Department of Health & Social Care

Review of patient safety across the health and care landscape

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Executive summary

About this review

This review was commissioned by the Secretary of State for Health and Social Care, following a review into the operational effectiveness of the Care Quality Commission (CQC) in summer 2024.

The review was asked to look at 6 specific organisations that were established to either assure - or contribute to improving - the safety of care, while also making reference to the wider landscape of organisations influencing quality of care. The 6 organisations are:

- CQC
- Health Services Safety Investigations Body (HSSIB)
- Patient Safety Commissioner
- National Guardian's Office
- Healthwatch England and Local Healthwatch
- the patient safety learning aspects of NHS Resolution

The review was asked to consider whether there are overlaps and gaps in functions across organisations, and make recommendations as to the future roles of the 6 organisations.

Background and context

Over the last 10 years, there has been an increasing focus on the safety of care with a number of high-profile failures, for example in Mid Staffordshire NHS Foundation Trust.

The reaction to these has typically been to set up a public inquiry or review into what went wrong, with subsequent recommendations for changes that often establish new organisations and bodies external to the mainstream work of the commissioners and providers of care.

While this is understandable, it has led to a growth in the number of organisations considering safety and the wider quality of care, with the resulting impact of even more recommendations and a cluttered landscape.

This review is a first step in considering where change could most appropriately be made.

Definition and impact of quality (including safety) of care

While there is no universally agreed definition of quality in health systems, it is recognised as multi-dimensional. These dimensions typically include safety, effectiveness and patient or user experience, as well as accessibility, equity and efficiency. CQC considers the management and leadership of care (referred to as 'well led') alongside safety, effectiveness and user experience ('caring' and 'responsive care').

Safety is often understood as minimising harm that arises during the giving of care, and is concerned with:

> "the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare."

Of around 600 million patient interactions with the NHS a year, around 3,000 (1 in 200,000) result in a safety investigation. International comparisons suggest that, if the UK had performed at the level of the top decile of Organisation for Economic Co-operation and Development (OECD) countries in 2022, there could have been 780 fewer deaths per year due to unsafe care.

Effective care means care that should be provided to evidence-based standards to people who need it. Ineffective care results in considerably more avoidable harm.

Of the avoidable deaths in 2022 in England and Wales, around 65% could be attributed to conditions considered preventable (around 82,000 deaths). While many of the underpinning drivers of ill health are beyond the scope of the NHS, there remains considerable opportunity to ensure more consistent delivery of high-quality care.

For example, 4.4 million people have diabetes, but less than two-thirds receive recognised best practice care. In the worst-performing GP practice, the figure was under 2%. In financial year 2022 to 2023, complications from diabetes included approximately:

- 9,500 limb amputations
- 48,000 strokes
- 34,000 heart attacks
- 155,000 cases of heart failure

Similar treatment gaps occur in all areas of care along with considerable variation in the outcomes of care.

Poor user experience can arise for many reasons, including:

- failing to involve patients or users in decisions about their own care
- failing to listen to patients or users highlighting concerns
- not supporting people to better manage their own care, resulting in poor compliance with drug and non-drug interventions

Inequity and inequalities are evident across all dimensions of quality - people living in some of the poorest parts of the country die on average 10 years earlier than those in more affluent areas, and satisfaction with services differs by age, gender, race and socio-economic status. Unsafe and ineffective care disproportionately impacts those from disadvantaged groups and those same groups report higher levels of dissatisfaction in care delivery.

Poor management of care contributes to unsafe care, ineffective care and poor user experience. Research from 2019 found that poor or inadequate management results in a 5% efficiency gap. Applying this to NHS trusts, it is a cost of over £5 billion each year, which equates to 330,000 quality-adjusted life years (QALYs) using Department of Health and Social Care (DHSC) estimates of cost per QALY. More recent analysis suggests that productivity in acute hospitals has declined since financial year 2019 to 2020 by about 8%. This equates to around £6 billion per year or around 400,000 QALYs.

The quality landscape

Across England, numerous organisations and professional groups have a role in high-quality care, including those with a specific remit for safety.

DHSC, NHS England and the UK Health Security Agency (UKHSA) are responsible for setting overarching policies, guidelines and strategic priorities at the national level.

NHS England, integrated care boards (ICBs), local authorities, private health insurers, and providers (NHS trusts, private providers, primary care providers including GPs and dentists, and social care providers) have prime responsibility day-in day-out for commissioning, providing and assuring high-quality care. This is where the principal focus for ensuring safe and high-quality care should sit.

CQC was established in 2009 as the independent regulator of the health and care sector.

Outside of commissioners and providers (and CQC as the main regulator), a wide range of organisations and professional bodies - around 40 in total - have a formal role in quality of care including the safety of care. This includes setting standards, monitoring performance, advocating for changes or supporting improvement. These organisations and bodies include:

- service regulators
- professional regulators
- standard-setting bodies
- royal colleges and faculties
- safety and improvement bodies
- organisations established to be the 'voice of the user'

Data on the quality of care is collected through a range of mechanisms, including national clinical audits commissioned by the Healthcare Quality Improvement Partnership (HQIP) and other registries and audits (such as those run by colleges, NHS England and others).

At least 30 advisory bodies and a large number of professional associations operate across a range of specialties and areas of care. The majority of these are funded, directly or indirectly, from the DHSC budget.

In addition, a range of academic, private and charitable organisations consider quality of care and publish recommendations.

Functions needed for a high-quality health and care system

In order to determine where there is overlap in the roles of these organisations and identify gaps, the review sets out the functions required to ensure a high-quality health and care system. These can be grouped into 4 areas:

- developing a strategy
- delivering health and care
- assuring delivery
- improving

Ten main findings of the review

Finding 1: there has been a shift towards safety (vs other areas of quality of care) over the last 5 to 10 years, with considerable resources deployed, but relatively small improvements have been seen

The last 10 years have seen an increasing focus on safety in comparison with other dimensions of quality of care - for example:

- a number of organisations and professional bodies have been established to consider different aspects of safety
- multiple reviews and inquiries into safety have been carried out
- an increasing number of recommendations and other directions relating to safety have been given to commissioners and providers of services

Safety has also commanded significant resource. The various new organisations and bodies cost money (at least £60 million per year), while DHSC-sponsored reviews and inquiries into safety are estimated to have cost at least £100 million based on known costs. The indirect costs are considerably more.

Recommendations often include increases in staffing levels - both to direct patient care staff and supervisory staff. 'Safe staffing tools' are used in each shift to set out the expected staffing levels. Combined, these have potentially contributed to the considerable growth in hospital staffing and funding over the last 10 years. There has been, for example, a 34% increase in full-time equivalent (FTE) nurses and a 37% increase in doctor FTEs in acute hospitals between financial years 2013 to 2014 and 2023 to 2024, while occupied bed days have increased by 3% and weighted activity by 23%. This has been accompanied by a 79% increase in nurse managers over the same time period.

However, there has been mixed progress in improving safety. At the same time (partly related to the health and care system and partly to wider social determinants of health), life expectancy remains lower than the most recent period before the COVID-19 pandemic, with:

- increasing obesity levels
- increased numbers of people living with long-term conditions (over and above that expected from an ageing population)
- continued high levels of variation in the number of people receiving effective care, particularly for those with long-term conditions such as diabetes and coronary heart disease

It appears that the focus on safety has been at the expense of other aspects of quality of care.

Finding 2: there has been limited strategic thinking and planning with regard to improving quality of care

Strategic thinking and planning with regard to improving quality of care has been limited in recent years and has not systematically considered the allocation of resources to maximise quality of care or the optimal provider structures necessary to support quality.

The last comprehensive strategy to improve quality was High quality care for all: NHS Next Stage Review final report (published in 2008), though the Five Year Forward View (2014) and the NHS Long Term Plan (2019) did include initiatives aimed at improving quality of care.

All recognised the significant potential impact of improving the effectiveness of care with an emphasis on improved care for people with long-term conditions and frailty. This should have led to a shift in resources (money and staff) away from acute hospital care and towards primary and community (neighbourhood) care, but the opposite has happened.

There is a National Quality Board (NQB), which was formed in 2009, but to date it has not developed a comprehensive quality strategy.

Finding 3: there is a large number of organisations carrying out reviews and investigations. A very high number of recommendations have been made to the NHS, most of which lack any cost-benefit analysis

The growth in new organisations and professional bodies, along with multiple reviews and inquiries, has resulted in an overwhelming number of recommendations.

The Thirlwall Inquiry has found that there have been over 1,400 recommendations from 30 inquiries that have taken place in England and Wales in the last 30 years related to its terms of reference alone. The various inquiries and reviews into maternity care over the last 5 years have resulted in over 450 recommendations.

The NHS in England has significantly enhanced its own capacity and capability to undertake reviews and investigations over the last 5 to 10 years with the establishment of the Patient Safety Incident Response Framework (PSIRF) and Learn from patient safety events (LFPSE) service. Of the 600 million patient or user interactions with the NHS in England each year, current (unpublished) estimates indicate that up to 3,000 patient safety incident investigations are conducted by trusts on an annual basis. Around 15,000 other learning responses are captured following patient safety events.

Recommendations are often focused on inputs, rather than outputs or outcomes, and fail to recognise the balance of risks within organisations and across systems. The review heard that the existence of so many recommendations causes considerable confusion for staff. They result in more clinical staff moving into supervisory roles to check that other

clinical staff are adhering to the recommendations. The overwhelming majority of recommendations lack data as to the cost of implementation or the expected impact.

This risks disempowering local provider boards and clinical teams, where safety responsibility must sit every day.

Finding 4: a large number of organisations look at user experience or advocate on behalf of the 'voice of the user', yet few boards in the NHS have an executive director for user or customer experience

Multiple organisations:

- carry out surveys
- 'listen to communities'
- support the co-design of care
- advocate for patients and users

This causes confusion for patients and users, who are unsure about the status of different groups, and results in inefficiencies, sub-scale inputs and a failure to ensure representativeness. Their distance from the commissioners and providers of health and care risks a lack of action and change.

At the same time, it is notable that most NHS boards lack an executive director for customer or user experience, which is the norm in other consumer-focused industries.

Finding 5: the current system for complaints and concerns is confusing and may lack responsiveness

The system for managing and learning from concerns and complaints is highly fragmented. Over 20 different organisations offer a place for patients or users to share feedback, either formally or informally, including concerns and complaints about serious harm or side effects.

Patients, users, and patient and user groups describe a confusing landscape where they do not understand who to complain to and how. Complaints and concerns are often poorly handled with patients, users, and patient and user groups describing delays and poor-quality responses.

About 11% of healthcare complaints (28,780 in financial year 2023 to 2024) are referred to the Parliamentary and Health Services Ombudsman. This compares with around 1.3% of complaints in the rail industry being referred to the Rail Ombudsman. The Local Government and Social Care Ombudsman receives about 3,000 complaints a year.

The system is particularly challenging for those who have, or believe they have, been harmed or suffered poor outcomes as a result of care.

Finding 6: some of the organisations under review have expanded their scope

It is notable that some of the organisations under review have expanded their scope of work beyond the original remit. While this is done with the admirable intention of improving the safety of care delivery, it can create further complexity, recommendations and confusion.

For example, HSSIB was originally established, along the lines of safety investigatory bodies in other industries, to look at specific cases or incidents of severe harm, but it has since broadened its work into making more systemic recommendations.

The Patient Safety Commissioner was set up to look at how patients and users could better report complications from medicines and medical devices in order to improve their safety, but it has taken on a far wider role as an advocate for other patient safety themes.

CQC was established with the purpose of assessing the quality of health and care providers and, more recently, integrated care systems (ICSs). However, it has expanded its remit and now develops tools to support ICBs to better understand the health needs of particular communities.

Finding 7: a greater strategic focus on care delivery and management is needed to improve quality of care

Delivery, management and improvement of care are the responsibility of providers and their boards, but there has been relatively less attention paid to associated governance structures. There is:

- variation in the effectiveness of boards
- variable understanding of risks, and how to effectively balance risks across an organisation and a wider system
- variable accountability and responsibility for high-quality care
- a lack of detailed performance appraisals for staff
- a lack of incentives (and disincentives) to support and embed high-quality care
- inconsistent role modelling of behaviours that embed high-quality care

For some providers, their small size makes it hard to put in place governance structures - for example, in smaller GP and dental practices, and small and medium-sized enterprises (SMEs) in adult social care and private healthcare.

Standardisation of core processes and practices is lacking within and across providers, particularly in comparison with other high-risk industries (such as rail, maritime, construction or aviation) and healthcare organisations internationally.

Technology to support the provision of safe and high-quality care is under-developed and under-used - again in comparison with other industries and some other healthcare systems.

Approaches to improvement are variable and lack a well resourced national quality support infrastructure.

Finding 8: the National Guardian's Office duplicates work carried out by providers

The responsibilities of the National Guardian's Office are to lead, train and support the network of Freedom to Speak Up Guardians, working with NHS England and other healthcare-related organisations to expand into primary care and other areas of health. Since the National Guardian's Office was created, Freedom to Speak Up Guardians have been established in provider organisations with support offered from, for example, NHS England.

The guardian role was designed to sit as an independent function, but the current hosting of the National Guardian's Office within CQC results in the role being distant to the people it needs to support and influence. Placing the responsibility for Freedom to Speak Up Guardians firmly within commissioners and providers should raise the profile and importance of staff voice, and allow a more rapid response.

Ensuring that these functions are happening in all commissioners and providers should be a core function of CQC as the independent regulator of health and care.

Finding 9: insufficient use is made of the NHS's data resources to generate insights and support improvement

The NHS is one of the most data-rich healthcare systems in the world and has historically been at the forefront of collecting and reviewing data for clinical audit purposes.

There is considerable opportunity to build on this with more data sharing across organisations. There is also the potential to use advanced analytics and artificial intelligence (AI) to generate far greater insights, enabling organisations to identify and focus on the most significant issues and challenges to improve care.

Finding 10: there is insufficient focus on developing a national strategy for quality of social care

While adult social care has not been the primary focus of this review and is a fundamentally different market to healthcare, the review has been struck by the lack of national attention to the quality of social care. In particular:

- as it pertains to outcome indicators
- how much less data there is about quality of care in social care
- the lack of agreement as to the metrics that would best define and describe quality in adult social care

While there is a plethora of organisations considering the quality of healthcare, the quality of social care falls predominately to the Social Care Institute for Excellence (SCIE) and CQC.

Five conclusions of the review

I have drawn 5 principal conclusions from the findings above:

1. Action is needed to address gaps in functions. In particular, a strategic approach to improvement and innovation in quality of care (including safety) is needed that:
    - considers allocation of resources to maximise health outcomes
    - co-ordinates and prioritises the many recommendations and 'asks' of providers
2. There is a need to streamline, simplify and consolidate functions where considerable duplication and overlap currently exist - specifically when it comes to:
    - user, patient or community engagement
    - capturing and learning from user or patient experience, or the 'voice of the user'
    - investigations
3. Too many functions sit outside of the commissioners and providers of care who are ultimately responsible for improving quality (including safety). This results in limited impact from the very many inquiries, reviews, investigations and resulting recommendations that are made.
4. Within commissioners and providers, there needs to be a far greater focus on:

- building skills and capabilities
- effective governance structures
- clearer accountability for quality (including safety) of care

5. CQC was established as the independent regulator of health and care. It needs to rebuild public, professional and political confidence, and should also house functions where independence is required.

Nine recommendations

Recommendation 1: revamp, revitalise and significantly enhance the role of the National Quality Board

A revamped, revitalised and reinforced NQB should be responsible for developing a comprehensive strategy to improve quality of care that is in line with the aims of DHSC and the NHS in England. This should build on data and analysis about current quality of care, evidence and examples of high-quality care and, where appropriate, recommendations from previous reviews and inquiries.

This strategic approach should:

- recognise the need to balance across all dimensions of quality
- build on the principle of healthcare value (seeking to maximise outcomes per pound spent) so that both outcomes and costs are continually optimised
- ensure resources are allocated to maximise life expectancy and quality of life - the common purposes of DHSC and the NHS in England

NQB should:

- build and maintain a repository of recommendations
- operate a clearing-house function to prioritise existing and new recommendations (such as those based on evidence of cost-effectiveness and that fit with strategic priorities)
- avoid unfunded mandates being imposed on the system without due consideration
- where appropriate, ensure ongoing monitoring of the implementation, and impact, of prioritised recommendations

It should draw lessons from other industries and health and social care systems to strengthen concepts of:

- balance of risk
- standardised care models and operating processes
- robust governance structures
- optimal improvement approaches

NQB could be co-chaired by the chairs of CQC and NHS England, transitioning over time to the lead non-executive director for quality on the board of DHSC, and be directly accountable to the Secretary of State for Health and Social Care.

Recommendation 2: continue to rebuild the Care Quality Commission (CQC) with a clear remit and responsibility

CQC should remain the independent regulator and oversight body across the health and care system.

However, it needs to adopt tailored approaches to assessments by sector and within sectors, taking into account the structure of commissioners (including private health insurers) and providers, as described in more detail in the previous review into the operational effectiveness of CQC.

As part of its assessment framework for larger organisations, it should focus on the role of boards, governance and accountability systems. It should assess boards on their ability to improve all aspects of quality of care while effectively balancing risks across organisations and wider health and care systems.

For those (usually smaller) organisations where lack of governance structures may be more of an issue, it should offer a more customised approach.

For all providers, it should draw on comprehensive and detailed data to meaningfully identify risks.

Where independence from and oversight of commissioners and providers of health and care is required, CQC should host those functions.

Recommendation 3: continue the Health Services Safety Investigation Body's role as a centre of excellence for investigations and clarify the remit of any future investigations

Most investigations into safety incidents should continue to be managed within provider organisations and commissioners (ICBs), with support from regions where required, to ensure they are:

- mobilised quickly
- conducted with a high level of expertise
- rapidly resolved, where feasible, and lessons are learnt

HSSIB should operate as a dedicated, expertise-led investigation facility that can be used in a responsive way to minimise the number of externally commissioned reviews and inquiries that might otherwise be required.

HSSIB should collaborate with DHSC (through NQB) to agree the scope of any investigations it carries out. Recommendations arising from all investigations should be considered as part of the clearing-house function of NQB.

Consideration should be given to the role of HSSIB in improving the quality of other investigations (for example, service reviews led by royal colleges or the Parliamentary and Health Service Ombudsman).

The functions of HSSIB should be transferred to CQC. It should continue to operate as a discrete branch within CQC and retain its independence for providers.

Recommendation 4: transfer the hosting arrangement of the Patient Safety Commissioner to the Medicines and Healthcare products Regulatory Agency (MHRA), and broader patient safety work to a new directorate for patient experience within NHS England, transferring to the new proposed structure within DHSC

The original function of the Patient Safety Commissioner - to promote the safety of and enable the user voice to feed back on adverse impacts of medicines and medical devices - should sit with MHRA, which has direct responsibility to monitor medicines and medical devices.

This move would:

- offer improved clarity about where responsibility for the voice of patients lies when it comes to the safety of medicines and medical devices

- build on MHRA's current work to capture adverse events more effectively (such as through use of technology)

The wider remit adopted by the Patient Safety Commissioner should be integrated into DHSC to support improvements to patient safety and patient experience, including managing and learning from complaints.

This should be reflected in a significantly enhanced profile for the patient voice through a new director of patient experience within the new DHSC structure. It is notable that the executive team of NHS England (and providers within the system) lack a director of customer experience or similar. This is in contrast with other large-scale consumer-focused organisations, which do not outsource their customer experience function.

The patient experience directorate should:

- take responsibility for significantly improving the complaints function across the NHS
- seek to improve wider patient voice and engagement work
- take responsibility for advocacy support for people wishing to complain, which is currently carried out in local authorities

There should be consideration of formal support for those who have, or believe they have, suffered unsafe care.

Recommendation 5: bring together the work of Local Healthwatch, and the engagement functions of integrated care boards (ICBs) and providers, to ensure patient and wider community input into the planning and design of services

The statutory functions of Local Healthwatch relating to healthcare should be combined with the involvement and engagement functions of ICBs to listen to and promote the needs of service users. This should incorporate patient participation groups (PPGs) and patient or user engagement teams in provider organisations.

This will:

- ensure greater clarity and improved effectiveness in bringing patient, user and community inputs into care planning
- support clearer accountability from all organisations within an ICS to their local populations

Local patient and user engagement teams would be supported by the new patient experience directorate within DHSC.

The statutory functions of Local Healthwatch relating to social care (a very small proportion of the work of Local Healthwatch) should be transferred to local authorities in order to improve the commissioning of social care.

The strategic functions of Healthwatch England should be transferred to the new directorate for patient experience at DHSC.

CQC should assess whether every ICB and provider is listening to patients and users effectively.

Recommendation 6: streamline functions relating to staff voice

Staff should be supported and encouraged to share concerns - with a clear role for Freedom to Speak Up Guardians in commissioner and provider organisations.

The functions of the National Guardian's Office should be aligned with those in commissioner and provider organisations. Placing the responsibility for Freedom to Speak Up Guardians firmly within commissioners and providers should:

- raise the profile and importance of staff voice
- allow a more rapid response

The responsibilities of the National Guardian for Freedom to Speak Up in the NHS and the National Guardian's Office should be incorporated into providers. This means the distinct role of National Guardian is no longer required.

Aside from Freedom to Speak Up Guardians, other routes that staff can take to escalate concerns, as per national government guidance, should remain.

Ensuring that these functions are happening in all commissioners and providers should be a core function of CQC as the independent regulator of health and care.

Recommendation 7: reinforce the responsibility for and accountability of commissioners and providers in the delivery and assurance of high-quality care

Ultimately, it is only the providers of care and commissioners (including NHS England and DHSC) who can improve quality of care. Far greater emphasis and attention should be given to how:

- individual providers (NHS trusts, primary care providers including GPs and dentists, private providers, and domiciliary and residential social care providers) deliver high-quality care

- their commissioners (DHSC, NHS England and ICBs, private health insurers and local authorities) commission on the basis of all dimensions of quality (including use of resources) and hold providers to account

This needs to be accompanied by clearer governance and accountability structures within organisations with:

- role modelling of positive actions from top to bottom
- continual measurement
- detailed appraisals
- reward mechanisms
- a commitment to learning

Relative roles of different organisations and accountability structures within NHS England are being considered as part of the revised operating model described in the 10 Year Health Plan, and through the integration of NHS England into DHSC.

Recommendation 8: technology, data and analytics should be playing a far more significant role in supporting the quality of health and social care

Technology - in particular the use of AI - has the potential to significantly improve the safety, effectiveness and responsiveness of care delivery, and the use of resources. This will potentially result in major gains in safety and wider quality of care, including user experience and wider patient outcomes.

Advanced analytics and AI would enable far greater insights into where and why poor-quality care is happening - and at significantly lower cost. To achieve this, data needs to be high quality, easily shareable and accessible by all organisations, patients and users, and the wider public.

Aligning recommendations to the Sudlow Review and building on the federated data platform could provide real-time data on all aspects of quality.

Significant investment in digital and data capacity should be taken forward through the 10 Year Health Plan.

Recommendation 9: there should be a national strategy for quality in adult social care, underpinned by clear evidence

While recognising the fundamental differences of adult social care to healthcare, greater consideration should be given to developing a strategy for improving the quality of social

care. As set out in the review into the operational effectiveness of CQC, this should include:

- the most appropriate metrics to assess quality
- how to disseminate best practice care
- how to ensure more effective commissioning of adult social care

Proposals for NHS Resolution

Outside of these recommendations, the review has considered the role of NHS Resolution and recommends it continues with its role as already established.

Lessons learnt from its reviews and any associated recommendations should be considered within the remit of a revamped NQB.

Next steps

Improving safety and wider quality of care should be the primary remit of any health and care system. There is an opportunity to:

- allocate resources to the health and care interventions that will maximise life expectancy and quality of life
- ensure consistent high-quality care through clearer and stronger governance and accountability structures

Further work to set out how commissioning and provider structures will support improvements in quality of care is taking place as part of the 10 Year Health Plan.

It is entirely feasible to see a step change improvement in outcomes of care - the opportunity to act should be grasped.

Other regulations, requirements and roles

Throughout the course of this review, the very large number of requirements, regulations, roles and organisations that purport to address safety have been raised. These include:

- the large number of organisations highlighted in this review
- new roles that have emerged over the last few years - for example, the guardians of safe working hours
- the multiple levels of 'checkers' - for example, the safeguarding teams in ICBs

- the extensive mandatory training for all staff, which is often out of kilter with the role and its potential risks - for example, extensive fire safety training for GPs

- the extensive paperwork required to be completed by staff - for example, lengthy forms for psychiatrists to complete after mental health consultations

It is not clear that a robust cost-benefit analysis has been conducted before introducing these changes - but what is clear is that they take frontline staff away from looking after patients and users. It is suggested that further work is carried out to quantify the cost-benefit of all of these, led by NQB.

Introduction

This review was commissioned by the Secretary of State for Health and Social Care, following a review of the operational effectiveness of CQC, which highlighted the highly fragmented landscape of bodies influencing quality of care.

Previous analyses of the safety and wider quality landscape in the NHS in England have similarly highlighted multiple organisations charged with looking at quality of care - in particular, safety - and have suggested the need for rationalisation[1].

The review of patient safety across the health and care landscape: terms of reference include:

- mapping the broad range of organisations that impact on quality (and therefore have links to safety), but not examining them in detail
- focusing on the following 6 organisations overseen by DHSC that have a significant role in patient or user safety:
    - CQC
    - National Guardian's Office
    - Healthwatch England and the Local Healthwatch network
    - HSSIB
    - Patient Safety Commissioner
    - NHS Resolution (patient safety-related learning functions only, not clinical negligence functions)

The review is primarily focused on healthcare settings, driven by the remit of the 6 bodies under review. However, social care is referenced where appropriate to allow for:

- a more complete mapping of the safety landscape
- comparisons that might highlight opportunities for further work and investigation

The National Guardian's Office, HSSIB, the Patient Safety Commissioner and NHS Resolution do not have equivalents covering adult social care.

[1] Vincent C and others. 'Redesigning safety regulation in the NHS.' BMJ 2020: volume 368, article m760.

Methodology

The review is based on:

- desktop research and analysis
- a large number of submissions sent into the review (for instance, by academic researchers and charities focused on patient safety)
- discussions with a wide range of experts and leaders in the space, including:
    - commissioners and providers of health and social care
    - patients and users
    - those who have been harmed by poor-quality care

An advisory group guided the work.

A full list of people spoken to and organisations who have submitted materials is shown in 'Appendix 1: contributions to the review' below.

Definition and impact of quality (including safety) of care

While there is no universally agreed definition of quality in health systems, it is recognised as multi-dimensional[2] [3]. These dimensions typically include safety, effectiveness and patient or user experience, as well as accessibility, equity and efficiency. Specifically:

- safe, so those who receive care are not harmed avoidably in the process
- effective, so evidence-based care is provided to those who need it, while low-value care is minimised
- positive patient or user experience (also referred to as 'personalised care', 'caring', 'responsive care' or 'patient-centred care'), so people have a good experience of care that is responsive to and respectful of their needs, values, preferences and cultural background
- accessible and timely, so people can use services when they need to do so
- equitable, so care does not vary because of characteristics such as geography, gender, socio-economic status or ethnicity
- efficient and well managed, so the available resource is used in the best possible way to maximise outcomes and avoid waste

CQC considers the management and leadership of care (referred to as 'well led') alongside safety, effectiveness and user experience.

For the purpose of this review, quality of care is defined as including safety, effectiveness and user experience, while also recognising the importance of equity and the management or leadership of care delivery. Access is assumed to be part of all of these.

Safety

Safety is often understood as minimising harm that arises during the giving of care, and is concerned with "the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare"[4].

[2] World Health Organization. Health topics - Quality of care. 2025.
[3] Institute of Medicine's Committee on Quality of Health Care in America. 'Crossing the quality chasm: a new health system for the 21st century.' 2001. Washington DC: National Academies Press.
[4] Vincent C. 'Patient safety.' 2010. Wiley: John Wiley and Sons.

Individual episodes of care may be affected - for example, involving an operation on the wrong body part. Whole units or organisations might also be deemed to be unsafe - for example, because their structure, systems, processes or governance structures expose patients to risk of avoidable harm.

Unsafe care may be linked to errors, deviations, omissions, accidents and, on rare occasions, intentional harm[5]. It is hard to quantify the number of deaths due to medical error[6]. A study from 2015 estimated that 3.6% of deaths in hospitals had a 50% probability of being preventable, but this included a wide definition[7]. This aligns with other studies that reviewed inpatient deaths and asked physician reviewers to judge preventability, which was typically in the range of 1% to 3%[8] [9]. An international comparison by the Institute of Global Health Innovation at Imperial College London and Patient Safety Watch, Global State of Patient Safety 2023, placed the UK 21st out of 38 countries in 2023. Imperial College London's National State of Patient Safety 2024 report found that, if the UK had performed at the level of the top decile of OECD countries in 2022, there could have been 780 fewer deaths per year due to unsafe care[10].

There are approximately 240 million medication errors[11] (40% of which are due to incorrect administration in care homes) and around 400 never events a year[12]. Of around 600 million patient interactions with the NHS a year, there were 2.2 million incidents reported in 2022 of which 71% caused no harm and 26% caused low harm. NHS England told the review that around 3,000 incidents result in a safety investigation[13].

