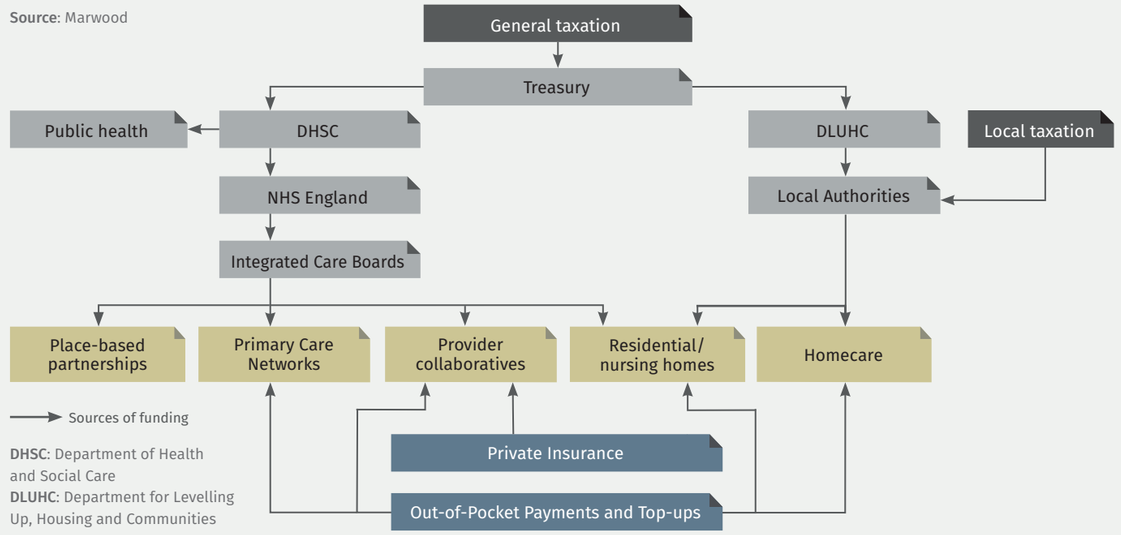
Overview Of Health & Social Care In England 5

Key Messages For Overview Of Health & Social Care In England

- The NHS has continued to be a major policy focus of the Conservative government under Boris Johnson – and is likely to remain an area of focus under the new PM due to the scale of challenges across the sector
- In April 2022, the NHS' most significant structural reform was launched with the granting of Royal Assent of the Health and Care Act – this has created significant disruption in what had become an increasingly static commissioning environment across local health economies
- System transformation objectives have been developed across new Integrated Care System (ICS) footprints, with the new Integrated Care Boards (ICBs) at the wheel. These will be supported by input from NHS-led Provider Collaboratives which may reshape how mental health services are commissioned and delivered, with impact on the role of the private sector within them
- The 2022 spring budget statement in March 2022 – presented by the then Chancellor of the Exchequer, Rishi Sunak, introduced measures to help deal with rising costs of living, alongside new spending commitments. As part of this, the government doubled the NHS efficiency target from 1.1% to 2.2% a year, freeing up £4.75 billion to fund NHS priority areas over the next three years
- Social care services, including older people's and learning disability services remain primarily funded by local authorities whose budgets have faced reductions in central government funding. Funding reform has been prioritised due to the structural challenges emphasised by Covid-19 – rising demand, unmet need, and staffing recruitment difficulties
- The Health and Social Care Levy introduced by government in April 2022 will raise additional funds, but most of this will go towards the NHS, while funding that is destined to adult social care is for reform rather than services. The adult social care reform White Paper published in December 2021 set out a 10-year vision for reform of the sector, including proposals for housing, workforce and market-shaping
- An inflationary environment across England has pressured local authority budgets further during 2022, but local areas continue protecting statutory service funding at the expense of other services – in 2021/22, social care accounted for 17.6% of local authorities' budgets, the same as in 2020/21, but down slightly from 17.9% in 2019/20

