professional standards authority

for health and social care



Safer care for all

Solutions from professional regulation and beyond

RLIT0001736_0001

www.professionalstandards.org.uk/safer-care-for-all

The Professional Standards Authority currently has five key functions.

- To drive improvements in the 10 statutory regulators in health and social care by undertaking annual reviews of effectiveness
- To provide a safety net for any fitness to practise decisions that are insufficient to protect the public
- To raise standards for health and social care professionals in non-statutory roles through its Accredited Registers programme
- To give independent advice to the Privy Council on the quality of appointments processes for regulator council members
- To use research and policy development to improve regulation and registration to better protect patients, service users and the public.

Our Vision - Safer care for all through high standards of conduct and competence in health and social care professionals.

Our Mission - To protect patients, service users and the public by improving the regulation and registration of health and social care professionals.

For more information about the Authority and how we are funded visit: www.professionalstandards.org.uk/about-us/how-we-work

The professional regulators we oversee:

- General Chiropractic Council (GCC)
- General Dental Council (GDC)
- General Medical Council (GMC)
- General Optical Council (GOC)
- General Osteopathic Council (GOsC)
- General Pharmaceutical Council (GPhC)
- Health and Care Professions Council (HCPC)
- Nursing and Midwifery Council (NMC)
- Pharmaceutical Society of Northern Ireland (PSNI)
- Social Work England (SWE)

The Professional Standards Authority also accredits registers of practitioners who are not regulated by law. The full list of registers that have been accredited under our Accredited Registers programme can be found on our website here: www.professionalstandards.org.uk/what-we-do/accredited-registers/find-a-register

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Twenty years of the Professional Standards Authority



The Professional Standards Authority for Health and Social Care (the Authority) was established by Parliament in 2002 to improve the regulation of healthcare professionals. This followed recommendations from the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. The inquiry found that regulatory failures had contributed to the issues identified at Bristol Royal Infirmary. It highlighted the risks caused by 'fragmentation and lack of clarity about responsibility for regulating the quality of healthcare'. Regulators needed to become more independent of the professions, and more coordinated between themselves.

The Authority was set up to put the public interest at the heart of regulation, and bring some consistency and coordination to the work of the regulators.*

Parliament extended the Authority's remit in 2012 following the publication of the Command Paper Enabling Excellence. It identified the need for decisions about regulation of professions to be based on risk, and for a process to make sure appointments to regulator Councils remained independent, following the planned abolition of the Appointments Commission. The Authority was given powers of accreditation to raise standards in the unregulated workforce, and a duty to advise on appointments to regulators' Councils. In 2015, the Authority and the regulators were given the same overarching objective of public protection. This strengthened our collective duty to act in the interests of patients, service users and the public.



In the Authority's lifetime, new regulators have been set up and new professions have been brought into regulation or transferred between regulators. The Authority now oversees 10 regulators, covering over 1.7 million medical, nursing, midwifery, dental, pharmaceutical, allied health, optical, social work, osteopathic and chiropractic professionals. During the last 10 years, the Accredited Registers programme has also grown. It now encompasses over 60 different occupations with 100,000 practitioners on registers. Over this time, the Authority has adapted its work to support improvements in regulation and registration to protect the public.

* Our founding legislation is the National Health Service and Healthcare Professions Act 2002. We were set up as the Council for the Regulation of Healthcare Professions, then became the Council for Healthcare Regulatory Excellence, before being renamed the Professional Standards Authority in 2012.

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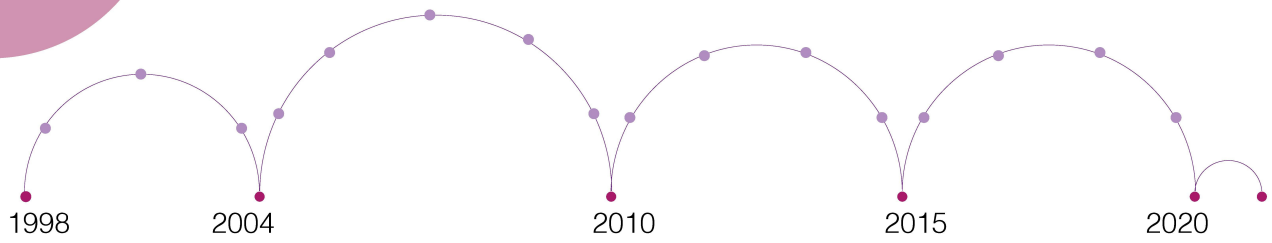

Key milestones in professional regulation

1998-2004

Into the modern era: the Kennedy reforms

Alongside other key events during this period, the Kennedy Report into failings in children's heart surgery at Bristol Royal Infirmary led to significant reforms. This included the creation of the Council for the Regulation of Health Professionals (predecessor body to the Authority), to coordinate the regulators and ensure greater focus on the public interest. The report also recommended a duty of candour for professionals.

2004-2010

From self-regulation to shared regulation: post-Shipman reforms

Strong criticism of regulation arising from the report into Harold Shipman's crimes established the importance of lay involvement in the fitness to practise process, the separation of investigation and adjudication and the need for ongoing competence checks which lead to the introduction of revalidation for doctors.

2010-2015

NHS is redesigned, but regulatory reform stalls

Government White Paper Enabling Excellence is published drawing on right-touch regulation principles (influenced by the Better Regulation agenda) and leading to the creation of the Accredited Registers. Structural change to the NHS occurs, however, the Law Commissions' Bill to simplify professional regulation is not taken forward. The Francis Report into the failings at Mid-Staffordshire criticises the fragmented nature of the regulatory system and leads to the introduction of the duty of candour for professionals.

2015-2020

Rethinking regulation

The Authority and all regulators are given the overarching objective of public protection. Government announces reforms based on *Rethinking regulation* and the Law Commissions' proposals. The Government response to the reform consultation is published in 2019 outlining reforms to regulators' fitness to practise processes, governance and rulemaking powers. The Inquiry into Hyponatremia Related Deaths in Northern Ireland finds failings in the care provided and subsequent investigation. It underlines ongoing challenges with candour and transparency.

2020+

To be continued

Work on proposals for regulatory reform continues against the backdrop of the COVID-19 pandemic. The Paterson, Cumberlege, and Ockenden reports describe a fragmented system with patient safety concerns falling through the gaps and the patient voice being lost.

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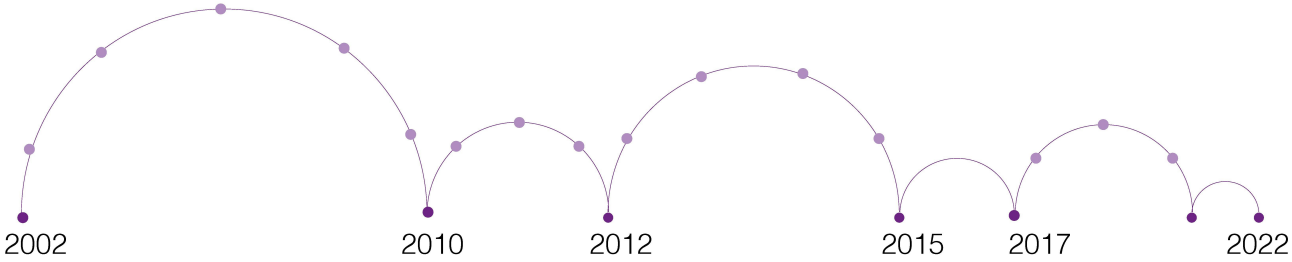

Key highlights for Professional Standards Authority

2002

A body to keep professional regulation focused on the public interest

The National Health Service Reform and Healthcare Professions Act 2002 creates the body that will become the Authority. Ministers describe us as the 'guardian of the public interest'.

2010

A new way of thinking about regulation

We publish *Right-touch regulation*. It sets out a framework for developing regulatory policy, and becomes influential both in the UK, and internationally.

2012

Into a new era for the Authority

The Health and Social Care Act 2012 changes our name to the Professional Standards Authority for Health and Social Care, gives us financial independence from government and grants us powers in relation to regulator council appointments and Accredited Registers.

2015 and 2016

A call for structural reform

After moves to review the law underpinning the regulators stall, we make the case for more radical reforms in *Rethinking regulation and Regulation rethought*. The reports highlight how disjointed the system is and the problems this causes, and argue for a reduction in the number of regulators – preferably down to a single organisation.

2017

A blueprint for reforming the way regulators work

We publish *Right-touch reform*, outlining detailed proposals for how regulators could be more effective. Many proposals within it are picked up in the Government reform consultation, *Promoting professionalism, Reforming regulation*.

2022

Let's work together for safer care

We mark 20 years since our creation and publish *Safer care for all – solutions from professional regulation and beyond* with a call to action to work collaboratively to tackle key patient and service user safety issues.

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Foreword from the Chair and Chief Executive of the Professional Standards Authority

As we mark 20 years since the establishment of the Professional Standards Authority, we take a look at some of the biggest challenges affecting the quality and safety of health and social care across the UK. There is no doubt that professional regulation has improved over the last two decades. From greater transparency in decisions about professionals, to governance changes to manage the influence of professional interests, there is much to welcome.

However, the recent Ockenden report into maternity failings at Shrewsbury and Telford Hospital NHS Trust revealed harm on a shocking scale, caused by two decades of poor care, and warned us that the contributory factors are unlikely to be limited only to this Trust. Are patients safer now than they were at the turn of the millennium?[1] Are we learning from these public inquiries?

Now is a time of both challenge and change in health and social care. The pandemic transformed the way social work is delivered, and disrupted the relationship between the NHS and its patients.[2,3] We are only beginning to understand the long-term effects on the care we receive.

At the same time, the Health and Care Act will embed far-reaching changes in the way that health and social care are delivered in England. The Scottish Government wants to create a National Care Service that would put state-funded social care on a similar footing to health. Public confidence in the health and social care sectors across the UK is being tested by successive high-profile failings, from the hyponatraemia and neurology inquiries in Northern Ireland, to maternity and social care failings at Cwm Taf and Brithdir in Wales.[4,5,6,7] Services UK-wide are facing workforce shortages on an unprecedented scale, and health inequalities are growing.