[5] Dixon-Woods M. 'Report to the Thirlwall Inquiry: addressing part C of the terms of reference'. INQ0102624 - Expert report of Professor Mary Dixon-Woods. 2024.
[6] Shojania KG and Dixon-Woods M. 'Estimating deaths due to medical error: the ongoing controversy and why it matters.' BMJ Quality & Safety 2017: volume 26, issue 5, pages 423-428.
[7] Hogan H, Zipfel R, Neuburger J, Hutchings A, Darzi A, Black N and others. 'Avoidability of hospital deaths and association with hospital-wide mortality ratios: retrospective case record review and regression analysis.' BMJ 2015: volume 351, article h3239.
[8] Hayward RA and Hofer TP. 'Estimating hospital deaths due to medical errors: preventability is in the eye of the reviewer.' JAMA 2001: volume 286, issue 4, pages 415–420.
[9] Manaseki-Holland S, Lilford RJ, Bishop JR and others. 'Reviewing deaths in British and US hospitals: a study of two scales for assessing preventability.' BMJ Quality & Safety 2016: volume 26, issue 5.
[10] It should be noted that this analysis includes 'treatable mortality' and so broadens the scope of what is traditionally viewed as patient safety by considering causes of death that can mainly be avoided through timely and effective healthcare interventions, including secondary prevention, screening and treatment. We did not use figures from the National State of Patient Safety 2024 because this report does not include a breakdown of the causes of preventable deaths. We wanted a number that only reflects deaths caused by unsafe care.
[11] Elliott R, Camacho E, Campbell F and others. 'Prevalence and economic burden of medication errors in the NHS in England: rapid evidence synthesis and economic analysis of the prevalence and burden of medication error in the UK.' Policy Research Unit in Economic Evaluation of Health and Care (EEPRU) Interventions 2018: EEPRU Research Report 057. Universities of Sheffield and York.
[12] See page 7. In previous reporting periods (2020 to 2021, 2021 to 2022 and 2022 to 2023), the number of never events has been around 400 per year (the lowest was 364 in 2020 to 2021, and the highest 407 in 2021 to 2022). 'Never events' are defined by NHS England as "serious incidents that are entirely preventable".
[13] Unpublished information provided to the review by NHS England on 6 December 2024.

Payments for clinical negligence in financial year 2023 to 2024 were over £2.8 billion (around half of this for maternity claims), accounting for 1.7% of the entire NHS budget. These are payments that are, by definition, for harm that could have been avoided.

Effectiveness

Effective care means care that should be provided to evidence-based standards to people who need it. Ineffective care results in considerably more avoidable harm. In 2022, there were 125,600 avoidable deaths of 576,000 total - around 1 in 5 of all deaths[14].

While many of the underpinning drivers of ill health are beyond the scope of the NHS, there remains considerable opportunity to ensure more consistent delivery of high-quality care.

Of the avoidable deaths in 2022 in England and Wales, around 65% could be attributed to conditions considered preventable (around 82,000 deaths)[15]. For example, some cancers are almost wholly preventable, but ineffective care results in avoidable deaths. 99.8% of cases of cervical cancer are preventable through HPV vaccination, but uptake of the vaccine varies from 73.6% to just 51.3% in the most deprived decile[16]. Late detection of cancer has a significant impact on life expectancy, but only 54% of cancers are diagnosed at stage 1 and stage 2, when they are more treatable[17].

Failure to provide appropriate treatment also causes significant morbidity. 5.6 million people in the UK are estimated to have diabetes with a further 550,000 at risk. In England, 47% of those with type 1 diabetes and 62% of those with type 2 diabetes received the recommended care in 2023 to 2024 - however, in some GP practices, the proportion of people with diabetes receiving recommended care is as low as 1.8%[18].

Poor care increases the risk of complications. Each year, people with diabetes suffer approximately[19]:

- 9,500 limb amputations

[14] Office for National Statistics (ONS). Avoidable mortality in England and Wales: 2021 and 2022. 2024.
[15] ONS. Avoidable mortality in England and Wales: 2021 and 2022. 2024.
[16] DHSC. Fingertips - Public health profiles - Population vaccination coverage: HPV vaccination coverage for two doses (13 to 14 years old) (Female). 2023.
[17] See the data for the most recent 3-year period (2019 to 2021) in 'Unadjusted and case-mix adjusted percentage of cancers diagnosed at stages 1 and 2' taken from: NHS England. Case-mix adjusted percentage of cancers diagnosed at stages 1 and 2 by sub-ICB in England, 2021. 2023.
[18] NHS England. National Diabetes Audit Core Report 1: Care Processes and Treatment Targets 2023-24, Underlying data. 2024. See: 'Type 1 registrations' tab of 'National Diabetes Audit 2023-24 Data Release, England' spreadsheet.
[19] Diabetes UK. 'Diabetes is Serious - recovering diabetes care: preventing the mounting crisis' (PDF, 8.44MB). 2022. These statistics are calculated from per week figures on page 9 of the report.

- 48,000 strokes
- 34,000 heart attacks
- 155,000 cases of heart failure

There are over 6.4 million people living with cardiovascular disease (CVD) in England, contributing to over 140,000 deaths per year. An estimated 30% of adults have high blood pressure and most are not receiving effective treatment. Around 50% of heart attacks and strokes are associated with high blood pressure[20].

There are 2.7 million people living with chronic kidney disease in England, contributing to an associated 40,000 to 45,000 premature deaths per year[21]. Of these, 21% remain undiagnosed and 27% of patients with chronic kidney disease at stages 3 to 5 are not optimally treated. This led to 29,580 patients being put on dialysis and over 3,000 patients receiving a kidney transplant in 2021.

Each year, almost 500,000 people with long-term conditions are admitted to hospital on an emergency basis This could have been avoided if they had received good care in the community[22].

In England, there are an estimated 826,000 people living with dementia, with an associated 62,000 deaths per year. Over 35% of those living with dementia are undiagnosed. Just 6% of eligible patients currently receive treatment[23].

Sub-optimal care occurs in planned or elective care with, for example, complication rates for hip replacement surgery (one of the most common surgeries) varying from less than 0.2% to 5%[24], with an average of 0.8%[25].

Ineffective care also results from delays in people receiving care - for example, delayed care for acute heart disease, stroke or cancer. Again, there are considerable variations in care, with 80% of stroke patients in Kent receiving a brain scan within an hour of arriving at hospital but only 40% in Shropshire[26]. For cancer care, the target of 96% of people treated

[20] British Heart Foundation. Heart statistics - Key statistics factsheets. See 'BHF Statistics Factsheet – England' (PDF, 883KB). 2025.
[21] Carnall Farrar. 'Value in health: improving productivity, quality and prevention in the NHS.' 2025.
[22] NHS England. NHS Outcomes Framework Indicators, April 2024 release - 2.3.i Unplanned hospitalisation for chronic ambulatory care sensitive conditions. 2024. See: 'Indicator data' for 2022 to 2023.
[23] Carnall Farrar. 'Value in health: improving productivity, quality and prevention in the NHS.' 2025.
[24] GIRFT in partnership with the Royal National Orthopaedic Hospital NHS Trust, NHS England and NHS Improvement. 'Getting it right in orthopaedics: reflecting on success and reinforcing improvement - a follow-up on the GIRFT national specialty report on orthopaedics' (PDF, 5MB). 2020.
[25] GIRFT. News - Study supports orthopaedic trend to stop traditional post-operative precautions for hip replacement patients. 2022.
[26] DHSC. Independent investigation of the NHS in England. 2024.

within 31 days of a decision to treat has not been met since December 2020[27]. While many of these challenges are long-standing, some were exacerbated by the COVID-19 pandemic.

Patient or user experience

Poor user experience can arise for many reasons, including:

- failing to involve patients or users in decisions about their own care
- failing to listen to patients or users highlighting concerns
- not supporting people to better manage their own care to improve non-drug interventions[28]

Data suggests that giving greater prominence to patient and user feedback and co-design of care can significantly improve the quality of care.

Equity

Inequities and inequalities are evident across all dimensions of quality - people living in some of the poorest parts of the country die on average 10 years earlier than those in more affluent areas[29], and satisfaction with services differs by age, sex, gender, race and socio-economic status[30]. Unsafe and ineffective care disproportionately impacts those from disadvantaged groups and those same groups report higher levels of dissatisfaction in care delivery[31].

Management of care

Poor management of care contributes to unsafe care, ineffective care and poor user experience.

Research from 2019 found that poor or inadequate management results in a 5% efficiency gap[32]. Assuming a £100 billion spend on NHS trusts per year, a 5% efficiency gap across NHS trusts would mean £5 billion each year, which equates to around 333,000 QALYs

[27] NHS England. Statistics - Cancer waiting times. 2024.
[28] Øvretveit J. 'Does improving quality save money?: a review of evidence of which improvements to quality reduce costs to health service providers.' 2009: the Health Foundation.
[29] ONS. Life expectancy for local areas in England, Northern Ireland and Wales: between 2001 to 2003 and 2020 to 2022. 2024.
[30] Care Quality Commission. Adult inpatient survey 2023. 2024.
[31] NHS England. GP Patient Survey - Survey and reports. 2025.
[32] Kirkpatrick I and Malby B. 'What do NHS managers contribute?' 2022: NHS Confederation.

using DHSC estimates of cost per QALY[33]. More recent analysis suggests that productivity in acute hospitals has declined since financial year 2019 to 2020 by about 8%[34]. This equates to around £6 billion per year or around 400,000 QALYs.

Further details of the impact of unsafe, ineffective, poorly experienced, inequitable and poorly managed healthcare are detailed in 'Appendix 2: definition and impact of quality (including safety) of care' below.

[33] The estimated QALYs are based on the marginal cost-effectiveness of NHS Spending estimate of £15,000 per QALY used by DHSC. This is based on research on the marginal cost-effectiveness of NHS spending across different programme budgeting categories in different areas - see: Claxton K, Martin S, Soares M, Rice N and others. 'Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold.' Health Technology Assessment 2015: volume 19, issue 14, pages 1-503.
[34] NHS England. NHS productivity update - February 2025. 2025.

The 6 organisations under review

The 6 organisations reviewed are summarised below. More detail on each organisation is in appendices 4 to 9.

1. Care Quality Commission (CQC)

The factual information in this section was provided in a submission to the review by CQC. Some of this information can be found on the CQC website.

CQC is the independent regulator of healthcare and adult social care in England.

It monitors, inspects and regulates services to make sure they:

- meet fundamental standards of safety
- provide effective care to maximise outcomes
- are caring and responsive to user needs
- are well led, with robust governance structures and processes in place

CQC was established in 2009 under the Health and Social Care Act 2008, which brought together the Commission for Social Care Inspection (CSCI), Mental Health Act Commission and Healthcare Commission. It is an executive non-departmental public body sponsored by DHSC and is accountable to Parliament and the Secretary of State for Health and Social Care.

It is responsible for the registration, inspection and monitoring of providers of health and social care, and those who are carrying out a regulated activity. Its system of registration designates those who may lawfully engage in activities regulated by CQC. Once registered, services are obliged to continue to demonstrate compliance with the registration conditions.

CQC conducts performance assessments and rates providers of services (with some exceptions). Assessments and ratings are publicly available. CQC has a range of other statutory responsibilities - for example:

- investigations into maternity and neonatal care (through the Maternity and Newborn Safety Investigations (MNSI) programme)
- monitoring the Mental Health Act 1983
- assessing how local authorities deliver their duties under the Care Act 2014

- publishing the annual State of Care report

CQC can be instructed to carry out a particular review or investigation if requested by the Secretary of State for Health and Social Care under section 48 of the Health and Social Care Act 2008.

Within CQC, the specialist MNSI unit is responsible for investigating maternal and newborn safety incidents. The unit is functionally independent from CQC and outlined within the CQC (Maternity and Newborn Safety Investigation Programme) Directions 2023. According to the MNSI annual report 2023 to 2024, it reviews around 600 cases of adverse events for mothers and/or newborns a year (around 0.1% of all births). In financial year 2022 to 2023, it was agreed that the programme would continue for a further 5 years pending review.

As of 21 November 2024, CQC had 2,989 FTE direct employees and 153 ‘other' employees, including:

- agency staff
- inward secondments
- bank inspectors
- specialist advisers
- commissioners
- second opinion appointed doctors that are paid per session

CQC's total financial resource for financial year 2022 to 2023 was £263.8 million.

2. Health Services Safety Investigations Body (HSSIB)

The factual information in this section was provided in a submission to the review by HSSIB. Some of this information can be found on the HSSIB website.

Most investigations into adverse events are conducted locally, but those meeting defined criteria may be undertaken by HSSIB.

The Healthcare Safety Investigation Branch (HSIB) was established within the NHS Trust Development Authority in 2017, modelled on accident investigation bodies from other industries following a recommendation from the 2015 Public Administration Select Committee report into incident investigations in the NHS.

HSSIB, replacing HSIB, was established in 2023 as a non-departmental body under the Health and Social Care Act 2022. HSSIB has the same core remit as HSIB, but its powers and scope were expanded to include prohibition on disclosure and allow an investigator, where considered necessary, to:

- seize materials
- compel personnel to give evidence
- enter or inspect premises in England

HSSIB has a remit to investigate patient safety concerns that meet its criteria, which largely concern seriousness and impact. It also investigates safety issues in the independent sector. The act made statutory provision for:

- ‘safe space’ protections for evidence gathered during HSSIB investigations, formally described as ‘prohibition on disclosure’
- increased powers to require people and organisations to co-operate with patient safety investigations

The act sets out a statutory duty not to assess blame or liability and protect the identity of individuals. HSSIB was not able to retain the maternity programme because the Health and Care Act 2022 does not make provision for maternity investigations under HSSIB.

HSSIB carries out independent patient safety investigations across the NHS and in independent providers, which do not find blame or liability with individuals or organisations. It can investigate any patient safety issue or concern linked to NHS-provided or privately provided healthcare in England. Investigations identify risks to the safety of patients and make recommendations to address those risks. HSSIB provides education and training in safety investigations to providers, and shares investigation tools and techniques.

HSSIB is an executive non-departmental public body sponsored by DHSC and is accountable to the Secretary of State for Health and Social Care. Section 111(2) of the Health and Care Act 2022 gives the Secretary of State the power to direct HSSIB to carry out an investigation.

HSSIB has 44.3 FTE staff made up of experts in safety science or human factors from other safety critical industries with military, legal and clinical backgrounds. HSSIB's budget is £5.6 million each year, which it receives directly from DHSC.

3. Patient Safety Commissioner

The factual information in this section was provided in a submission to the review by the Office of the Patient Safety Commissioner. Some of this information can be found on the Patient Safety Commissioner website.

The role of Patient Safety Commissioner was proposed in the recommendations of the independent First do no harm: the report of the Medicines and Medical Devices Safety Review, led by Baroness Cumberlege, which was published in 2020. The report focused on specific issues relating to the use of hormone pregnancy tests, sodium valproate and pelvic mesh.

The role of Patient Safety Commissioner was established by the Medicines and Medical Devices Act 2021, which specified 2 principal duties - to promote the:

- safety of patients with regard to the use of medicines and medical devices
- importance of the views of patients and other members of the public in relation to the safety of medicines and other medical devices

The work of the Patient Safety Commissioner has since broadened to become an advocate for wider patient safety improvements such as Martha's Rule.

The Patient Safety Commissioner is a public appointment, but there is no separate legal entity and no ‘office’ that can employ people separately from DHSC. The commissioner's office is therefore directly funded and staffed by DHSC.

The Office of the Patient Safety Commissioner has 4.8 FTE employees and an annual budget of £600,000, which comes from DHSC.

4. NHS Resolution

The factual information in this section was provided in a submission to the review by NHS Resolution. Some of this information can be found on the NHS Resolution website.

The NHS Litigation Authority was established by Order of the Secretary of State in October 1995 as a special health authority of DHSC. The organisation's original purpose was to establish and administer indemnity schemes that were designed to meet the liabilities of health service bodies. NHS Resolution handles both clinical and non-clinical claims for compensation on behalf of:

- NHS trusts
- independent sector providers of NHS care

- general practice

In financial year 2023 to 2024, NHS Resolution paid out over £2.8 billion in compensation and associated costs.

The main scheme, the Clinical Negligence Scheme for Trusts (CNST), operates on a membership basis. Contributions to the scheme are assessed with the support of actuarial advice, and are based on a combination of claims experience and activity (including risk weightings for different specialties and staffing levels). Annual contributions cover the costs of claims on a 'pay-as-you-go' basis and amount to around £20 million per year for a trust with an average-sized maternity unit. CNST's contribution methodology is reviewed on an ongoing basis. In financial year 2023 to 2024, NHS Resolution received 10,834 claims under the CNST.

The role and scope of the organisation has expanded and evolved since 1995. Following mergers initiated after arm's length body reviews, its remit now includes handling contract disputes in primary care, formerly managed by the Family Health Services Appeal Unit (FHSAU), and supporting the resolution of concerns about practitioner performance, formerly managed by the National Clinical Assessment Service (NCAS). In addition, significantly, NHS Resolution was directed to administer state-backed indemnity for general practice from 2019, which had previously sat with medical defence organisations.

NHS Resolution receives around 900 requests a year for advice from healthcare organisations with concerns about the practice of individual doctors, dentists and pharmacists. In financial year 2023 to 2024, NHS Resolution saw a 21% increase in new requests for advice compared with the previous financial year.

NHS Resolution is responsible for the management of the Healthcare Professional Alert Notices (HPAN) system. This is a system where notices are issued to inform NHS bodies and others about any registered healthcare professional who may pose a significant risk of harm to patients, staff or the public. HPANs are usually used while the professional regulator (GMC, NMC and others) is considering the concerns and provide an additional safeguard during the pre-employment-checking process.

In 2013, the NHS Litigation Authority was also asked to support the NHS to better understand and learn from claims, concerns and disputes in order to improve safety of care provision. The organisation became known as NHS Resolution in 2017, a title that better demonstrates its wider functions to both settle claims expeditiously and learn the safety lessons of these claims.

The most serious claims that NHS Resolution sees are those involving brain injury at birth, which accounted for 56.7% of the total value of claims in financial year 2023 to 2024. NHS

Resolution's safety and learning function leads work in maternity through 2 programmes - the Maternity Incentive Scheme (MIS) and the Early Notification Scheme (EN).

The MIS is delivered through the CNST and involves 10 safety actions overseen by the MIS Collaborative Advisory Group[35]. Trusts that can demonstrate they have achieved all 10 safety actions recover their contribution to the MIS fund and are eligible for a share of any unallocated funds. Trusts that are unsuccessful can bid for discretionary funding to take action to improve.

MIS is reviewed and updated regularly by the Collaborative Advisory Group and is currently undergoing evaluation supported by the THIS Institute, which will consider the:

- robustness of processes for defining and reviewing the standards and safety actions
- potential correlation between safety actions compliance and the risk of adverse events occurring

The EN scheme proactively investigates specific brain injuries at birth for the purposes of determining if negligence has caused the harm. When MNSI investigates cases where brain injuries occur at birth, NHS Resolution asks the NHS trust to share a copy of MNSI's final report. The report is reviewed by NHS Resolution's internal specialist clinical and legal teams to decide whether the case meets the criteria for an EN investigation. This helps NHS Resolution to:

- take proactive action to reduce legal costs and improve the experience for the family and affected staff
- share learning rapidly with the individual trust and wider system
- improve the process for obtaining compensation for families, meeting needs in real time where possible

This review has focused on NHS Resolution's patient safety-related learning functions, which includes around 13 FTEs (around 1.76% of total FTE with a budget of £1.4 million) working directly on supporting learning from claims. Other staff within the organisation are also involved in aspects of maternity safety through the administration of MIS, and the Practitioner Performance Advice service.

NHS Resolution's full expenditure budget is £3.2 billion, of which the vast majority relates to the settlement of claims in relation to its indemnity schemes and is mostly funded

[35] The Collaborative Advisory Group was established by NHS Resolution to bring together other arm's length bodies and the royal colleges to support the delivery of the MIS and has also advised NHS Resolution on the refined safety actions.

through its members. Obstetric claims accounted for 56.7% of the total value of all claims in financial year 2023 to 2024. £292 million is funded directly by DHSC.

5. Healthwatch England

The factual information in this section was provided in a submission to the review by Healthwatch England. Some of this information can be found on the Healthwatch website.

Healthwatch England is the statutory body whose purpose is to:

- understand the needs, experiences and concerns of people who use health and social care services
- speak out on their behalf at a national as well as local level

Healthwatch England was established under the Health and Social Care Act 2012. It has been active since April 2013 and is hosted by CQC. Its statutory functions are to:

- provide leadership, guidance, support and advice to Local Healthwatch organisations
- escalate concerns about health and social care services that have been raised by Local Healthwatch to CQC. CQC is required to respond to advice from the Healthwatch England Committee
- provide advice to the Secretary of State for Health and Social Care, NHS England and English local authorities. Bodies to whom advice is given are required to respond in writing

Healthwatch England's purpose is to be the statutory body to listen to feedback from service users and promote service improvement at a national and local level. It aims to:

- support marginalised groups to speak up and access advice
- encourage decision-makers to act on public feedback
- involve communities and strengthen the Healthwatch network to ensure all voices across England are heard

Healthwatch England reports annually to Parliament, with the Secretary of State for Health and Social Care accountable for its activities in Parliament. The Secretary of State is also required to consult Healthwatch England on the annual NHS mandate, which sets the objectives for the NHS.

Healthwatch England has 36 FTEs. Healthwatch England's budget for financial year 2024 to 2025 is £3.2 million, funded by DHSC through CQC.

Local authorities are legally required to establish a Local Healthwatch to capture feedback on health and care services. Each Local Healthwatch operates under a contract or grant from the local authority, detailing statutory duties and local priorities. They are accountable to that local authority. Local Healthwatch received £25.4 million in financial year 2023 to 2024, with funding levels set by each of the 153 local authorities and drawn from 2 sources - the Local Reform and Community Voices grant and the local government finance settlement. The 153 Local Healthwatch organisations employ 570 FTEs (around 4 each). This funding is non-ringfenced, allowing local authorities discretion over its allocation.

Local Healthwatch is not accountable to Healthwatch England.

While Healthwatch England and Local Healthwatch have responsibility for both healthcare and social care, the overwhelming majority of their work relates to healthcare.

Each Local Healthwatch publishes an annual report that is made public and distributed to Healthwatch England, the local authority, NHS England, ICBs, local authority scrutiny committees and CQC.

6. National Guardian's Office

The factual information in this section was provided in a submission to the review by the National Guardian's Office. Some of this information can be found on the National Guardian's Office website.

A National Guardian's Office was established in 2016 on a non-statutory basis, funded by CQC and NHS England on the recommendation of Sir Robert Francis's Freedom to Speak Up review. It:

- provides training, support and guidance to Freedom to Speak Up Guardians
- conducts case reviews
- reports annually to the boards of CQC and NHS England

The National Guardian for Freedom to Speak Up in the NHS ('the National Guardian') and the National Guardian's Office train and support a network of 1,300 Freedom to Speak Up Guardians across England, offering guidance to encourage employees to share concerns about patient safety.

The National Guardian's Office:

- conducts speak up reviews to assess and improve practices
- works with CQC on well led frameworks and collects data to support inspections
- supports NHS England to explore escalation routes for serious concerns
- shares themes and learning from speaking up cases
- provides national leadership and support for Freedom to Speak Up principles to a wide range of health-related organisations - for example, hospices

The National Guardian's Office was set up as an independent office - but not as a regulator - within CQC from April 2016. While the National Guardian's Office is not named in legislation, the function is set out in regulation 4A(2) of the CQC (Additional Functions) (Amendment) Regulations 2023, A 2021 government plan to introduce guardians in social care was cancelled, but some local authorities, such as Leeds, have adopted the model.

The National Guardian is a non-statutory appointment by CQC. It is required by government to:

- publish an independent annual report that is laid before Parliament to showcase best practice
- hold the government and the system to account
- advocate for change

The National Guardian's Office has 16 FTEs (CQC employees) and is funded by DHSC through CQC and NHS England. The funding for financial years 2023 to 2024, 2024 to 2025, and 2025 to 2026 is £1.5 million per year (£1.27 million from NHS England and £0.3 million from CQC).

Speaking up data to date shows that Freedom to Speak Up Guardians in the NHS handled around 30,000 cases in financial year 2023 to 2024, increasing from 7,000 in financial year 2017 to 2018. Of these cases, 18.7% included a direct element of concerns about patient safety or quality, 19.8% involved bullying and harassment, and 38.5% involved inappropriate attitudes or behaviours.

The work of the National Guardian and Freedom to Speak Up Guardians is supported by the NHS England LFPSE framework. The National Guardian's Office is reflected in the NHS Standard Contract whereby all NHS providers also need to have a guardian who is trained by the National Guardian's Office.

The NHS Staff Survey has seen a change in staff reporting that they feel secure in raising any concerns regarding clinical practice – from 68% in 2015 to 75% in 2021 and 71.5% in 2023. The proportion of staff feeling confident that their organisation would address their concerns was 56% in 2015 and 56.8% in 2023.

The wider quality landscape

For the purpose of this review, the organisations and bodies involved in quality of care in some way in England have been divided into 12 categories. The first 3 categories concern core organisations that are responsible for quality of care at different levels, including:

- NHS England (as the national commissioning board)
- local commissioners (ICBs, local authorities and private health insurers)
- those providing services (NHS trusts, private healthcare providers, primary care providers including GPs and dentists, and social care providers)

The remaining 9 categories describe the multiple organisations that may control, direct or seek to influence the activities of services - for example, by:

- setting standards or expectations, or making recommendations
- undertaking monitoring activity, which may involve requests or requirements for information through to formal inspections
- operating various financial and reputational incentives and sanctions

These organisations have different functions. They range from formal bodies with statutory responsibilities through to more self-organised advocacy groups and professional associations. They are joined by more ad-hoc inquiries, reports, reviews and investigations that may all make recommendations. CQC is the principal regulator for the quality of health and social care. Many other organisations have a responsibility for elements of quality of care.

This mapping shows that health and care in England is characterised by an exceptionally high level of institutional complexity, where services may become answerable to a large number of bodies, each with its own organisational dynamic and administrative requirements to be satisfied. Different agencies and bodies with a say in the NHS can contribute to fragmentation, ambiguity and diffusion of responsibility, leading to “the problem of many eyes”[36] where accountability for quality is not clearly demarcated, coherent or authoritative.

The result is that multiple competing pressures, expectations and priorities may be created. This:

[36] Bovens M. 'Analysing and assessing accountability: a conceptual framework.' European Law Journal 2007: volume 13, issue 4, pages 447-468.

- causes confusion, dissipation of energy, and a lack of co-ordination and integration among organisations providing care
- hampers a strategic view of how resources can best be allocated to improve quality of care, life expectancy and quality of life

A full list of organisations is in 'Appendix 9: detailed description of the wider quality landscape' and a visual illustration of the approximate mapping of functions to organisations can be found in 'Appendix 11: functions table'.

1. National overseeing and commissioning bodies (3)

DHSC, NHS England and UKHSA are responsible for setting overarching policies, guidelines and strategic priorities at the national level. They provide direction, allocate resources and establish frameworks for:

- healthcare delivery
- quality improvement
- public health protection

The National Quality Board (NQB) is part of DHSC. NQB - on behalf of NHS England, CQC, UKHSA, the National Institute for Health and Care Excellence (NICE), DHSC, Healthwatch England, the National Guardian's Office and HSSIB - is responsible for:

- championing the importance of quality
- driving system alignment of quality across health and care

NQB provides advice and recommendations on issues relating to quality, and is intended to influence, drive and ensure system alignment of quality programmes and initiatives.

2. Local commissioning bodies (153 local authorities, 42 ICBs and approximately 5 large private health insurers)

ICBs and local authorities are responsible for commissioning health and care services to meet the population’s needs effectively. This means:

- developing strategies for the future of health and care services to:
    - maximise outcomes
    - ensure high-quality and efficient care

- allocating resources in order to deliver against the strategy
- contracting for, and assuring delivery of, services to make sure they are high quality, efficient and effective

Private health insurance companies similarly commission - or purchase - services for their members.

3. Providers (many)

There are:

- 229 NHS trusts and approximately 7,000 GP practices
- around 11,000 dental practices[37]
- 190 independent acute medical care hospital providers (where the largest 5 providers make up approximately 70% of the market and the largest 30 make up 90%[38])
- 19,000 social care providers, including more than 6,000 care home providers (of which around 10 comprise 18% of the market) and 13,600 domiciliary care providers[39]

Providers, both public and private, are responsible for delivering high-quality care in line with their contractual obligations. Their responsibilities include putting in place systems, processes and internal assurances to:

- address risks
- improve care outcomes
- meet regulatory standards

4. Statutory service and professional regulators (17)

Statutory regulators are legally empowered organisations with functions including:

- standard setting

[37] Figure of dental practices refers to independent practices providing NHS and private dental care from: The King's Fund. NHS dentistry In England explained. 2023.
[38] A provider may own more than one acute hospital, according to: 'UK Healthcare Market Review', 34th edition. LaingBuisson, London.
[39] DHSC analysis of the Using CQC data care provider directory with filters, accessed August 2024, using the location type of 'social care organisation' for a broad definition of adult social care and treating each brand as a single provider. See also the Review into the operational effectiveness of the Care Quality Commission: full report.

- monitoring of compliance (such as through inspection and data gathering)
- modification (for example, through enforcement action)

They include service regulators and professional regulators.

Service regulators (8)

Service regulators focus on the quality (including safety) of healthcare services, overseeing specific sectors to ensure environments, services, research and practices meet established safety standards.

The principal quality regulator for health and social care is CQC. CQC (including MNSI) is part of this review. It is funded by DHSC and fees from registered providers.

The following other regulators have specific roles in different aspects of quality of care, including safety:

- Environment Agency - funded by the Department for Environment, Food and Rural Affairs (Defra), and fees and charges from permits, licences and regulatory activities
- Health and Safety Executive (HSE) - primarily funded by the Department for Work and Pensions (DWP)
- Health Research Authority (HRA) - funded by DHSC
- Human Fertilisation and Embryology Authority (HFEA) - funded by clinical fees and DHSC
- Human Tissue Authority (HTA) - funded by DHSC and licence fees
- MHRA - funded by DHSC and pharmaceutical companies and manufacturers for licensing and regulation services

Professional regulators (9)

Professional regulators set standards for practice, competence and conduct in their respective professions. They license and uphold standards for practitioners across specialties, maintaining public trust in healthcare professionals.

The largest 2 are:

- GMC, which maintains the register of around 395,000 medical practitioners

- NMC, which maintains the register of around 841,000 nurses, midwives, public health nurses, and nursing associates

Both regulators:

- have a council structure including 'lay' and 'registrant' members
- publish professional standards for registrants
- can investigate allegations of impaired fitness to practise (where there is concern that the standards are not met)
- have the power to impose restrictions on practice or to remove individuals from their registers following fitness to practise procedures

Only a very small minority of concerns raised with professional regulators progress to formal fitness to practise procedures, leaving the vast majority of concerns to be handled locally by employers.