Healthcare funding flows in England

Source: Marwood



DHSC: Department of Health and Social Care
DLUHC: Department for Levelling Up, Housing and Communities

Source: Marwood

Population

Total

67.0M

Life expectancy

79.0 years 82.9 years

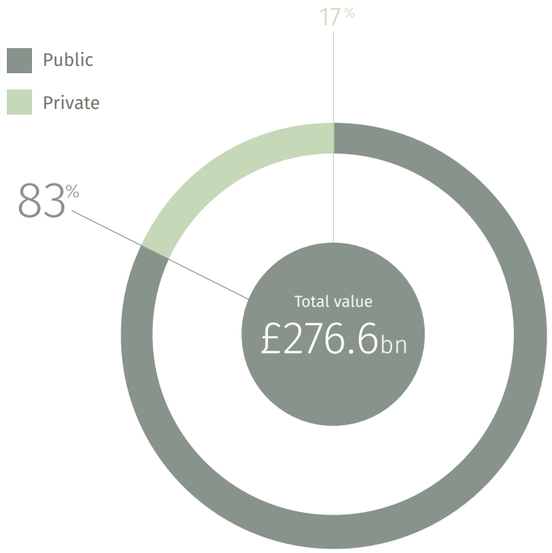
Population distribution (%)

- 29.1% are aged between 0 and 24
- 52.3% are aged between 25 and 64
- 18.6% are aged over 65

Source: ONS (2021)

Selected health and social care data

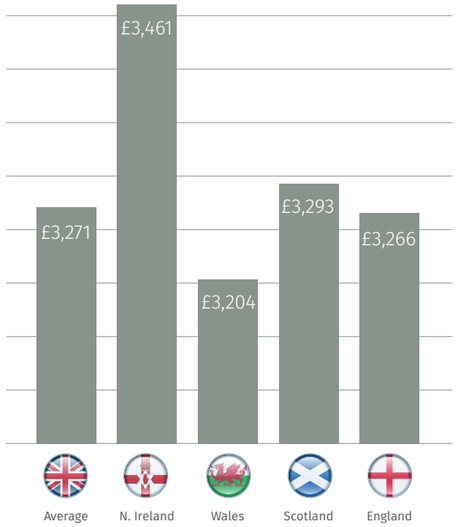
UK healthcare expenditure (2021)



Data: UK healthcare expenditure by source of healthcare financing scheme

Source: OECD (2022), Marwood Analysis

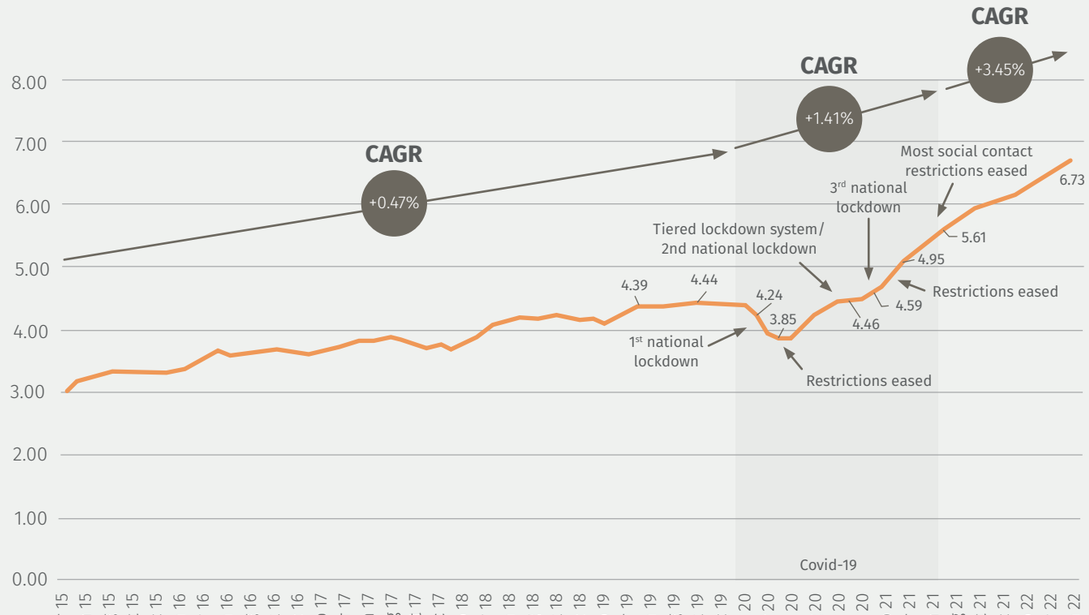
Health expenditure per capita in the UK nations (2020/21)