In addition, the UK Governments are working on a much-needed transformation of professional regulation. They are considering the number of regulators, and which roles in health and social care should be regulated, as they bring about fundamental changes to the powers and governance of existing professional regulators.

We see the commitment and dedication shown by UK health and care professionals. We also recognise that the pandemic has exacerbated pre-existing challenges for our health and social care services, and in doing so taken a huge personal toll on many.[8]

We know that there is a shared commitment to public protection across the regulators and registers we oversee, and a desire to support professionals to provide safe and high-quality care in challenging times. However, it is clear to anyone involved in keeping patients and service users safe that there is still a lot to do. Important though they are, the current reforms do not, in themselves, provide many solutions to the challenges we are facing. What they might do is give the regulators some of the tools to do so, and we hope that our report will help with this.

Now is the time to ask some difficult questions of the frameworks that are there to keep patients and service users safe, and the role of professional regulation within these frameworks.

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As the oversight body for the health and care professional regulators and registers, we are in a unique position to look across the health and social care landscapes around the UK, and report on the themes and issues that we see.

In this publication we give our view on some of the unresolved challenges for patient and service user safety in 2022 and beyond. We explore how professional regulation, and in some cases the wider system, might need to adapt to these challenges. They comprise:

- The impact of inequalities on patients, service users and registrants, and on public confidence more widely
- The challenges facing regulators in adapting to new disruptive factors in how health and care professionals deliver care, such as financial conflicts of interest, new business models and technological changes
- The workforce crisis and how professional regulation may need to evolve to better support workforce needs across the UK
- How to make learning cultures and individual accountability work together for patient and service user safety.

These are wide, complex topics. Although it has an important part to play, professional regulation is just one part of the picture. We are acutely aware that each of these issues requires and deserves much deeper consideration than we can give it here. However, we hope that our bird's-eye perspective will help us understand the problems and identify some ways forward.

They are serious issues which are too big for regulation, or individual UK countries, to tackle alone, and will have to be addressed collectively. They must also be discussed, and solutions developed hand-in-hand with patients and service users.

The Authority is looking at challenges that extend beyond our direct remit because we want to draw attention to gaps that it is in the public interest to fill. We don't claim to have all the answers, and acknowledge that others may have different views, but we do know that we all share a commitment to public protection. We hope that by publishing this report, we can stimulate further debate, which will ultimately result in improvements that will benefit patients and service users across the UK.

Let's work together towards safer care for all.



Caroline Corby, Chair

GRO-C



Alan Clamp, Chief Executive

GRO-C

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The Essentials – what this report is all about

This report examines the current state of professional health and care regulation in the UK, but it goes beyond that in identifying and proposing solutions to some of the huge challenges in health and social care today.

We set out here what this report is all about – the things the sector needs to know, and what we want to happen.

What are the problems?

Our report considers four main themes:

- **Tackling inequalities:** there are still unequal and unfair outcomes for protected groups in aspects of professional regulation. There is also a lot we still do not know about how inequalities affect all-important complaints mechanisms when care has gone wrong – or indeed what this could tell us about biases in care itself. Professional regulation must work to address its own issues, and support professionals to help tackle inequalities in the design and delivery of care. But as a sector, we also need to be better at hearing diverse voices, and collecting, analysing and sharing data.
- **Regulating for new risks:** changes in the way that care is funded and delivered are sometimes made with limited focus on the risks and impacts on patients and service users, and how to manage them. Reforming the regulators gives us an opportunity to address known problems, and may even build in some agility for the future – if we take the opportunity presented to us. But we also need better, more reliable ways to anticipate these changes.
- **Facing up to the workforce crisis:** workforce shortages are putting patients and service users at risk across the UK. Engrained attitudes to professional regulation and qualifications aren't helping. It is time to rethink the contribution of professional regulation to workforce planning.
- **Accountability, fear, and public safety:** just cultures and individual accountability are both essential to better, safer care, and must coexist. Professional regulation should be clearer about its role, to reduce unnecessary anxiety and inappropriate complaints.

  We need to find ways for these new approaches to safety such as 'safe spaces', to incorporate openness with patients, service users and families, and action against individuals where it is needed for public safety.

Our examination of these themes also identified a sector-wide problem:

- **Structural flaws in the safety framework:** the patient and service user safety landscape is fragmented and complex. Concerns raised often fall between organisations, or are left unaddressed due to jurisdiction issues or insufficient powers. Large-scale failures of care still occur frequently, and inquiries and reviews highlight similar themes and issues, with the system seemingly unable to prevent their recurrence. Each body looks at the problems principally through the lens of its own remit, often prejudging the nature of the solutions as a result. We need a new framework focused on safety that spans organisational and sectoral boundaries.

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What are the solutions?

To address the structural flaws in the safety framework across health and social care, we would like to see:

- An independent Health and Social Care Safety Commissioner (or equivalent) for each UK country to identify current, emerging, and potential risks across the whole health and social care system, and bring about the necessary action across organisations.
- With respect to the issues identified across our four themes, they would help to identify:
- Risks affecting protected groups differentially [Tackling inequalities]
- Emerging risks in how care is funded and delivered that are going unaddressed [Regulating for new risks]
- Risks relating to workforce shortages and how practitioners are regulated [Facing up to the workforce crisis]
- Unintended risks arising, or likely to arise, from existing, or proposed, national approaches to patient and service user safety [Accountability, fear, and public safety].

They would also coordinate public inquiries and reviews, and monitor how recommendations are implemented.

To address problems relating to the four themes of the report, we propose:

- A sector-wide initiative to improve collection, analysis and sharing of demographic data of complainants, to help to understand and address inequalities in care and complaints handling [Tackling inequalities]
- That Governments ensure the current reforms to the professional regulators equip them to respond to risks arising from developments in how care is funded and delivered [Regulating for new risks]
- A coherent practitioner regulatory strategy to support delivery of national workforce strategies across the UK [Facing up to the workforce crisis]
- That the Authority brings stakeholders together to find ways for the 'safe spaces' approach of the Healthcare Safety Investigations Branch (HSIB) England, and other local and national initiatives to improve safety culture, and support candour and accountability. This will include patients, service users and families, professionals, regulators, and many others. [Accountability, fear, and public safety]

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Executive summary - Safer care for all – solutions from professional regulation and beyond

There have been many improvements in health and care professional regulation over the last two decades, leading to greater transparency, better governance and a clear focus on public protection. However, the disheartening recurrence of failings indicates that significant challenges remain in the quality and safety of health and social care across the UK.

Our report, *Safer care for all – solutions from professional regulation and beyond,* examines a selection of key issues from the perspective of professional regulation, across four key themes:

- tackling inequalities
- regulating for new risks
- facing up to the workforce crisis
- accountability, fear and public safety.
- These are big problems, and we do not have all of the answers. However, our key recommendations provide possible ways forward, to cut across organisational boundaries in a fragmented health and care landscape.

As well as the recommendations for others, and our own specific commitments, we will use our oversight role to encourage co-operation, collaboration, and coherence across the system. In doing so, we will attempt to overcome some of the challenges inherent in improving such a complex system.

We will also try to influence Governments to take action within their jurisdictions, starting with the current legislative reforms to the regulators we oversee.

The issues we have identified in our report lead to one, overarching conclusion – that the UK needs a more robust approach to ensuring that health and social care are safer for everyone, overseen by people focused on this aim, with the tools to realise it.

Our overall recommendation, therefore, is that:

Each UK country should have a Health and Social Care Safety Commissioner, or equivalent function, with broad responsibility for identifying, monitoring, reporting, and advising on ways of addressing patient and service user risks.



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This summary sets out our main findings, recommendations, and commitments as the Professional Standards Authority, in support of safer care for all.

No more excuses: tackling inequalities in health and care professional regulation

There are major inequalities in healthcare with disparities in how groups of patients and service users gain access to, and experience services. Staff also face inequalities and discrimination in the workplace, and within the regulatory process, which can lead on to patient safety issues.

Regulators and registers are alive to these issues but are still to resolve the disproportionate representation of groups with protected characteristics throughout the regulatory process.

Patients and service users sharing one or more protected characteristics may be more likely to experience poorer outcomes and may be vulnerable to major failures of care. However, there is little understanding of the demographic profile of complainants or the potential barriers to complaining.

Professional regulation and registration alone will not solve the wider societal problem of inequalities. However, regulators and registers are in an influential position with their oversight of a professional or practitioner's journey from training through to registration and practice.

There are further areas where regulators, registers and the Authority itself must do more to bring about change, and we need further debate and discussion around the role of health and social care professionals in tackling discrimination and health inequalities.

Recommendations:

We recommend that:

- Regulators and registers work collaboratively to improve the diversity of fitness to practise panels, other decision-makers and senior leadership to ensure they reflect the diversity of the community more closely
- Regulators and registers work with other health and care bodies to gain a better understanding of the demographic profile of complainants and reduce barriers to raising complaints for particular groups
- Regulators and registers review how their fitness to practise processes and guidance address allegations of racist and discriminatory behaviour
- Demographic data on complaints made to the health and care services across the UK is recorded and made available for all bodies to use.

The Commissioner role we discuss in our report could also address the following recommendation:

- Demographic data on complaints should be analysed at a cross-sector level to identify disproportionate impacts and risks to protected groups.

The Authority's commitments to safer care

- We will ensure that the application of our Equality, Diversity, and Inclusion (EDI) standards for regulators is stretching and stimulates continuous improvement.
- We will work to ensure a consistent approach across both regulated and unregulated practitioners through our Accredited Registers programme and will be introducing clearer requirements for registers on EDI later this year.
- We will look at our own processes to ensure that we are not reinforcing or exacerbating inequalities in the regulatory system. Our Equality, Diversity and Inclusion Action Plan: 2022-23 outlines a range of commitments we have made both in relation to our internal processes and our external role.
- We will use our oversight role to encourage co-operation, collaboration, and coherence across the system, noting the inherent challenges in trying to address safety concerns when it is so fragmented.

The future is now: keeping pace with changes in how care is funded and delivered

There are huge changes underway in the provision of health and care with an increase in high street provision and increasing use of technology. These models of care are not all new, and are unevenly spread between UK countries and sectors. The prevalence of commercial providers and the conflicts of interest this can bring, along with online services, and new and innovative models of care, represent a growing trend away from established models of provision. They also open up new risks to patients and service users, and put professionals in difficult positions, where commercially-focused drivers cut across professional judgement, or new technologies blur lines of accountability.