The work of all the professional regulators is overseen by the Professional Standards Authority, which:

- reviews the performance of the regulators
- scrutinises their decisions about fitness to practise
- can appeal those decisions

Professional regulators are funded through fees charged to the professionals and businesses they regulate. In rare cases, some government funding may be provided for specific initiatives or projects.

5. Information and standards organisations (6)

The main source of information and standards is NICE, which:

- establishes and maintains standards and best practices to ensure high-quality care
- develops evidence-based guidelines and frameworks that healthcare providers and professionals use to deliver consistent, reliable services

NICE is primarily funded by DHSC.

In addition, the British Standards Institution (BSI) and International Organization for Standardization (ISO) set standards and operate as private not-for-profit companies.

There are also some private audit and accreditation services (such as CHKS and the United Kingdom Accreditation Service (UKAS)), which accredit organisations providing diagnostic services and medical laboratories, and the Joint Accreditation Committee (JACIE).

6. Quality improvement, safety investigations and advisory bodies (7)

Quality improvement, safety investigations and advisory bodies have a role in seeking to improve safety and regulatory compliance across the health and care system. They include the following:

- Commission on Human Medicines (CHM) and British Pharmacopoeia Commission (BP) - both funded by MHRA
- Healthwatch England (under review) - funded by DHSC through CQC (also included in the list of user voice organisations under '9. Organisations supporting, learning from and advocating for the 'user voice'' below)
- HSSIB (under review) - funded by DHSC
- National Guardian’s Office (under review) - funded by DHSC through CQC and NHS England
- NHS Resolution (under review) is predominantly a claims resolution agency but with a more recent patient safety function to draw learnings from claims. It also manages concerns about individual practitioner performance and houses the HPAN system. It is funded by DHSC and NHS trusts
- Patient Safety Commissioner (under review) - funded by DHSC (also included in the list under '9. Organisations supporting, learning from and advocating for the 'user voice'' below)

7. Royal colleges and faculties (19)

Royal colleges are professional bodies that set standards and supervise training (including admission to specialist registers through examinations) for the various healthcare specialties.

They may:

- offer guidance, professional development and training to their members

undertake clinical audits, best practice reviews, accreditation and quality improvement programmes[40]

Some colleges may be commissioned by provider organisations to conduct service reviews, typically when a local organisation has detected a problem and wants an independent assessment.

There are 11 medical royal colleges and 8 faculties in England.

The Royal College of Nursing and the Royal College of Midwives operate both as royal colleges and as trade unions.

All royal colleges and faculties are primarily funded through membership fees, examinations, events and other related activities. Some receive funding for specific national projects - for instance, from DHSC, NHS England, HQIP or other bodies.

8. Professional peer review bodies (many)

Professional peer review bodies support high-quality research and audit on health and social care. As part of this, national clinical audits and registries collect data against specific standards of care. They require participating clinical centres to:

- prepare information on specific measures (usually by reviewing clinical records or prospectively establishing data collection systems) using standardised definitions
- submit the data to a central register using a standardised template

The National Clinical Audit and Patient Outcomes Programme (NCAPOP), which covers both the National Clinical Audit Programme and the Clinical Outcome Review Programmes, is supported by NHS England and commissioned by HQIP. Participation in NCAPOP audits is mandatory for NHS organisations following the introduction of a contractual requirement in 2012.

The National Clinical Audit Programme includes 30 audits. There are 5 Clinical Outcome Review Programmes.

The Getting it Right First Time (GIRFT) programme is designed to improve the treatment and care of patients through an in-depth review of services, benchmarking and the presentation of a data-driven evidence base to support change.

[40] For example, the Royal College of Anaesthetists' Anaesthesia Clinical Services Accreditation.

Around 60 other large-scale audits, registries and similar projects are run by various groups and bodies and may be included in the NHS England Quality Accounts list.

9. Organisations supporting, learning from and advocating for the 'user voice' (many)

Multiple organisations with a formal role in the health and care ecosystem are involved in user experience work, including the following:

- advocacy support for those seeking to complain about the care they have received from NHS organisations is commissioned by local authorities with £15 million direct funding from DHSC
- CQC (part of this review), which, among other activities focused on the patient voice, runs a number of NHS patient surveys including the adult inpatient survey, the urgent and emergency care survey, the community mental health survey and the maternity survey
- individual provider organisations, who may, among other mechanisms, operate advice, support and information groups - for example, patient advice and liaison services (PALS) and PPGs - to both support patients and users, and learn from them
- Healthwatch England (part of this review)
- local authorities - through their health and wellbeing boards, and overview and scrutiny committees
- Local Healthwatch (part of this review)
- NHS England, which runs a number of large patient surveys (including the GP Patient Survey and the National Cancer Patient Experience Survey), and ICBs, which frequently survey the populations they serve. The NHS Friends and Family Test is a survey of patients, which gives them the opportunity to submit feedback to providers of NHS-funded care or treatment. It has one simple question that asks how likely - on a scale ranging from extremely unlikely to extremely likely - they are to recommend the service to their friends and family if they needed similar care or treatment
- the Parliamentary and Health Services Ombudsman and Local Government and Social Care Ombudsman
- the Patient Safety Commissioner (part of this review), which is focused on patient and user input in relation to medicines and medical devices

In addition, numerous charities and other organisations play a role here as listed under '12. Charities, academia, think tanks and consulting companies' below.

Organisations involved in the user voice may conduct a range of activities including:

- surveying users or patients and communities for input on the future of health and care
- involving users or patients in designing services - also known as 'co-design'
- supporting and learning from complaints
- supporting and learning from those who have been harmed or believe they may have been harmed
- advocating for greater involvement of patients and users in their own care
- measuring outcomes of care from the perspective of the patient - known as patient-reported outcome measures (PROMs)

10. National advisory groups (29)

National advisory groups, such as the Confidentiality Advisory Group (CAG) and public health advisory committees, are expert bodies that provide input on healthcare policy, safety and improvements to help shape national policies.

They consist of specialised committees and forums that contribute insights on a range of areas including:

- clinical practices
- public health
- patient confidentiality
- safety protocols

A full list is in 'Appendix 9: detailed description of the wider quality landscape' below.

11. Professional associations and societies (many)

Professional associations provide resources to support the provision of high-quality care. They:

- develop and disseminate evidence-based clinical guidelines and best practice recommendations

- provide continuing professional development opportunities through conferences, workshops and online learning

- serve as a resource for best practice, advocacy and networking within their specialties

Multiple organisations execute this function, varying in size. A few specific examples include the British Society for Haematology and the Association for Paediatric Palliative Medicine. More examples are in 'Appendix 9: detailed description of the wider quality landscape' below.

12. Charities, academia, think tanks and consulting companies (many)

A number of organisations carry out research, review different aspects of the quality of health and care, and make recommendations. Some examples are:

- academic research centres - such as the Healthcare Improvement Studies (THIS) Institute, Centre for Health Policy and Institute of Global Health Innovation at Imperial College London

- charities - such as Patient Safety Learning, National Voices, the Patients Association, Care Rights UK, Making Families Count, Action Against Medical Accidents (AvMa) and Baby Lifeline

- commercial organisations - such as InHealth Associates and Guardian Service

- think tanks - such as the Nuffield Trust, the Health Foundation and the King's Fund

Workforce and staff experience

Outside of the National Guardian's Office, the NHS conducts an annual survey to gather staff experiences across the NHS, which can also provide useful information on quality of care.

The NHS Staff Survey has been carried out every year since 2003. It typically gets a relatively strong response, with 707,000 respondents in 2023 out of more than 1.4 million members of staff - a response rate of 48%. The survey is conducted by Picker on behalf of NHS England.

The aggregated survey results are official statistics, which are used by a wide range of NHS organisations to:

- inform understanding of staff experience locally, regionally and nationally

- improve staff experiences

Inquiries, reviews and reports

In addition, since the first public inquiry into unsafe care at Ely Hospital in Cardiff in 1968, a large number of inquiries and DHSC-sponsored reviews have been carried out. The findings and reports influence quality and safety.

Among the highest profile since 2000 are:

- To Err Is Human: Building a Safer Health System (2000)
- An organisation with a memory: report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer (2000)
- The Bristol Inquiry (2001)
- The Shipman Inquiry (2002)
- High quality care for all: NHS Next Stage Review final report (2008)
- Transforming care: a national response to Winterbourne View hospital (2012)
- Mid Staffordshire NHS Foundation Trust Public Inquiry (2013)
- Berwick review into patient safety (2013)
- Morecambe Bay Investigation (2015)
- Better Births: improving outcomes of maternity services in England - a five year forward view for maternity care (PDF, 3.69MB) (2016)
- The Gosport Independent Panel (2018)
- The Independent Medicines and Medical Devices Safety (IMMDS) Review (2020)
- The Paterson Inquiry (2020)
- Independent investigation into maternity and neonatal services in East Kent (2022)
- Independent review into patient safety concerns and governance processes related to the North East Ambulance Service (2023)
- The Ockenden review of maternity services at Shrewsbury and Telford Hospital NHS Trust (2022)
- The Infected Blood Inquiry (2024)

- The Lampard Inquiry (ongoing)
- The Thirlwall Inquiry (ongoing)

Collectively, these reports have made thousands of recommendations as to how care could be improved with particular focus on the safety of care delivery.

Some recommendations have been adopted by the government, NHS or private providers, but some have not. Some have been very specific (such as continuity of carer for maternity care), while others have been more generic (for example, duty of candour).

Core functions needed to ensure a high-quality health and care system

To determine where there is overlap in the roles of organisations and identify gaps, the review set out the functions required to ensure a high-quality health and care system. This can inform the future requirements from different organisations - based on the principle that 'form follows function'.

Sixteen core functions are described below, which are consistent across industries and countries. These have been grouped into 4 areas:

- developing a strategy
- delivering health and care
- assuring delivery
- improving

Across the health and care system in England, these functions are carried out by the wide range of organisations and professional bodies listed above. 'Appendix 11: functions table' shows a mapping of functions to organisations.

A clear strategy to improve quality of care

Having a clear strategy to improve quality is a fundamental first step. This requires:

1. Defining the purpose, vision or ultimate aim of an organisation. For example:

- the stated aims of the NHS in England are to "improve health and care outcomes, improve people's experiences of health and care services, reduce pressure on frontline services, make health and care services more efficient"
- the stated aim of DHSC is to "help people live more independent, healthier lives for longer"
- the stated aim of UKHSA is to "prevent, prepare for and respond to infectious diseases and environmental hazards, to keep all our communities safe, save lives and protect livelihoods"

2. Understanding the starting point - meaning:

- what current quality of care (safety, effectiveness, user experience and equity) is

- how well managed services are
- how well resources are used

This may draw on multiple sources of data and information, including that collected during assurance (see core function 13 under 'Monitoring and assuring quality' below).

3. Reviewing the clinical and managerial evidence base, academic research and examples from other industries or other healthcare systems, and defining what 'good' looks like in order to deliver on the purpose or aims.

4. Identifying a clear, coherent and actionable set of priorities that is consistent with the goals and values of the organisation, including those relevant to allocative and technical efficiency and equity.

5. Setting out structures to deliver against the aims, and enable high-quality and efficient delivery of services, including optimal commissioner and provider structures and robust governance structures.

6. Allocating resources in order to maximise delivery against the aims, taking account of the need to balance across competing needs and priorities.

7. Engaging with users, communities, staff and wider stakeholders on strategy and priority setting.

Delivering high-quality care

Delivery includes:

8. Developing, agreeing and implementing highly optimised operating processes and service models to deliver safe, effective, responsive, efficient and equitable services, using standardisation and technology where possible and appropriate.

9. Optimising the resources required at a local level to deliver high-quality care, noting that standardised approaches typically use less resources.

10. Putting in place organisational and governance structures ('from board to ward') to:

- make clear the standards expected
- Introduce processes for monitoring performance against standards, including continuous review of data and inputs
- ensure support for improvement where needed

11. Providing leadership that:

- puts quality at the centre of care
- recognises the role of high-quality management - including operational management and people management
- embeds, models, recognises and rewards behaviours that enable high-quality care

12. Training, development and accreditation of staff.

Monitoring and assuring quality

Monitoring and assuring quality includes:

13. Seeking input from users, measuring outputs and outcomes, carrying out audits and investigations, and quantifying the use of resources (which feeds into core function 2 above).

14. Ensuring compliance with planned processes and expected outcomes.

15. Managing the impact of severe harm, taking enforcement action where needed and ensuring redress where appropriate.

Improving

16. Continuously improving - reviewing, learning, listening, changing and adapting - to address sub-optimal adherence to agreed strategies and processes, and expected outputs and outcomes.

Findings of the review

There are 10 main findings as follows:

1. There has been a shift towards safety (vs other areas of quality of care) over the last 5 to 10 years, with considerable resources deployed, but relatively small improvements have been seen.

2. There has been limited strategic thinking and planning with regard to improving quality of care.

3. There is a large number of organisations carrying out reviews and investigations. A very high number of recommendations have been made to the NHS that often lack any cost-benefit analysis.

4. A large number of organisations look at user experience or advocate on behalf of the 'voice of the user', yet few boards in the NHS have an executive director for user or customer experience.

5. The current system for complaints and concerns is confusing and may lack responsiveness.

6. Some of the organisations under review have expanded their scope.

7. A greater strategic focus on care delivery and management is needed to improve quality of care.

8. The National Guardian's Office duplicates work carried out by providers.

9. Insufficient use is made of the NHS's data resources to generate insights and support improvement.

10. There is insufficient focus on developing a national strategy for quality of social care.

Finding 1: there has been a shift towards safety (vs other aspects of quality of care) over the last 5 to 10 years, with considerable resources deployed, but relatively small improvements have been seen

The last 10 years have seen an increasing focus on safety in comparison with other dimensions of quality of care - for example:

- a number of organisations and professional bodies have been established to consider different aspects of safety
- multiple reviews and inquiries into safety have been carried out
- an increasing number of recommendations and other directions related to safety have been given to commissioners and providers of services

As I identified in my review into the operational effectiveness of CQC, since the launch of the single assessment framework in 2023, the organisation pivoted to prioritise assessments of the safety of care over assessments of the effectiveness of care and outcomes. NHS England published its own Patient Safety Strategy[41] in 2019.

Safety has also commanded significant resource. The new organisations and bodies cost money (around £60 million per year[42]), while DHSC-sponsored reviews and inquiries into safety are estimated to have cost at least £100 million.

Recommendations often include increases in staffing levels and supervisory roles. Recommendations, combined with 'safe staffing tools', have potentially contributed to the considerable growth in hospital staffing and funding over the last 10 years. There has been, for example, a 34% increase in nurse FTEs and a 37% increase in doctor FTEs between financial years 2013 to 2014 and 2023 to 2024, while occupied bed days increased by 3% and weighted activity by 23%.

This resulted in acute sector spend per capita increasing by 32% over the same time period, compared with a total increase in NHS spending of 23%. In contrast, primary care spend per capita increased by 5% and community care spending fell by 5%.

There was a 79% increase in manager nurses between financial years 2013 to 2014 and 2023 to 2024. The increase in hospital-based staff has become more marked in the last 5 years, with a 22% increase in the nursing workforce and 19% in the medical workforce since financial year 2019 to 2020. Over the same time period, weighted activity has increased by 6% and occupied bed days by 3%[43].

However, there has been limited progress in improving safety. There were improvements in the years leading up to the COVID-19 pandemic - for example, the proportion of patients recorded as 'harm free' in that they did not have one of 4 ‘harms’ (pressure ulcers, falls,

[41] NHS England. The NHS Patient Safety Strategy. 2019.
[42] DHSC. Health and Care Act 2022: combined impact assessments. 2022. This figure relates to the costs of medical examiners taken from 'Summary document and analysis of additional measures’ (PDF, 755KB) plus the costs of running the organisations under review.
[43] Carnall Farrar. 'Value in health: improving productivity, quality and prevention in the NHS.' 2025.

urinary tract infections (UTIs) in patients with a catheter or venous thromboembolisms (VTEs)) on a single day - increased between 2013 and 2017 from 93.1% to 94.1%[44].

Over the last 5 years, though, progress has slowed in some areas. Previous reductions in hospital-acquired Clostridium difficile (C. difficile) infections have begun to rise again[45]. Rates of VTE-related deaths have also risen, since they fell to their lowest rate in financial year 2018 to 2019 and peaked during the COVID-19 pandemic (financial year 2020 to 2021)[46] - this was partly related to the fact that COVID-19 infection increases the risk of thromboembolic events[47].

Other safety-related measures suggest progress has been maintained. For example, the number of inpatient hip fractures continues to decline nationally. The number of suicides of mental health service users, including inpatients, has shown steady improvement[48]. Data from NHS England's national patient safety team shows that, where there is focused work in areas covered by the NHS Patient Safety Strategy, safety is being improved.

The most recent report from the Institute of Global Health Innovation at Imperial College London and Patient Safety Watch suggests more limited gains[49] with, on some measures (12 out of 22), patient safety deteriorating.

Other aspects of quality of care have had relatively less attention or resource allocated - in particular:

- effectiveness
- user experience
- equity
- the leadership and management of care delivery

[44] DHSC. Independent investigation of the National Health Service in England: Technical Annex. 2024. Statistical significance not explicitly stated.
[45] DHSC. Fingertips - Public health profiles - C. difficile infection rates. 2024.
[46] NHS England. NHS Outcomes Framework Indicators, April 2024 release - 5.1 Deaths from venous thromboembolism (VTE) related events within 90 days post discharge from hospital. 2024.
[47] Sutanto H and Soegiarto G. 'Risk of thrombosis during and after a SARS-CoV-2 infection: pathogenesis, diagnostic approach, and management.' Hematology Reports 2023: volume 15, issue 2, pages 225-243.
[48] See: Nuffield Trust. Suicide in mental health service users. 2024. And: The University of Manchester. National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH) - Annual report 2023: UK patient and general population data 2010-2020. 2023.
[49] Illingworth J, Fernandez Crespo R, Hasegawa K, Leis M, Howitt P and Darzi A. 'The National State of Patient Safety 2024: prioritising improvement efforts in a system under stress.' Imperial College London. 2024.

Effectiveness has not seen the same growth in the number of bodies as safety, and remains under-supported in terms of improvement resource. Life expectancy remains lower than the most recent period before the COVID-19 pandemic with:

- increases in obesity levels
- increased numbers of people living with long-term conditions (over and above that expected from an ageing population)[50]
- a decrease in the number of people receiving effective care, particularly for those with long-term conditions[51]

Effective use of resources has declined with, for example, increasing unit costs of hospital-based care due to an increase in staffing levels without corresponding increases in activity or outcomes[52]. Medical and nursing productivity between financial year 2013 to 2014 and financial year 2023 to 2024 has fallen by 11% and 8%, respectively. While productivity has increased over the last year, it remains below pre-pandemic levels[53] [54].

In making decisions about resources and organisation and delivery of care, health systems need to consider all dimensions of quality, recognising that it is not always easy to balance them.

A general principle is that health systems should seek 'allocative efficiency', so that resources are deployed to yield the largest benefit overall in terms of health and society[55]. When seeking to improve the impact of spending, the opportunity costs need to be recognised - every time resources are used in one way, the opportunity to use them another way for something that might also be beneficial (or more beneficial) is lost.

It appears that a focus on safety over the last 5 to 10 years has been to the detriment of other aspects of quality of care, particularly effectiveness.

[50] See, for example, NHS England's Health Survey for England, 2021 part 2 statistics to see the rising trend in long-term conditions, and the Health Foundation's 'Health in 2040: projected patterns of illness in England' report, both published in 2023, for a future projection.
[51] See the analysis of the NHS England GP Patient Survey done by the Nuffield Trust: Care and support for long term conditions. 2025.
[52] DHSC. Independent investigation of the NHS in England. 2024.
[53] Carnall Farrar. 'Value in health: improving productivity, quality and prevention in the NHS.' 2025.
[54] NHS England. NHS productivity update - February 2025. 2025.
[55] Street A and Gutacker N. 'Health economics.' 2024: Cambridge University Press.

Finding 2: there has been limited strategic thinking and planning with regard to improving quality of care

Strategic thinking and planning with regard to improving quality of care has been limited in recent years and has not systematically considered the allocation of resources to maximise quality of care or the optimal provider structures necessary to support quality.

The last comprehensive strategy to improve quality was High quality care for all: NHS Next Stage Review final report (published in 2008), although the Five Year Forward View (2014) and the NHS Long Term Plan (2019) did include initiatives aimed at improving quality of care. All recognised the significant potential impact of improving the effectiveness of care with an emphasis on improved care for people with long-term conditions and frailty.

This should have led to a shift in resources (money and staff) away from acute hospital care and towards primary and community (neighbourhood) care, but the opposite has happened. Lord Darzi's independent investigation of the NHS in England in 2024[56] found that, although the NHS has had the strategic intention to shift spending from reactive care in hospitals to more proactive care in the community setting, care has moved in the other direction.

Nationally, strategy is led by DHSC, NHS England and UKHSA, including:

- setting standards
- reviewing the evidence base
- taking input from a wide range of bodies

There is NQB, which was formed in 2009, but to date it hasn't developed a comprehensive quality strategy.

At a local level, strategy is carried out by ICBs, local authorities and private health insurers, all of which are responsible for ensuring they commission services to maximise health and wellbeing and access to high-quality care. However, as others have commented (most notably the Hewitt Review: an independent review of integrated care systems and the aforementioned Darzi review), there are:

- a lack of commissioning capabilities
- restrictions on the ability of local organisations to allocate resources to maximise outcomes

[56] DHSC. Independent investigation of the NHS in England. 2024.

Input is typically taken from several bodies, primarily NICE, which:

- reviews a number of drugs, devices and interventions for different conditions
- seeks to develop guidelines based on:
    - academic research
    - real-world evidence and data
    - the views of users, patients and clinicians

In social care, SCIE provides input on high-quality care. Other inputs come from the royal colleges and academia, and think tanks and charities, though the latter 2 groups tend to refer to the management of care rather than the clinical evidence base.

While strategy setting and associated planning should take into account recommendations from previous reviews and inquiries, the review has heard that this is complicated by the high number of organisations and professional bodies making recommendations - which often publish these with no reference to wider system strategies.

Finding 3: there is a large number of organisations carrying out reviews and investigations. A very high number of recommendations have been made to the NHS, most of which lack any cost-benefit analysis

Multiple bodies and organisations:

- carry out investigations into health and care
- issue directions or recommendations to provider organisations
- undertake various forms of monitoring activity

This is added to by ad-hoc investigations, inquiries, report and reviews.

NHS trusts and ICBs carry out thousands of investigations and reviews each year. The NHS has significantly enhanced its own capacity and capability to undertake reviews and investigations over the last 5 years with the establishment of the PSIRF and LFPSE.

Of the 600 million patient interactions with the NHS every year (or 1.7 million per day), current (unpublished) estimates indicate up to 3,000 patient safety incident investigations are conducted by trusts on an annual basis.

All patient safety incidents that are thought to have led to a death must be investigated, as must all never events. Some categories of incident must also be referred to other processes, such as MNSI investigation. About 15,000 other learning responses (such as after action reviews) are captured following patient safety events.

ICBs conduct or commission between 100 and 200 patient safety incident investigations on an annual basis[57].

NHS England commissions independent patient safety incident investigations when issues are escalated by providers or ICBs because they are not able to conduct an effective investigation more locally (for example, due to capability or the need to ensure greater independence). There are around 80 ongoing at any one time. Around 65 are commissioned by one of NHS England's regional teams, while the remainder are either commissioned by NHS England nationally or regionally with some national input[58].

The Parliamentary and Health Service Ombudsman carries out detailed investigations into some of the complaints it receives. There were 840 detailed investigations out of the 28,780 complaints received in financial year 2023 to 2024.

HSSIB was established to build skills and capabilities in order to carry out investigations into cases of severe harm, rather than commissioning independent reviews and inquiries. HSSIB published 19 patient safety investigations with associated recommendations in financial year 2022 to 2023 and will publish 20 in financial year 2024 to 2025,

CQC has the powers to look into patterns of poor-quality care and conduct reviews or investigations under section 48 of the Health and Social Care Act 2008. In the last 5 years, CQC has published 3 substantial reviews[59] and set out recommendations for improvement. Within CQC, MNSI carries out about 600 investigations a year into maternity and newborn care where concerns have been raised either by families or by NHS trusts in England.

NHS Resolution has a statutory responsibility to look at claims data and develop insights to improve the safety of care. It publishes reports and makes recommendations for improvement - for example, recommendations to improve emergency medicine[60].

NHS Resolution is also responsible for issuing notices to inform NHS bodies and others about any registered healthcare professional who may pose a risk of significant harm

[57] Unpublished information provided by NHS England on 6 December 2024.
[58] Unpublished information provided by NHS England on 6 December 2024.
[59] See: Out of sight – who cares?: restraint, segregation and seclusion review (2020), Protect, respect, connect – decisions about living and dying well during COVID-19 (2021), and the Special review of mental health services at Nottinghamshire Healthcare NHS Foundation Trust (2024).
[60] See page 21 of: NHS Resolution. Corporate reports and publications - Annual report and accounts 2023/24. 2024.

through its management of the HPAN system. The professional regulatory bodies carry out investigations into the actions of individual practitioners. For example, GMC received 10,031 fitness to practise enquiries in 2023 of which 761 went to investigation. This is out of a total of almost 395,000 registered medical practitioners[61]. There were 5,774 referrals to NMC in financial year 2023 to 2024 of which 3,845 (72%) were deemed to require no further investigation, 531 were referred to another body, and 622 interim orders were imposed. This is of a total of 841,000 professionals on the register, which includes midwives, nurses, those dual registered and nursing associates.

Royal colleges carry out investigations on the request of an individual provider (such as a NHS trust) or NHS England - so-called 'invited reviews'. Medical directors or chief executives can request a review, as can fellows and members of a college, subject to agreement with their trust board. Some royal colleges carry out several investigations a year (for example, the Royal College of Physicians carried out 10 invited reviews in 2021), while others may only undertake a small number or none.

All deaths in England and Wales are independently reviewed, either by a coroner, where they have a duty to investigate, or by a medical examiner.

Coroners:

- review all deaths within certain parameters (for example, unexpected and unexplained deaths)
- decide which ones need to proceed to a full inquest

In 2023, in England and Wales, 195,000 deaths (33.5% of 581,000 registered deaths) were reported to coroners[62]. An inquest may result in a 'prevention of future deaths' report to highlight areas of concern and make recommendations for future care. Of the 195,000 deaths reported to the coroner in 2023, 36,900 inquests were opened and 569 prevention of future deaths reports were issued, although not all of these relate to healthcare[63]. There is a legal 56-day requirement for the respondent to reply to the prevention of future deaths report. The response is then published by the Office of the Chief Coroner.

Medical examiners (who are senior medical practitioners) review all non-coronial deaths in England and Wales (66.5% of all deaths in 2023 or 386,000). There are approximately 2,500 medical practitioners who have undertaken the medical examiner training. Medical examiners:

[61] GMC. Doctors' fitness to practise statistics and reports - Doctors' fitness to practise annual statistics - 2023 annual statistics. 2024.
[62] Ministry of Justice. Coroners statistics 2023. 2024.
[63] Ministry of Justice. Coroners statistics 2023. 2024.

- carry out a review of case notes for the deceased
- discuss the case with the medical practitioner who attended the patient before they died
- offer a conversation to the bereaved

Medical examiners are expected to ensure that more appropriate deaths are referred to the coroner and signpost deaths for internal review where required.

Statutory public inquiries have the power to compel witnesses to share information about the care of individual patients or groups of patients in order to identify the reasons for unsafe or poor-quality care and make recommendations. There have been a number of high-profile statutory public inquiries in recent years as outlined previously (see 'Inquiries, reviews and reports' in the '12. Charities, academia, think tanks and consulting companies' part of 'The wider quality landscape' section above).

Non-statutory reviews consider particular areas of care and examine how care is provided, often speaking to multiple users or patients and their representatives, and making recommendations. Examples are the Cumberlege review into the safety of medicines and medical devices, the Kirkup review into maternity and neonatal services in East Kent and the Ockenden review of maternity services at Shrewsbury and Telford Hospital NHS Trust.

Each of these national bodies, inquiries and reviews considers different elements of safety, sometimes in response to previous problems and cases of unsafe care. However, the disparate nature of them results in the lack of a coherent national message, and a lack of ownership.

This very busy landscape also results in an overwhelming number of recommendations. The Thirlwall Inquiry has found that there have been over 1,400 recommendations from 30 inquiries that have taken place in England and Wales, primarily in the last 30 years, related to its terms of reference alone. The various inquiries and reviews into maternity care over the last 5 years have resulted in over 450 recommendations.

Recommendations and directions are of varying quality and value. Not all are evidence based, capable of being operationalised or likely to be effective in targeting the problem they were designed to solve.

Some recommendations are contradictory or overlap with others. The overwhelming majority of recommendations lack data as to the cost of implementation or the expected impact.

Recommendations are often focused on inputs, rather than outputs or outcomes, and fail to recognise the balance of risks within organisations and across systems. Setting

standards or recommendations that increase resources in one area of care reduces the capacity available for other areas, which may subsequently harm a greater number of people.

The review heard that the existence of very large numbers of recommendations:

- causes considerable confusion for staff
- increases training requirements
- results in more and more clinical staff moving into supervisory roles to check that other clinical staff are adhering to the recommendations
- has a questionable impact on safety and wider quality

Provider organisations typically must address multiple priorities, targets, standards, requirements, guidance directions, programmes, incentives and measures that are set externally, and are answerable to the many different bodies outlined in this review with overlapping and potentially conflicting requirements. The sheer number and complexity of recommendations has been described as "priority thickets"[64] that prevent effective change from taking place.

People spoken to as part of the review told us:

- "We are drowning in recommendations."
- "We have so many recommendations, it’s an industry now – not actually changing things."
- "It is difficult to keep up with all the learning, and then you end up with lots of things to do and lots of training, but it's not clear how they all align."
- "The energy for improved safety has been lost."
- "Local provider boards (where safety responsibility must sit every day) are disempowered. They feel done-to by lots of random requests and directions."