Data: Health expenditure per capita in the UK nations (2020-21)

Source: HM Treasury (2021)

Number of people waiting for elective care treatment in England (million)



Healthcare

The NHS reforms

In April 2022, the Health and Care Act received Royal Assent. The Act has enabled the NHS' most significant structural reform since its inception. The legislation's primary intention is to increase collaboration between different parts of the healthcare system. This is meant to make it easier for health and care organisations to deliver joined-up care for people who rely on a multitude of services and builds on earlier recommendations by NHS England and NHS Improvement.

When the NHS was founded, individual healthcare providers within the system focussed on treating isolated conditions and illnesses, with very little collaboration between different providers and services. Since the reforms in 2012, Clinical Commissioning Groups received budget allocations from NHS England to fund healthcare services across different service lines such as primary care, acute hospitals and mental health. As the complexity of people's care needs has increased, the treatment of isolated condition system was perceived to struggle to provide adequate care. In order to address this, the 2022 Health and Care Act introduces Integrated Care Systems (ICS). These partnerships aim to remove the barriers between healthcare providers and commissioners across almost all health services to deliver more joined-up care. ICS work together with the private sector, charities, the voluntary sector and local authorities to meet the healthcare needs of the local populations they are responsible for.

The new system will be organised through 42 ICSs across England. Each ICS is made up by two separate bodies: an integrated care board (ICB) and an integrated care partnership (ICP). ICB's main responsibilities include allocating the NHS England budget to commissioned healthcare providers and producing five-year strategic plans – essentially taking over the tasks previously undertaken by Clinical Commissioning Groups (CCGs). Meanwhile, ICPs will not commission services, but instead, will aim to meet

wider public health, healthcare and social care needs by bringing together local authorities and other stakeholder organisations.

Service commissioning will be undertaken within a three-tier geographical system which includes systems, places and neighbourhoods. On the smallest scale, neighbourhoods present populations of 30,000 – 50,000 people and will be largely served by primary care providers – including GPs, dentists and community pharmacies - through Primary Care Networks (PCNs). Places now connect PCNs to acute and secondary care providers, the voluntary sector and local authorities to serve groups of 250,000 to 500,000 people. Finally, systems will work to improve population health and provide better care for a population of between 1 and 3 million people by connecting healthcare partners across all sectors.