As the delivery of healthcare continues to evolve and change, regulators need to be able to meet the challenges head-on with agility.

By and large, healthcare professional regulators are aware of the issues and are already taking action to manage risks and protect the public. However, they are sometimes reluctant to intervene (for example in matters relating to commercial practices) even where there is a legitimate case for doing so. This is partly due to the risk of challenge if there is no specific duty to act. They are also hampered by outdated and overly prescriptive legislation, and some lack the powers they need to protect the public effectively.

The four UK Governments' current programme of regulatory reform may give regulators more flexibility to respond to emerging risks. It presents an ideal opportunity to take a fresh look at some of these issues and assess whether they need to do more to address them. Governments and regulators should aim to be ahead of the curve in respect of new delivery models, rather than constantly struggling to catch up.

Appropriate scrutiny and action on these issues is made more challenging by the number and range of bodies involved. No one body or organisation is able to take a bird's-eye-view of the emerging risks to patients and service users and identify possible solutions. We need more reliable mechanisms for anticipating changes that open up public protection gaps across the sector, in partnership with patients and service users – it should not be left to individual bodies within their limited remits.

Recommendations:

We recommend that:

- Governments use the current healthcare professional regulation reform programme to:
  - **a.** Review the adequacy and effectiveness of the powers of regulators with a role in regulating businesses
  - **b.** Consider whether there is a case for extending business regulation powers to all regulators whose registrants work in 'high street' practices
  - **c.** Ensure regulators have the agility to address the challenges brought about by new approaches to funding and delivering care, including the introduction of new technologies.
- Regulators tackle business practices that fail to put patients first, risk undermining confidence in the professions, or fail to allow registrants to exercise their professional judgement. A cross-sector review should be conducted of the effectiveness of arrangements to address financial conflicts of interest among healthcare professionals.
- Governments, regulators and registers review how they will determine the lines of accountability for new technologies used in health and care.

We have also identified a gap that would ideally be filled by the Health and Social Care Safety Commissioners:

- We recommend the development of reliable mechanisms for anticipating changes in service provision that open up public protection gaps across the sector, and identifying ways to address them.

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Facing up to the workforce crisis and regulation's future role

The UK is facing a serious health and social care workforce shortage which it must address if care is not to suffer, and patients and service users come to harm. To address shortages in the statutorily regulated workforce, Governments, regulators, and employers must succeed in retaining existing professionals, and recruiting and training additional ones.

The latter may mean regulators challenging conventions about education and training, and Governments setting up clear pathways. Another option may be to look at those working in unregulated roles who are already helping to address staffing shortages and consider whether they, with appropriate safeguards, might be able to play more of a role. Professionals will also need to have the skills required to prepare them for the needs of different groups of patients and service users and future changes in the delivery of health and care.

Addressing these issues will not be easy. It takes time and money to train more health and care professionals, it may be hard to incentivise existing staff to stay or to recruit quickly enough to relieve pressures. A coordinated, coherent approach is needed to up-skill the workforce to prepare them for new models of care and provide care to diverse groups of patients and service users, and address emerging risks in healthcare provision. These problems need resolving quickly, and safely – with regulatory arrangements playing a key part.

Recommendations

We recommend that:

- Regulators and registers work collaboratively to identify opportunities to speed up workforce supply, equip practitioners to deal with future challenges in how care is delivered, close safety gaps and protect patients and service users.
- There is a clear process to guide the development of new health and care roles including the scope and purpose of the role, and the process for deciding on the level of assurance required.
- There should also be an agreed way of deciding when to deviate from taking a UK-wide approach based on a review of risks and benefits alongside consideration of the national context.
- Those involved in health and care workforce planning and delivery across the UK actively support additional and alternative means of assurance as a means of managing risks to patients and service users.
- The four UK Governments work together to develop a coherent strategy for the regulation of people, to support delivery of their national health and social care workforce strategies.

Recommendation that could form part of the Health and Social Care Safety Commissioner's role:

- Identifying risks relating to workforce shortages and how practitioners are regulated. This would help to inform the regulatory strategies

The Authority's commitments to safer care

- The Authority will use its oversight role, expertise and convening power to support the development of these regulatory strategies by the UK Governments.

Accountability, fear, and public safety

It is unclear how we can make individual accountability work in a system that is safe for patients and service users, and fair to professionals. The big push towards learning and just workplace cultures is vital in achieving safety aims, and allowing professionals to practise without fear of being unfairly punished if things go wrong. There is, however, a risk of individual accountability being overlooked. The Ockenden report highlighted the simultaneous desire to learn from harm, and impose appropriate accountability for unacceptable failures.

Individual accountability is crucial in keeping people safe in health and care, and professional regulation is integral to this framework. This should be understood when inquiries and reviews investigate major failings.

We have to acknowledge that aspects of professional regulation will always be feared to an extent – and fitness to practise in particular. But there are things regulators can do to alleviate this. Professionals' fear of being unfairly blamed is partly driven by misunderstandings about the role of the regulators, so action taken by regulators needs to be fair and transparent, with clear explanations of how and why decisions are taken. Employers also have a key role in addressing issues locally, communicating the regulator's expectations and referring members of staff where there are concerns.

Just culture approaches to patient safety, such as that promoted by NHS England, rightly include questions about individual responsibility, and where it may be necessary to look more closely at an individual's involvement in an incident. These policies should be clear – as the NHS guidance is – about when it is appropriate or necessary to refer a concern to the regulator – based on the regulator's own criteria.

We have concerns, though, about the safe spaces approach taken by Healthcare Safety Investigations Branch (HSIB) for England, because its high threshold for referral to the regulator does not match the regulators' own. It also seems to run counter to the professional duty of candour that requires professionals to be open and honest when things have gone wrong.

We should acknowledge that well-meaning, new, national approaches to safety and redress can cut across existing patient safety mechanisms. Governments should therefore proceed with caution and review them for unintended consequences.

Although the following recommendations may go some way to alleviating some of the tension between accountability and just learning cultures, we recognise the limits of the work we have been able to do on this. To do justice to the complexity – and urgency – of this issue, we need to have an open, sector-wide conversation, with input from patients and service users, professionals, employers, and many others.

Recommendations

We recommend that:

- Regulators should do more, both individually and collectively, to clarify and explain their approach to cases where a professional has been involved in a patient or service user safety incident.
- The UK Government should ensure that the 'safe spaces' investigation approach being implemented in England does not cut across the duty of candour or otherwise negatively impact on transparency or accountability.

Recommendations that could form part of the Health and Social Care Safety Commissioner's role:

- There should be an independent mechanism for centralised coordination and oversight of public inquiries.
- Policy checks should be introduced to ensure that any new national approaches linked to patient and service user safety are coherent with, and do not undermine, existing mechanisms.

The Authority's commitments to safer care

- The Authority will bring people together to find ways for the HSIB England's 'safe spaces' approach, and other initiatives for improving safety culture, to support candour and accountability. This will include patients, service users and families, professionals, regulators, and many others.

Safer care for all: an overarching safety body

Our report illustrates how fragmented the landscape we are operating in is – health, social care, and four countries, each with complex patient and public safety mechanisms spanning numerous different bodies.

For too long, individual organisations with different and specific remits have been expected to work together to address workforce and patient and service user safety issues. This approach is structurally flawed as there is generally no accountability for joint working and collaboration. Bystander apathy and differing organisational priorities also present significant barriers. Everyone understandably looks at the problem through the lens of their own remit, but no one has the overview.

This applies to Inquiries too. While they focus on extreme cases, they are a key driver for change. The Inquiries into failures in children's heart surgery at Bristol Royal Infirmary[9] and the Shipman murders[10] transformed the way professional regulation works. The current system is still imperfect, but it has improved greatly when compared to the previous professional-dominated framework. Inquiries are a mixed bag of statutory and non-statutory, with significant variations in remit that are often unexplained. As far as professional regulation is concerned, some have a strong focus on the actions of regulators (Shipman, Mid-Staffordshire) while others do not (Paterson, Ockenden).



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Recommendation

We recommend that:

- Each UK country has a Health and Social Care Safety Commissioner, or equivalent function, with broad responsibility for identifying, monitoring, reporting, and advising on ways of addressing patient and service user risks.
- The commissioners should sit above all other health and care organisations, spanning public as well as private provision. They would also be independent of Governments, and transparent in both their approach and outputs. From this unique oversight position, and working closely with key stakeholders including service users, they would fulfil the following roles:

Risk intelligence

- Review data on risks produced by other organisations to identify national or local trends
- Carry out meta-analyses of inquiry findings to identify trends
- Report specifically on any inequalities concerns arising from the safety data.

Expertise

- Make recommendations for addressing risks identified through the intelligence function
- Identify gaps in the patient and service user safety landscape, and make recommendations for addressing them
- Identify gaps in data collection and make recommendations for addressing them
- Recommend ways in which data collection can be improved and harmonised across the sector
- Signpost people with complaints to the correct organisation (and record concerns as part of its intelligence role)
- Carry out policy checks to ensure that any new national approaches linked to patient and service user safety are coherent with, and do not undermine, existing mechanisms to the ultimate detriment of patient safety.

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Inquiries secretariat

- Coordinate inquiries and reviews into health and care failings to bring greater coherence to terms of reference and approaches
- Report on progress against inquiry recommendations so that lessons are learned and mistakes are not repeated.

When it comes to the problems in this report, the Commissioners would help to identify:

- Risks affecting protected groups differentially [Tackling inequalities],
- Emerging risks in how care is funded and delivered that are going unaddressed [Regulating for new risks],
- Risks relating to workforce shortages and how practitioners are regulated [Facing up to the workforce crisis], and
- Unintended risks arising, or likely to arise, from existing, or proposed, national approaches to patient and service user safety [Accountability, fear, and public safety].

Safer care for all – solutions from professional regulation and beyond shows how the key issues of inequalities, new risks, the workforce crisis and accountability all lead us to this inevitable recommendation.

Without a role whose only responsibility is to make the system safer, we will each continue to look at patient and service user safety through our own lens – and potentially compromise public protection.

Work with us towards safer care for all.



Before you read this report

The issues covered in this report go beyond the limits of professional regulation, so we could be seen as overstepping our remit.