In 2022, the Interim Chief Investigator of HSSIB convened a Recommendations to Impact Collaborative Group that drew together, on DHSC's behalf, representatives of its arm's length bodies to consider the large number of quality and safety recommendations being made. The group's first report, Recommendations but no action: improving the

[64] Dixon-Woods M and Martin G. 'Organisational culture: problem-sensing and comfort-seeking.' 2023: THIS Institute, NHS Providers and the Health Foundation.

effectiveness of quality and safety recommendations in healthcare, published in September 2024, made several observations including:

- healthcare providers are being “swamped” by the large number of recommendations being made, which are often in addition to regulatory actions
- some recommendations duplicate or conflict with others, making it difficult for providers to know which ones to implement
- individual providers can interpret recommendations in different ways, potentially resulting in inconsistency
- when recommendations are not costed, those that align with existing funding streams are more likely to be prioritised and acted upon

A recent report from the House of Lords Statutory Inquiries Committee has drawn similar conclusions, noting that:

> "insufficient implementation monitoring has damaged the reputation of public inquiries and made them less effective."

There has been some work to try and combat these problems. For example, to manage the volume of recommendations for maternity services, NHS England has created a National Maternity and Neonatal Recommendations Register, which can be accessed through its FutureNHS platform.

Finding 4: a large number of organisations look at user experience or advocate on behalf of the 'voice of the user', yet few boards in the NHS have an executive director for user or customer experience

Multiple organisations provide support for the 'voice of the user'.

This includes a broad range of roles and functions, which can be used interchangeably, causing further confusion. It includes:

- carrying out surveys
- seeking feedback
- supporting users to complain (more in next finding)
- involving patients, users and communities in the co-design of services
- advocating for and supporting patients and users to be more involved in their own care

- measuring the outcomes of care from a patient or user perspective

These are described in more detail below.

Surveys of users, patients or communities

Multiple surveys are carried out each year. NHS England carries out at least 10 specific surveys including, for example, the GP Patient Survey and the National Diabetes Experience Survey. NHS England also routinely surveys patients and their relatives to ask for feedback about care through the Friends and Family Test.

CQC carries out at least 5 surveys each year including the adult inpatient survey, the community and mental health survey and the maternity survey. NHS England is currently responsible for surveys into adult social care and adult carers. It is not clear how these surveys are used to inform strategies to improve quality of care.

Locally, individual providers, ICBs and local authorities regularly carry out public engagement such as community outreach, surveys and public meetings to inform local decision making.

Integrated care partnerships (ICPs) bring together local authorities, individual providers and ICBs at an ICS level to develop a strategy to improve health and care in line with the 4 objectives of ICSs. As part of this work, they involve the people who live and work in the area, drawing on input from ICB and local authority community engagement teams, including Local Healthwatch.

A typical ICB might talk to local communities, user groups and patients several times a year to hear what matters to them and understand their views on local services. Local authorities will also carry out public engagement, sometimes through their Local Healthwatch organisation and sometimes directly through both health and wellbeing boards and overview and scrutiny functions.

Alongside this, ICBs and local authorities encourage residents to participate in consultations. PPGs, Local Healthwatch organisations, and individual health and care providers also carry out their own research and work with public and patient groups to gain input on specific areas of care.

Many of the wider organisations and professional bodies, as well as charities and patient-led campaigning groups, might also survey patients, residents and communities. Some of these use social media, but this remains patchy. Patient Safety Learning, for example, collects people's experiences through its patient safety platform the hub.

Across all surveys, there are concerns about representativeness - for instance:

- constraints on data governance can make it hard to:
    - know who is, and who isn't, responding to surveys
    - reach out to particular population or patient groups
- the fragmented nature of surveys makes it harder to ensure comprehensive inputs and statistical significance

In some geographies, the complexity of this landscape has been recognised and different health and care patient or user experience teams have joined forces to align approaches and resources. For example, Healthwatch in Leeds has co-ordinated organisations to develop the People's Voices Partnership (PVP) to:

- set a system-wide ambition
- work to share principles
- identify specific joint activities that will help deliver the ambition to put the voice of the people of Leeds at the centre of health and care decision-making - in particular, those facing the greatest health inequalities

The budgets are not pooled but activities are co-ordinated, and organisations allocate individual resources into citywide priorities such as a:

- collective insight library
- drive to improve care by focusing on the '3Cs' (communication, coordination and compassion)
- citywide complaints group
- joint listening exercise, the 'Big Leeds Chat'

Co-design of care

Many providers and commissioners of services involve users or patients and wider communities in the design and improvement of services. This happens at multiple levels, from setting high-level plans (for example, through the 10 Year Health Plan work) to redesigning care pathways - nationally, regionally, sub-regionally (through ICSs and local authorities) and locally (through individual providers).

Local Healthwatch and Healthwatch England support this work, as do many of the wider charities such as National Voices and the Patients Association.

Advocating for and supporting individual patients and users to be more involved in their own care

Many of the organisations involved in supporting users and patients advocate for a more 'patient-centred' (or 'user-centred' in adult social care) model of care. While this can mean different things to different people, it tends to mean:

- greater knowledge sharing
- improved consent to care
- improved understanding of what sort of care is most appropriate to people's needs
- building understanding in order to improve compliance with treatment or care

Understanding patient or user views on the outcomes of care - PROMs

There has been increasing interest over the last 30 years in exploring outcomes of care from a patient or user perspective, rather than from a clinical or medical perspective. This has identified that patients or users can be disappointed in the impact of a care intervention, even though clinically the outcome is seen to be satisfactory.

One of the most notable examples is joint surgery, where patients or users may report poorer outcomes than surgeons[65], typically due to the surgery not having as positive an impact on their quality of life as they might have expected. NHS England now carries out regular surveys or audits of patient-reported outcome measures (PROMS) for joint surgery. Other countries have similarly sought to develop clinical outcome measures that take into account patient or user perspectives[66].

The multitude of organisations and bodies involved and their different roles:

- causes confusion for patients and users, who are unsure about the status of different groups
- results in inefficiencies, sub-scale inputs and a failure to ensure representativeness

Yet, at the same time, most NHS boards - provider and commissioner - lack an executive director for user or customer experience. This is in contrast with other consumer-facing

[65] Nakano N, Shoman H, Olavarria F and others. 'Why are patients dissatisfied following a total knee replacement?: a systematic review.' International Orthopaedics 2020: volume 44, pages 1,971-2,007.
[66] Pagels AA, Stendahl M and Evans M. 'Patient-reported outcome measures as a new application in the Swedish Renal Registry: health-related quality of life through RAND-36.' Clinical Kidney Journal 2019: volume 13, issue 3, pages 442-449.

industries where there would typically be a director of customer experience or chief customer officer[67].

Finding 5: the current system for complaints and concerns is confusing and may lack responsiveness

In financial year 2023 to 2024, 241,992 complaints were received by NHS organisations - 107,745 for hospital and community health services and 134,777 for GP and dental services. The number of complaints has been steadily increasing over the last 2 decades from 174,872 in financial year 2013 to 2014. This represents a 38% increase compared with an increase in patient activity of between 13% (inpatient activity) and 27% (outpatient activity) over the same time period[68] [69].

In financial year 2023 to 2024, complaints concerning:

- communications totalled 33,594
- nutrition or hydration totalled 24,197
- staff values and behaviour totalled 19,977

The number of patient complaints about hospitals and community health services that were fully upheld was 27,087, and the number upheld in GP and dental services was 41,320.

The NHS complaints procedure, which all NHS organisations are required to operate, is governed by the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009. The regulations specify that a complaint may be made by "a person who receives or has received services" or "a person who is affected, or likely to be affected, by the action, omission or decision… which is the subject of the complaint".

The scope of a complaint that can be made under the NHS complaints procedure, while wide, is not unlimited. For example, it cannot be used to:

- ask for care or treatment for the first time
- ask for a second opinion
- get compensation

[67] See, for example, such roles at British Airways, Transport for London and Aviva plc.
[68] NHS England. Data on written complaints in the NHS, 2023-24. 2024.
[69] The King's Fund. Activity in the NHS. 2024.

- complain about an issue where legal action is already being taken

Alongside operating the NHS complaints procedure, every NHS trust in England is required to have a PALS. First established following the National Health Service Reform and Health Care Professions Act 2002, PALS have responsibilities to:

- listen to concerns, comments and questions from patients and their representatives
- provide helpful support and accurate information and advice to resolve concerns as quickly as possible
- assist staff who are raising a concern on behalf of patients
- provide information about the NHS complaints procedure and how to get independent help if a further complaint is being considered

In addition, £15 million a year of funding is provided from DHSC through the local authorities social services grant to local authorities, which commission a range of organisations to provide 'advocacy support' to people looking to make a complaint.

There are more than 70 different types of channels or organisations that offer a place for patients or users to share feedback, either formally or informally, about the quality of healthcare services, including concerns about serious harm or side effects. People can also approach:

- Local Healthwatch
- local authorities (through individual councillors)
- charities and user groups (such as National Voices or the Patients Association)

If a satisfactory resolution is not provided within 6 months, the complainant has the right to escalate the issue to the Parliamentary and Health Service Ombudsman. The Parliamentary and Health Service Ombudsman is the 'organisation of last resort' for patient and user complaints.

In social care, complaints can be received by:

- individual care providers
- local authorities
- the Local Government and Social Care Ombudsman

About 11% of healthcare complaints (28,780 in financial year 2023 to 2024) are referred to the Parliamentary and Health Services Ombudsman, of which 840 proceeded to a detailed investigation and 472 were fully or partly upheld. This compares with around 1.3% of complaints in the rail industry being referred to the Rail Ombudsman[70].

In financial year 2023 to 2024, the Local Government and Social Care Ombudsman received 2,982 social care complaints of which 926 proceeded to a detailed investigation and 742 were upheld. There is no national data on numbers of complaints to local authorities.

New NHS Complaint Standards were published in 2021. The standards, which are published on the Parliamentary and Health Service Ombudsman's website, apply to all NHS providers and are supported by a model complaint-handling procedure and guidance on using the standards in practice. The intention is that NHS organisations will follow similar processes across the country and introduce a better, more consistent approach to complaint handling. This guidance is non-binding and, given how recently it was introduced, its impact is not yet clear.

Complaints about professional misconduct in relation to a particular individual can be made to the relevant professional regulator, including the GMC and the NMC, overseen by the Professional Standards Authority.

People can make complaints both to a professional regulator and under the NHS complaints procedure, but the regulator may decide to wait until the organisational investigation has concluded before initiating its own processes. As noted above, although high numbers of complaints to professional regulators are made each year by patients and families, only a minority are heard by a professional misconduct committee. Many are screened out at an early stage.

Patients and families may also raise concerns by making a claim for clinical negligence, under tort law, though they can only do this when harm appears to have occurred arising from a breach of duty of care that directly results in an injury or loss. Claimants must prove, on the balance of probabilities, that the care provided has caused the damage because it was delivered in a negligent way. Responsibility for managing clinical negligence claims against the NHS lies with NHS Resolution.

Finally, and increasingly, patients and families may raise concerns by using social media and mobilise through campaigning and advocacy. Recent years have seen multiple examples of this, including, among others, campaigns on:

[70] In 2023, 346,429 complaints were closed by rail operators and 4,423 cases raised with the Rail Ombudsman (PDF, 1.19MB).

- poor maternity care
- deaths among those with learning disabilities
- abuse and neglect of older people

The Patient Safety Commissioner, CQC and HSSIB are not able to receive individual complaints and concerns. CQC is, however, able to draw on user or patient feedback that is shared with it during the assessment and inspection of services. The Patient Safety Commissioner can similarly draw on comments or inputs in relation to medicines and medical devices.

Complaints and concerns are often poorly handled with patients or users and patient or user groups describing delays and poor-quality responses. Many complaints are not handled within the statutory timeframe of 6 months. A recent survey found that over half of people who made a formal complaint were dissatisfied with both the process and the outcome of their complaint.

The ombudsmen can publish public interest reports, which should be considered at provider board level, but there is no legal obligation to implement any recommendations. The ombudsmen do publish, in their annual reports, a list of those organisations that have and have not complied[71].

More generally, limited data about complaints is published by health and care organisations. Complaints data is not collected centrally so wider lessons cannot be learnt.

The review has heard considerable concern from patient or user groups about the complaints process and the confused landscape. It is particularly challenging for those who have, or believe they have, been harmed or suffered poor outcomes as a result of care. There have been proposals from some legal and patient support groups for a 'harmed patient pathway' for use by the NHS.

Complaints, concerns and feedback about individuals, providers and the system as a whole can:

- support improvements in care
- improve service delivery
- identify trends regarding patient experience, quality and safety respectively

[71] See the Parliamentary and Health Service Ombudsman's annual report and accounts 2023 to 2024 and the Local Government and Social Care Ombudsman's adult social care complaint reviews.

This needs to be given greater emphasis by boards, teams and individual clinicians.

Finding 6: some of the organisations under review have expanded their scope

Some organisations in the review have expanded their scope - and this has not necessarily been driven by an overarching strategic vision or in co-ordination with other bodies.

While this is done with the admirable intention of improving safety of care delivery, it can create further complexity, recommendations and confusion. For example:

- HSSIB was originally established, along the lines of other safety investigatory bodies, to look at specific cases or incidents of severe harm, but it has since broadened its work into wider system management

- the Patient Safety Commissioner was set up to look at how patients and users could better report complications from medicines and medical devices in order to improve their safety, but it has taken on a far wider role as an advocate for other patient safety themes. Most recently, for instance, it published a set of patient safety principles that go well beyond the remit of improving the safety of medicines and medical devices

- CQC was established with the purpose of assessing the quality of health and care providers and, more recently, ICSs. However, it has expanded its remit and now develops tools to support ICBs to better understand the health needs of particular communities

Finding 7: a greater strategic focus on care delivery and management is needed to improve quality of care

In comparison with the resource that goes into investigations, recommendations, setting standards and monitoring, relatively little support goes into the day-to-day management and improvement of care.

Delivery, management and improvement of care are the responsibility of providers and their boards, but the review heard a number of comments about why this does not happen consistently, particularly in relation to the delivery of safe care. Specifically:

Operating processes and service models are not standardised

Despite the advantages of the NHS as a 'single payer', very little resource goes into designing and testing large-scale solutions, including standardised operating processes and service models. This results in significant waste as organisations seek to come up

with their own solutions, which may be sub-optimal, resulting in high levels of variation in care delivery and quality of care.

This is in comparison with other high-risk industries (such as rail, maritime, construction and aviation) where standardisation would be the norm. The KAIZEN™ approach, which is widely applied in these industries, emphasises continuous improvement through the development and refinement of standardised processes. This is not to say that everything should be dictated from Whitehall, but rather that more consistent operating processes could:

- bring far greater clarity
- enable training and measurement
- support improved safety - and wider quality - of care

Several other high-performing healthcare systems - for example, in Singapore as well as Kaiser Permanente and Intermountain Health in the USA - have successfully implemented standardised care protocols that are tailored to local needs, while adopting a 'comply or explain' approach (where both are encouraged to ensure continuous learning). These lead to measurable improvements in patient safety, outcomes and efficiency[72].

Investment in improving management is needed

As well as frontline clinical care, improvement needs to involve areas such as:

- operational management
- human resource management
- procurement and supply chain management
- facilities management

Investment in improving management could make a significant difference across all areas of quality[73].

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[72] Intermountain Health. News - New Intermountain study finds implementing standardized care guidelines for rehab leads to better outcomes and improved quality of life for knee-replacement patients. The 2 studies in question are: Minick KI, Hunter SJ, Capin JJ and others. 'Improved outcomes following a care guideline implementation: part 1 of an analysis of 12,355 patients after total knee arthroplasty.' Journal of Orthopaedic & Sports Physical Therapy 2023: volume 53, issue 3, pages 143-150. And: Capin JJ, Minick KI, Stevens-Lapley JE and others. 'Variation in outcomes and number of visits following care guideline implementation: part 2 of an analysis of 12,355 patients after total knee arthroplasty.' Journal of Orthopaedic & Sports Physical Therapy 2023: volume 53, issue 3, pages 151-158.

[73] Dixon-Woods M. 'Report to the Thirlwall Inquiry: addressing part C of the terms of reference'. INQ0102624 - Expert report of Professor Mary Dixon-Woods. 2024.

Technology is under-developed and under-used

There is a lack of technology to support the provision of safe care. Other industries - and (a few) other healthcare systems - are further advanced in using technology to embed safe practice through:

- standardised collection of patient data in advance of any consultation
- tools to support better-quality prescribing decisions
- technology to enable diagnosis (such as AI-generated read-outs of electrocardiogram tests, cardiotocography or diagnostic images)
- automation of care (for instance, robotic surgery)
- continual monitoring to spot and reduce errors in real time

While technology offers considerable opportunities to improve quality of care, it also presents challenges for regulation. For example:

- should the efficacy and safety of technology be compared to that of human operators or be expected to be close to 100%?
- if technology can help reduce waiting lists but isn't fully proven, should it be used?
- which body should regulate a diagnostic tool that substitutes for doctors, nurses or other clinicians?

Variation in the effectiveness of governance structures

Governance structures do not consistently support safe, high-quality care with:

- variable effectiveness of boards
- variable understanding of risks and how to effectively balance risks across an organisation and a wider system
- unclear accountability and responsibility for high-quality care
- a lack of detailed data-driven performance appraisals for staff
- a lack of incentives (and disincentives) to support and embed high-quality care
- inconsistent role modelling of behaviours that embed high-quality care

Previous work carried out by Monitor, in particular, emphasising the importance of the board in ensuring high-quality care has reduced in pre-eminence over the last few years.

Lack of measurement, review and feedback mechanisms

There is insufficient ongoing measurement, review and feedback mechanisms at all levels - from frontline teams through to clinical directorates and boards.

Poor performance and appraisal processes

Performance appraisals for members of staff are insufficiently robust or detailed. This means that frontline staff, managers and boards lack clear consequences for poor-quality care.

Inconsistent staff training, development and credentialing

Training and development of staff can sit distant to many providers, often taking place in other organisations. This makes it difficult for providers to ensure consistent standards.

Credentialing (checking the credentials) of staff has historically been raised as a concern due to some high-profile cases, such as the Paterson Inquiry, where poor performers were able to work across multiple NHS and private provider sites, which were seemingly unaware of their previous practice.

Smaller practices and enterprises are limited in what they can achieve

The small size of some providers makes it hard to put in place governance structures - for example, in smaller GP and dental practices, SMEs in adult social care and private healthcare.

Consider the role of commissioners and local authorities

Outside of providers, the role of commissioners in contracting for, and assuring the quality of, care needs to be made clearer. Similar consideration should be given to local authority commissioning of care.

Introduce a national quality support infrastructure

As well as being clearer about what good commissioning, delivery and management of care looks like, there also needs to be far more support around the improvement of quality of care, including safety.

Approaches to improvement are variable and lack a well resourced national quality support infrastructure.

Finding 8: the National Guardian's Office duplicates work carried out by providers

The responsibilities of the National Guardian's Office are to lead, train and support the network of Freedom to Speak Up Guardians by working with NHS England and other healthcare-related organisations. Freedom to Speak Up focuses on improving workplace cultures by:

- ensuring workers are confident to speak up
- providing expert support and guidance
- challenging organisations to do better
- offering an additional channel to hear concerns outside of line management, HR and other traditional routes

Sir Robert Francis played an important role in establishing the National Guardian's Office, with the expectation that the National Guardian would:

> "advise NHS organisations to take appropriate action where they have failed to follow good practice, or advise the relevant systems regulator to make a direction to that effect."

There is now an extensive network of Freedom to Speak Up Guardians across the NHS and wider healthcare organisations. Those working in NHS organisations are supported by Freedom to Speak Up experts at a local level and, if required, issues can be escalated at a national level to NHS England. There is also a list of government-prescribed whistleblowing people and bodies, which includes CQC, Healthwatch England or the National Guardian's Office. This applies to staff working in independent healthcare organisations as well as in the NHS.

Speaking up data to date shows that Freedom to Speak Up Guardians in the NHS handled around 30,000 cases in financial year 2023 to 2024, increasing from 7,000 in financial year 2017 to 2018. Of these cases:

- 18.7% included a direct element of concerns about patient safety or quality
- 19.8% involved bullying and harassment
- 38.5% involved inappropriate attitudes or behaviours

There has been a small increase in staff reporting that they feel secure in raising any concerns regarding clinical practice – from 68% in 2015 to 75% in 2021 and 71.5% in 2023[74].

The National Guardian role was originally designed to sit as an independent function, partly to build a network of Freedom to Speak Up Guardians and partly to provide a national voice and leadership. However, the National Guardian network has now been established and clear routes for staff to escalate concerns have been set out by government, so it is not clear that there is a need for an independent oversight body.

The National Guardian's Office has, at times, found it hard to engage with the leadership of the NHS and, as a result, can lack the impact required. The current hosting of the National Guardian's Office within CQC results in the role being too distant from the people it needs to support and influence.

Placing the responsibility for Freedom to Speak Up Guardians firmly within commissioners and providers should:

- raise the profile and importance of staff voice
- allow for a more rapid response

There will still be a need to ensure a level of independence to support Freedom to Speak Up functions. In many organisations, this role is played by a senior non-executive director and these arrangements should continue.

Ensuring that these functions are happening in all commissioners and providers should be a core function of CQC as the independent regulator of health and care.

Finding 9: insufficient use is made of the NHS's data resources to generate insights and support improvement

The NHS is one of the most data-rich healthcare systems in the world and has historically been at the forefront of collecting and reviewing data for clinical audit purposes.

There is considerable scope to build on this leading position with more data sharing across organisations. There is also the potential to use advanced analytics to generate far greater insights, enabling organisations to identify and focus on the most significant issues and challenges that must be faced to improve care.

[74] This information was provided in a submission to the review by the National Guardian's Office. Some of this information can be found at on the National Guardian's Office website.

HQIP is responsible for the measurement of the clinical outcomes of care through the 30 national clinical audits that it contracts for and manages. It also subcontracts some work to other organisations such as MBRRACE-UK. Other national audit work takes place through royal colleges - for instance, the Royal College of Anaesthetists' national audit projects (NAPs) - and provides an effective form of peer review and learning.

Measurement of safety takes place through various nationally agreed metrics such as community infection or VTE rates. Similarly, measurement of effectiveness takes place through national data sets covering areas such as the numbers of people receiving vaccinations. Other data can be drawn from:

- the Quality and Outcomes Framework (QOF) database (such as the number of people with diabetes receiving effective care)
- routine Hospital Episode Statistics (which capture, for example, numbers of admissions to hospital for different conditions or complications)

In theory, these systemic, national data sources can be used by local clinicians, teams, directorates, boards and commissioners to continually monitor and review quality of care. However, the review heard that often these multiple data sources neither align nor generate meaningful insights.

The Sudlow Review looked at how health data could generate insights for the benefit of patients and the public. The review found that access to national data collections is "difficult, slow or impossible", which hinders research that could improve health and wellbeing by:

- better understanding the causes of diseases
- developing better diagnosis, prevention and treatment strategies
- testing these strategies in clinical trials
- assessing their uptake, effectiveness and safety in the ‘real world’

Finding 10: there is insufficient focus on developing a national strategy for quality of social care

While adult social care has not been the primary focus of this review, the review has been struck by the lack of national attention to the quality of social care - in particular:

- as it pertains to outcome indicators
- how much less data there is about quality of care in social care

- the lack of agreement as to the metrics that would best define and describe quality in adult social care

Adult social care is a fundamentally different market to healthcare - over a third of social care is funded by individuals with largely free choice as to provider, while publicly funded care is commissioned by 153 local authorities on behalf of their residents.

Local authority commissioning of adult social care is regulated by CQC, and local authorities are held to account for the effectiveness of their commissioning through local elections every 4 years.

Services are delivered by an independent market of around 6,000 care homes and 13,600 domiciliary care providers. Individual providers of adult social care are required to meet specific quality requirements, as defined in the CQC regulations and against which they are inspected by CQC.

At a local level, local authorities have duties under the Care Act 2014 to shape the local provider market and ensure a range of high-quality services are available. However, at a national level, the review was surprised to find no clear strategy or plans to drive improvements in quality - to, for example, address the significant proportion of falls and medicine prescribing and dispensing errors that occur in adult social care services.

There is less data collected on the quality of social care than healthcare. The Adult Social Care Outcomes Framework does bring together some indicators, but these are only published at a local authority level on an annual basis.

While there is a plethora of organisations considering the quality of healthcare, the quality of social care falls predominately to SCIE and CQC. Healthwatch does cover social care, as well as healthcare, but this is much less of a focus in its work.

Local authorities are not required to submit data nationally on complaints or feedback. National numbers of complaints are only analysed by the Local Government and Social Care Ombudsman for the cases that reach them. There is no data collected nationally from providers on, for example:

- missed visits in domiciliary care
- falls
- UTIs
- bed sores
- other clinical indicators

While the Personal Social Services Annual Social Care Survey does provide key performance indicators of user experience (for example, overall satisfaction with care or the extent to which users feel 'clean' and 'safe'), it only covers users of local authority-funded care and cannot be mapped to individual provider level.

It is not clear how best practice is disseminated among providers - for example, the outcomes of recent research findings such as Care England's 'decaf by default', which provided evidence of the beneficial impact of initiatives focused on reducing falls and distress in care homes.

That said, adult social care providers clearly recognise the importance of high-quality care, placing considerable emphasis on ensuring quality and acknowledging the role of CQC in assessing care quality.

For example, HC-One focuses on ensuring a culture of not tolerating any small unkindness and of 'no blame'. As a provider, it:

- carries out regular care home visits and monitoring
- conducts learning conversations at care home, area, group and board level
- escalates concerns to an independent board sub-committee
- completes internal CQC-equivalent inspections 4 times a year, with monitored scores
- monitors data such as complaints, whistleblowing and clinical indicators through dashboards, which can lead to questions and feed into learning conversations

HC-One told the review that 30% of all staff bonuses are based on quality results with a further 30% on staff turnover, which is one of the most important drivers of quality.

Learning from other industries

While it is not possible to completely apply lessons from other industries to healthcare, there are a number of themes that can be applied from other complex, high-risk sectors[75].

Summarising at a high level, other industries are more likely to have the following in place:

Streamlined and more visible routes for users to complain, with clear standards and expectations

The Office for Rail and Road (ORR) sets out a clear process for making a complaint on its website and there are clearly visible notices in place at train stations, on trains and online.

Complaints are made to train companies directly and a response should be provided within 20 working days. If the complainant is not happy with the response, they can ask the train company to look again and it has a maximum of 40 working days to find a resolution.

If the complaint is still not resolved, it can be escalated to the Rail Ombudsman.

There were 348,929 complaints closed by train operators in the latest year (1 April 2023 to 31 March 2024), which is a rate of 22 complaints per 100,000 journeys[76]. Around 4,500 of these (1.3%) are referred to the ombudsman[77].

Clear strategy and plans to ensure 'high-quality' services with a clearer sense of the balance of risk

Many organisations recognise the need to address balance of risk at a board level - and to set out clear standards, operating models and metrics throughout.

This is underpinned by robust governance structures, appraisals and reward structures.

Safety management systems with far greater use of standardised operating processes

Other safety-critical industries identify and implement models for effective risk management, including safety and quality management systems and/or high reliability

[75] Macrae C and Stewart K. 'Can we import improvements from industry to healthcare?' BMJ 2019: volume 364, article l1039.
[76] ORR. Passenger rail service complaints: January to March 2024 (PDF, 1.54MB). 2024.
[77] In 2023, 346,429 complaints were closed by rail operators and 4,423 cases raised with the Rail Ombudsman (PDF, 1.19MB).

systems[78]. These are typically based on assessing levels of 'safety maturity', alongside safety assurance processes.

ORR has developed a safety maturity assessment tool, the Risk Management Maturity Model (RM3), in collaboration with the rail industry. This includes having clear health and safety policies, leadership and board governance focused on:

- ensuring processes are followed, continually reviewed and revised
- organising for control and communication
- securing co-operation and competence
- planning and implementation
- monitoring, audit and review

More extensive use of technology to underpin processes

All industries are working at pace to continually increase and improve the use of technology to underpin processes that, historically, have been solely reliant on people to manage.

Other safety-critical industries have developed digital tools for reporting safety incidents that ensure data can be analysed, understood and fed into safety management systems in real time. They also have systems in place that use real-time, industry or system-wide data to understand flow.

For example, in aviation, it is easy to see how quickly flow across the end-to-end pathway for passengers can come to a halt if one function is unable to operate effectively. System-wide, live data is consistently used to make precise calculations, adjusting to different risks and enabling flow to be maintained. Data visibility across global operations in aviation contributes to continuous improvement and increased collaboration.

AI is increasingly being tested in other industries to understand its ability to predict changes in risk profiles, enabling safety teams to proactively manage and mitigate these risks.

[78] Macrae C. 'Regulating reliably: building high-reliability regulators in healthcare.' Journal of the Royal Society of Medicine 2025: volume 11, issue 1, pages 11-15.

Leadership and management aligned behind high-quality care

Safety – and wider quality – are critical responsibilities of boards in most industries. This includes identifying potential risks and managing them to an acceptable level.

Safety and risk management systems are reviewed at board level alongside other performance indicators (such as customer and workforce satisfaction, and operational and financial performance) with:

- clear plans, performance indicators and targets
- continuous measurement and review of all areas of performance

This approach enables effective risk-informed decision-making across the business and is usually managed top-down, which means the board of the organisation is responsible for all areas of performance.

Clear lines of accountability within and across organisations are crucial. For example, the European Union Aviation Safety Agency, the aviation regulator, requires there to be clearly defined roles of responsibility and accountability throughout the operator, including a direct safety accountability of the accountable manager. An accountable manager is an individual who is responsible for ensuring regulatory standards are met.

Accountability flows through to individual employees, with detailed appraisals based on a range of indicators including customer satisfaction and adherence to safety management processes.

This is also the case in a number of other healthcare systems internationally, which recognise and reward staff on the basis of customer satisfaction and clinical outcomes.

Creating a culture that supports improved safety and wider quality

Other industries - and many health and care systems - recognise the importance of embedding a culture of continuous improvement within organisations.

This does not happen by accident - it happens through rigorous leadership and management (as outlined above under 'Leadership and management aligned behind high-quality care') and by developing skills, capabilities or knowledge of improvement techniques. This is underpinned by:

- setting clear standards of behaviours
- positive role modelling throughout an organisation (starting with the board)

- measurement accompanied by recognition and reward for positive behaviours

Mechanisms that encourage and enable employees to raise concerns

Regulations in many industries aim to ensure an open and fair culture, enabling people to raise concerns.