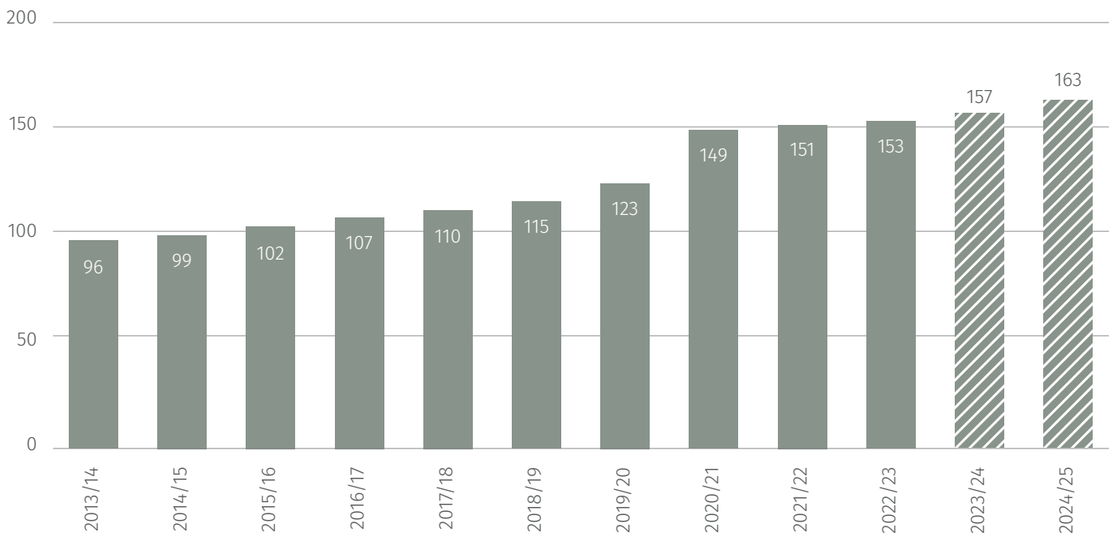
With the introduction of ICSs, the NHS seeks to provide better care for patients with complex issues, improve local population health and reduce healthcare inequalities. The Health and Care Act also relaxes procurement rules by introducing a Provider Selection Regime. This Regime will enable private providers to be more easily commissioned by the NHS, fostering collaboration between the public and private healthcare sectors further.

Funding

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

Healthcare funding was set to increase 3.4% above the level of inflation until 2023/24. However, due to the sharp rise in inflation to 8.8% in July 2022, this commitment has been jeopardised. NHS funding is decided upon in cash term and does not factor in the volatility of inflation. As such, the £177 billion the government allocated to in cash terms for healthcare funding in 2024/2025 will now fall £2.5 billion short in real terms, when accounting for inflation. As per the NHS Spring Statement of 2022, the government has not increased the NHS budget to account for inflation, nor adjusted expectations for the delivery of healthcare services.

Total NHS revenue budget allocations (£, bn - nominal terms)



Source: NHS Funding Settlement, Spring Budget (2013/14 to 2024/25)

In 2022/23, the NHS was allocated £153 billion. This funding translates to the NHS revenue expenditure – money spent on healthcare services by NHS England and ICBs.

The Spending Review 2021 provided the NHS with a three-year capital settlement covering 2022/23 to 2024/25. As part of that settlement, the NHS published guidance in April 2022 on the capital allocations to 2024/25. It is expected that this guidance will be updated annually to confirm financial envelopes ahead of each financial year and set out any changes or additional funds. The total NHS capital allocation for 2022/23 has increased to £7.9 billion, up from £6.2 billion in 2021/2022. On top of this, the 2021 Spending Review will add £10.45 billion in capital spending over the three years spanning 2022/23 to 2024/25.

In 2021, the government announced that the Health and Social Care Levy would increase National Insurance by 1.25% from April 2022 onwards. This Levy is expected to generate £36 billion over the course of three years and is set to fund a £8 billion attempt to tackle the elective care backlog as a result of the Covid-19 pandemic, and a further £5.4 billion for social care reforms.

Recent developments have also demonstrated that the Levy remains an essential piece of policy. Following the announcement that Boris Johnson would resign as PM, several of the Conservative leadership hopefuls have raised whether the focus of the funding raised via the Levy could be redirected. Liz Truss, a Conservative leadership candidate, stated over the summer that she would give £13bn to the adult social care sector if elected. It remains to be seen whether a new PM would actually reprioritise some of the funding so that social care gets a bigger share than previously envisaged.

Payment system

The NHS is the main payer for healthcare in England. Historically, there have been limited additional healthcare costs to the individual under the public healthcare system, with charges for many users to contribute towards the cost of pharmaceutical prescriptions and dentistry.