However, we have consciously decided to do this, as patient and service user safety issues, and how we resolve them, extend to the whole health and care system. Where appropriate,we have made suggestions and recommendations for organisations beyond professional regulation.

We focus on how these issues apply within the health and social care sectors across the UK, recognising that, whilst the systems in England, Scotland, Wales and Northern Ireland have much in common, they also have their own characteristics, advantages, and challenges.

Stakeholders within each UK country will need to reflect on how our findings and recommendations apply to them.

Our report uses a wide range of terminology and language. Where possible we have tried to use terminology appropriate to the specific context, and language mirroring that of source materials, or how stakeholders routinely express themselves.

However, in some cases, such as when we are referring to patients and service users, we have used non-technical language to make the report clearer and more accessible.We acknowledge that this may not reflect the language more generally used, or preferred, by some readers but hope that you will understand the logic of our approach.

As we mention in our foreword, we offer our conclusions and recommendations up for wider discussion and debate. We hope that you will take them in the spirit intended and, if you disagree, will engage with us on alternative approaches.

We recognise that ultimately, it will be up to the UK countries, individually and collectively, to work out how to deal with the problems raised in our recommendations to Governments;

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Safer care for all

Solutions from professional regulation and beyond

but as a UK-wide organisation we have tried to suggest solutions that will give patients and service users a consistent experience wherever possible.

We have made a number of recommendations for professional regulators and registers, including working collaboratively.

We recognise that not all organisations are the same size, and that your input may depend on the resources you have available. We want to work with you to help bring about these changes.

We have also made recommendations that we will take forward; and intend to use the findings of our report to inform both our immediate priorities and our long-term strategic objectives.

We want to play our part and work with patients and service users, regulators and other stakeholders to address some of the knotty problems that we have discussed in this report, to further our shared aim of protecting the public.

Putting it plainly

We have tried to write this report and put across our points as plainly as possible. However, we realise that health, social care and regulation lend themselves to specialist terminology and many, many abbreviations. To help make this report easier to read, the first use of an organisation/acronym will be spelt out in full and thereafter we will use the abbreviation – for example, the Royal College of Nursing (RCN), Care Quality Commission (CQC) or Artificial Intelligence (AI). We also use the term Government, the UK Government or Governments throughout the report. Most of our recommendations and the issues we have highlighted are UK-wide so we use the term governments and government interchangeably referring to the four governments of the UK.

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No more excuses – tackling inequalities in health and care professional regulation

‘All the skeletons of inequalities came out of proverbial cupboards’

British Association for Physicians of Indian Origin (BAPIO) report on differential attainment in the medical profession during Covid-19, 2021

In this chapter we look at how inequalities are arising in professional regulation and affecting users of health and care services as well as professionals; and propose some ways of helping to address them.

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Alongside many others, the health and social care sectors are going through a period of self-reflection around equality, diversity and inclusion (EDI).

The NHS Race and Health Observatory (NHSRHO) recently reported stark racial inequalities in access to and experience of health and care. Their findings reveal disparities in maternal and neonatal healthcare, mental health services, digital inclusion and access to health services, genetic testing and genomic medicine studies, as well as within the NHS workforce. Their report focuses specifically on actions for the health service in England but much of the research referenced is UK-wide.

Where they exist, the statistics on healthcare outcomes are shocking – for example, black women are four times more likely than white women to die in childbirth in the UK.[11] Such inequalities are also present in outcomes within social care although data is scarcer.[12,13]

The UK Government has announced plans to address health inequalities as part of its broader levelling up agenda, launching separate independent reviews into ethnic inequalities around medical devices and tobacco control.[14] It has also created the Office for Health Improvement and Disparities to take on some of the functions of Public Health England, with an explicit focus on tackling health inequalities.[15] The Scottish Government has highlighted the potential benefits of improving equality of access to social care services across Scotland for different groups.[16]

These are just some first steps. Governments and public health and care services across the UK, the independent sector, and all bodies involved in the safety and quality of health and social care still have much to do. The work will need to be done in partnership with patient and service user groups and explore the diversity of views and experiences across protected and socio-economic characteristics.

Awareness of the impact discrimination and inequality have on health professionals is growing; particularly as workforce pressures and challenges around recruitment and retention are increasing in both health and social care. Two thirds of healthcare workers who died from Covid-19 were from an ethnic minority background.[17]

The impact of harms caused by major medical failures on particular groups is also becoming clearer. In 2020, we saw reports published for four major patient safety scandals primarily affecting women.[18] This included the Ockenden Inquiry's report into failings at Shrewsbury and Telford Hospital NHS Trust, published in March 2022, revealed avoidable harm to mothers and babies on a major scale.

As mentioned above, the aspects of inequality we cover here fall into two main categories:

- inequality affecting registrants
- inequality affecting patients and service users.

We acknowledge that this is a vast subject, focusing on race discrimination alone could make up this entire report. Much of this chapter does just that, partly because much of the research carried out in this area focuses on race. However, we recognise that other inequalities are just as important and may have an impact on large sections of the population. The most recent ONS (Office for National Statistics) data reports that over 20% of the population of Great Britain are disabled as defined by the Equality Act.*[19]

* We note that Northern Ireland is not covered by the Equalities Act and is subject to separate equalities legislation: https://www.equalityni.org/Legislation

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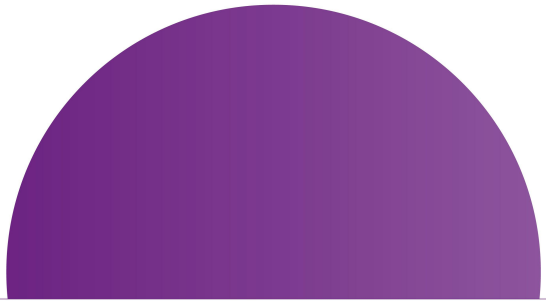
As well as inequalities relating to protected characteristics as defined in law we are becoming more aware of those around socio-economic status — particularly with the rising cost of living. The Health Foundation's 2020 report, marking 10 years since the influential Marmot Review, found that people in more deprived areas can expect to spend more of their lives in poor health. Improvements to life expectancy have stalled, and declined for the poorest 10% of women, the health gap has grown between wealthy and deprived areas and there are growing geographical disparities across the UK for health outcomes and life expectancy.[20]

Time and capacity constraints have left us unable to cover all types of inequalities in the same level of detail in this report, but we have done so where we can. We recognise that there is more work to do in uncovering the detailed issues arising for different groups.



Addressing inequalities within professional regulation and registration

> 'There is no doubt that the generation of overseas doctors who came to the UK at the invitation of the UK Government, [were] full of optimism and ambition... there was little support to underpin challenges round arriving in a different culture, speaking English but not necessarily with an understanding of local idiom or accent, and facing significant amount of racism not just from patients but from others in the system.'
>
> **UK trained BAME GP, Fair to refer?** [21]

Professional regulators have long been aware that their processes may have a disproportionate impact on certain groups of registrants. The extent of these concerns is now becoming more apparent and regulators, and the Authority along with them, need to address these problems more directly and urgently. At a minimum we should ensure that regulation does not reinforce or perpetuate wider system inequalities within health and care.

There are a number of points at which inequalities can affect a professional's career as a direct or indirect result of regulation. Evidence shows different levels of academic and career attainment amongst certain groups of students, particularly women and those from ethnic minority backgrounds. As BAPIO highlight, despite making up almost 40% of the medical workforce, international medical graduates are more likely to experience these differentials. This includes in entry to training, assessment, research and academia, career progression and leadership.[22]

According to the the Royal College of General Practitioners' (RCGP) annual report from 2017/18, the pass rate of the Applied Knowledge Test (AKT) for white doctors was 86.8% and 60.7% for all minority ethnic doctors.

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For the Clinical Skills Assessment (CSA), 93.8% of white graduates passed, compared with 83.4% of UK-educated minority ethnic graduates and 39% of internationally-educated minority ethnic graduates.[23]

The NMC has examined variations in revalidation rates amongst nurses and midwives. Their independent evaluation suggests that men, people over 65, black and minority groups, and disabled nurses and midwives may find it more difficult to fulfil what the process asks of them.[24]

In England, amongst NHS staff as a whole (all staff groups taken together), Black and minoritised ethnic (BAME) staff are more likely to enter local disciplinary processes. In 70% of NHS Trusts, the likelihood of BAME staff entering the local disciplinary process is more than for white staff. In over a quarter of NHS Trusts, the likelihood of BAME staff entering the disciplinary process is more than twice as high as for white staff (Equality and Diversity Council, 2019).[25]

GMC commissioned research into the fitness to practise process shows that black and minority ethnic (BAME) registrants are twice as likely to be referred to the GMC by employers compared to white doctors; and that international medical graduates (IMGs) are more likely to be subject to more serious sanctions through the fitness to practise process.[26] This is echoed in the findings of other regulators which indicate that BAME professionals are overrepresented at all stages of the fitness to practise process.[27]

Data is key in identifying and tackling EDI issues. Although it is not the only way regulators can understand the diversity of their registrants, it is an important element of recognising the impact of their own processes. Whilst regulators have improved in this area, not all of them hold adequate data, as historically they have not asked registrants to provide this information at the point of registration or renewal. This means that comprehensive data is lacking across the regulators we oversee.

If they want to fill this gap, it is important that regulators communicate clearly with registrants and build trust in why they need their data and what they intend to do with it. Social Work England is having to find ways to overcome the challenges it has experienced as a new regulator gathering this data – just 4% of social workers had submitted diversity data as of February 2022.[28] Other regulators have been more successful for example the GOC has been able to gather data on almost 100% of registrants, although over a longer period.[29]

Those who managed to secure this information have begun to look at where the impacts arise within their processes in more detail, and how they will address them. Specific actions taken by regulators in relation to the fitness to practise process include providing further guidance for employers on criteria for referral,[30,31] and improved training, including on unconscious bias, for those involved in fitness to practise decision-making.

It is positive to see regulators setting themselves targets, for example the GMC's ambition to eliminate disproportionate referral of BAME registrants into the fitness to practise process by 2026 and differential attainment by 2031.[32] They continue to report their progress towards these targets and we will continue to monitor it in our reviews of their performance.