The Civil Aviation Authority and maritime industry fund a Confidential Human Factors Incident Reporting Programme (CHIRP) where anyone working in these industries can raise safety concerns in confidence. Staff can also raise concerns about:

- bullying
- harassment
- discrimination
- victimisation

This recognises the impact such concerns have on staff, as well as the second-order safety implications.

A similar organisation, CIRAS, operates a confidential safety hotline that serves the transport sector, including rail, buses, highways, ports and transport supply chains. This is operated by a not-for-profit subsidiary of the Rail Safety and Standards Board.

Recognising the need for tailored and implementable recommendations

The Air Accidents Investigation Branch (AAIB) recognised the 'noise' coming from having too many recommendations in the aviation sector and, as a result, changed its philosophy on recommendations to highlight the risk and outcome of different areas of safety, without specifying the solution, as the recipient is often best placed to develop this.

This is a similar approach to prevention of future deaths reports. The coroner highlights concerns but doesn’t recommend specific action - this is for the provider of the service to decide. Recommendations must be evidence based and there should be no implication of ‘blame or liability’. Those involved in the investigation are consulted early about the potential safety issue, and the preference is for safety actions to be taken proactively, thereby removing the need for a safety recommendation.

Since 2019, AAIB has been responsible for monitoring the actions taken in response to an aviation safety recommendation. This monitoring information is reported to the State Safety Board as part of the UK State Safety Programme.

Similarly, the Marine Accident Investigation Branch monitors the progress of accepted safety recommendations in the marine space, which are included in its annual reports to the Secretary of State for Transport.

Regulation based on the presence of safety management systems rather than individual areas of safety

The regulator of the rail industry, ORR, permits UK rail organisations to operate on the basis that they have clear safety management systems in place.

These systems need to be re-authorised approximately every 5 years.

The effectiveness of the application of the safety management systems is judged through ongoing regulatory supervision and inspection.

Conclusions of the review

I have drawn 5 principal conclusions from the findings above:

1. Action is needed to address gaps in functions. In particular, a strategic approach to improvement and innovation in quality of care (including safety) is needed that:

- considers allocation of resources to maximise outcomes
- co-ordinates and prioritises the very many recommendations and 'asks' of providers

2. There is a need to streamline, simplify and consolidate functions where considerable duplication and overlap currently exist - specifically when it comes to:

- user, patient or community engagement
- capturing and learning from user or patient experience, or the 'voice of the user'
- investigations

3. Too many functions sit outside of the commissioners and providers of care who are ultimately responsible for improving quality (including safety). This results in limited impact from the very many inquiries, reviews, investigations and resulting recommendations that are made.

4. Within commissioners and providers, there needs to be a far greater focus on:

- building skills and capabilities
- effective governance structures
- clearer accountability for quality (including safety) of care

5. CQC was established as the independent regulator of health and care. It needs to rebuild public, professional and political confidence, and should also house functions where independence is required.

Recommendations of the review

Recommendation 1: revamp, revitalise and significantly enhance the role of the National Quality Board

A revamped, revitalised and reinforced NQB should be responsible for developing a comprehensive strategy to improve quality of care that is in line with the aims of DHSC and the NHS in England. This strategy should build on:

- data and analysis about current quality of care
- evidence and examples of high-quality care
- where appropriate, recommendations from previous reviews and inquiries

This strategic approach should:

- recognise the need to balance across all dimensions of quality
- build on the principle of healthcare value (seeking to maximise outcomes per pound spent) so that both outcomes and costs are continually optimised
- ensure resources are allocated to maximise life expectancy and quality of life - the common purposes of DHSC and the NHS in England

More specifically, NQB should set out a vision of quality of care that:

- describes 'what good looks like' for the various dimensions of quality
- recognises the need to balance priorities across dimensions

It should also build expertise in assessing healthcare value, including a more comprehensive assessment of:

- which interventions deliver what impact
- what costs could be under different delivery models combined with optimal operational and clinical performance

NQB should develop an overarching strategy for how improvement and innovation can best be supported across health and care, recognising:

- lessons from other industries and health and social care systems to strengthen concepts of:

    - balance of risk
    - standardised care models and operating processes
    - robust governance structures
    - optimal improvement approaches
- the need for a focus on improvement and innovation in:
    - the operational functioning of the NHS - such as basic management systems including HR, finance, procurement, estates and facilities
    - clinical care
- the benefits of large-scale collaboration and co-design, combined with robust evaluation, building on learning from previous successful improvement efforts in the NHS

When it comes to data, NQB should:

- agree on an integrated, evidence-based set of the most meaningful and helpful metrics to use to assess quality at a national strategic level across all dimensions of health
- oversee the development of a data improvement and innovation strategy that considers how advanced analytics could be used at scale to:
    - build better, stronger, more accurate or case-mix adjusted data that generates greater insights
    - make more effective use of existing NHS data resources (including large-scale audits or registries and routine data)

The organisation should be tasked with:

- building and maintaining a repository of recommendations from multiple sources
- operating a clearing house function to co-ordinate and prioritise recommendations

This prioritisation should be based on high-quality analysis, including the evidence base for likely benefit, cost and cost-effectiveness, and fit with strategic priorities.

As part of this, the NQB should:

- ensure that unfunded mandates (such as those arising from reports, reviews, inquiries, investigations, guidance and activities of various bodies) are not imposed on providers without due diligence

- where appropriate, oversee the implementation of prioritised recommendations with ongoing monitoring and evaluation of their impact

Responsibility for building and maintaining the register should sit within DHSC.

NQB could be co-chaired by the chairs of CQC and chair of NHS England, transitioning over time to the lead non-executive director for quality on the board of DHSC, and be directly accountable to the Secretary of State for Health and Social Care.

Recommendation 2: continue to rebuild the Care Quality Commission with a clear remit and responsibility

The review of the operational effectiveness of CQC identified a number of actions that CQC needs to take to improve performance and restructure the single assessment framework.

CQC should remain the principal independent regulator that is responsible for oversight of the health and care system. It should:

- develop sector-specific approaches to registration and assessment, including:

    - describing 'what good looks like' through its assessment framework, monitoring and enforcement

    - taking into account the structure of commissioners, private health insurers and providers (as detailed in the previous review into CQC)

- set standards for the quality of health and care in co-ordination with NQB, ensuring that standards are aligned with the future strategic direction of NHS England and DHSC

- ensure all 5 questions of quality (safety, effectiveness, user experience - caring and responsive - and well led) are assessed, including use of resources

- assess:

    - how well providers (across sectors) are identifying risks in their systems

    - how well the risks are being controlled

    - what mechanisms are in place for improvement

CQC also needs to renew its focus on the role of governance, boards and accountability systems. It should specifically review commissioner and provider boards on their ability to:

- improve all aspects of quality of care
- effectively balance risks across organisations and wider health and care systems

For those (usually smaller) organisations where lack of governance structures may be more of an issue than among larger organisations, it should offer a more customised approach.

Where independence from and oversight of commissioners and providers of health and care is required, CQC should host those functions.

Recommendation 3: continue Health Services Safety Investigation Body's role as a centre of excellence for investigations and clarify the remit of any future investigations

Most investigations into safety incidents should continue to be managed within provider organisations and commissioners (ICBs), with support from regions where required, to ensure they are:

- mobilised quickly
- conducted with a high level of expertise
- rapidly resolved, where feasible, and lessons are learnt

NHS England, transferring to the new proposed structure within DHSC, should support excellence in investigation and learning throughout the health and care system.

HSSIB should continue to operate as a dedicated, expertise-led incident investigation facility that can be used in a responsive way to minimise the number of externally commissioned reviews and inquiries that might otherwise be required.

HSSIB should collaborate with DHSC (through NQB) to agree the scope of any investigations it carries out.

HSSIB should have a role advising and supporting best practice in local investigations. It should share learnings and retain its role in upskilling health organisations through its education function.

Recommendations arising from all HSSIB investigations should be considered as part of the clearing-house function of NQB (see 'Recommendation 1'). This should ensure a clear

distinction between HSSIB's patient safety investigations, and the wider leadership of patient safety investigations and policy by DHSC.

Consideration should be given to the role of HSSIB in:

- improving the quality of other investigations (for example, service reviews led by royal colleges or the Parliamentary and Health Service Ombudsman)
- ensuring that learning from recommendations of such investigations is co-ordinated

The review has considered whether the more complex investigations carried out by MNSI should be incorporated into HSSIB to strengthen expertise as part of the wider review that is to be conducted regarding the future of the MNSI programme. Although this could be a positive step in terms of creating a centre of excellence for investigations, the review recognises that such a transition - so soon after MNSI's move into CQC - could be disruptive and risk delays to some investigations being carried out.

The review has considered whether HSSIB itself should remain an independent organisation or move into CQC in order to further consolidate patient safety functions. In many industries, regulation and investigation are different functions[79], which would suggest a separation. At the same time, consolidation of HSSIB with CQC would:

- help to clarify roles
- enable a clear link between identifying poor performance and investigating its cause

It is therefore recommended that the functions of HSSIB should be transferred to CQC. It should continue to operate as a discrete branch within CQC and retain its independence for providers.

Recommendation 4: transfer the hosting arrangement of the Patient Safety Commissioner to MHRA, and broader patient safety work to a new directorate for patient experience within NHS England, transferring to the new proposed structure within DHSC

The original function of the Patient Safety Commissioner - to promote the safety of and enable the user voice to feed back on adverse impacts of medicines and medical products - should be hosted by MHRA, which has direct responsibility to monitor medicines and medical devices. This move would:

[79] For example, in the aviation sector, consider the AAIB and the Department for Transport.

- offer improved clarity about where responsibility for the voice of patients lies when it comes to the safety of medicines and medical devices

- build on MHRA's current work to capture adverse events more effectively (such as through use of technology)

The wider remit adopted by the Patient Safety Commissioner should be integrated into a new directorate for patient experience within NHS England (later transferring to the new structure within DHSC) to support improvements to patient safety and patient experience, including:

- patient, user and community engagement

- managing and learning from complaints

This should be reflected in a significantly enhanced profile for the patient voice and the introduction of a new board-level director of patient experience. The directorate should also take responsibility for advocacy support for people wishing to complain, which is currently carried out in local authorities.

It is notable that the executive team of NHS England (and providers within the system) lacks a director of customer experience or similar. This is in contrast with other large-scale consumer-focused organisations, which do not outsource their customer experience function.

A focus on patient and user safety and experience would:

- include a far simpler and more robust process to submit complaints and feedback about care (for example, using the NHS App)

- ensure that boards were better able to learn from complaints

- allow close working with CQC to ensure a common set of standards for patient or user experience (referred to within CQC as 'caring' and 'responsive' care)

The work could include building on the NHS Complaint Standards (developed by the Parliamentary and Health Services Ombudsman in partnership with stakeholders) to support organisations to proactively use feedback from complaints to improve services.

There should be consideration of formal support for those who have, or believe they have, suffered unsafe care.

The patient experience directorate in NHS England, transferring to the new proposed structure in DHSC should:

- have clear executive ownership
- become a central function of the organisation
- as such, directly impact policies governing the commissioning and provision of care

Recommendation 5: bring together the work of Local Healthwatch, and the engagement functions of integrated care boards (ICBs) and providers, to ensure patient and wider community input into the planning and design of services

The statutory functions of Local Healthwatch relating to healthcare should be combined with the involvement and engagement functions of ICBs to listen to and promote the needs of service users. This should incorporate PPGs and patient or user engagement teams in provider organisations. This will:

- ensure greater clarity and improved effectiveness in bringing wider patient, user and community inputs into care planning
- support clearer accountability from all organisations within an ICS to their local populations

Local patient and user engagement teams would be supported by the new patient experience directorate within DHSC.

The statutory functions of Local Healthwatch relating to social care (a very small proportion of the work of Local Healthwatch) should be transferred to local authorities in order to improve the commissioning of social care. The combined functions should:

- provide insights into the work of ICBs and local authorities (as commissioners), as well as strategic planning more widely
- support the co-design of services
- continue to be driven by the needs of local communities, operating locally at place level, while ensuring benefits of scale by influencing across an ICS-wide footprint

The strategic functions of Healthwatch England should be transferred to the new directorate for patient experience at DHSC. The directorate would have an explicit responsibility to:

- encourage feedback
- ensure a significant improvement to complaints functions across the system

This would allow the existing deep patient advocacy expertise of Healthwatch England and Local Healthwatch to have a greater impact, thanks to:

- closer alignment with the commissioning and provision of care
- greater emphasis being placed on the patient voice by DHSC, commissioners and providers

We have considered each of the 3 core strategic functions of Healthwatch England – see '5. Healthwatch England' in the previous section 'The 6 organisations under review'.

The current role of Healthwatch England to provide advice to the Secretary of State should move to the new patient experience directorate in DHSC.

The current obligation for Local Healthwatch to raise concerns about quality of care with CQC and ensure patient, user and community input into strategy and plans should change. There should instead be an obligation for ICBs (for healthcare) and local authorities (for social care) to be responsible for:

- listening to communities and users
- ensuring strategies and plans take into account patient, user and community input

This should allow for far more rapid resolution of areas of concern. CQC would explicitly test this in its assessment of ICSs.

It is recognised that, for this change to be meaningful and impactful - and to have the confidence of users and patients - DHSC, local authorities and all 42 ICBs would need to fully embrace the ethos, responsibility and imperative to listen to the voice of users. The rationalised and simplified structure locally should enable this to happen in a more meaningful way, while the creation of a patient experience directorate within DHSC should ensure a visible focus on patient and user experience in healthcare across the system.

To fully enact these functions, ICBs and local authorities will need to exploit the benefits offered by digital tools. These should be used to:

- capture and enable patient, user and community inputs
- build associated data and analytical capabilities to:
    - ensure robust outputs
    - enable accurate assessment of the views of disparate populations and users

As part of its wider responsibilities, a core function of CQC should be to assess whether every ICB and provider is listening to patients and users effectively, using existing local networks.

Recommendation 6: streamline functions relating to staff voice

There is a need to strengthen the importance of listening to and acting on staff voice, as identified in the recent publication of the National State of Patient Safety 2024, which highlighted the recent NHS Staff Survey results and the need for greater confidence in the system.

Staff should be supported and encouraged to share concerns about quality and safety as part of a data, evidence and learning-led culture that fosters improvement. The currently variable priority and quality of systems when it comes to supporting the freedom to speak up[80] needs to be addressed by organisations through the work of Freedom to Speak Up Guardians.

The functions of the National Guardian's Office could be more aligned with other staff voice functions in NHS England, such as the NHS England Freedom to Speak Up case management function (currently in the workforce, training and education directorate) and NHS England's own internal Freedom to Speak Up function. This would:

- ensure greater access by Freedom to Speak Up Guardians to resources such as data and insights
- strengthen and streamline the function by bringing together compliance against policy from an organisational perspective (currently under the remit of NHS England) and compliance with guardian training (currently the responsibility of the National Guardian's Office)
- reinforce the importance of listening to and acting on worker voice

Now that guardians have been established across providers, the responsibilities of the National Guardian for Freedom to Speak Up in the NHS and National Guardian's Office should be incorporated into providers. This means that the distinct role of National Guardian is no longer required.

[80] Martin G, Chew S, McCarthy I, Dawson J and Dixon-Woods M. 'Encouraging openness in health care: policy and practice implications of a mixed-methods study in the English National Health Service.' Journal of Health Services Research & Policy 2023: volume 28, issue 1, pages 14-24.

As part of its wider inspection responsibilities, a core function of CQC should be to assess whether every commissioner and provider has effective Freedom to Speak Up functions, with the right skills and training.

Recommendation 7: reinforce the responsibility and accountability of commissioners and providers in the delivery and assurance of high-quality care

Ultimately, it is only the providers of care and commissioners (including NHS England and DHSC) who can improve quality of care. Far greater emphasis and attention should be given to how:

- individual providers (NHS trusts, primary care providers including GPs and dentists, private providers, and domiciliary and residential social care providers) deliver high-quality care
- their commissioners (DHSC, NHS England and ICBs, private health insurers and local authorities) commission on the basis of all dimensions of quality (including use of resources) and hold providers to account

There is a need to clarify governance and accountability throughout the system with a much stronger role and accountability for boards.

DHSC, NHS England, commissioners in local authorities and ICBs and providers should demonstrate clear and aligned governance and accountability structures including:

- role modelling of positive actions from top to bottom
- continual measurement
- detailed appraisals
- reward mechanisms
- a commitment to learning

Commissioners and providers should operate effective quality and safety management systems that cover all aspects of quality, including efficiency or use of resources and people management. Examples of quality management systems from other providers and sectors could be built on.

Commissioners and providers should be incentivised to engage in large-scale improvement activities that include more systematic sharing of best practice and support standardisation of processes and practices to:

- maximise the quality of care delivery
- minimise harm
- improve operational effectiveness
- manage costs

These activities need to be resourced and co-ordinated appropriately, building on national and international evidence about how this can be done[81]. In order to further incentivise high-quality care, Quality Accounts (annual reports about the quality of services offered by healthcare providers) could be re-energised.

National audits and improvement programmes are all internationally recognised as effective tools for evaluating and improving the quality of care delivery, including safety. Some prime examples are the:

- GIRFT initiative
- Sentinel Stroke National Audit Programme (SSNAP)
- NAPs within the Royal College of Anaesthetists

They could and should be used far more by the boards of commissioners and providers to identify opportunities for improvement.

The skills and capabilities of commissioner and provider leadership teams need particular attention - specifically their ability to use effective management processes to maximise quality of care and allocate resources accordingly by:

- reviewing complex data
- meaningfully listening to patient and user feedback
- co-designing services
- effectively questioning care givers and managers

The above applies to social care as well as healthcare. In social care, particularly, a more strategic approach to commissioning is required, including better use of framework agreements (with fewer providers) and widespread use of outcomes-based

[81] Martin G and Dixon-Woods M. 'Collaboration-based approaches.' 2022: Cambridge University Press.

commissioning. This should drive greater quality of care for individuals, and allow for greater levels of innovation in providers.

Relative roles of different organisations and accountability structures within NHS England are being considered as part of the revised operating model described in the 10 Year Health Plan, and through the integration of NHS England into DHSC.

Recommendation 8: technology, data and analytics should be playing a far more significant role in supporting the quality of health and social care

Technology - in particular the use of AI - has the potential to significantly improve the safety, effectiveness and responsiveness of care delivery, and the use of resources. This will potentially result in major gains in health outcomes, life expectancy and quality of life.

There are multiple examples of where technology is already improving safety and wider quality of care. These include the use of:

- digital social care records that allow, for example, linked data sets to improve access to reablement services
- chat bots to provide advice and direct patients and users to the most appropriate service
- falls prevention and detection technology
- data systems to identify and prevent drug interactions
- automated monitoring of vital signs such as blood pressure and oxygen levels
- rapid analysis of electrocardiograms (ECGs - heart traces) and cardiotocography (CTGs - monitoring a baby's heart rate in pregnancy)
- automated diagnosis of imaging and pathology to rapidly identify cancers and other problems
- robotics for surgery

Technology can improve safety, outcomes and user experience - as well as the efficiency of care delivery by freeing up resources to enable higher volumes of effective care to be delivered.

Technology can also enable the user voice - for example, allowing for feedback to be given through the NHS App or SocialQR codes. A central repository for all patient and user experience data would provide real-time feedback to inform policy and service design.

There is a wealth of data that is produced and collated by the NHS. Every contact an individual has in a primary care and acute setting is recorded, and improvements to data quality could and should be made, particularly across mental health and community care. This should be used to far greater effect to improve safety and wider quality of care.

For instance, taking the data that the NHS already collects across primary and secondary care and linking it together, in a safe and ethical manner, at the patient level would help commissioners to identify at-risk population cohorts. Neighbourhood teams would be equipped to engage, enrol, assess and manage individuals, based on personalised care plans to meet their needs, which would optimise interventions and reduce avoidable deaths.

NHS longitudinal data at patient, provider and ICB level could be used to evaluate safety and quality in providers based on a multitude of demand (such as population health) and supply (such as funding, staffing or models of care) side variables.

There is great potential to support real-time data on all aspects of quality, including safety, by:

- providing visibility of existing data sets, linked at the appropriate organisation level in adherence with data protection principles
- aligning this approach with recommendations from the Sudlow Review
- building on the federated data platform

Advanced analytics and AI would enable far greater insights than are humanly possible into where and why poor-quality care is happening - and potentially at significantly lower cost. To achieve this, data needs to be high quality, and easily shareable and accessible by all organisations, patients and users, and the wider public. This needs to be supported by investment in technology.

The 10 Year Health Plan refers to the infrastructure required. Aligning recommendations to the Sudlow Review and building on the federated data platform could provide real-time data on all aspects of quality.

Regulators will also need to consider how to regulate new technologies and should compare the outcomes with current levels of quality or safety, not hypothetical 100% safety.

While there is enormous untapped technological potential across health and care delivery and management, it must be clear where responsibility sits for driving forward this agenda. This is referred to in the 10 Year Health Plan. The plan also addresses the need for significant investment in digital and data capacity, alongside a strategy for using technology effectively.

Recommendation 9: there should be a national strategy for quality in adult social care, underpinned by clear evidence

Adult social care functions differently to healthcare. A significant proportion of social care is organised privately and paid for by self-funders, while publicly commissioned care is the responsibility of local authorities.

However, within this complex delivery chain, there is an opportunity to set out 'what good looks like' (building on work by NICE, SCIE and CQC) and:

- develop and agree a set of metrics to assess quality of care (outputs and outcomes rather than inputs)
- agree how to disseminate best practice
- ensure appropriate governance structures, systems and processes are in place across all providers

Consideration should be given to consistent data sets, which all social care providers should collate to ensure a clear and consistent approach to data management across health and social care.

Further opportunities to ensure effective commissioning of adult social care, as set out in the previous review into the operational effectiveness of CQC, should also be considered.

A national strategy for quality of social care will need to align with or be embedded into the Casey Commission.

Proposals for NHS Resolution

Outside of these recommendations, the review has considered the role of NHS Resolution and recommends it continues with its role as already established.

However, more work needs to be done to ensure lessons learnt from its reviews are shared more widely, and that this is considered within the remit of a revamped NQB.

Next steps

The 10 Year Health Plan has set out a vision and plan for a health and care system that enables a step change in the quality of care to improve health outcomes, life expectancy and quality of life, while also reducing inequalities in health. Maximising the use of existing resources will require far greater consideration of:

- effectiveness
- user experience
- the management of care delivery

In turn, this will require a greater focus on:

- prevention
- moving to improved primary, community, mental health and social care to provide improved care for those with long-term conditions
- far more substantive adoption of data and digital tools

A number of areas have been highlighted in the 10 Year Health Plan and will need to be taken forward in the implementation of the plan. These are:

- being clear how management and governance mechanisms within commissioners and providers need to evolve to ensure robust governance structures and systems
- considering how more standardised operating processes and models of care will be developed and implemented across all providers
- detailing how a rapid acceleration in data and technology can be realised to support safer, higher-quality care

Outside of the 10 Year Health Plan, other areas have been raised for longer-term consideration. These include:

- consolidating the investigatory functions of the royal colleges, medical examiners and professional regulators into a wider investigatory function and/or organisation
- the role of national clinical directors in setting standards and agreeing which data or metrics to use
- the role of MHRA and NICE in assessing new technology

The review is aware that primary and secondary legislation will need to be changed to enact some of the recommendations, and further work to develop and implement the changes will be required.

DHSC should continue to explore options to review its wider arm's length body landscape to identify areas of duplication, gaps and opportunities for transformation, beyond the 6 organisations looked at by this review. This could include a review of all regulatory bodies to ensure there is a balance between robust regulation, and commissioners and providers taking responsibility for the provision of high-quality care. This should apply to all aspects of quality of care - not just safety.

Improving safety and wider quality of care should be the primary remit of any health and care system. There is an opportunity to allocate resources to the interventions that will maximise life expectancy and quality of life - and ensure high-quality care through more robust commissioning and management of care delivery.

It is entirely feasible to see a step change improvement in outcomes of care - the opportunity to act should be grasped.

Other regulations, requirements and roles

Throughout the course of this review, the very large number of requirements, regulations, roles and organisations that purport to address safety have been raised. These include:

- the large number of organisations highlighted in this review
- new roles that have emerged over the last few years - for example, the guardians of safe working hours
- the multiple levels of 'checkers' - for example, the safeguarding teams in ICBs
- the extensive mandatory training for all staff, which is often out of kilter with the role and its potential risks - for example, extensive fire safety training for GPs
- the extensive paperwork required to be completed by staff - for example, lengthy forms for psychiatrists to complete after mental health consultations

It is not clear that a robust cost-benefit analysis has been conducted before introducing these changes - but what is clear is that they take frontline staff away from looking after patients and users. It is suggested that further work is carried out to quantify the cost-benefit of all of these, led by NQB.

Appendix 1: contributions to the review

Over the course of this review, we received valued contributions from the following people and organisations.

CEOs and leaders of the 6 bodies being reviewed

We spoke to leaders and CEOs of:

- Local Healthwatch
- CQC
- Healthwatch England
- HSSIB
- the National Guardian for Freedom to Speak Up in the NHS and the National Guardian's Office
- NHS Resolution
- the Patient Safety Commissioner and the Office of the Patient Safety Commissioner

Leaders of organisations involved in patient safety

We spoke to leaders of the following patient safety organisations:

- Academy of Medical Royal Colleges
- General Osteopathic Council
- General Medical Council
- General Optical Council
- General Pharmaceutical Council
- General Dental Council
- Health and Care Professions Council
- Local Government and Social Care Ombudsman
- MHRA

- NHS Confederation
- NHS England
- NHS Providers
- Office of the Chief Coroner
- Parliamentary and Health Services Ombudsman
- Professional Standards Authority
- Royal College of Anaesthetists
- Royal College of Emergency Medicine
- Royal College of General Practitioners
- Royal College of Obstetricians and Gynaecologists
- Royal College of Ophthalmologists
- Royal College of Pathologists
- Royal College of Physicians
- Royal College of Physicians of Edinburgh
- Royal College of Psychiatrists
- Royal College of Radiologists
- Royal College of Surgeons of Edinburgh
- Royal College of Surgeons of England

We also consulted a number of:

- leaders from adult social care providers
- senior leaders at NHS foundation trusts
- leaders from private providers
- users and user groups including those harmed by poor care

Finally, the review joined a meeting of the NQB to receive input.

Experts in safety

We spoke to the following safety experts:

- Professor Anthony J Avery OBE
- Lord Ara Darzi, Co-Director of the Institute of Global Health Innovation and the National Institute for Health and Care Research (NIHR) Imperial Patient Safety Translational Research Centre, Imperial College London
- Sir Bernard Jenkin MP, Chair of the Public Administration Select Committee between 2010 and 2015, which recommended the creation of HSSIB, and Chair of the Joint Committee on the Draft Health Services Safety Investigations Bill in 2018, which conducted the pre-legislative scrutiny of the draft legislation that is now enacted in part 4 of the Health and Social Care Act 2022
- Dr Bill Kirkup, independent investigator
- Professor Carl Macrae, Professor of Organisational Behaviour and Psychology, Nottingham University Business School, University of Nottingham
- Charles Vincent, Professor of Psychology, University of Oxford
- Sir Cyril Chantler
- Donna Ockenden, Chair of the Independent Review of Maternity Services, Nottingham University Hospitals NHS Trust
- Professor Ellie Lindsay, Founder of the Lindsay Leg Club Foundation
- The Rt Hon Jeremy Hunt MP, Co-Chair of the All-Party Parliamentary Group on Patient Safety
- Sir Liam Donaldson, Chair of the NHS North East and North Cumbria ICB and World Health Organization (WHO) Special Envoy for Patient Safety
- Professor Murray Anderson-Wallace JP
- Dr Nicola Byrne, National Data Guardian for health and social care in England
- Peter Howitt and Melanie Leis, Institute of Global Health Innovation, Imperial College London

- Dr Rebecca Rosen and Sarah Reed, the Nuffield Trust
- Sir Robert Francis KC

Review advisory board

The following members of the advisory board supported this review:

- Adam Doyle, Chief Executive, Sussex ICB
- Professor Andy Hardy, Chief Executive, University Hospitals Coventry and Warwickshire NHS Trust
- Angela Hillery, Group Chief Executive, Northampton Healthcare NHS Foundation Trust and Leicestershire Partnership NHS Trust
- Cath Roff MBE, Project Director, Adult Social Care Transformation, Leeds City Council
- Cathy Elliott, Chair, West Yorkshire ICB and Deputy Chair, West Yorkshire Health and Care Partnership
- Dr Chris Streather, Medical Director and Chief Clinical Information Officer, NHS England London Regional Team
- Clare Panniker, Regional Director, East of England NHS England
- David Flory, joint Chair of Liverpool University Hospitals NHS Foundation Trust and Liverpool Women's NHS Foundation Trust
- David Hare, Chief Executive, Independent Healthcare Providers Network
- Dr David Selwyn, Chief Executive, Sherwood Forest Hospitals NHS Foundation Trust
- Dominic Hardisty, Chief Executive, Avon and Wiltshire Mental Health Partnership NHS Trust
- Ian Smith, Chair, Surrey Heartlands ICB
- James Tugendhat, Chief Executive, HC-One
- Sir Jim Mackey, Chief Executive, Newcastle Hospitals NHS Foundation Trusts
- Dr Kathy McLean, Chair of University Hospitals Derby and Burton, and Nottingham and Nottinghamshire ICB

- Len Richards, Chief Executive, Mid Yorkshire Teaching NHS Trust
- Lena Samuels, Chair, North London NHS Foundation Trust and Chair, Hampshire and Isle of Wight ICB
- Lesley Watts, Chief Executive, Chelsea and Westminster Hospital NHS Foundation Trust
- Mark Cubbon, Chief Executive, Manchester University NHS Foundation Trust
- Professor Martin Green, Chief Executive, Care England
- Professor Mary Dixon-Woods, Director of THIS Institute and the Health Foundation, and Professor of Healthcare Improvement Studies in the Department of Public Health and Primary Care at the University of Cambridge
- Matthew Winn, Chief Executive, Cambridgeshire Community Services NHS Trust, and Norfolk Community Health and Care Trust
- Professor Mike Holmes, Partner, Haxby Group and Chair, Nimbuscare York
- Sam Allen, Chief Executive, North East and North Cumbria ICB
- Sim Scavazza, Interim Chair, Buckinghamshire, Oxfordshire and Berkshire West ICB
- Simon Williams, Director of Social Care Improvement, Local Government Association
- Sue Symington, Chair, Humber and North Yorkshire ICB
- Professor Vic Rayner OBE, Chair, Care Provider Alliance
- Vincent Sai, Group Chief Executive and Partner, Modality Partnership

Other contributors

The review received information from a number of other users, patients or organisations, including:

- Andrea Kinkade, CEO Lifeways
- AvMa
- Care Rights UK
- Cath Holmes, Director of Care Quality, Anchor

- Cygnet Health
- Dawn Hodgkins, Director of Regulation, Independent Healthcare Provider Network
- Local Government Association
- Making Families Count
- Merope Mills and Paul Laity, parents of Martha Mills and patient safety campaigners
- Michael Roberts, former CEO of Safer Care Victoria and Managing Director of UCLPartners
- NICE
- Patient Safety Learning
- Picker
- Robyn Davis, parent of Orlando Davis and patient safety campaigner
- Samantha Smith, parent and patient safety campaigner
- Spire Healthcare
- Sue Sheath, Director of Regulation and Quality Improvement, Barchester Healthcare
- The Guardian Service
- WCS Care

Appendix 2: definition and impact of quality (including safety) of care

While there is no universally agreed definition of quality in health systems, it is recognised as multi-dimensional. There are a range of definitions in use in health and care systems across the world including:

- WHO defines quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes, based on evidence-based professional knowledge"[82]

- the Institute for Medicine (2001) emphasises that quality care should be safe, effective, patient-centred, timely, efficient and equitable[83]

- CQC uses 5 questions or 'domains' to assess the quality of health and social care services - safe, effective, caring, responsive to people's needs and well led[84]

Different definitions typically include safety, effectiveness and patient or user experience, as well as accessibility, equity and efficiency. Specifically:

- safe, so those who receive care are not harmed avoidably in the process

- effective, so evidence-based care is provided to those who need it, while low-value care is minimised

- positive patient or user experience (also referred to as 'personalised care', 'caring', responsive care' or 'patient-centred care'), so people have a good experience of care that is responsive to and respectful of their needs, values, preferences and cultural background

- accessible and timely, so people can use services when they need to do so

- equitable, so care does not vary because of characteristics such as geography, gender, socio-economic status or ethnicity

- efficient and well managed, so the available resource is used in the best possible way to maximise outcomes and avoid waste

[82] WHO. Health topics - Quality of care. 2025.
[83] Institute of Medicine's Committee on Quality of Health Care in America. 'Crossing the quality chasm: a new health system for the 21st century.' 2001. Washington DC: National Academies Press.
[84] CQC. How we do our job - The five key questions we ask. 2022.