Following the 2012 reforms, CCGs allocated the NHS England budget to healthcare providers in their local areas. Following the 2022 NHS reform, CCGs have been replaced by ICBs, which are responsible for allocating funding to meet patient needs for local service provision. Fundamentally, the introduction of ICSs may result in fewer buyers, as former CCGs club together under new organisational structures to arrange services on new footprints. However, with the various geographical tiers (places, neighbourhoods, systems) established by the 2022 reforms, it remains to be seen whether ICSs actually maximise their new purchasing decisions, as coordination and collaboration will be required across health and care services as well as the different geographical tiers.

Primary health services, including general practitioners, continue working together through Primary Care Networks, and are funded by the ICBs based on number of patients and their estimated level of need.

Acute care services provided by NHS providers have historically been 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. Increasingly, NHS providers may also be reimbursed through block contracts and mixed models. In future, new private provider contracts will be established through the local arrangements in keeping with the Provider Selection Regime.

Following the 2022 NHS reforms, mental health services will be organised through Provider Collaboratives. Through these collaboratives, the private sector can be commissioned across a wide range of mental health services, which extend beyond the mental health care typically commissioned in the past. As such, the introduction of the Provider Collaboratives could have a substantial impact on the way the private sector integrates with NHS-funded mental health care.

Approximately 13% of the British population is covered by private medical insurance, with the majority of plans being offered as part of employee benefit packages. However, as a result of the pandemic, views on private healthcare have shifted significantly. The enormous Covid-19 elective care backlog has made the NHS inaccessible to many and public satisfaction with the NHS has plummeted to a 25-year low. As a result, 1 in 6 people now consider seeking out private providers for their healthcare needs and self-pay admissions have risen by 35% between 2019 and 2021. Over this time period, there was a 165% increase in private hip replacements and a 122% increase in knee replacements performed in the private sector. Out-of-pocket payments remain common in the dental and fertility sectors, with notable growth in access to private GP appointments too.

Provider landscape

Services are provided by a mix of public and private providers. Primary care providers include 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, in contrast to being partner. As of March 2022, there are over 45,000 GPs divided over almost 6,500 practices. However, the NHS is seeing a sustained decrease in the number of GPs per population – from 52 per 100,000 in 2015, to 45 per 100,000 in 2022.

The secondary care landscape is primarily composed of public hospitals (NHS Trusts). Services are provided by consultants (specialist doctors), nurses and other healthcare professionals, such as radiographers 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 and support the national healthcare system by providing primary, secondary and mental health care, as well as social care. Under the provisions outlined in section 75 of the Health and Social Care Act 2012, CCGs were required to launch competitive tenders for contracts whose total value was over £615,278. However, under the 2022 Health and Social Care Act, these procurement rules have been replaced by the Provider Selection Regime, which aims to bolster collaboration and reduce the rigidity of the procurement rules. The Regime allows for smooth continuation of contracts with private providers that benefit the NHS, offers authoritative bodies, such as ICBs, autonomy to identify suitable providers to meet healthcare needs, and allows for competition between different healthcare providers on the market. Altogether, the introduction of the Act eases contract continuation for long-term private providers and offers other private providers the opportunity to enter the market at a time where the NHS faces increased demand due to the Covid-19 pandemic.

Regulation

The healthcare system in England is subject to significant and stringent regulatory oversight. The Care Quality Commission (CQC) is responsible for the regulation of 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 individually. CQC has inspected and rated every provider delivering healthcare services in England, providing a comprehensive and unique picture into the quality of care across sectors. Better performing providers are likely to be inspected less frequently and commissioned more often. As the 2022 reforms set out to create a more collaborative healthcare landscape, there has been a shift towards regulating care systems in addition to individual providers. Through the 2022/23 System Oversight Framework, care system performance will be analysed to regulate and improve systemic care provision, whilst maintaining quality of care across individual providers.

The Healthcare Safety Investigation Branch (HSIB) is responsible for independent investigations into NHS-funded care across England. HSIB is funded by the DHSC and hosted by NHS England. Since 2018, the body has had a maternity investigation programme, but in 2022, it was announced that a new agency would take over HSIB's independent and 'family-focused' investigations of maternity services.