The regulators acknowledge inequality issues and are all committed to addressing them. It can be difficult for them to pinpoint the causes and, even when they can, dealing with them may not be fully within their control in a structurally unequal society.

Fitness to practise referrals from employers may be the result of the culture within their organisations. However, the reasons behind over-referral of BAME registrants into the fitness to practise process may be complex. For example, it may also be the case that referral rates for white registrants are too low. This may be because employers are less likely to refer cases involving white registrants (for reasons we do not fully understand), or because employers

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and colleagues give them more support to resolve their concerns earlier in the process.

This ultimately shows us the structural disadvantages that exist for certain groups of professionals skewing their experience within the regulatory process.

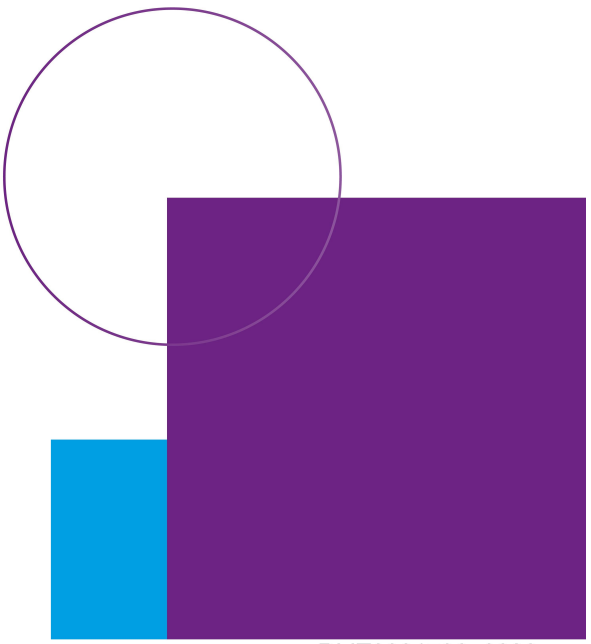
As we will see in the following section, there is little information available about the characteristics of complainants. This too could be a factor in the over-representation of particular groups with protected characteristics in the fitness to practise process. As well as unconscious bias training, it may also mean equipping investigators with the tools to interrogate the information included within a referral, to consider wider factors and avoid progressing cases that are not well-founded. It will be important for regulators to continue working to understand the causes of all these problems so that they can address them effectively.

It is clear that there are still significant disparities in the experience of different groups within the regulatory process and it is the regulators' responsibility to address this.[33]

As well as tackling disproportionate referrals this includes acknowledging the impact of systemic racism and ensuring that the regulatory process mitigates, as far as possible, the structural advantages/disadvantages that this gives to different groups of professionals. Another area needing further work is the diversity of senior leadership. There is an increasing body of evidence that having more diverse leadership can accelerate change and help to crystallise priorities for organisations. A number of regulators have taken some action in this area, for example, by taking steps to improve the diversity of candidates for recruitment to non-executive positions, or by introducing the role of 'Associate' Council members. However, progress has been slow. The GMC Chair, Dame Clare Marx, was the first female Chair since the organisation was formed in 1858 and although this was welcome, it was also long overdue.[34]

An area that may lend itself to joint-working between regulators is improving the diversity of the pool of available decision-makers, particularly in fitness to practise. We examined the issue of fitness to practise Panel member diversity in our 2019 report on how public confidence is taken into account when fitness to practise decisions are made, carried out following the Williams Review into the Bawa-Garba case. We concluded that currently regulators are drawing panellists from the same pool, which leads to people with similar backgrounds and experience being overrepresented on fitness to practise Panels. We recommended that: 'Regulators should ensure that Panels have access to a wide range of public views and seek to ensure that Panel members are drawn from a sufficiently diverse pool.[35]

We think that regulators and registers should work collaboratively to improve the diversity of fitness to practise panels, other decision-makers and senior leadership to ensure they more closely reflect the diversity of the community. Within the Authority we will also be considering our own role in encouraging action through our review of the relevant performance review standard (Standard 3). Further details on the areas we intend include in this review are given in the final section of this chapter.



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Inequalities felt by patients and service users

> 'They will say to you "email me" but older people don't have a computer… I don't want to use a computer.'
>
> **'Focus group participant, Breaking down the barriers - Older people and complaints about health care** [36]

The demographics of complainants

Despite an increasingly clear picture of the disparities in access to and experience of care, surprisingly little is known about those who make complaints and the barriers facing particular groups in complaining about poor care or misconduct by health and care professionals.

We have previously described the complex patient safety landscape and the challenges for all patients in navigating the system and understanding where and with whom to raise concerns.[37] It would not be surprising if this complexity had a differential impact on different groups of patients or service users.

During the pandemic, access to technology became an issue for certain groups of both registrants and complainants, as regulators began holding remote hearings and sharing papers and evidence for fitness to practise proceedings by email. The issue of digital exclusion, which spans different groups, may also be a barrier to patients complaining about their care in the first place, despite the benefits of improved access technology can bring to others.

Analysis of the demographics of complainants, and research looking at barriers to complaining appear to be relatively limited. A 2015 Parliamentary and Health Service Ombudsman report examined the barriers facing older people in making complaints about health and care and found that there were a number of factors affecting their willingness to complain about their care.[38] More recently, the Patients Association published a report from the Patient Coalition for AI, Data and Digital Tech in Health which highlighted the impact of digital health inequalities alongside a growing movement to digitise service provision.[39]

Some regulators have actively sought the views of people raising concerns about professionals. More of this work would provide a basis for addressing any difficulties particular groups encounter in raising concerns about care. Its absence is likely to perpetuate the problems around access and experience.

Regulators should work with other health and care bodies to gain a better understanding of the demographic profile of complainants and reduce barriers to raising complaints for particular groups.

An underlying problem is that national, routine data on health and care service complaints is limited in scope across the different parts of the UK. NHS Digital publishes data on complaints made to the NHS in England but this only captures certain categories of information about the complainant including age and status (patient, parent, guardian, carer, other).[40] Healthwatch has previously raised this issue to encourage maximum learning from the information gleaned from complaints.[41] Demographic data about complainants to health services in Scotland, Wales and Northern Ireland is also limited.

Data on social care complainants appears to be even more limited, in part due to the structure of social care provision across the UK. The Local Government and Social Care Ombudsman publish data on complaints they receive about adult social care providers and local authorities in England, but this does not include any demographic information about complainants.[42]

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Without this information, it is impossible to get a clear picture of the problems different groups of patients and service users encounter and address them effectively.

A further structural barrier is emerging in England. Currently national oversight of complaints made to Trusts is fulfilled by NHS England through NHS Digital. The Integrated Care System (ICS) framework formalised by the Health and Care Act has moved responsibility for commissioning primary care services from NHS England to local ICSs. As it stands, it is possible there will be no national oversight of complaints received as a matter of course. Healthwatch England has called on the Government to use the NHS mandate to instruct NHS England and ICS leaders to design a national system for learning from complaints which may provide an opportunity to use data to inform consistent action.[43] We support this but believe that demographic data captured needs to be broader in scope to allow meaningful lessons to be learned.

In the long term, demographic data on complaints made to the health and care services across the UK should be recorded and made available for all bodies to use. This data should be analysed at a cross-sector level to identify disproportionate impacts and risks to protected groups.

For England this would build on the recommendation by the NHS Race and Health Observatory that NHS Digital should produce national NHS statistics on service use by ethnic group, age and gender.[44]

The role of the patient voice in improving the quality and safety of care

Ensuring that diverse patient voices are heard is crucial in improving the safety and quality of care. As highlighted in the previous section, this is more challenging without more detailed information on who is making complaints.

The response to Covid-19 brought agility and innovation to the fore at a time of crisis. However, as the Patients Association,[45] National Voices[46] and others have reported, the pandemic left many users of health and care services feeling isolated and unsupported as well as impacting on patient and public involvement in policy-making and service delivery.

For many, the patient voice has always been undervalued, and sometimes unheard, in health and care. This has often been the case with major failures of care where patients and families have been ignored or their concerns minimised. An area for consideration and potentially further research is the disproportionate impact of harm, particularly arising from major failures of care, on groups of patients and service users sharing protected characteristics. A superficial observation at this stage is that people affected by such incidents are likely to share either one or multiple protected characteristics. Both the Cumberlege Review[47] and Paterson Report[48] highlighted harm caused to predominantly female patients and the difficulties faced by those trying to raise the alarm. The Cumberlege Review described a 'denial' of women's concerns.[49]

Maternity failings – often involving harm to mothers – are the frequent subject of inquiries. The Care Quality Commission (CQC) has raised concerns about the variation in quality in maternity services across England and limited progress in implementing recommendations to improve outcomes for particular groups.[50] The recently published Ockenden Report highlights another shocking example of avoidable harm and death in maternity services with families

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forced to campaign for years to have their concerns addressed. On the back of other, similar, findings the inquiry raises a question about whether the voices of patients, and particularly women, are listened to both in terms of the care they receive and when they are making complaints.

Looking more widely at other failures of care and examples of abuse and neglect across the UK such as Winterbourne View, Muckamore Abbey and Brithdir Nursing Home, there is a clear theme of those with protected characteristics, including older people and those with disabilities, being amongst those regularly affected by serious care failure. Research indicates that: 'ethnic minority consumers may experience inequity in the safety of care and be at higher risk of patient safety events'.[51]

This is a complex area but, for regulators, it reinforces the need to understand who is affected by failures of care and what more can be done to mitigate the risks for particular groups. It also highlights that the patient and service user voice needs to be strengthened and amplified; and that proper partnership with patients and service users must be built into health and care provision and regulation. The CQC's 2021-25 Equality Objectives support its aim of 'amplifying the voices of people most likely to have a poorer experience of care or have difficulty accessing care'.[52] This needs to be reflected in reality across health and care.

The déjà-vu experienced by many reading the Ockenden Report exposes a key problem relating to public inquiries: the lack of any mechanism to identify themes and learnings, and to ensure that recommendations acted upon in a coherent way.[53] This problem is exacerbated by the variation in how particularly, non-statutory inquiries and reviews are set up and managed. Typically, governments deal with individual inquiry reports separately, and the recent responses to Paterson, Cumberlege and others bear this out.