CQC considers the management and leadership of care (referred to as 'well led') alongside safety, effectiveness and user experience. Well led care refers to robust governance and management systems that ensure and improve quality of care, as well as effective use of resources to maximise benefits to patients and users.

For the purpose of this review, quality of care is defined as including safety, effectiveness and user experience, while recognising the importance of equity and the management or leadership of care. Access is assumed to be part of all of these.

Safety

'Safety' refers to the avoidance of unintended or unexpected harm to people during the provision of healthcare. This recognises that ‘zero harm’ is not feasible - some harms cannot be avoided, such as adverse reactions to drugs[85].

WHO defines patient safety as:

> "the absence of preventable harm to a patient and reduction of risk of unnecessary harm associated with health care to an acceptable minimum."

Harm[86] is:

> “preventable if it occurs as a result of an identifiable, modifiable cause and its future recurrence can be avoided by reasonable adaptation to a process, or adherence to guidelines.”

The NHS Patient Safety Strategy, defines patient safety as:

> “maximising the things that go right and minimising the things that go wrong for people experiencing healthcare.”

Around half of patient harm is estimated to be preventable and it occurs in approximately 6% of healthcare interactions[87], with the majority reported as 'low harm'. Unsafe care may

[85] Panagioti M, Khan K, Keers R N, Abuzour A, Phipps D, Kontopantelis E and others. 'Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis.' BMJ 2019: volume 366, article l4185.
[86] Panagioti M, Khan K, Keers R N, Abuzour A, Phipps D, Kontopantelis E and others. 'Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis.' BMJ 2019: volume 366, article l4185.
[87] Panagioti M, Khan K, Keers R N, Abuzour A, Phipps D, Kontopantelis E and others. 'Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis.' BMJ 2019: volume 366, article l4185.

be linked to errors, deviations, omissions, accidents and, on rare occasions, intentional harm[88].

Harm can happen in all health and care settings and, while significant harm can and does occur, it is relatively rare in the context of NHS and social care activity. It is hard to quantify the number of deaths due to medical error[89]. A study from 2015 estimated that 3.6% of deaths in hospitals had a 50% probability of being preventable but this included a wide definition[90]. This aligns with other studies that reviewed inpatient deaths and asked physician reviewers to judge preventability, which was typically in the range of 1% to 3%[91] [92].

The Institute of Global Health Innovation at Imperial College London and Patient Safety Watch's patient safety country ranking system uses 4 indicators to rank countries. These indicators are:

- maternal mortality
- treatable mortality
- adverse effects of medical treatment
- neonatal disorders

It placed the UK 21st out of 38 countries in 2023, though the differences between the top 23 countries are marginal. The analysis found that, if the UK had performed at the level of the top decile of OECD countries, there could have been 780 fewer deaths per year due to unsafe care[93].

Examples of harm include:

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[88] Dixon-Woods M. 'Report to the Thirlwall Inquiry: addressing part C of the terms of reference'. INQ0102624 - Expert report of Professor Mary Dixon-Woods. 2024.
[89] Shojania KG and Dixon-Woods M. 'Estimating deaths due to medical error: the ongoing controversy and why it matters.' BMJ Quality & Safety 2017: volume 26, issue 5, pages 423-428.
[90] Hogan H, Zipfel R, Neuburger J, Hutchings A, Darzi A, Black N and others. 'Avoidability of hospital deaths and association with hospital-wide mortality ratios: retrospective case record review and regression analysis.' BMJ 2015: volume 351, article h3239.
[91] Hayward RA and Hofer TP. 'Estimating hospital deaths due to medical errors: preventability is in the eye of the reviewer.' JAMA 2001: volume 286, issue 4, pages 415–420.
[92] Manaseki-Holland S, Lilford RJ, Bishop JR and others. 'Reviewing deaths in British and US hospitals: a study of two scales for assessing preventability.' BMJ Quality & Safety 2016: volume 26, issue 5.
[93] Illingworth J, Shaw A, Fernandez Crespo R, Leis M, Fontana G, Howitt P and Darzi A. 'Global State of Patient Safety 2023.' Imperial College London: 2023. It should be noted that this analysis includes 'treatable mortality' and so broadens the scope of what is traditionally viewed as patient safety by considering causes of death that can mainly be avoided through timely and effective healthcare interventions, including secondary prevention, screening and treatment. We did not use figures from the National State of Patient Safety 2024 because this report does not include a breakdown of the causes of preventable deaths. We wanted a number that only reflects deaths caused by unsafe care.

- prescribing errors, dispensing errors or side effects from medications (237 million per year[94] out of a total of 1.2 billion prescription items dispensed in the community each year). A significant proportion of these (approximately 92 million medication errors) occur in care homes due to incorrect administration[95]

- diagnostic errors, accounting for an estimated 60% of patient safety incidents in primary care[96]

- accidents, with over 290,000 patient accidents such as slips, trips or falls reported in the NHS in financial year 2021 to 2022

- never events (for example, wrong site surgery) - around 390 never events occurred in financial year 2023 to 2024[97]

Underlying reasons for the above are complex but can be due to:

- lack of agreed or standardised ways of working

- lack of infrastructure - including a lack of appropriate equipment or staff for the level of care being delivered[98]

- sub-scale units with less activity facing certain structural challenges (for example, fewer staff with the necessary experience to build expertise or less specialist provision in a fragmented service model), which may lead to delays in care and harm patients[99]

- poor monitoring or reviewing of care processes (which caused 21% of incidents in the 2021 to 2022 financial year)

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[94] Elliott R, Camacho E, Campbell F and others. 'Prevalence and economic burden of medication errors in the NHS in England: rapid evidence synthesis and economic analysis of the prevalence and burden of medication error in the UK.' Policy Research Unit in Economic Evaluation of Health and Care (EEPRU) Interventions 2018: EEPRU Research Report 057. Universities of Sheffield and York.
[95] Elliott RA, Camacho E, Jankovic D and others. 'Economic analysis of the prevalence and clinical and economic burden of medication error in England.' BMJ Quality & Safety 2021: volume 30, issue 2, pages 96-105.
[96] Cheraghi-Sohi S, Holland F, Singh H and others. 'Incidence, origins and avoidable harm of missed opportunities in diagnosis: longitudinal patient record review in 21 English general practices.' BMJ Quality & Safety 2021: volume 30, issue 12, pages 977-985.
[97] See page 7 of: NHS England. Provisional Never Events 2023/24 data: 1 April 2023 – 31 March 2024. 2023.
[98] Kraindler J, Gershlick B and Charlesworth A. 'Failing to capitalise: capital spending in the NHS.' Health Foundation: 2019. This research estimates the maintenance backlog and additional capital funding needed to deliver high-quality care. Related Health Foundation-funded research by the Health Services Management Centre at the University of Birmingham, 'Restricted capital spending in the English NHS: a qualitative enquiry and analysis of implications' (PDF, 657KB), referenced in the former report, interviewed directors and managers at NHS trusts, revealing serious concerns that spending restrictions are impacting service efficiency and, in several cases, the quality of patient care. The latter research highlights the impact of equipment shortages and failures, and reliance on ageing diagnostic equipment.
[99] Nuffield Trust. 'Rethinking acute medical care in smaller hospitals.' 2018.

- issues with patient access, admission, transfer and discharge (which caused 11% of incidents in the 2021 to 2022 financial year)

- lack of, or fragmented, data to identify side effects of interventions - such as the use of vaginal mesh in gynaecological surgery

- poor training - a study of 29 care homes in the West Midlands found a significant reduction in falls, severe pressure ulcers and UTIs following the delivery of informed training and staff support[100]

Between 2010 and 2020, there was a significant increase in the number of incidents reported by NHS staff (from 1.2 million to 2.2 million per year out of a total of 600 million interactions) against a backdrop of wider improvements in the quality of care, which suggests a more transparent and open reporting culture[101]. Most of the reported incidents caused no harm (71%) or low harm (26%).

There were improvements in safety in the years leading up to the COVID-19 pandemic. The proportion of patients recorded as 'harm free' - in that they did not have one of 4 'harms' (pressure ulcers, falls, UTIs in patients with a catheter or VTEs) on a single day - increased between 2013 to 2017 from 93.1% to 94.1%[102].

Over the last 5 years, progress has slowed in some areas. This reflects in part the disruption caused by the pandemic. For example, previous reductions in hospital-acquired C. difficile infections have begun to rise again[103] and rates of VTE-related deaths have also risen, since they fell to their lowest rate in financial year 2018 to 2019 and peaked during the COVID-19 pandemic in 2020 to 2021[104] - this was partly related to the fact that COVID-19 infection increases the risk of thromboembolic events[105].

Other safety-related measures suggest progress has been maintained. For example, the number of inpatient hip fractures continues to decline nationally. The number of suicides of

[100] Damery S, Flanagan S, Jones J and Jolly K. 'The effect of providing staff training and enhanced support to care homes on care processes, safety climate and avoidable harms: evaluation of a care home quality improvement programme in England.' International Journal of Environmental Research and Public Health 2021: volume 18, issue 14, article 7581.
[101] Calculated from monthly data in: Illingworth J, Shaw A, Fernandez Crespo R, Leis M, Howitt P, Durkin M, Neves AL and Darzi A. 'National State of Patient Safety 2022: what we know about avoidable harm in England.' Imperial College London: 2022.
[102] DHSC. Independent investigation of the National Health Service in England: Technical Annex. 2024. Statistical significance not explicitly stated.
[103] DHSC. Fingertips - Public health profiles - C. difficile infection rates. 2024.
[104] NHS England. NHS Outcomes Framework Indicators, April 2024 release - 5.1 Deaths from venous thromboembolism (VTE) related events within 90 days post discharge from hospital. 2024.
[105] Sutanto H and Soegiarto G. 'Risk of thrombosis during and after a SARS-CoV-2 infection: pathogenesis, diagnostic approach, and management.' Hematology Reports 2023: volume 15, issue 2, pages 225-243.

mental health service users, including inpatients, has shown steady improvement[106]. Data from NHS England's national patient safety team shows that, where there is focused work in areas covered by the NHS Patient Safety Strategy, safety is being improved.

The impact of patient harm is profound. One study of patients and families in the USA found that they experience psychological, physical, financial and social harms because of medical errors. These can persist for decades, leaving "psychological scars" that are exacerbated by[107]:

- a lack of transparency
- poor error management
- ineffective communication

Moreover, patient harm also contributes to significant economic impact - according to NHS England, improving patient safety could save £100 million per year in care costs. In addition, payments for clinical negligence in financial year 2023 to 2024 equated to over £2.8 billion.

Effectiveness

Effective care provides evidence-based healthcare services to those who need them. This is a broad term and there are very many examples of where ineffective care results in poor outcomes for patients with impact on their:

- quality of life
- day-to-day functioning
- life expectancy

The impact of ineffective care is significantly greater than the impact of unsafe care.

Effective care spans the following areas.

[106] See: Nuffield Trust. Suicide in mental health service users. 2024. And: The University of Manchester. National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH) - Annual report 2023: UK patient and general population data 2010-2020. 2023.
[107] Ottosen MJ, Sedlock EW, Aigbe AO, Bell SK, Gallagher TH and Thomas EJ. 'Long-term impacts faced by patients and families after harmful healthcare events.' Journal of Patient Safety 2021: volume 17, issue 8, article e1145-e1151.

Prevention of ill-health

Poor health status resulted in 81,792 avoidable deaths in 2022 due to preventable conditions. A 2018 report found that approximately 14 million people in England live with one or more long-term health conditions[108]. Much of the historic and projected growth is in conditions such as hypertension, diabetes, anxiety and depression, and chronic pain[109]. Heart disease is the leading cause of death and is related to high cholesterol, air pollution, smoking, being overweight and obesity – much of which could be prevented.

There are an estimated 12 million people with obesity in England, contributing to 31,000 deaths per year. Obesity rates in adults increased from 23% in financial year 2015 to 2016 to 26% in financial year 2022 to 2023[110]. Over 60% of adults are classified as overweight or obese[111].

While many of the underpinning drivers of ill health are beyond the scope of the NHS, there remains considerable opportunity to ensure more consistent delivery of high-quality care.

There are over 26.8 million people (59% of the population) with low-density lipoprotein cholesterol over 3.5 millimoles per litre (mmol/L) who are currently untreated. Reducing everyone to below 2.5mmol/L would prevent 810 deaths a year from a heart attack and 1,200 a year from a stroke. Reducing everyone's cholesterol by 1mmol/L would reduce CVD deaths by 25%[112].

Over half a million more people (in England) are at risk of developing type 2 diabetes in a year. The NHS Diabetes Prevention Programme has been shown to cut the risk of developing type 2 diabetes by more than a third among participants who completed the programme. Since its launch in June 2016, 1.6 million people have been referred and, of these, just under half have attended an initial assessment[113].

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[108] Stafford M, Steventon A, Thorlby R and others. 'Briefing: understanding the health care needs of people with multiple health conditions.' The Health Foundation: 2018. For a definition of the term 'multiple long-term health conditions', see also: NIHR. 'What we do - Multiple long-term conditions research.' 2025.
[109] Watt T, Raymond A, Rachet-Jacquet L and others. 'Health in 2040: projected patterns of illness in England.' The Health Foundation: 2023.
[110] Office for Health Improvement and Disparities (OHID). Update to the Obesity Profile on Fingertips. 2024. See specifically: 'Obesity Profile: short statistical commentary May 2024'.
[111] OHID. Obesity Profile update: May 2023. 2023. See: 'Obesity Profile: short statistical commentary May 2023'.
[112] Carnall Farrar. 'Value in health: improving productivity, quality and prevention in the NHS.' 2025.
[113] Valabhji J, Barron E, Bradley D, Bakhai C and others. 'Early outcomes from the English National Health Service Diabetes Prevention Programme.' Diabetes Care 2020: volume 4, issue 1, pages 152-160.

Every 4 minutes, someone dies from cancer in the UK and 1 in 2 people will develop cancer during their lifetime. There were 37,000 avoidable deaths from cancer in 2022[114]. Smoking and/or being overweight or obese are the biggest causes of cancer[115].

Uptake of vaccination and screening programmes

Vaccinations reduce the likelihood of developing serious illnesses - for example, 99.8% of cervical cancer cases are preventable with the HPV vaccination. HPV vaccination prevented an estimated 687 cervical cancers by mid-2020[116], but vaccination in 13 to 14-year-old girls in financial year 2022 to 2023 varied from 51.3% in the most-deprived decile to 73.6% in the least-deprived decile[117].

Breast cancer screening can prevent about 1,300 breast cancer deaths annually[118] - however, there are still around 2 million eligible women who did not attend a mammogram in the last 3 years[119].

Care for those with long-term conditions to prevent complications

Failure to provide appropriate treatment also causes significant morbidity. In the UK, 4.4 million people are estimated to have either type 1, type 2 or rarer forms of diabetes and a further 1.2 million are estimated to have undiagnosed type 2 diabetes. In England, only 47% of those with type 1 diabetes and 62% of those with type 2 diabetes received the 8 NICE recommended care processes for people with diabetes in 2023 to 2024. The variation in delivering effective care between GPs is large with the worst-performing GP practice only providing recommended care to 1.8% of their patients with type 2 diabetes[120].

There are 1.8 million people with HbA1c (glycated haemoglobin or blood glucose) levels higher that the NICE-recommended treatment target, which is a marker of poorly managed

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[114] ONS. Causes of death - Dataset: Avoidable mortality in England and Wales. 2024. See: '2022 edition of this dataset' and go to Table 1 ('Worksheet 1: Age-standardised avoidable mortality rates by sex and cause, England and Wales: 2001 to 2022') for the total number of deaths caused by neoplasms in England in 2022.
[115] Cancer Research UK. Causes of cancer - Smoking, tobacco and cancer and Causes of cancer - Obesity, weight and cancer - How does obesity cause cancer? 2025.
[116] Falcaro M, Soldan K, Ndlela B and Sasieni P. 'Effect of the HPV vaccination programme on incidence of cervical cancer and grade 3 cervical intraepithelial neoplasia by socioeconomic deprivation in England: population based observational study.' BMJ 2024: volume 385, article e077341.
[117] DHSC. Fingertips - Public health profiles - Population vaccination coverage: HPV vaccination coverage for two doses (13 to 14 years old) (Female). 2023.
[118] Marmot MG, Altman DG, Cameron DA, Dewar JA, Thompson SG and Wilcox M. 'The benefits and harms of breast cancer screening: an independent review.' British Journal of Cancer 2013: volume 108, issue 11, pages 2,205-2,240.
[119] NHS England. Breast Screening Programme, England, 2022-23. 2024. See: 'Breast Screening Programme England - 2022-23 - Data Tables' and go to 'Table 1: Summary statistics on breast cancer and the NHS Breast Screening Programme'.
[120] DHSC. Fingertips - Public health profiles - Diabetes - Care processes. 2024.

diabetes[121]. Poor care increases the risk of complications. In 2022, 1.9 million people suffered complications including[122]:

- amputations (approximately 9,500 per year)
- strokes (approximately 48,000 per year)
- heart attacks (approximately 34,000 per year)
- heart failure (approximately 155,000 per year)

Poorly managed diabetes results in approximately 7,000 deaths per year[123].

There are an estimated 6.4 million people living with CVD in England, contributing to around 143,000 deaths per year (around a quarter of all deaths). An estimated 30% of adults have high blood pressure and most are not receiving effective treatment. Around 50% of heart attacks and strokes are associated with high blood pressure[124].

There are 2.7 million people living with chronic kidney disease in England, contributing to an associated 40,000 to 45,000 deaths per year. Of these, 18% remain undiagnosed and 32% of patients with chronic kidney disease at stages 3 to 5 are not optimally treated. This led to 29,580 patients on dialysis and 3,000 patients receiving a kidney transplant in 2021[125].

Chronic leg disease can result in significant morbidity from leg ulcers where, again, there is considerable variation in the effectiveness of care given. Leg ulcers are half as likely to recur at 24 to 48 weeks when effective care is given[126]. Generally, improvements in wound care - for example, through minimising variation - could generate a net benefit of more than £14 billion over 30 years[127].

In England, there are an estimated 826,000 people living with dementia, with an associated 62,000 deaths per year. Over 35% of those living with dementia are undiagnosed. Just 6% of eligible patients are currently receiving treatment[128].

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[121] DHSC. Fingertips - Public health profiles - HbA1C: IFCC-HbA1c <= 58 mmol/mol in patients with diabetes without frailty (denominator incl. PCAs). 2024.
[122] Diabetes UK. 'Diabetes is Serious - recovering diabetes care: preventing the mounting crisis (PDF, 8.44MB)'. 2022. These statistics are calculated from per week figures on page 9 of the report.
[123] Diabetes UK. 'Diabetes is Serious - diabetes care: is it fair enough?' (PDF, 17.3MB). 2023.
[124] British Heart Foundation. Heart statistics - Key statistics factsheets. See 'BHF Statistics Factsheet – England' (PDF, 883KB). 2025.
[125] Carnall Farrar. 'Value in health: improving productivity, quality and prevention in the NHS.' 2025.
[126] Lindsay E, Renyi R, Bawden R and others. 'The role of social models of care in wound management' (PDF, 987KB). 2018: The Lindsay Leg Club Foundation.
[127] Kent Surrey Sussex Academic Health Science Network (KSS) Insights. 'Health impact assessment: National Wound Care Strategy Programme' (PDF, 746KB). 2020.
[128] Carnall Farrar. 'Value in health: improving productivity, quality and prevention in the NHS.' 2025.

Ineffective community-based care is a particular problem for older people, resulting in more older people being admitted to hospital. People with frailty are more likely to be admitted to hospital, even for minor conditions (such as falls), and are at higher risk of longer stays (20% of all people with frailty are admitted as an emergency stay lasting more than 21 days). This, in turn, decreases their mobility and independence and, therefore, their life span[129]. People with frailty have higher emergency admission rates and mortality rates than non-frail people[130].

Each year, almost 500,000 people with long-term conditions are admitted to hospital on an emergency basis. This could have been avoided if they had received good care in the community[131].

Effective cancer care

A late diagnosis of cancer increases the risk of death and decreases an individual's likelihood of receiving palliative care. A late diagnosis also negatively affects the health system as patients are more likely to need emergency care[132]. Data for the most recent 3-year period (2019 to 2021), released in December 2023, shows that only 54% of cancers are diagnosed at stage 1 and stage 2[133].

In September 2024, 74.8% of all suspected cancer patients in England were diagnosed or cleared within 28 days (the standard is 75%), but only 67.3% (vs a standard of 85%) received a diagnosis and started treatment within 62 days of an urgent referral. In the same time period, 90.6% started treatment within 31 days of doctors deciding on a treatment plan vs an operational standard of 96%. The target of 96% of people treated within 31 days of a decision to treat has not been met in the last 3 years[134].

Effective care for people who are acutely unwell

Delays in urgent and emergency care have consequences for patients. It was estimated that there were nearly 14,000 excess deaths in 2023 associated with waits of 12 hours or more in A&E[135]. In May 2024, average ambulance response times for category 2 calls

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[129] Hopper A. 'Geriatric medicine: GIRFT programme national specialty report' (PDF, 3.8MB). 2021: NHS England.
[130] Wernly B, Bruno RR, Beil M and others. 'Frailty's influence on 30-day mortality in old critically ill ICU patients: a bayesian analysis evaluating the clinical frailty scale.' Annals of Intensive Care 2023: volume 13, issue 1, article number 126.
[131] NHS England. NHS Outcomes Framework Indicators, April 2024 release - 2.3.i Unplanned hospitalisation for chronic ambulatory care sensitive conditions. 2024. See: 'Indicator data' for 2022 to 2023.
[132] Blaney J, Crawford G, Elder T and others. 'Hospital cancer deaths: late diagnosis and missed opportunity.' BMJ Supportive & Palliative Care 2011: volume 1, issue 2, pages 135-139.
[133] See the data for the most recent 3-year period (2019 to 2021) in 'Unadjusted and case-mix adjusted percentage of cancers diagnosed at stages 1 and 2' taken from: NHS England. Case-mix adjusted percentage of cancers diagnosed at stages 1 and 2 by sub-ICB in England, 2021. 2023.
[134] NHS England. Statistics - Statistical work areas - Cancer Waiting Times. 2024.
[135] Royal College of Emergency Medicine (RCEM). Almost 300 deaths a week in 2023 associated with long A&E waits despite UEC Recovery Plan. 2024. See: 'RCEM explains: long waits and excess deaths' (PDF, 244KB).

were almost twice as long as their target[136]. In financial year 2022 to 2023, less than 30% of higher-risk heart attack patients taken directly to hospital received their treatment within 120 minutes[137].

For heart attack patients, the median 'call-to-door' time (from 999 call to an ambulance bringing the patient to hospital) was 28 minutes longer in financial year 2022 to 2023 than it was 10 years earlier[138]. Similarly, for stroke patients (where delays can lead to significant mortality and morbidity[139]), the duration from onset to arrival at hospital has continuously increased, since financial year 2013 to 2014, from approximately 150 mins to almost 250 minutes in financial year 2023 to 2024[140]. Effectiveness of heart and stroke care varies from hospital to hospital - for example, 80% of stroke patients in Kent receive a brain scan within an hour of arriving at hospital, but only 40% of stroke patients in Shropshire do[141].

Effective care for people having a planned procedure

Ineffective care also results in delays in access to planned care with, for example, ineffective perioperative care resulting in on-the-day surgery cancellations[142].

There are considerable variations in complication rates associated with surgery. Poor perioperative care results in 250,000 out of the 10 million people undergoing an elective procedure each year being at elevated risk of complications[143]. The rate of post-operative complications, such as dislocation, following hip replacement surgery (one of the most common surgeries) is around 0.8%[144] and surgical site infection rates vary from less than 0.2% to 5% - a 25-fold variation[145].

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[136] DHSC. Independent investigation of the NHS in England. 2024. Category 2 calls include serious conditions such as stroke, sepsis, heart attack or major burns. The target is set at 18 minutes. In May 2024, the average response time was 32 minutes.
[137] National Institute for Cardiovascular Outcomes Research (NICOR). 'Management of a heart attack: Myocardial Ischaemia National Audit Project (MNAP) with reference to the National Audit of Percutaneous Coronary Intervention (NAPCI) - National Cardiac Audit Programme (NCAP) 2024 summary report' (PDF, 6.7MB). 2024. This refers to the 'call-to-balloon' time for higher-risk ST-elevation myocardial infarction (STEMI) patients.
[138] NICOR. 'NCAP Aggregate Report 2024' (PDF, 6.6MB). 2024.
[139] UCI Health. Blog - Delaying stroke care can be deadly. 2021.
[140] The Sentinel Stroke National Audit Programme (SSNAP). 'Stroke – State of the Nation Report 2024.' 2024: HQIP. See graph on page 5.
[141] DHSC. Independent investigation of the NHS in England. 2024.
[142] Centre for Perioperative Care (CPOC). CPOC manifesto: a blueprint for NHS efficiency. 2024.
[143] The Royal College of Anaesthetists. 'Perioperative medicine: the pathway to better surgical care' (PDF, 1.4MB). 2019.
[144] GIRFT. News - Study supports orthopaedic trend to stop traditional post-operative precautions for hip replacement patients. 2022.
[145] GIRFT in partnership with the Royal National Orthopaedic Hospital NHS Trust, NHS England and NHS Improvement. 'Getting it right in orthopaedics: reflecting on success and reinforcing improvement - a follow-up on the GIRFT national specialty report on orthopaedics' (PDF, 5MB). 2020.

Patient or user experience

People-centred care responds to individual preferences, needs and values. Poor user experience can result in patients discontinuing treatment or not attending appointments, which can result in delayed diagnosis and treatment. Patients receiving conflicting information or inappropriate treatments can lead to avoidable hospital admissions and unnecessary tests and surgeries, all of which can lead to ineffective care of patients - regardless of the nature of their condition[146].

Adherence to a treatment regime, as per NICE guidance for people with long-term conditions such as diabetes, is associated with lower all-cause mortality and hospitalisation risk[147]. Non-adherence leads to poorer outcomes[148]. There is evidence that good communication and strong patient-physician relationships can help with knowledge of care management and therefore the likelihood of a successful recovery[149].

Management and leadership of care

Good management and leadership play an important role in improving quality of care[150]. Conversely, poor management and leadership of care can result in poorer quality of care – a lack of robust management systems and processes can result in higher mortality rates, lower patient satisfaction[151] and poorer clinical outcomes[152].

The number of managers working in the NHS has declined over the last 10 years and managers now make up only 2% of the workforce, which is far lower than in the economy as a whole (9.5%)[153].