HSIB was set up in 2017, by the then health secretary Jeremy Hunt, as a non-statutory body, run as an organisational arm of NHS Improvement, but overseen by the DHSC. However, the reason put forward for the new body is that legal changes to HSIB will mean evidence given to it must be kept private – a measure which is not wanted for maternity investigations.

Social Care

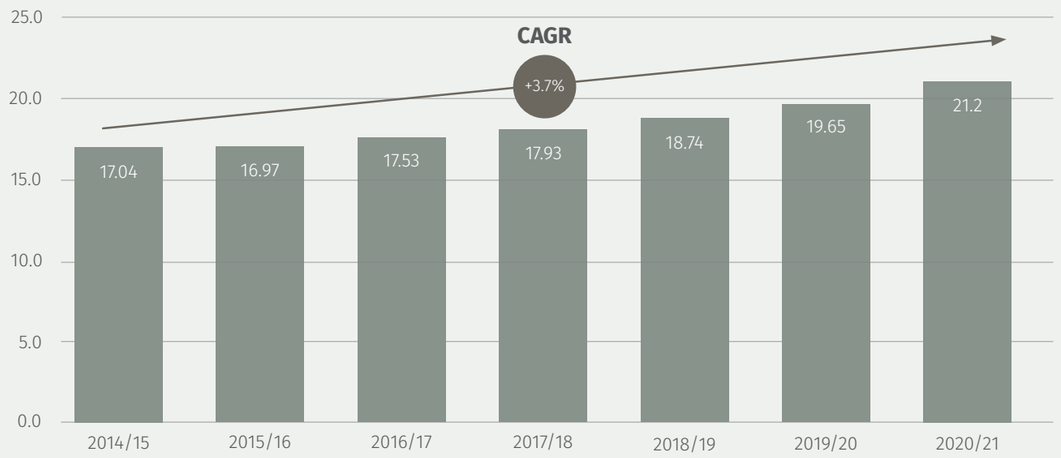
Funding

Publicly funded adult social care covers services for adults with a physical or mental illness 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 central government grants and local taxation. Adult social care has been under significant pressure for years and the number of older people requiring social care is projected to rise by 20% over the following two decades.

Since 2016/2017, social funding has increased through a variety of funding streams. Short-term ring-fenced funding from the government, the Better Care Fund grant and increased freedom for local authorities through the social care precept all contribute to social care funding. Despite these, the social care budget will be unable to bridge the social care 'funding gap', as an additional £3.9 billion will be required in 2024/2025, inflation notwithstanding, to meet demographic demands and cover rising wages.

Following a period of decline after 2010, social care expenditure has risen by 6% in real terms from 2015/16 to 2019/20. In 2020/2021, local authorities increased their gross expenditure on social care to £21.2 billion, up by £1.6 billion from 2019/2020. This increase represents a 1.3% rise in real terms and was primarily spent on long term support. To increase funding for adult social care further, the local government financial settlement will increase local authorities' core spending power by 4% between 2022/2023 and 2023/2024. Furthermore, between 2022 and 2025 the Health and Social Care Levy will provide an additional £5.4 billion for adult social care, including £3.6 billion to reform the current social care payment system.

Local authority adult social care expenditure (£, bn)



Data: Local authority expenditure on adult social care, in £ billions (2014/15 to 2020/21)

Source: NHS Digital

Payment system

Social care providers are exposed to a mix of public and private payments, as 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. With inflation taken into consideration, fewer people were eligible for publicly funded social care in 2020/2021. Those who do not qualify for local authority funding pay the full cost of nursing home services on an out-of-pocket basis.

In September 2021, the government announced a reform of the current needs test by introducing a £86,000 social care cap as part of the Build Back Better plan. This plan, which will go into action in October 2023, ensures that individuals will never pay over £86,000 for their personal care over a lifetime. Important to note is that costs of living in residential care are not included in the cap. Furthermore, the threshold at which people receive public funding support will increase to £100,000, up 330% from £23,250.