This is an observation rather than a criticism, and we recognise that governments are generally under pressure to be seen to respond to each individual occurrence quickly. However, this structural issue in the way that inquiry responses are managed has often failed to address issues and themes which may cut across multiple inquiries, including:

patterns in the demographic profile of those affected

- the challenges faced by complainants in getting their voices heard
- problems caused by the complexity of the system and gaps between organisations
- specific problems arising from care provided within the independent sector and/or from commercial or financial interests. [This finding supports the recommendation for the Health and Social Care Safety Commissioners.]



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Coming together to address inequalities and discrimination

> ‘We found that the very inequalities we were trying to tackle were being hampered by the culture which sustains such inequalities.’

Dr Charlotte Woodhead, King’s Institute of Psychiatry, Psychology & Neuroscience [54]

Poor culture, poor care?

There is clear evidence to demonstrate that poor cultures, where discrimination and inequality are allowed to persist, are bad for both professionals, and patients and service users. They may also have an impact on public confidence, quality of care and patient safety as well as on the wellbeing of staff. Tackling this will require a collaborative, coordinated effort from all bodies involved in the provision and regulation of health and care. We know that some of this work is already underway.

The impact of discrimination and inequality on staff morale, wellbeing and retention is well documented.[55] NHS Providers recently reported Trust Boards in England’s views that there is still much to do to embed race equality as a core part of their business. Respondents acknowledged the need for more support for staff facing discrimination and more work to improve retention.[56] As set out in our chapter on workforce, the magnitude of the workforce pressures faced by the health and care service makes this even more urgent.

However, discrimination and poor culture also have a significant impact on patients. This may include both discriminatory behaviours between staff, from staff to patients, and from patients to staff.

Perceptions of discrimination from staff may have an impact on the willingness of patients to access care.[57] Research suggests that implicit bias by healthcare professionals can have an impact on ‘patient–provider interactions, treatment decisions, treatment adherence, and patient health outcomes’.[58]

It also seems likely that a discriminatory or unequal workplace culture more generally is likely to have a negative impact on patient experience, patient outcomes and patient safety.* The NHS Race and Health Observatory highlights research showing that, ‘the greater the proportion of ethnic minority NHS staff who report experiencing discrimination at work, the lower the levels of patient satisfaction’.[59]

While patient experience and satisfaction have not always been seen as a helpful measure of safety and effectiveness of care, evidence suggests that there is likely to be a relationship between patient experience, patient safety and clinical effectiveness.[60]

What the direct impact might be on patient safety (i.e. the prevention of errors and adverse effects) is less well understood. However, as we know from the inquiry into events at Mid-Staffordshire and other public inquiries, cultures where staff feel bullied or isolated may mean that major failures of care go unreported and unresolved to the detriment of patient safety. It seems logical that, where staff feel bullied or discriminated against, or where patients feel unable to raise concerns, the risks for patients will increase.

* Patient outcomes and patient safety are closely interrelated, but in this context we use outcomes to refer to ‘measurable changes in health, function or quality of life that result from… care’ (see: Great Ormond Street Hospital for Children NHS Foundation Trust, 2020, Clinical Outcomes. Available at: https://www.gosh.nhs.uk/conditions-and-treatments/clinical-outcomes/#:~:text=Clinical%20outcomes%20are%20measurable%20changes,that%20result%20from%20our%20care); by patient safety we mean: ‘the prevention of errors and adverse effects to patients associated with health care’ (see: World Health Organisation: https://www.euro.who.int/en/health-topics/Health-systems/patient-safety)

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Our research looking at the impact of breaches of sexual boundaries between colleagues bears this out. It found that workplace cultures where staff feel uncomfortable or bullied by colleagues are likely to pose risks for patients.[61] Research into sexual misconduct and dishonesty has also shown that poor workplace culture can embed and exacerbate negative behaviour amongst staff.[62]

Unfortunately, the most recent NHS England Staff Survey demonstrates that such experiences remain widespread and, in some cases, are increasing[63,64] The Equality and Human Rights Commission reports that lower-paid ethnic minority workers in health and social care feel they are treated differently compared to their white counterparts, particularly during the Covid-19 pandemic. They also fear raising concerns, and even reported not having access to mechanisms for doing so.[65] The 2020 NHS Wales Staff Survey found that 16% of staff had been bullied or harassed by a colleague and 10% by a manager.[66] The 2019 survey for the health service in Northern Ireland revealed a slight increase in staff experiencing discrimination at work.[67] Although the most recent NHS Scotland Staff Experience Report paints a broadly positive picture, the Scottish Pulse Survey National Report of health and care staff in 2020 reports instances of bullying and harassment; cases reported in the media suggest that this remains an issue to a greater or lesser degree across the UK.[68]

All of this demands that system and professional regulators, as well as healthcare providers, should come together to tackle discriminatory and offensive behaviour from and towards staff.

Employers, system regulators and inspectorates across the UK have an important and influential position in reinforcing the right kind of culture within provider organisations. In England, the CQC has created a more ambitious role for itself in its equality objectives for 2021-25. This includes using data to assess the culture and leadership of health and care services.[69] Healthcare Inspectorate Wales's latest Strategic Plan contains their commitment to creating an equality strategy to ensure that it meets the needs of minority groups adequately in its work.[70]

In England, the NHS Workforce Race Equality Standard has resulted in a series of positive actions.[71] The recent introduction of a Workforce Race Equality Standard for social care is likely to focus this sector on making improvements too.[72]

We recognise that it is not the professional regulators' gift to address some of these problems directly and that they will need to prioritise actions and work collaboratively with other UK bodies to bring about change.

However, there are things that employers and regulators can do to support action to tackle discrimination, improve workplace culture and ultimately improve outcomes for patients which include:

- Developing clear and consistent standards and guidance (particularly for registrants in leadership and management positions) and disseminating them effectively.
- Adopting a firm and consistent approach in enforcing expected standards of behaviour in employment settings and via the fitness to practise process.
- Training and educating current and future professionals in the significance of equality and fair and open cultures in health and care, and of tackling workplace discrimination.
- Supporting professionals to tackle workplace discrimination and manage difficult situations and signposting them to the mechanisms and resources available.

In overseeing the regulators and scrutinising their final fitness to practise decisions we have observed a variable approach to how they deal with racist behaviour, both within their sanctions guidance and in practice. This is not to suggest that regulators do not take such behaviour seriously – we know they do. However, although we have not carried out a systematic review of decisions in this area, examples such as the

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Hayes case demonstrate that, sometimes panels are uncertain about what kind of sanction to impose.[73]

It is also important to note that cases ending up within the fitness to practise process are likely to represent the more obvious cases of racist behaviour, as opposed to more subtle or insidious behaviours and micro-aggressions that can also be very damaging.

Regulators and registers should review how their fitness to practise processes, including their indicative sanctions guidance and other fitness to practise guidance, address allegations of racist and discriminatory behaviour.

Guidance should be clear that racism and other discrimination are a serious breach and may result in removal from the register. However, we also think that we need research to improve understanding of the impact that such behaviours may have on both public safety and confidence. We know that regulators recognise that we need a consistent approach which can be more powerful than individual actions. The Authority is ideally placed to support collaboration in this area. We will work with our regulatory colleagues to explore how we can use our oversight and policy and research function to make it happen effectively.

A step-change in challenging inequality and discrimination

It is essential that action taken by professional regulators is part of the wider push to address inequalities within health and care. With greater awareness of health inequalities comes the wider question of whether health professionals should have a more explicit role in ensuring they, themselves, are informed of issues affecting different groups, and supporting action to address these disparities. For example, there is evidence suggesting limited understanding by some healthcare professionals of issues affecting women going through the perimenopause and menopause due to insufficient focus on these topics in medical training.[74]

The approach also varies amongst accredited registers, with many giving their registrants information and guidance to support them in providing care to a diverse population. For example, the British Association for Counselling and Psychotherapy (BACP) has published research on counselling and female genital mutilation (FGM), and on LGBT issues.[75]

In New Zealand, the Medical Council has taken a proactive approach with its requirements for doctors around 'cultural safety', intended to address the well-documented poorer health outcomes for Maori patients. The requirements ask doctors to consider: 'Challenging the cultural bias of individual colleagues or systemic bias within health care services, which may contribute to poor health outcomes for patients of different cultures' in their practice.[76]

While all regulators address discrimination in their codes, the strength of the wording they use varies. Some require registrants to actively challenge discriminatory behaviour, other wording focuses on respecting and providing for diversity and difference.

We think that as part of wider thinking around how regulators and registers can work within the system to address inequalities, they should consider whether health professionals should have a more explicit duty to support work to tackle inequalities within health and care. This could also then be reinforced through training, guidance and continuing fitness to practise requirements. As mentioned at the start of this chapter, this is increasingly a focus for all Governments across the UK.

We recognise that some regulators are already looking at what more can be done within standards, for example the GMC say of their planned review of Good Medical Practice: 'We'll also review our guidance to see if we can do more to address the inequalities and systematic issues that exist in medicine. This will help to create more inclusive supportive environments for all.'[77]

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This is unlikely to be a quick fix and some professionals may be concerned about what seems to be an increase in expectations, at a time when many are already feeling overworked and under pressure. Others may see it as already part of the role of a health or care professional. We will do what we can to create the space for such discussions about the role of professionals and professional regulation in this complex area.

Regulators have done a significant amount of work in this area to date, although progress varies. It is impossible to capture it all here, but the Authority reviews this work in detail as part of the annual performance review of each regulator against the Standards of Good Regulation introduced in 2019, under Standard 3: 'The regulator understands the diversity of its registrants and their patients and service users and of others who interact with the regulator and ensures that its processes do not impose inappropriate barriers or otherwise disadvantage people withprotected characteristics.'[78]

This Standard is recent, and the Authority is intending to review, in consultation with stakeholders, whether our expectations are sufficiently clear and ambitious for us to drive change. We have recently published our own EDI Action Plan and in the accompanying blog outlined some of the questions we intend to ask as part of this review including:

- What is the minimum information that regulators need in order to claim credibly that they have an understanding of the diversity of their registrants and the communities they serve?
- Can a regulator that has a significant disproportion of minority registrants in its fitness to practise process be regarded as meeting our standards? Is it enough that they're doing work to address it?
- What do we expect regulators to do to ensure that their registrants are providing proper care to a diverse population?[79]

The inter-regulatory EDI Forum provides an important space for regulators to share best practice. We will work with this group on how to define new expectations under this standard.