Poor management and leadership can result in resources not being directed at the most effective interventions - for example:

- not investing in primary prevention or the management of long-term conditions and instead focusing on late-stage treatment[154]

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[146]) Øvretveit J. 'Does improving quality save money?: a review of evidence of which improvements to quality reduce costs to health service providers.' 2009: the Health Foundation.
[147] See, for example, this study from the USA: US Centers for Disease Control and Prevention (CDC). How people with type 2 diabetes can live longer. 2022.
[148] Khunti N, Khunti N and Khunti K. 'Adherence to type 2 diabetes management.' The British Journal of Diabetes 2019: volume 19, no 2.
[149] Toole J, Kohansieh M, Khan U, Romero S and others. 'Does your patient understand their treatment plan? Factors affecting patient understanding of their medical care treatment plan in the inpatient setting.' Journal of Patient Experience 2020: volume 7, issue 6, pages 1,151-1,157.
[150] Kirkpatrick I and Malby B. 'What do NHS managers contribute?' 2022: NHS Confederation.
[151] Dorgan S, Layton D, Bloom N, Homkes R and others. 'Management in healthcare: why good practice really matters' (PDF, 895KB). 2010: McKinsey & Company.
[152] Kirkpatrick I and Malby B. 'What do NHS managers contribute?' 2022: NHS Confederation.
[153] Kirkpatrick I and Malby B. 'What do NHS managers contribute?' 2022: NHS Confederation.
[154] AbdulRaheem Y. 'Unveiling the significance and challenges of integrating prevention levels in healthcare practice.' Journal of Primary Care & Community Health 2023: volume 14, article 21501319231186500.

- failing to adopt evidence-based interventions or focus spend on the most cost-effective interventions - for example, adopting a less invasive treatment for bowel cancer could not only benefit a patient's quality of life but could save the NHS £1.2 billion[155]

- failing to allocate resources based on the resulting impact on outcomes. There is currently significant variation in the cost-effectiveness of each additional pound spent - in particular, across cancer, respiratory and neurological services[156]

- failing to invest in technology to underpin the implementation of best practice processes[157]

- not using resources in the most efficient way. Evidence suggests that treating patients as a day case could free up hundreds of beds per pathway per year in each hospital[158], resulting in better care for those patients - and releasing resources to provide more care for others

Poor management and leadership can also result in poor use of resources in the delivery of care, which is often associated with poorer overall quality of care – for instance, through:

- inefficient staffing models

- poor procurement

- poor operational processes

- failure to adopt technology

Examples include:

[155] Bowel Cancer UK. News - A less invasive treatment approach for bowel cancer could save over £1 billion. 2022. The study in question is: Henderson RH, French D, McFerran E and others. 'Spend less to achieve more: economic analysis of intermittent versus continuous cetuximab in KRAS wild-type patients with metastatic colorectal cancer.' Journal of Cancer Policy 2022: volume 33, article 100342.
[156] Claxton K, Martin S, Soares M, Rice N and others. 'Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold.' Health Technology Assessment 2015: volume 19, issue 14, pages 1-503
[157] Hibbert PD, Stewart S, Wiles LK and others. 'Improving patient safety governance and systems through learning from successes and failures: qualitative surveys and interviews with international experts'. International Journal for Quality in Health Care 2023: volume 35, issue 4, page 0.
[158] NHS Supply Chain. News - PLASMA+ increased day case rates, released inpatient bed capacity, reduced readmission rates, and improved patient experience in value-based procurement pilot. 2024.

- minimising missed GP appointments could release millions of clinical hours and save over £200 million[159]

- £3.4 billion out of £7.9 billion of spend on equipment and consumables is outside the NHS Supply Chain[160], failing to make the most of its collective buying power

- discharging people who no longer need to be in hospital is better for their recovery and reduces delays in A&E or for ambulances. Across England there were, on average, 12,340 beds (which equates to 13% of all general beds) occupied by patients medically ready for discharge in October 2024[161]

Poor management of care contributes to unsafe care, ineffective care and poor user experience.

Research from 2019 found that poor or inadequate management results in a 5% efficiency gap[162]. Assuming a £100 billion spend on NHS trusts per year, a 5% efficiency gap across NHS trusts would cost £5 billion each year, which equates to around 333,000 QALYs using DHSC estimates of cost per QALY [163]. More recent analysis suggests that productivity in acute hospitals has declined since financial year 2019 to 2020 by about 8%[164] - this equates to around £6 billion per year or 400,000 QALYs.

Equity

There is inequity across all dimensions of quality, leading to inequality in experience and outcome for patients[165]. Health inequalities cause a 10-year difference in life expectancy between different parts of the country[166].

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[159] Based on the 8 million outpatient appointments in 2023 to 2024 that were 'did not attends (DNAs)' - see: NHS England. Hospital Outpatient Activity - Hospital Outpatient Activity 2023-24. 2024. Also see: NHS England. News - Missed GP appointments costing NHS millions. 2019.
[160] House of Commons Committee of Public Accounts. 'NHS Supply Chain and efficiencies in procurement - Twenty-fourth report of session 2023-24.' 2025.
[161] NHS England. Statistical work areas - Discharge delays (Acute). See: 'October 2024: Daily-discharge-sitrep-monthly-data-webfile-October2024.xslx' and go to 'Table 2: Number of patients who no longer meet criteria to reside and number of patients who were / were not discharged'.
[162] Kirkpatrick I and Malby B. 'What do NHS managers contribute?' 2022: NHS Confederation.
[163] The estimated QALYs are based on the marginal cost-effectiveness of NHS Spending estimate of £15,000 per QALY used by DHSC. This is based on research on the marginal cost-effectiveness of NHS spending across different programme budgeting categories in different areas - see: Claxton K, Martin S, Soares M, Rice N and others. 'Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold.' Health Technology Assessment 2015: volume 19, issue 14, pages 1-503.
[164] NHS England. NHS productivity update - February 2025. 2025.
[165] Marmot M, Goldblatt P, Allen J and others. 'Fair society, healthy lives (the Marmot Review): strategic review of health inequalities in England post-2010.' 2010: Institute of Health Equity.
[166] ONS. Life expectancy for local areas of Great Britain: between 2001 to 2003 and 2021 to 2023. 2024. See, for example, male life expectancy in Blackpool, Lancashire (73.1 years old) compared with Hart, Hampshire (83.4 years old).

Variations in both safety and effectiveness are significant - in 2021, 21% of hospital trusts in the Midlands and East of England had higher than expected mortality rates compared with none in London. If all NHS hospital trusts had mortality rates that matched the top 10% each year, there would have been 32,332 fewer deaths each year between 2011 and 2021[167].

The following groups of people are at higher risk of experiencing health inequalities:

- those from some ethnic backgrounds
- those living in deprived areas
- some specific population groups (for example, people experiencing homelessness)

There is evidence from a range of settings that patients from some ethnic backgrounds are at increased risk of[168]:

- hospital-acquired infections
- adverse drug effects
- pressure ulcers

Babies of Asian and Black ethnicity and those born in more deprived areas have higher rates of neonatal mortality and stillbirth[169]. An investigation by HSSIB found that babies from some ethnic groups were at greater risk of harm where jaundice had not been identified due to their skin colour.

Factors that contribute to health inequalities include:

- communication (especially for patients who are less proficient in the system's dominant language)
- provider-patient interaction (for example, Black patients being less likely to receive appropriate pain relief)

[168] Illingworth J, Shaw A, Fernandez Crespo R, Leis M, Howitt P, Durkin M, Neves AL and Darzi A. 'National State of Patient Safety 2022: what we know about avoidable harm in England.' Imperial College London: 2022.
[168] Wade C and others. 'Action on patient safety can reduce health inequalities.' BMJ 2022: volume 376, article e067090.
[169] Gallimore ID, Matthews RJ, Page GL and others. 'MBRRACE-UK perinatal mortality surveillance: UK perinatal deaths of babies born in 2022 - state of the nation report.' MBRRACE-UK: 2024.

- biases present in medical school curriculums (for example, dermatological signs not being taught on darker skin)

COVID-19 has exacerbated existing health inequalities by impacting the social determinants of health such as education[170].

Satisfaction with services differs between groups. The following groups reported better experiences than those not matching these criteria across most areas of care:

- older people
- men
- those not considered frail or disabled

However, those from other groups reported lower satisfaction with care[171], including:

- those living in the most deprived areas
- those with a disability
- those with 3 or more long-term health conditions

[170] Wade C and others. 'Action on patient safety can reduce health inequalities.' BMJ 2022: volume 376, article e067090.
[171] GP Patient Survey. GP Patient Survey - Surveys, reports and materials - 2024. 2024. Based also on Ipsos's analysis of the GP Patient Surgery 2024. For the technical annex, which shows significance and reliability calculations, see: GP Patient Survey – Technical annex - 6. Data analysis 2024. 2024.

Appendix 3: about the Care Quality Commission

Remit and scope

The Care Quality Commission (CQC) is the independent regulator of healthcare and adult social care in England. It monitors, inspects and regulates services to make sure they:

- meet fundamental standards of safety
- provide effective care to maximise outcomes
- are caring and responsive to all users
- are well led with robust governance structures and processes in place

CQC conducts performance assessments and rates providers of services (with some exceptions). Assessments and ratings are publicly available. CQC takes action to protect those who use services.

CQC has a range of other statutory responsibilities - for example:

- its role in market oversight
- monitoring the Mental Health Act 1983
- publishing the annual State of Care report

History and context

CQC was established in 2009 under the Health and Social Care Act 2008, which brought together the CSCI, Mental Health Act Commission and Healthcare Commission.

Since then, CQC has been through a number of iterations:

- the first phase was based on a generalist approach to inspection and the emphasis was on compliance or non-compliance with standards
- in 2013, CQC introduced a new approach to inspections and ratings following numerous critical reports
- in 2021, CQC launched A new strategy for the changing world of health and social care to:

    - drive improvements and encourage innovation across the health and care system
    - tackle health inequalities
- most recently, the Health and Care Act 2022 gave CQC powers to assess care at local authority and ICS level

Accountability

CQC is an executive non-departmental public body sponsored by DHSC, and is accountable to Parliament and DHSC.

Size (FTE and budget)

As of 21 November 2024, CQC had 2,989 FTE direct employees and 153 ‘other' employees, which includes:

- agency staff
- inward secondments
- bank inspectors
- specialist advisers, commissioners or second opinion appointed doctors that are paid per session

CQC's staff turnover during financial year 2022 to 2023 was 15.6% (10.4% in financial year 2021 to 2022).

CQC is funded through 5 core aspects:

- fee income (annual fees charged to registered providers)
- revenue grant-in-aid (an allocation provided by DHSC for costs that, under HM Treasury rules, are not chargeable through their fee structure)
- capital grant-in-aid (provided by DHSC to fund capital expenditure activity as this is not chargeable through fees)
- non-cash allocation (provided by DHSC to fund depreciation for non-chargeable activity)
- contracts and other income

In financial year 2022 to 2023, the total financial resource available to CQC for revenue and capital activities amounted to £263.8 million and £263 million was spent.

Impact

CQC establishes quality standards, conducts inspections, publishes the outcomes of those inspections and enforces compliance - all with the aim of:

- providing more information to users and patients
- holding providers accountable
- fostering a culture of continuous improvement

CQC also:

- produces guidance for providers, and shares best practice, through targeted projects in sectors and across themes
- aggregates insights to show systemic trends across health and social care
- holds providers to account

Appendix 4: about the Health Services Safety Investigations Body

Remit and scope

The Health Services Safety Investigations Body (HSSIB) carries out independent patient safety investigations across the NHS and independent providers, which do not find blame or liability with individuals or organisations.

HSSIB:

- can investigate any patient safety issue or concern linked to NHS healthcare in England
- works to understand why patients may have been harmed or could be at risk of harm, aiming to reduce the likelihood of patient safety incidents occurring
- shares learnings and supports patient safety improvements across the whole healthcare system in England

The purpose of its investigations is to:

- identify risks to the safety of patients
- address those risks by helping to improve the systems and practices behind NHS or other healthcare services in England

Furthermore, where an investigation relates to an incident outside of the NHS, HSSIB must consider whether, in relation to any risks identified, the systems and practices used in the provision of similar NHS services could be improved.

HSSIB assesses each issue against 4 criteria:

- the actual or potential harm to patients' lives, health or wellbeing
- the scale of the safety issue, and how widespread and systemic the issue may be
- to what extent the issue is related to health inequalities
- the potential for an HSSIB safety investigation to highlight new learning and drive improvement

History and context

Following the Mid Staffordshire NHS Foundation Trust Public Inquiry, Berwick review into patient safety and An organisation with a memory, in 2014 the Learning from failure: the need for independent safety investigation in healthcare report highlighted ongoing issues and proposed the creation of a small, permanent independent agency charged with co-ordinating major inquiries and safety investigations in the NHS.

The 2015 Public Administration Select Committee report into incident investigations in the NHS supported this idea, suggesting the formation of a body that would:

- have clear investigation criteria and independence
- bring together safety investigation expertise
- sit independent from the wider system

The proposed body, however, would not investigate all NHS incidents.

By 2016, DHSC had explored this concept, leading to the establishment of the Healthcare Safety Investigation Branch (HSIB) in 2017, modelled on accident investigation bodies from other industries. A new national safety investigator for healthcare: the road ahead expanded on the potential role for the new HSIB.

The Health and Care Act 2022 established HSIB's role by creating a new body (HSSIB) with the same core remit, but expanding its powers and scope to help improve patient safety through high-quality investigations and education. HSIB used to sit in the Trust Development Authority (TDA) - however, during the merger of NHS Improvement and NHS England, HSIB had to move out of TDA into NHS England. The Health and Care Act 2022 allowed HSSIB to become independent.

When it was first established, HSIB carried out independent safety investigations into NHS-funded care across England through 2 programmes - national investigations and maternity investigations.

After the passing of the Health and Care Act 2022, the national investigations programme remained under HSSIB and the maternity investigations programme, now known as the Maternity and Newborn Safety Investigations programme (MNSI), moved to CQC. This is because the Health and Care Act 2022 did not make provision for maternity investigations under HSSIB.

Accountability

HSSIB is an arm's length body of DHSC and accountable to the Secretary of State for Health and Social Care.

Size (FTE and budget)

HSSIB is an entirely remote-working organisation and its FTE is 44.30. Its funding allocation is approximately £5.6 million grant-in-aid.

HSSIB is an expert team of safety scientists or human factors experts from other safety-critical industries with military, legal and clinical backgrounds.

Investigations and insights

In financial year 2023 to 2024, 19 investigation reports were published by HSIB or HSSIB and at least 20 more in financial year 2024 to 2025. These reports:

- contain safety recommendations to drive system-wide improvement
- address national systems, policies and guidance
- contain safety observations
- share opportunities for localised change and improvement that have been identified by investigations with ICBs and providers

HSSIB requests a response from organisations who receive its recommendations, which must outline what actions they intend to take, and these responses are then reviewed and graded. HSSIB has recently established a process for following up on these actions to understand:

- the impact of actions taken
- any barriers to implementation

Education

HSSIB's education programme aims to share learning from systems-focused investigations at a national level that translate to local systems of work. HSSIB shares:

- investigation tools and techniques, which are designed to lead to a deeper understanding of systems thinking
- learning from patient safety incidents to lead to safer care

Since its inception in October 2023, the programme has attracted over 17,000 enrolments across 8 courses. The learning outcomes build upon the PSIRF implementation requirements and cover:

- human factors
- safety science
- systems thinking

All programmes are CPD accredited and recognised by the Chartered Institute of Ergonomics and Human Factors.

These courses are offered free of charge to NHS staff across England, with an estimated commercial value of over £2.5 million each year, while costing HSSIB £700,000.

HSSIB delivers 2 of the 5 modules of the level 3 and 4 NHS Patient Safety Syllabus to 555 patient safety specialists across England, building the skills and capabilities of local investigators.

Appendix 5: about the Patient Safety Commissioner

Remit and scope

The role of Patient Safety Commissioner was established by the Medicines and Medical Devices Act 2021, which specified 2 principal duties - to promote the:

- safety of patients with regard to the use of medicines and medical devices
- importance of the views of patients and other members of the public in relation to the safety of medicines and other medical devices

History and context

The role of Patient Safety Commissioner was proposed in the recommendations of the 2020 Independent Medicines and Medical Devices Safety (IMMDS) Review led by Baroness Cumberlege. The report focused on specific issues relating to the use of:

- hormone pregnancy tests
- sodium valproate
- pelvic mesh

Accountability

The Patient Safety Commissioner's role is intended to be independent but, in practice, the necessary proximate relationship with DHSC (closer than any other body within the scope of this review) puts some qualifications on the reach and remit of the commissioner. The law also places a limit on the commissioner's ability to take on, advocate for or investigate the cases of individuals.

The Patient Safety Commissioner is accountable to DHSC, although DHSC doesn't provide any further mandate or tasking.

An original set of governance documents were drawn up to support the Patient Safety Commissioner's first year of operation - a framework agreement and letters of finance. These reflected the original purpose of overseeing a remainder of the Cumberlege recommendations for valproate and mesh patients, and are now significantly out of date. See the Patient Safety Commissioner's original terms of reference for more details.

There has never been any requirement from DHSC or NHS England that the Patient Safety Commissioner should do work that contributes to NHS England's NHS Patient Safety Strategy – although it does align when possible.

Size (FTE and budget)

The Patient Safety Commissioner is a public appointment, but there is no separate legal entity and no 'office' that can employ people separately from DHSC. The commissioner's office is therefore directly funded and staffed by DHSC civil servants.

The Office of the Patient Safety Commissioner has 4.8 FTE Civil Service employees and an annual budget of £600,000, which comes from DHSC.

It is not funded to be operational in nature.

Impact

The Patient Safety Commissioner has made 3 sets of recommendations under her statutory powers to:

- DHSC on redress for those harmed by valproate and pelvic mesh
- the Secretary of State for Health and Social Care around Martha's Rule
- NHS England on the safe use of the most potent teratogens

Work on valproate has led to better labelling and a rapid reduction in numbers of women taking valproate during pregnancy.

The Patient Safety Commissioner:

- has also raised a number of patient concerns about the safety of a range of medicines (at varying degrees of severity) with MHRA
- works to ensure patients receive the right information to consent to procedures as part of a shared decision-making process, as a matter of course, and irrespective of type of healthcare professional
- has also convened a resolution for the Royal College of Obstetricians and Gynaecologists, the GIRFT programme and the Campaign against Painful Hysteroscopy, following patient correspondence around the procedure and a lack of informed consent

Read more about patients' experiences of the Patient Safety Commissioner.

Appendix 6: about NHS Resolution

Remit and scope

NHS Resolution's 4 service areas are:

- claims management - delivering expertise in handling both clinical and non-clinical claims for compensation on behalf of the NHS in England
- Practitioner Performance Advice (formerly the National Clinical Assessment Service):
    - providing advice, support and interventions in relation to concerns about the individual performance of doctors, dentists and pharmacists
    - managing the healthcare professional alert notices (HPANs) system - this is a system where notices are issued to inform NHS and other bodies about any registered healthcare professional who may pose a significant risk of harm to patients, staff or the public. HPANs are usually used while the regulator is considering the concerns and provide an additional safeguard during the pre-employment checking process
- primary care appeals (formerly the Family Health Services Appeal Unit) - offering an impartial resolution service for the fair handling of primary care contracting disputes between primary care contractors and NHS England
- safety and learning:
    - supporting the NHS to better understand and learn from claims, concerns and disputes
    - helping providers of NHS care to understand their own claims risk profiles and target safety activity
    - sharing learning across the NHS

This review has only looked at NHS Resolution's safety and learning functions.

History and context

The NHS Litigation Authority was established by order of the Secretary of State in October 1995 as a special health authority of DHSC. The organisation's original purpose was to establish and administer indemnity schemes for meeting the liabilities of health service bodies.

Now known as NHS Resolution, it handles both clinical and non-clinical claims for compensation on behalf of the NHS in England.

Size (FTE and budget)

NHS Resolution has 759 FTE staff, of which 13.8 FTE comprise the safety and learning function (1.8% of total FTE) who are specifically engaged in patient safety activity.

Around 64 other staff do work with patient safety aspects:

- across the clinical side of NHS Resolution's early notification scheme
- through the administration of the Maternity Incentive Scheme (MIS)
- in the Practitioner Performance Advice service where they deliver a specialist function that has a safety aspect

NHS Resolution’s full expenditure budget is £3.2 billion, of which the vast majority relates to the settlement of claims in relation to its indemnity schemes, and is mostly funded through its members. £292 million is funded directly by DHSC. The safety and learning function has a budget of £1.4 million.

The main scheme, the Clinical Negligence Scheme for Trusts (CNST), operates on a membership basis. Contributions to the scheme are assessed with the support of actuarial advice, and are based on a combination of claims experience and activity (including risk weightings for different specialties and staffing levels). Annual contributions cover the costs of claims on a ‘pay-as-you-go’ basis and amount to around £20 million per year for a trust with an average-sized maternity unit. CNST’s contribution methodology is reviewed on an ongoing basis.

Impact

It is not straightforward for NHS Resolution to quantify its precise impact upon patient safety due to the complexities of the healthcare landscape, and the fact that patient safety is impacted by numerous competing and complementary factors at once.

NHS Resolution actively monitors its contribution through:

- performance indicators
- reviews of significant workstreams
- interviews with stakeholders – including independent feedback

- surveys of users of services, such as an annual survey of the MIS and follow-up contact with people who access its learning products to seek feedback on where practice has changed

- independent advice and support on the development of robust methodologies to evaluate impact (for example, a recent academic partnership with London South Bank University)

NHS Resolution told the review that it undertakes annual qualitative research with 10 to 15 major stakeholders from external organisations including DHSC, NHS England and GMC. It reported that the latest survey, from July 2024, found that stakeholders agreed that NHS Resolution has a positive impact on outcomes through the proactive sharing of data and insights. It also indicated that it should consider how it could make further impact on the patient safety landscape by building greater awareness of its learning materials among frontline staff - for example, through even closer working with royal colleges and others involved in the development and provisioning of training.

NHS Resolution told the review that feedback from the annual stakeholder interviews indicated that the MIS has facilitated board discussions and placed maternity as a higher priority on trust board agendas.

NHS Resolution actively seeks close to real-time feedback from the educational and learning events that it holds. NHS Resolution told the review that, in the first 2 quarters of financial year 2024 to 2025, the safety and learning function facilitated 386 engagements with nearly 5,000 representatives of the NHS workforce. It received 140 pieces of feedback from member engagement, which found that 96% of members reported an increase in knowledge of NHS Resolution and 91% intended to share NHS Resolution's safety and learning resources with colleagues.

NHS Resolution told the review that it had seen positive outcomes due to the impact of its services. For example, the Maternity incentive scheme - an interim evaluation (PDF, 3.3MB) (2020 qualitative analysis) and more recent intelligence from MIS safety action leads shared at NHS Resolution's collaborative advisory group indicated that there had been:

- higher use of the perinatal mortality review tool compared with the devolved nations

- high reporting of eligible early notification qualifying cases to MNSI

- improvement in data submission, quality and compliance standards for the Maternity Services Data Set (MSDS)

- increased compliance with elements of the Saving Babies' Lives Care Bundle

- improved quality of evidence from NHS trusts, particularly board reporting

NHS Resolution also told the review that it had received positive feedback from annual stakeholder interviews indicating that it is the only scheme that directly incentivises the training for shoulder dystocia, which has been associated with significant improvements in neonatal outcomes, particularly reductions in brachial plexus injury.

Appendix 7: about Healthwatch England and Local Healthwatch

Remit and scope

Healthwatch aims to improve care quality by representing the experiences of health and social care users to decision-makers. Its statutory functions are to:

- provide leadership, guidance, support and advice to Local Healthwatch organisations
- escalate concerns about health and social care services that have been raised by Local Healthwatch to CQC. CQC is required to respond to advice from the Healthwatch England Committee
- provide advice to the Secretary of State for Health and Social Care, NHS England and English local authorities. Bodies to whom advice is given are required to respond in writing

Its primary strategic aims are to:

- support marginalised groups to speak up and access advice
- encourage decision-makers to act on public feedback and involve communities
- strengthen the Healthwatch network to ensure all voices across England are heard

The Secretary of State for Health and Social Care is also required to consult Healthwatch England on the annual NHS Mandate, which sets the objectives for the NHS.

Healthwatch does not provide statutory NHS complaints advocacy, though some local branches offer this service. Healthwatch also engages with the Patient Safety Commissioner on issues like medication safety and medical devices.

History and context

Healthwatch was established under the Health and Social Care Act 2012 to represent the needs and concerns of people using health and social care services. It has been active since April 2013.

Size (FTE and budget)

Healthwatch England has a team of 36 staff members. While their remit broadly covers patient listening, the organisation is not designated specifically as a patient safety organisation, meaning none of its staff are dedicated exclusively to patient safety.

Local Healthwatch, represented by 153 individual organisations, employs 570 FTE staff members, averaging 4.08 staff per location. These staff members are responsible for delivering Healthwatch services to their local communities. However, like Healthwatch England, the remit of Local Healthwatch is broad, and no staff members are assigned exclusively to patient safety.

Healthwatch England's budget for financial year 2024 to 2025 is £3.2 million, funded by DHSC through CQC. Local Healthwatch received £25.4 million in financial year 2023 to 2024, with funding levels set by each of the 153 local authorities and drawn from 2 sources - the Local Reform and Community Voices Grant and the local government finance settlement. This funding is non-ringfenced, allowing local authorities to exercise discretion over its allocation.

Local Healthwatch has broad responsibilities across health and care services, but funding is limited and uneven. Most organisations receive between £100,000 and £250,000 - however, 18% receive under £100,000, with only 19 organisations funded above £250,000.

Accountability

Healthwatch England operates under a national committee responsible for:

- setting strategy
- overseeing policies
- ensuring effective operations

This committee is a statutory body within CQC and includes a chair, appointed by the Secretary of State for Health and Social Care, and at least 6 non-executive members.

Healthwatch England reports annually to Parliament, with the Secretary of State for Health and Social Care accountable for its activities in Parliament. DHSC oversees Healthwatch England's funding and ensures compliance with governance standards. CQC's Chief Executive acts as Healthwatch England's Accounting Officer. Healthwatch England's Chief Executive manages daily operations, budgeting and reports to the CQC Chief Executive. The chair of Healthwatch England is an ex-officio member of the CQC board.

Local authorities are legally required to establish a Local Healthwatch to provide health and social care feedback for their communities. Each Local Healthwatch operates under a contract or grant from the local authority, detailing statutory duties and local priorities, and is accountable to that local authority.

Local Healthwatch is not accountable to Healthwatch England, although Healthwatch England supports the organisations by offering leadership and general guidance, and raising concerns with CQC as necessary

Each Local Healthwatch publishes an annual report, which is made public and distributed to Healthwatch England, the local authority, NHS England, ICBs, local authority scrutiny committees and CQC.

Impact

Healthwatch, while not solely a patient safety organisation, plays a crucial role in promoting patient safety by amplifying patient voices. Since 2013, Healthwatch has made a significant impact, aiding over a million people annually to voice their concerns and access advice.

Healthwatch England's national impact

Healthwatch England's national influence spans the following areas:

- patient listening and system improvements, including:
    - NHS Long Term Plan - Healthwatch engaged 40,000 people to shape NHS priorities for the next decade
    - Suffering in silence report - it collaborated on a consumer-led complaints system, which is now part of CQC's inspection framework
    - COVID-19 feedback - it provided policy makers with insights from 19,000 people on varied services, including primary and mental health care
    - national data opt-out – it developed a simpler system for patients to control data use, advancing NHS data-handling transparency
- ensuring accessible services for all, including:
    - accessible information standard - Healthwatch's advocacy led to a forthcoming updated standard for improved accessibility
    - GP appointment choice - it secured patients' rights to choose between face-to-face and digital GP appointments
    - patient transport support - it improved non-emergency transport criteria, addressing challenges faced by those in need of reliable transport to healthcare facilities

- targeted efforts to enhance safety and quality, including:
    - fairer NHS dentistry - Healthwatch highlighted access issues, influencing contract changes and a dental recovery plan for low-income individuals and children
    - safer hospital discharges - it advocated for post-discharge support, resulting in welfare checks covering mental and financial needs
    - maternal mental health support - its feedback led to a plan for improved postnatal checks and mental health service access, enhancing safety for new mothers

Examples of Local Healthwatch's impact

Healthwatch Derbyshire enhanced hospital discharge pathways. Its report on hospital discharge led Derbyshire ICS to create a discharge improvement lead role aimed at:

- improving person-centred discharge
- reducing readmissions
- easing transitions for vulnerable groups, such as people with dementia

Healthwatch Milton Keynes did work on mental health inpatient wards. Its work led to improvements in care, discharge and safety for women on a mental health inpatient unit, which includes women with learning disabilities.

Healthwatch Bolton escalated a case where a patient was discharged from Royal Bolton Hospital with a 'do not attempt resuscitation' order without informing the patient or their next of kin, prompting its inclusion in a staff workshop to improve communication practices.

Healthwatch City of London received information from a resident of over-dispensing, which led to a pharmacy investigation and improved GP communication. It also contributed to a patient panel to emphasise the importance of annual medicine checks.

Appendix 8: about the National Guardian's Office

Remit and scope

The National Guardian's Office leads, trains and supports a network of Freedom to Speak Up Guardians across England, offering guidance and reviews to encourage employees to share concerns about patient safety. The office's roles include:

- developing and maintaining, alongside elearning for healthcare, the e-learning modules Speak Up, Listen Up, Follow Up for all workers. These are publicly available online to all staff
- supporting, training and registering a network of around 1,300 Freedom to Speak Up Guardians in various healthcare settings, including the management of annual compliance training to ensure guardians are complying with best practice and implementing the policy and guidance within their organisations
- conducting speak up reviews to assess and improve practices, recommending actions for improvement when organisations fail to follow best practices
- providing national leadership and advocating for Freedom to Speak Up principles to a wide range of health-related organisations - for example, hospices
- working with CQC on ‘well led’ frameworks and data to support inspections
- working with NHS England to explore escalation routes for serious concerns, particularly in cases of intentional harm
- sharing themes and learning from speaking up cases, which are published quarterly, and its end-of-year report
- providing board development sessions to boards looking to develop their speaking up arrangements or who require support in improving existing arrangements
- seeking to learn from organisations that are further into their cultural improvement journey

The National Guardian is a 'prescribed person'.

History and context

The National Guardian for Freedom to Speak Up in the NHS ('the National Guardian') and the National Guardian's Office were set up as an independent office, but not as a regulator, within CQC from 4 April 2016.

The National Guardian's Office does not have statutory functions. However, Freedom to Speak Up is part of the 'well led' domain of CQC inspections.

It was established in 2016 following the Mid Staffordshire NHS Foundation Trust Public Inquiry and the recommendations from Sir Robert Francis's Freedom to Speak Up review.