Local authority fees for care home services are set locally by each local authority. In 2020/2021, the average weekly local authority fee was £751, while the weekly fee charged to self-funders was approximately 40% higher at £1,058.

Homecare services are usually paid for on an hourly rate basis. Rates are also set locally by each local authority. In 2022/23, the UK Homecare Association set the minimum price of home care costs at £23.20 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. This 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 – especially as 28.5% of care staff left their job in 2020/2021, along with the rising costs of living. In November of 2021, the government launched a national recruitment campaign to attract individuals to a career in care and dedicated £500 million to train social care workers.

Provider landscape

The majority of social care service provision is delivered by private and voluntary organisations. Rather than providing direct care, local authorities commission third-party providers to deliver social care within a region. In 2021, there were 7,461 nursing and care home providers registered with the CQC, which offered beds across 15,407 locations. As of 2019, over 75% of all care and residential beds are owned by private providers, with the number of publicly owned share declining annually.

Between 2014 and 2021, the number of nursing home beds decreased gradually from 5.2 to 4.6 per 100 people aged over 75. Similarly, the number of residential care home beds has fallen from 11.3 in 2012 to 9.4 per 100 people aged 75 or older in 2021. This decrease can partially be accounted for by the government's commitment to provide supportive care closer to home.

In 2021, 7,861 homecare agencies provided social care services at homes across 11,021 locations, a 34.1% increase from 8,219 in 2015. A 2021 National Audit Office report found that the top ten providers share around 16% 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 were rated good or outstanding.

In May 2021, CQC launched a new five-year 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 such, the CQC will shift its resources towards providers where quality of care is perceived to be low or inadequate. As before, the CQC will ensure safe services which continuously learn and improve. However, a key difference will be a greater focus on encouraging services to work with local integrated systems to improve the quality of care. To further improve care quality, the government pledged £30 million to support local areas to innovate the way in which they provide care.

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.

During the Covid-19 pandemic, the nation was horrified by the murders of Arthur Labinjo-Hughes and Star Hobson, two young children who were failed by the children's social care system. Despite repeated involvement of local authorities, both children's situations were deemed 'safe' by social services. The pandemic has emphasised the crucial need for a children's social care reform, to restructure an overburdened system and to protect the most vulnerable.