The registers of non-statutorily regulated practitioners that we accredit have huge potential to help build a picture of the wider workforce, particularly those roles that have good coverage under the programme, such as counselling and psychotherapy. Although some are making strides in this area, not all currently collect data on EDI within their processes or have clear plans in place for doing so. The Authority will consult on a new EDI standard for the Accredited Register programme in 2022.



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No more excuses: our conclusions

Professional regulation and registration alone will not be able to solve the problem of inequalities. However, regulators and registers are in an influential position as they oversee professional or practitioner pathways, from training through to registration and practice. Furthermore, the evidence of differential experience of different groups within the regulatory process shows very clearly that it is something regulators should tackle.

As these issues cut across the whole health and care system it will be important that the action we take is broad enough to accommodate care delivered in different ways and by different groups of practitioners. Although the majority of the registers we accredit have significant progress to make in this area, their practitioners may have an increasingly important part to play.*

We welcome the work carried out so far but accept the difficulties of addressing some of these issues, particularly if they are linked to wider societal attitudes or deep-rooted inequalities; for example those arising from sharp socio-economic divisions as described by the Marmott Review.[80] It has to be acknowledged, however, that efforts to date have failed to address many of the concerns. We have highlighted areas where collective activity by regulators, registers and/or other bodies would achieve more, or where action can have a disproportionately large positive impact. As the various bodies in health and care will need to work together, it will be important for regulators to communicate and collaborate, both between themselves, and with others in the sector, to ensure that they are using the levers at their disposal to tackle shared challenges.

* For example, there is a growing move to make better use of social prescribing, a link role that often sits as part of the multi-disciplinary team in primary care networks, as a way of addressing inequalities and helping those from different groups to access the care they need. Dr Jagan John, Chair - North East London Clinical Commissioning Group and Clinical Director for Personalised Care in London. Social prescribing as a way of tackling health inequalities in all health settings. Available at: https://www.england.nhs.uk/blog/social-prescribing-as-a-way-of-tackling-health-inequalities-in-all-health-settings/

Recommendations

We recommend that:

- Regulators and registers work collaboratively to improve the diversity of fitness to practise panels, other decision-makers and senior leadership to ensure they more closely reflect the diversity of the community.
- Regulators work with other health and care bodies to gain a better understanding of the demographic profile of complainants and reduce barriers to raising complaints for particular groups.
- Regulators and registers review how their fitness to practise processes, including their indicative sanctions guidance and other fitness to practise guidance address allegations of racist and other discriminatory behaviour.
- Demographic data on complaints made to the health and care services across the UK is recorded and made available for all bodies to use.

Throughout this report, we build the case for a structural change in the world of health and care safety – a Commissioner role with oversight across both sectors, and a specific focus on identifying emerging risks to patients and service users and recommending action. Some of the gaps we identify would ideally be filled by this role, including the following recommendation:

- Demographic data on complaints should be analysed at a cross-sector level to identify disproportionate impacts and risks to protected groups.

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The Authority also needs to do more. We will:

- Ensure that the application of our standards for regulators is stretching and stimulates continuous improvement.
- Endeavour to bring consistency of approach across both regulated and unregulated practitioners through our Accredited Registers programme, where we will be introducing clearer EDI requirements for registers later this year.
- Examine our own processes to ensure that we are not reinforcing or exacerbating inequalities that arise in the regulatory system. Our Equality, Diversity and Inclusion Action Plan: 2022-23 which we published in April of this year outlines a range of commitments we have made both in relation to our internal processes and our external role.[81]
- Use our oversight role to encourage co-operation, collaboration, and coherence across the system, noting the inherent challenges in trying to address patient safety concerns when it is so fragmented. This is an issue we address further in the final chapter of this report and in our overarching recommendations.

Through all of this work, it will be essential to keep the focus on patients, service users and those seeking to raise concerns across all four countries of the UK, and the impact that addressing inequalities and discrimination can have in improving the safety and quality of health and care for all.



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The future is now: keeping pace with changes in how care is funded and delivered

> ‘Policies which are based on assumptions of how the world is today can limit our choices and put us in a position of constantly responding to change, rather than creating the conditions to achieve the future we want.’

Government Office for Science, 2021[82]

In this chapter we examine what we see as some lower profile, inter-connected risks that need attention. We also consider how the sector can become both more agile and better at anticipating extraneous developments that can affect professional judgement and practice.

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The face of care in the UK and globally is changing fast, and regulation is struggling to keep up, resulting in new risks to patients and service users.

A growing proportion of care in UK is being delivered by the private sector,[83] as 'high street' providers such as pharmacies and opticians are contracted to deliver more and more primary care services. Health professionals such as osteopaths, chiropractors and physiotherapists are also taking on 'first contact' roles, and it is becoming more common for local pharmacies, surgeries and dentists to be owned by large corporate bodies. The Covid-19 pandemic, and its knock-on effects on NHS waiting lists, also mean that more people are turning to the private sector for hospital treatment such as routine operations.[84]

The overall percentage of NHS expenditure used to buy healthcare from an array of private providers – excluding GPs – is currently around 18%, or £21 billion a year.[85]

In the social care sector, there is a wide range of different service providers, whereas, within the adult social care sector, the vast majority of care is delivered by independent home care and residential care providers. These are mainly for-profit companies but also include some voluntary sector organisations.[86] Years of underfunding of social care in England have put pressure on the sustainability of this way of working, with over a quarter of care homes at risk of going bust – and voices in the sector have questioned whether the social care levy will be enough to deal with the pressures on the system.[87,88]

We are seeing large corporate chains accused of 'hard sell' tactics, and other questionable practices, that seem to prioritise profit over the best interests of both patients and registrants. However, the regulation of 'high street' providers of healthcare is complex and piecemeal, and may not be fit for purpose.

The rise of private healthcare is likely to increase conflicts of interest for individuals. This problem is particularly acute in medicine, where doctors sometimes have a financial interest in the businesses they refer patients to, or in carrying out individual procedures and where the potential for harm is most severe. Several prominent cases including the Ian Paterson case have raised the alarm,[89] but, as this chapter reveals, regulation covering financial conflicts of interest in healthcare can be weak and poorly enforced.

At the same time, technology is transforming both how we deliver care, and the techniques and services on offer. Remote and virtual consultations have become widespread in sectors such as primary care[90] and counselling[91] and people can now access a whole range of healthcare online, including pharmaceutical, optical and dental services. Artificial Intelligence (AI) and robotics are reshaping the healthcare landscape, and have the potential to markedly improve personalisation, accuracy and patient safety.

The rise of virtual care has the potential to improve access to the health sector and make it more convenient, but also opens up new avenues to poor or illegal practice. Evidence suggests that online healthcare businesses are underperforming against their 'physical' competitors in terms of quality of care[92,93,94] and sometimes engage in risky practices.[95]

Similarly, new technology such as robotic surgery and AI has huge potential but also carries significant risk. Technological failure or AI running on biased or inaccurate data put patients at tangible risk and may exacerbate existing inequalities: but lines of accountability are unclear.

While there are many benefits, these developments also present new risks to patients which may undermine public confidence in the professions. Professional regulation can be one part of the solution.

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Regulating 'high street' providers of healthcare: the case for regulatory reform

> 'The legislation around business regulation is complex and does not provide for a clear and consistent system… We are currently restricted in our ability to enforce high standards in business regulation. It is relatively easy for a business to continue to operate even in the event of a serious sanction being applied.'

General Optical Council, 2013[96]

Healthcare is not just delivered in hospitals and GP surgeries. It is also delivered in thousands of opticians, pharmacies, dental practices, osteopathic practices and chiropractic clinics and many other settings up and down the UK's high streets. Several of the healthcare professional regulators also play a part in regulating these 'high street' providers. However, despite all regulators sharing the same overarching objective,*(1) regulators of high street practice have different powers, with no clear rationale for why. Outdated legislation and regulatory gaps can hinder regulators in holding healthcare providers to account, and the overall system of business regulation is fragmented and confusing.

There are three regulators with a significant role in overseeing business registrants. These are the pharmacy regulators the GPhC which covers Great Britain and the PSNI which covers Northern Ireland, and the optical services regulator for the UK, the GOC. The GPhC sets standards for, and inspects, individual pharmacy premises, working closely with the Medicines and Healthcare products Regulatory Agency (MHRA), the body responsible for regulating all medicines and medical devices in the UK. The GOC regulates optical businesses but has no powers of inspection.

In Northern Ireland, the Medicines Regulatory Group (MRG) within the Department of Health undertakes routine compliance visits to all registered pharmacies.*(2)

In contrast to the professional regulators, who largely have UK-wide mandates, are the devolved 'system regulators' such as:

- Care Quality Commission (CQC) in England
- Healthcare Improvement Scotland (HIS)
- Healthcare Inspectorate Wales (HIW)
- Care Inspectorate Wales (CIW)
- The Regulation Quality Improvement Authority in Northern Ireland (RQIA).

The GOC was created by the Opticians Act 1958, and its most recent governing legislation dates back to 1989, though it has been subject to piecemeal amendments.[97,98] As well as regulating individual registrant optometrists, dispensing opticians and optical students, the GOC also regulates optical businesses. It can take business registrants through fitness to practise procedures if they fail to meet its 'Standards for Optical Businesses'.[99]

* (1) The statutory overarching objective of the healthcare professional regulators (excluding the PSNI) is to protect the public. This includes: To protect, promote and maintain the health, safety and well-being of the public; To promote and maintain public confidence in the professions; and to promote and maintain proper professional standards and conduct.