A 2021 government plan to introduce guardians in social care was cancelled, but some local authorities, such as Leeds, have adopted the model.

Size (FTE and budget)

The National Guardian's Office is independently funded by CQC and NHS England.

Out of an established 20 staff, 16 FTE are CQC employees. The team includes a part-time data analyst on secondment and an independent chair working around 24 days a year. The office is considering revisiting posts paused due to financial constraints to address current gaps in team capacity.

The funding of the National Guardian's Office for financial years 2023 to 2026 will be £1.58 million per year, with NHS England contributing £1.27 million and CQC contributing £316,666 per year. The office's funding is agreed on a 3-yearly basis and governed by a memorandum of understanding between CQC, NHS England and the National Guardian's Office.

Accountability

The National Guardian's Office is a non-statutory appointment by CQC to lead cultural change in the health sector, promoting accountability and transparency. Oversight is maintained through:

- publications
- stakeholder engagement
- public consultations

The DHSC Permanent Secretary serves as Principal Accounting Officer and is responsible for the performance of the health system, including the National Guardian's Office, in Parliament. CQC's Chief Executive acts as its Accounting Officer.

Following Learning from Gosport: the government response to the report of the Gosport Independent Panel, the National Guardian's Office is required by government to publish an independent annual report, which is laid before Parliament to:

- showcase best practice
- hold the government and the system to account
- advocate for change

CQC oversees the National Guardian's budget and statutory functions. The National Guardian meets with ministers twice yearly and reports to the CQC Audit and Risk Assurance Committee and main board.

The National Guardian's Office has its own accountability and liaison board, which meets quarterly and is represented by its 3 funders. The board has an independent chair to support it to have an external, objective voice with an ability to challenge members, the National Guardian and officers in a constructive way. The National Guardian's Office also reports to NHS England's board on an annual basis.

Impact

Freedom to Speak Up Guardians have handled over 140,000 cases since they were first established in 2016. Last year, over 30,000 cases were raised with them, of which:

- 18.7% included a direct element of patient safety or quality
- 19.8% involved bullying and harassment
- 38.5% involved inappropriate attitudes or behaviours

There has been an increase in the number of staff in the NHS Staff Survey reporting that they feel secure in raising any concerns regarding clinical practice – from 68% in 2015 to 75% in 2021 and 71.5% in 2023. The number of staff with confidence that their organisation would address their concerns increased from 56% in 2015 to 56.8% in 2023.

The National Guardian's Office's 100 Voices campaign highlighted real-life stories from workers and Freedom to Speak Up Guardians, who shared their experiences of speaking up and the positive changes that have resulted.

The National Guardian's Office has carried out 9 case reviews where the office had received information to suggest that speaking up had not been handled in accordance with good practice. Where they found that good practice had not been followed, they recommended remedial action.

The office has collated recommendations from the case review reports and grouped them thematically. To help with gap analysis, they have included a tool that Freedom to Speak Up Guardians, and others responsible for speaking up in their organisations, can use to

review arrangements and develop plans and actions for improvement. The tool can be used, along with other guidance published on the National Guardian's Office website, as a self-review tool to identify and improve gaps in organisations' speaking up arrangements for the benefit of workers, their organisations and the people they support.

In February 2023, the National Guardian's Office published a focused review on ambulance trusts in England, which resulted in 5 recommendations for improvement, including a call for an independent cultural review, bringing together NHS England, the Association of Ambulance Chief Executives, CQC and partner organisations with ministerial oversight.

In early 2025, the National Guardian's Office will publish its second thematic speak up review into overseas trained workers. The review understands that this report will:

- make recommendations that build upon existing work within the system
- highlight cultural barriers, continuous improvement into building awareness of Freedom to Speak Up practices and where leaders can support the system by listening and acting on worker concerns

The National Guardian's Office:

- shares insights from local guardians to provide early warning signs of issues in the sector
- highlights areas of concern that impact upon worker wellbeing and retention

Appendix 9: detailed description of the wider quality landscape

These organisations have been divided into 12 categories.

1. National overseeing and commissioning bodies (3)

These are:

- DHSC
- NHS England
- UKHSA

The National Quality Board (NQB) is part of DHSC. NQB - on behalf of NHS England, CQC, UKHSA, NICE, DHSC, Healthwatch England, the National Guardian's Office and HSSIB - is responsible for:

- championing the importance of quality
- driving system alignment of quality across health and care

NQB provides advice and recommendations on issues relating to quality, and is intended to influence, drive and ensure system alignment of quality programmes and initiatives.

2. Local commissioning bodies (200)

The local commissioning bodies include:

- 42 ICBs
- 153 local authorities
- approximately 5 large private health insurers

3. Providers (many)

There are:

- 229 NHS trusts
- around 7,000 GP practices

- around 11,000 dental practices
- a large number of private providers, ranging from small one-off clinics to very large groups of hospitals. These include:
    - 190 independent acute medical care hospital providers (where the largest 5 providers make up approximately 70% of the market and the largest 30 make up 90%)
    - 19,000 care providers, including more than 6,000 care home providers (of which around 10 comprise 18% of the market)

4. Statutory service and professional regulators (17)

Service regulators (8)

The 8 service regulators are:

- CQC, including MNSI - funded by fees from registered providers (such as NHS trusts, private healthcare providers and adult social care services) and government grants from DHSC
- Environment Agency - funded by Defra and fees and charges from permits, licences and regulatory activities
- HFEA - funded by DHSC and clinical fees
- HRA - funded by DHSC
- HSE - primarily funded by DWP
- HTA - funded by DHSC and licence fees
- MHRA - funded by DHSC and pharmaceutical companies and manufacturers for licensing and regulation services
- Office for Standards in Education (Ofsted) - funded by the Department for Education

While there is a large number of regulators, it should be noted that the relative scale and span of the various regulators and oversight organisations differs considerably.

Specifically, CQC regulates all health and care – hundreds of millions of care episodes per year – while HFEA and HTA are focused on very specific areas. Similarly, HSE has a much smaller remit in healthcare.

Professional regulators (9)

The 9 professional regulators are:

- General Chiropractic Council (GCC)
- General Dental Council (GDC)
- General Optical Council (GOC)
- General Osteopathic Council (GOsC)
- General Pharmaceutical Council (GPhC)
- GMC
- Health and Care Professions Council (HCPC)
- NMC
- Social Work England

The professional regulators set standards for practice, competence and conduct in their respective professions. They license and uphold standards for practitioners across specialties, maintaining public trust in healthcare professionals.

The largest 2 are:

- GMC, which maintains the register of around 395,000 medical practitioners
- NMC, which maintains the register of around 841,000 nurses, midwives, public health nurses, and nursing associates

Both:

- have a council structure including 'lay' and 'registrant' members
- publish professional standards for registrants and can investigate allegations of impaired fitness to practise (where there is concern that the standards are not met)
- have power to impose restrictions on practice or remove individuals from their registers following fitness to practise procedures

Only a very small minority of concerns raised with professional regulators progress to formal fitness to practise procedures, leaving the vast majority of concerns to be handled locally by employers.

The work of all the professional regulators is overseen by the Professional Standards Authority, which:

- reviews the performance of the regulators
- scrutinises their decisions about fitness to practise
- can appeal those decisions

All professional regulators are funded by fees charged to professionals and businesses they regulate. In rare cases, some government funding may be provided for specific initiatives or projects.

5. Information and standards organisations (6)

The information and standards organisations are:

- NICE - primarily funded by DHSC
- BSI - a private, not-for-profit company
- CHKS - a private company
- ISO - an independent body
- JACIE - funded by accreditation fees paid by hospitals and clinics
- UKAS - plays a role in health and social care by accrediting organisations that provide diagnostic services, medical laboratories and other healthcare-related activities. It operates as a private, not-for-profit company

6. Quality improvement, safety investigations and advisory bodies (7)

These bodies are:

- Healthwatch England - funded by DHSC through CQC
- HSSIB - funded by DHSC
- National Guardian’s Office - funded by DHSC through CQC and NHS England
- NHS Resolution - funded by DHSC and contributions from NHS and foundation trusts through membership schemes (such as the CNST)
- Patient Safety Commissioner - funded by DHSC

- CHM and BP Commission - both funded by DHSC through MHRA

7. Royal colleges and faculties (19)

The royal colleges and faculties are as follows:

- Faculty of Dental Surgery
- Faculty of Forensic and Legal Medicine
- Faculty of Intensive Care Medicine
- Faculty of Occupational Medicine
- Faculty of Pharmaceutical Medicine
- Faculty of Public Health
- Faculty of Sexual and Reproductive Health
- Faculty of Sport and Exercise Medicine (UK)
- Royal College of Anaesthetists
- Royal College of Emergency Medicine
- Royal College of General Practitioners
- Royal College of Obstetricians and Gynaecologists
- Royal College of Ophthalmologists
- Royal College of Paediatrics and Child Health
- Royal College of Pathologists
- Royal College of Physicians of London
- Royal College of Psychiatrists
- Royal College of Radiologists
- Royal College of Surgeons of England

All royal colleges and faculties are primarily funded by membership fees. Some receive government grants for specific national projects.

8. Professional peer review bodies (many)

Professional bodies

The most significant professional bodies in this space are:

- CHKS - private organisation funded by fees from healthcare providers
- HQIP - mainly funded by DHSC, NHS England and the devolved administrations
- National Cancer Registry - funded by NHS England
- national clinical audits (listed below under 'National clinical audits') - funded by NHS England
- National Clinical Audit and Patient Outcomes Programme (NCAPOP), which covers both the National Clinical Audit programme and the Clinical Outcome Review Programmes - supported by NHS England and commissioned by HQIP. Participation in NCAPOP audits is mandatory for NHS organisations, following the introduction of a contractual requirement in 2012
- GIRFT programme, which is designed to improve the treatment and care of patients through in-depth reviews of services, benchmarking and the presentation of a data-driven evidence base to support change
- National Confidential Inquiry into Patient Outcome and Death (NCEPOD) - funded by DHSC with some support from devolved administrations
- National Joint Registry - indirectly supported by the NHS and private healthcare providers, which contribute fees for data submissions

National clinical audits

These are as follows:

- Falls and Fragility Fracture Audit (FFFAP) (includes the Hip Fracture Database)
- National Audit of Cardiovascular Disease Prevention in Primary Care (CVD Prevent) Workstream 3
- National Audit of Care at the End of Life (NACEL)
- National Audit of Dementia (NAD)

- National Adult Diabetes Audit (NDA)
- National Audit of Eating Disorders (NAED)
- National Audit of Metastatic Breast Cancer (NAoMe)
- National Audit of Primary Breast Cancer (NAoPri)
- National Bowel Cancer Audit (NBoCA)
- National Cancer Audit Collaborating Centre
- National Cardiac Audit Programme (NICOR)
- National Clinical Audit of Psychosis (NCAP)
- National Early Inflammatory Arthritis Audit (NEIAA)
- National Emergency Laparotomy Audit (NELA)
- National Epilepsy 12 Audit
- National Kidney Cancer Audit (NKCA)
- National Lung Cancer Audit (NLCA)
- National Maternity and Perinatal Audit (NMPA)
- National Non-Hodgkin Lymphoma Audit (NNHLA)
- National Obesity Audit
- National Oesophago-Gastric Cancer Audit (NOGCA)
- National Ovarian Cancer Audit (NOCA)
- National Paediatric Diabetes Audit (NPDA)
- National Pancreatic Cancer Audit (NPaCA)
- National Prostate Cancer Audit (NPCA)
- National Respiratory Audit Programme (NRAP)
- National Vascular Registry (NVR)

- Paediatric Intensive Care Audit Network (PICANet)
- Sentinel Stroke National Audit Programme (SSNAP)

Clinical outcome review programmes

These are as follows:

- Child Health Clinical Outcome Review Programme
- Maternal, newborn and infant outcome review programme
- Medical and surgical outcome review programme
- Mental health outcome review programme
- National Child Mortality Database (NCMD)

Around 60 other large-scale audits, registries and similar projects are run by various groups and bodies and may be included in the NHS England Quality Accounts list.

9. Organisations supporting, learning from and advocating for the 'user voice' (many)

These include the following:

- CQC, which, among other activities focused on the patient voice, runs a number of NHS patient surveys including the adult inpatient survey, urgent and emergency care survey, community mental health survey and maternity survey
- Healthwatch England - funded by DHSC through CQC
- individual provider organisations, who may, among other mechanisms, operate advice, support and information groups - such as PALS and PPGs - to both support patients and users and to learn from them
- local authorities - through their health and wellbeing boards, and overview and scrutiny committees. They also fund advocacy support for those seeking to complain about the care they have received from NHS organisations with £15 million direct funding from DHSC
- Local Healthwatch - funded by DHSC Local Reform and Community Voices grant through local authorities plus the final local government finance settlement

- NHS England, which runs a number of large patient surveys (including the GP Patient Survey and National Cancer Patient Experience Survey), and ICBs, which frequently survey the populations they serve. The NHS Friends and Family Test is a survey of patients, which gives them the opportunity to submit feedback to providers of NHS-funded care or treatment. It has one simple question that asks how likely - on a scale ranging from extremely unlikely to extremely likely - they are to recommend the service to their friends and family if they needed similar care or treatment

- Parliamentary and Health Service Ombudsman and the Local Government and Social Care Ombudsman - funded by Parliament

- Patient Safety Commissioner - funded by DHSC

10. National advisory groups (29)

The national advisory groups are as follows:

- Administration of Radioactive Substances Advisory Committee (ARSAC) - funded by DHSC through UKHSA

- Advisory Board on the Registration of Homeopathic Products (ABRHP) - funded by DHSC through MHRA

- Advisory Committee on Antimicrobial Prescribing, Resistance and Healthcare Associated Infection (APRHAI) - funded by DHSC through UKHSA

- Advisory Committee on Borderline Substances (ACBS) - funded by DHSC through NHS England

- Advisory Committee on Dangerous Pathogens (ACDP) - funded by DHSC through UKHSA

- Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) - funded by DHSC

- Advisory Group on Contraception (AGC) - independent, supported by private sector

- Advisory Group on Ionising Radiation (AGIR) - funded by DHSC through UKHSA

- British National Formulary Dental Advisory Committee - funded by DHSC through NHS England and NICE

- Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC) - funded by DHSC through UKHSA

- Committee on the Medical Effects of Air Pollutants (COMEAP) - funded by DHSC through UKHSA
- Committee on Mutagenicity of Chemicals in Food, Consumer Products, and the Environment (COM) - funded by UKHSA
- Confidentiality Advisory Group (CAG) - part of HRA, which is funded by DHSC
- Gene Therapy Advisory Committee - funded by DHSC through HRA
- Health Premium Incentive Advisory Group (HPIAG) - funded by DHSC
- Herbal Medicines Advisory Committee (HMAC) - funded by DHSC through MHRA
- Human Animal Infections and Risk Surveillance group (HAIRS) - hosted and funded by DHSC, through UKHSA, with some support from Defra
- Improving Quality in Physiological Services Programme (IQIPS) - supported by Royal College of Physicians, but funding also comes from fees paid by NHS and private healthcare providers seeing IQIPS accreditation
- Joint Advisory Group on Endoscopy (JAG) - operates as part of the royal colleges, which are funded by fees
- Joint Committee on Vaccination and Immunisation (JCVI) - funded by DHSC and indirect support through NHS budgets for implementing vaccine strategies
- Medical Advisory Group - funded by DHSC through NHS England
- New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) - funded by DHSC through UKHSA
- People's Advisory Forum (PAF) - funded by DHSC through UKHSA and government grants
- Pharmacy Advisory Group - funded by GPhC
- Prescribed Specialised Services Advisory Group (PSSAG) - funded by DHSC through NHS England
- public health advisory committees - funded by DHSC through NICE
- UK Advisory Panel for Healthcare Workers Infected with Bloodborne Viruses - funded by DHSC through UKHSA

- UK National Screening Committee (UK NSC) - funded by DHSC and devolved governments

11. Professional associations and societies (many)

These are as follows:

- Association of Directors of Adult Social Services (ADASS)
- Association of Paediatric Emergency Medicine
- Association for Paediatric Palliative Medicine
- British Academy of Childhood Disability
- British Association for Child and Adolescent Public Health (BACAPH)
- British Association for Paediatric Nephrology
- British Association of Community Child Health (BACCH)
- British Association of General Paediatrics (BAGP)
- British Association of Paediatric Surgeons (BAPS)
- British Association of Paediatricians in Audiology (BAPA)
- British Association of Perinatal Medicine (BAPM)
- British and Irish Paediatric Pathology Association (BRIPPA)
- British Cardiovascular Society (BCS)
- British Congenital Cardiac Association (BCCA)
- British Geriatrics Society
- British Inherited Metabolic Disease Group (BIMDG)
- British Institute of Radiology (BIR)
- British Paediatric Allergy Immunology and Infection Group (BPAIIG)
- British Paediatric and Adolescent Bone Group (BPABG)

- British Paediatric Neurology Association (BPNA)
- British Paediatric Respiratory Society BPRS)
- British Psychological Society (BPS)
- British Society for Genetic Medicine (BSGM)
- British Society for Paediatric and Adolescent Rheumatology (BSPAR)
- British Society for Paediatric Dermatology (BSPD)
- British Society for Paediatric Endocrinology and Diabetes (BSPED)
- British Society for Haematology
- British Society of Echocardiography (BSE)
- British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPHAN)
- Chartered Society of Physiotherapy
- Clinical Genetics Society
- College of Medicine and Integrated Health
- College of Paramedics
- College of Optometrists
- CoramBAAF
- Institute of Biomedical Science (IBMS)
- Institute of Healthcare Engineering and Estate Management
- Institute of Physics and Engineering in Medicine (IPEM)
- Paediatric Intensive Care Society (PICS)
- Paediatric Mental Health Association (PMHA)
- Professional Standards Authority
- UK Psychological Trauma Society (UKPTS)

These organisations receive income from membership fees and event revenue (from workshops, conferences and so on). They get no direct government funding.

12. Charities, academia, think tanks and consulting companies (many)

A large number of bodies carry out research and review different aspects of the quality of health and care. Some examples, including those who have inputted into this review, are:

Think tanks, academic and consulting companies

These are:

- Centre for Health Policy, Institute of Global Health Innovation, Imperial College London
- The Guardian Service
- The Health Foundation
- THIS Institute
- Making Families Count
- The Nuffield Trust
- InHealth Associates

Patient advocacy charities

These are:

- AvMa
- Care Rights UK
- Children's Cancer and Leukaemia Group (CCLG)
- The Lindsay Leg Club Foundation
- Mind
- National Voices
- Patients Association
- Shaping our Lives

Workforce and staff experience

Outside of the National Guardian's Office, the NHS conducts an annual survey to gather staff experiences across the NHS, which can also provide useful information on quality of care.

The NHS Staff Survey has been carried out every year since 2003. It typically gets a relatively strong response, with 707,000 respondents in 2023 out of more than 1.4 million members of staff - a response rate of 48%. The survey is conducted by Picker on behalf of NHS England.

The aggregated survey results are official statistics, which are used by a wide range of NHS organisations to:

- inform understanding of staff experience locally, regionally and nationally
- improve staff experiences

Inquiries, reviews and reports

In addition, since the first public inquiry into unsafe care at Ely Hospital in Cardiff in 1968, a large number of inquiries and DHSC-sponsored reviews have been carried out. The findings and reports influence quality and safety.

Among the highest profile since 2000 are:

- To Err Is Human: Building a Safer Health System (2000)
- An organisation with a memory: report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer (2000)
- The Bristol Inquiry (2001)
- The Shipman Inquiry (2002)
- High quality care for all: NHS Next Stage Review final report (2008)
- Transforming care: a national response to Winterbourne View hospital (2012)
- Mid Staffordshire NHS Foundation Trust Public Inquiry (2013)
- Berwick review into patient safety (2013)
- Morecambe Bay Investigation (2015)

- Better Births: improving outcomes of maternity services in England - a five year forward view for maternity care (PDF. 3.69MB) (2016)
- The Gosport Independent Panel (2018)
- The Independent Medicines and Medical Devices Safety (IMMDS) Review (2020)
- The Paterson Inquiry (2020)
- Independent investigation into maternity and neonatal services in East Kent (2022)
- Independent review into patient safety concerns and governance processes related to the North East Ambulance Service (2023)
- The Ockenden review of maternity services at Shrewsbury and Telford Hospital NHS Trust (2022)
- The Infected Blood Inquiry (2024)
- The Lampard Inquiry (ongoing)
- The Thirlwall Inquiry (ongoing)

Collectively, these reports have made thousands of recommendations as to how care could be improved with particular focus on the safety of care delivery.

Some recommendations have been adopted by the government, NHS or private providers, but some have not. Some have been very specific (such as continuity of carer for maternity care), while others have been more generic (for example, duty of candour).

Appendix 10: national surveys

NHS England surveys

NHS England carries out at least 10 surveys each year including:

- Cancer Quality of Life Survey
- Friends and Family Test
- GP Patient Survey
- National Cancer Patient Experience Survey
- National Diabetes Experience Survey
- Patient-Led Assessments of the Care Environment (PLACE)
- Personal Social Services Adult Social Care Survey
- Personal Social Services Survey of Adult Carers in England
- PROMs in England for hip replacement procedures
- Under 16 Cancer Patient Experience Survey

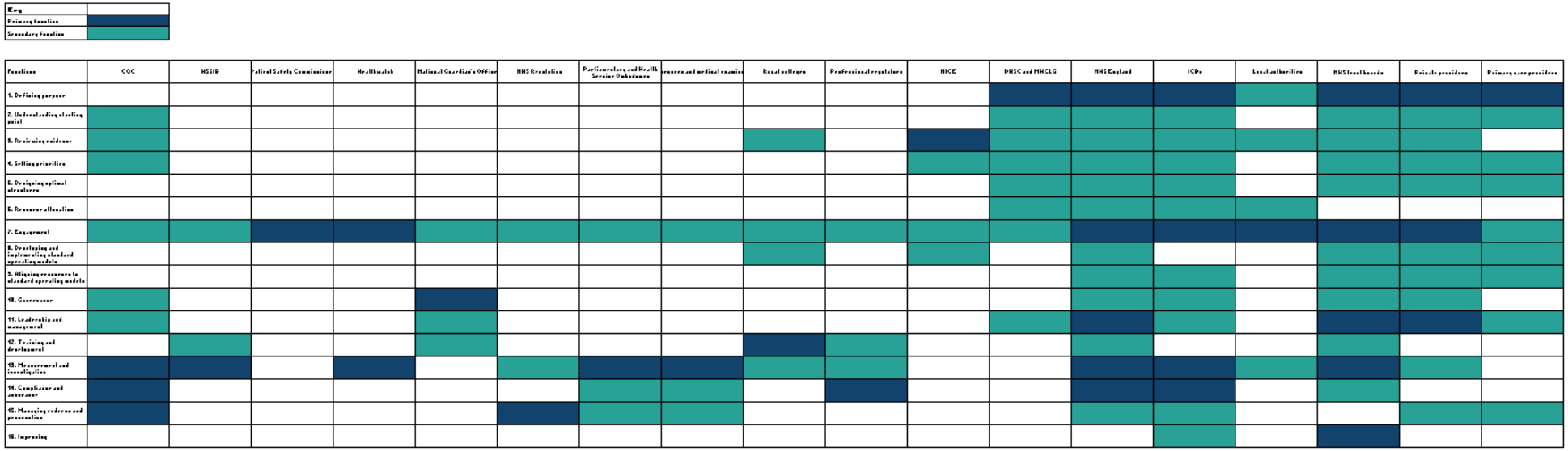
CQC surveys

CQC carries out at least 5 surveys each year, including the:

- adult inpatient survey
- children and young people's survey
- community mental health survey
- urgent and emergency care survey
- maternity survey

Appendix 11: functions table

Figure 1: an illustration of the approximate mapping of functions to organisations



The table above at Figure 1 is a visual illustration of the approximate mapping of 16 functions to the 18 organisations - or types of organisation - that exist across the patient safety landscape. It shows which functions they largely undertake and whether each function is a primary or secondary function.

Sixteen core functions are described and grouped into the following 4 areas:

- developing a strategy
- delivering health and care
- assuring delivery

- improving

Across the health and care system in England, these functions are carried out by the wide range of organisations and professional bodies shown in the table. The 18 organisations - or types of organisation - are:

- CQC
- HSSIB
- Patient Safety Commissioner
- Healthwatch
- National Guardian's Office
- NHS Resolution
- Parliamentary and Health Service Ombudsmen
- coroners and medical examiners
- royal colleges
- professional regulators
- NICE
- DHSC and the Ministry of Housing, Communities and Local Government (MHCLG)
- NHS England

- ICBs
- local authorities
- NHS trust boards
- private providers
- primary care providers

Developing a strategy

1. Defining purpose

Defining the purpose, vision or ultimate aim of the health and care system is typically carried out by the following organisations or types of organisation:

- DHSC and MHCLG
- NHS England
- ICBs
- NHS trust boards
- private providers
- primary care providers
- local authorities (to a lesser extent)

2. Understanding starting point

This relates to understanding the starting point of the health and care system and drawing on multiple sources of data and information, including that collected during assurance (see core function 13 under 'Monitoring and assuring quality' below).

No one organisation has prime responsibility for doing this across all areas of care, but the following organisations do contribute:

- CQC
- DHSC and MHCLG
- NHS England
- ICBs
- NHS trust boards
- private providers
- primary care providers

3. Reviewing evidence

This relates to reviewing the clinical and managerial evidence base, academic research and examples from other industries or other healthcare systems, and defining what 'good' looks like in order to deliver on the purpose or aims of the health and care system.

Here, NICE takes a lead role while other organisations also play a role. These are:

- CQC
- royal colleges

- DHSC and MHCLG
- NHS England
- ICBs
- local authorities
- NHS trust boards
- private providers

4. Setting priorities

Identifying a clear, coherent and actionable set of priorities that is consistent with the goals and values of the organisation, including those relevant to allocative and technical efficiency and equity, is not currently done in any single place across the health and care system. The following organisations contribute:

- CQC
- NICE
- DHSC and MHCLG
- NHS England
- ICBs
- NHS trust boards
- private providers

- primary care providers

5. Designing optimal structures

This relates to setting out structures to deliver against the aims of the health and care system, and enable high-quality and efficient delivery of services, including optimal commissioner and provider structures and robust governance structures.

Again, no one organisation takes overall leadership or responsibility for this. The following organisations contribute:

- DHSC and MHCLG
- NICE
- DHSC and MHCLG
- NHS England
- ICBs
- NHS trust boards
- private providers
- primary care providers

6. Resource allocation

This relates to allocating resources in order to maximise delivery against the purpose and aims of the health and care system.

No one organisation leads on this, but the following organisations play a role:

- DHSC and MHCLG

- NHS England
- ICBs
- local authorities

7. Engagement

Engaging with users, communities, staff and wider stakeholders on strategy and priority setting is a primary function of:

- Patient Safety Commissioner
- Healthwatch
- NHS England
- ICBs
- local authorities
- NHS trust boards
- private providers

It is also carried out to differing degrees by:

- CQC
- HSSIB
- National Guardian's Office

- NHS Resolution
- Parliamentary and Health Service Ombudsmen
- coroners and medical examiners
- royal colleges
- professional regulators
- NICE
- DHSC and MHCLG
- primary care providers

Delivering high-quality care

8. Developing and implementing standard operating models

This relates to developing, agreeing and implementing highly optimised operating processes and service models to deliver safe, effective, responsive, efficient and equitable services, using standardisation and technology where possible and appropriate.

No single organisation leads on this, but a number contribute to it - namely:

- royal colleges
- NICE
- NHS England

- trust boards
- private providers
- primary care providers

9. Aligning resources to standard operating models

No one organisation is responsible for setting out the optimal resources required at a local level to deliver high-quality care, but a number play a role in this - namely:

- NHS England
- ICBs
- NHS trust boards
- private providers
- primary care providers

10. Governance

Good governance includes:

- putting in place organisational and governance structures ('from board to ward') to make clear the standards expected
- establishing processes for monitoring performance against standards, including continuous review of data and inputs
- ensuring support for improvement where needed

The National Guardian's Office puts in place standards for staff to raise concerns and speak up.

Other organisations also consider governance structures. These include:

- CQC
- NHS England
- ICBs
- NHS trust boards
- private providers

11. Leadership and management

This relates to providing leadership that:

- puts quality at the centre of care
- recognises the role of high-quality management - including operational management and people management
- embeds, models, recognises and rewards behaviours that enable high-quality care

This is the responsibility of:

- NHS England
- NHS trust boards
- private providers

It is also carried out to differing degrees by:

- CQC
- National Guardian's Office
- DHSC and MHCLG
- ICBs
- primary care providers

12. Training and development

Training, development and accreditation of staff is a core function of the royal colleges. Other organisations also contribute to this - namely:

- HSSIB
- National Guardian's Office
- professional regulators
- NHS England
- NHS trust boards

Monitoring and assuring quality

13. Measurement and investigation

This relates to seeking input from users, measuring outputs and outcomes, carrying out audits and investigations, and quantifying the use of resources (which feeds into core function 2 under 'Developing a strategy' above).

This is a primary function of:

- CQC
- HSSIB
- Healthwatch
- Parliamentary and Health Service Ombudsmen
- coroners and medical examiners
- NHS England
- ICBs
- NHS trust boards

It is also carried out, to differing degrees, by:

- NHS Resolution
- royal colleges
- professional regulators
- local authorities
- private providers

14. Compliance and assurance

Ensuring compliance with planned processes and expected outcomes is a primary function of:

- CQC
- professional regulators
- NHS England
- ICBs

It is also carried out, to differing degrees, by:

- Parliamentary and Health Service Ombudsmen
- coroners and medical examiners
- NHS trust boards

15. Managing redress and prosecution

Managing the impact of severe harm, taking enforcement action where needed and ensuring redress where appropriate is a primary function of:

- CQC
- NHS Resolution

It is also carried out, to differing degrees, by:

- Parliamentary and Health Service Ombudsmen

- coroners and medical examiners
- NHS England
- ICBs
- private providers
- primary care providers

Improving

16. Improving

Continuously improving - reviewing, learning, listening, changing and adapting - to address sub-optimal adherence to agreed strategies and processes, and expected outputs and outcomes is a primary function of NHS trust boards. It is also carried out by ICBs.