Political environment

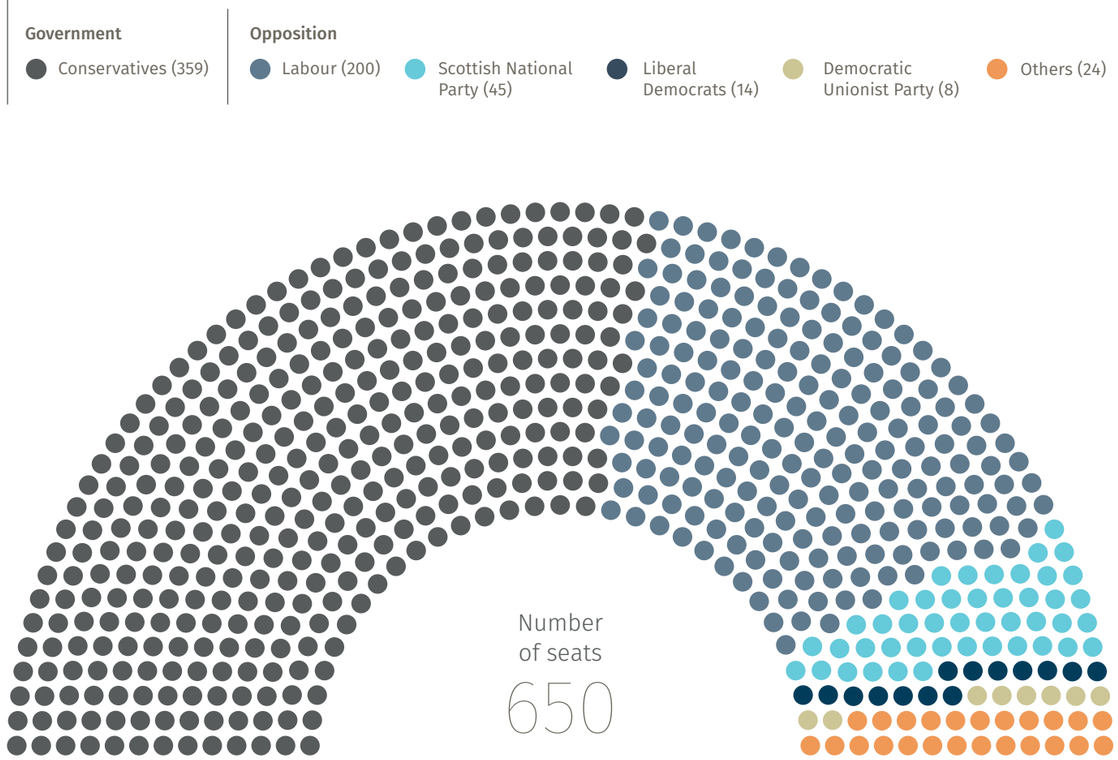
Boris Johnson had been Prime Minister since July 2019 following the resignation of his predecessor Theresa May. Having inherited a minority government and a Parliament highly divided over Brexit, Johnson called an early general election on 12 December 2019, which delivered the strongest Conservative 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. In 2022, Johnson's Government sought to move away from Brexit and turn to addressing internal policy issues. The government has prioritised implementing the Health and Social Care Act and has taken major steps in reforming adult and children's social care. To fund the major healthcare reform and to tackle Covid-19 backlog, the government introduced the Health and Social Care Levy in April 2022.

Despite forming a united front during the Covid-19 pandemic, Johnson's government faced many adversities in 2022. As the UK emerged from the pandemic, the PM was under heavy scrutiny following the Partygate scandal. Additionally, the public saw inflation rise steeply, experienced national railway strikes and faced the cost-of-living crisis under Johnson's leadership. As a result, both the public and his party lost their trust in the PM as a leader and Johnson faced a no-confidence vote in June 2022. Even though the PM won the vote by 59%, his Conservative Party lost seats through resignations and by-elections until in July when Boris Johnson announced that he would resign.

This came following a wave of resignations from Johnson's government and party, with one Conservative Party member after another publicly voicing their lack of confidence in the prime minister. During the summer, Liz Truss and Rishi Sunak participated in the contest for the Conservative leadership position. This has determined the new PM until the next UK general election, which must take place by 25 January 2025.

Composition of Parliament



A&E: Accident and Emergency

ABPI: Association of British Pharmaceutical Industries

APMS: Alternate Provider Medical Services

BDA: British Dental Association

BMA: British Medical Association

CAMHS: Children and Adolescent Mental Health Services

CAT: Competition Appeal Tribunal

CCG: Clinical Commissioning Group

CHC: Continuing Health Care

CMA: Competition and Markets Authority

CMU: Commercial Medicines Unit

CQC: Care Quality Commission

DHSC: Department of Health and Social Care

DLUHC: Department for Levelling Up, Housing and Communities

DRG: Diagnosis Related Groups

EMA: European Medicines Agency

EU: European Union

FNC: NHS Funded Nursing Care

FT: NHS 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: His Majesty's Revenue and Customs

IBCF: Improved Better Care Fund

ICB: Integrated Care Board

ICS: Integrated Care System

LA: Local Authority

LGA: Local Government Association

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 Results

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

Contact us

For more information on any of the content in this publication or to learn more about Marwood Group Advisory's capabilities, we encourage you to please contact us.

Heather Pfeiffer
Director, UK and European Healthcare Advisory
Email: HPfeiffer@marwoodgroup.com

Follow us on social media