(2) This is to ensure that the premises and the pharmacist on duty are complying with the standards of conduct and performance set by the PSNI and the Department and with obligations imposed on the profession of pharmacy under all medicines related legislation (see: Department of Health Northern Ireland, Medicines Regulatory Group enforcement actions. Available at: https://www.health-ni.gov.uk/articles/medicines-regulatory-group-enforcement-actions)

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However, there are a number of shortcomings in the GOC's governing legislation which hamper its ability to regulate the optical sector fully or impose meaningful sanctions. Firstly, as outlined above, the GOC has no powers to inspect optical businesses. This makes it difficult to spot issues early and give businesses advice or conditions to help them improve. The capacity to identify issues before things go wrong could significantly improve the GOC's ability to get 'upstream' of problems.[100]

Secondly, limitations to the GOC's legislation mean that certain businesses fall outside the requirement for mandatory registration with the regulator. Registration with the GOC is only required for 'bodies corporate'*(3) with particular management structures; and even then only if they use certain protected titles such as 'optometrist' or 'dispensing optician' in their company or trading name.[101] What this means in practice is that optical businesses can avoid having to register; either by using an alternative term such as 'eye care' or by virtue of their corporate structure. In 2013, the GOC estimated that only 2,200 of around 6,400 optical businesses were registered with them.[102] This leaves customers without the assurance that all optical businesses are complying with the GOC's standards and means that optical businesses are not operating on a level playing field.

Thirdly, even where the GOC is in a position to take action against a corporate registrant, the maximum fine they are entitled to impose is £50,000 (although there are other actions they can take such as imposing conditional registration, suspension or striking off).[103] While this amount may be significant for a small independent practice, it is less so for a large corporate chain, and is unlikely to act as a deterrent as the GOC states it should.[104]

The inadequacy of the fine was brought into sharp relief in 2019 when the GOC imposed the maximum penalty on Boots Opticians, a company which in the same year recorded a profit of £167 million.[105]

The GOC has raised concerns[106] about these issues and is seeking an extension to its powers, to require all optical businesses carrying out restricted functions to be registered.*(4) It has asserted that 'compulsory registration will better protect the public by ensuring a consistent approach to those activities that tend to be within the control of businesses as opposed to individual registrants.'[107] In the meantime, it continues to encourage businesses to register even where they are not required to do so. The GOC is also considering asking for powers of inspection to ensure that optical business comply with business standards.[108]

The GPhC has more modern legislation, established under the Pharmacy Order 2010. Businesses engaged in things like selling or supplying Pharmacy or Prescription Only Medicines (POMs) are required to register with the GPhC or PSNI, depending on location.[109] The GPhC sets the standards for registered pharmacies in Great Britain and has the power to inspect individual premises to assess whether they are meeting the standards. Where there are discrepancies the GPhC can issue improvement notices or conditions, or ultimately, disqualify a pharmacy owner and remove all their premises from the register.[110]

The GPhC's inspection and enforcement powers are unique among the healthcare professional regulators. They give it significant scope to influence a number of areas including governance, risk management and safe staffing.

* (3) A body corporate is a limited company or limited liability partnership that has been incorporated with Companies House. This does not include non-limited liability partnerships (except in Scotland) and sole traders.

(4) 'Restricted functions' are those under Part IV of the Opticians Act 1989 – testing of sight, fitting of contact lenses and sale and supply of optical appliances.

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However, there are also potential shortcomings in the GPhC's model. The Pharmacists Defence Association (PDA) says that 'treatment of pharmacy owners is in stark contrast with [GPhC's] treatment of individual registrants' and believes that 'the regulator should achieve a fair and balanced regulation regime that is equally demanding upon both pharmacists and the employers'.[111] The PDA believe that the GPhC is better equipped to use its powers against individual pharmacists than against pharmacy owners, and that as a result it is much more likely to take action against individual pharmacists than owners.

The picture is complex. In addition to the GOC and GPhC, there are other regulators overseeing registrants who primarily work in high street practices, but which have limited (or no) powers to regulate those businesses. The regulators of osteopaths and chiropractors have no powers in relation to the businesses that provide these services, but are not asking for these powers. Often these professionals work as sole traders, so regulating the business and the person are one and the same. On the other hand, dental practices, which are largely private sector businesses located on the high street, are inspected by the CQC. The GDC regulates the dental team across the whole of the UK but has no powers of inspection, and very limited powers to regulate business practices.[112] These sorts of disparities in the powers held by healthcare professional regulators make the regulatory landscape fragmented and confusing.

Adding to the confusion are the grey areas of practice available on the high street that sit between 'healthcare' and 'beauty treatments' such as aesthetic procedures including Botox and dermal fillers. Whilst regulated professionals can provide non-surgical, cosmetic treatments this is not always the case. This leaves the public with little assurance that practitioners carrying out potentially harmful procedures are competent to do so. There are growing concerns about practitioners administering non-surgical cosmetic treatments[113] with serious side-effects when they go wrong, such as scarring and infections. The UK Government aims to address these risks through a licensing regime which will 'introduce consistent standards that individuals carrying out non-surgical cosmetic procedures will have to meet, as well as hygiene and safety standards for premises.'[114]

Regulators face other challenges in holding corporate entities to account. Perhaps the most significant of these is the relative power imbalance between the regulator and some large corporations. Not only are regulators outstripped financially by large businesses, there is also the question of how feasible it would be, in practice, for regulators to impose the most serious sanction of erasure on a large chain. Boots for example has over 2,200 UK stores[115] Lloyds Pharmacy over 1,500,[116] and Specsavers almost 2,000.[117] These businesses play an integral role in the delivery of healthcare in the community. Were regulators to take the most extreme action of removing these businesses from the register it would leave a large number of people – in the short term at least – without a healthcare provider they can rely on. These businesses may, in effect, come close to being too big to fail.

Reform should be considered on two fronts: firstly, the powers of those regulators with a role in regulating businesses should be reviewed. This should focus on the effectiveness and adequacy of current powers (for example, inspection powers, powers to require businesses to register, levels of fines etc), and whether they are sufficient to protect the public and hold businesses to account.

Secondly, the UK Governments should consider extending business regulation powers to all regulators whose registrants work in 'high street' practices and, in doing so, should assess any regulatory gaps arising from the current system.*

* The Government committed to considering 'professional regulators' roles in regulating businesses and premises' in 2019 (See: Department of Health and Social Care, July 2019, Promoting professionalism, reforming regulation: Government response to the consultation. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/820566/Promoting_professionalism_reforming_regulation_consultation_reponse.pdf

The Authority has previously called for healthcare professions and high street premises to be regulated together,[118] and in our view this remains the most logical approach.

The Governments should use the current programme of regulatory reform to review the adequacy and effectiveness of the powers of regulators with a role in regulating businesses. It should also consider whether there is a case for extending business regulation powers to other regulators whose individual registrants work in 'high street' practices.

As the Governments have already set out their view that 'regulators should have broadly equivalent powers to maintain a level of consistency and effective public protection',[119] we hope these recommendations will support reform in this area.

Profit before patients? The role of healthcare professional regulators in scrutinising commercial practices

> 'At the opticians, the young woman testing my eyes declared I have cataracts… Without seeking to reassure me, the optometrist started a sales pitch for a treatment to cut off my cataracty old lenses and replace them with magical plastic ones. In fact, she priced up the operations right there: £4,000 for my left eye, £3,000 for the right… Upstairs choosing glasses, I was aggressively up-sold "varifocal" lenses… later I was called back. I asked the new optometrist about my cataracts. "You don't have cataracts," she said. "Your eyes are healthy." Nothing like a dose of rapacious private medicine to make you appreciate the NHS.'
>
> **Janice Turner, The Times, 9 February 2022**[120]

High street healthcare establishments such as pharmacies and opticians provide an essential public service. They often carry out procedures and services which are directly funded by the NHS, such as free eye tests, hearings tests, and the provision of NHS prescriptions. However, as well as being an essential part of the healthcare landscape, they are also private businesses, whether as small independent providers, or as part of large multinational chains. In common with businesses across all sectors, they use techniques designed to optimise profits, such as sales targets and employee incentives, or managing costs by keeping staffing levels to a minimum. Businesses have been criticised for these approaches, at times, amid claims that profit is sometimes put before the best interests of customers. As regulated healthcare settings, these businesses must achieve a fine balance between the best interests of patients and that of their bottom line.

Healthcare professional regulators overseeing high street practices are clear that patients must come before profits. The GPhC Standards for Registered Pharmacies[121] recognise that whilst businesses are subject to competing demands, including commercial ones, medicines themselves are 'not ordinary items of commerce' and pharmacies are 'a fundamental healthcare service'. As such, commercial interests should never come before the best interests of patients, as stipulated by Standard 2.6: 'incentives or targets do not compromise the health, safety or wellbeing of patients and the public, or the professional judgement of staff'. Similarly, the GOC's Standards for Optical Businesses[122] state that 'as a healthcare provider…. the care, well-being and safety of patients must always be your first concern.'

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However, while the standards set by regulators may be clear, there are longstanding and persistent concerns that some businesses are failing to adhere to either the letter or the spirit of these rules. Both pharmacies and opticians have been criticised for engaging in a range of practices that go against the best interest of patients. For the optical sector this includes 'hard sell' tactics to persuade customers to sign up for laser eye surgery, up-selling expensive lenses, or not always giving patients their prescription so that they can buy glasses elsewhere.[123] Examples of such practices were shown in a 2014 exposé of Optical Express,[124] which revealed that the company's training manual encouraged staff to use emotive language when discussing laser eye surgery, such as 'what price can you put on your eyesight?' A Which? investigation found repeated failures to explain the possible complications of the surgery.[125]

In the pharmacy sector, large chains such as Boots have been accused of failing to maintain safe levels of staffing as a deliberate tactic to increase profit margins[126] and of setting inappropriate sales targets.[127] Questions about unethical practice in the sector were brought into sharp focus during the Covid-19 pandemic when some pharmacies were found to be charging hugely inflated prices for essential products including hand sanitiser, face masks and paracetamol. This prompted the GPhC and the Competition and Markets Authority (CMA) to issue a joint letter warning pharmacies against 'unfair business practices.'[128]

Hard sell tactics, overcharging and failing to maintain safe staffing levels have clear implications for both public confidence and patient safety. However, patients and the public are not the only losers when healthcare businesses engage in questionable practices. Healthcare professionals employed by those businesses can be put in the difficult position of having to choose between meeting the targets set for them by their employers and upholding professional standards.

The GOC Registrant Survey 2021[129] found that almost a quarter (23%) of respondents had felt under pressure by an employer or a business to sell a product or service which they knew was not needed by the patient in the past year. Almost a third (29%) had felt pressure to meet commercial targets at the expense of patient care. People working for optical chains were more likely to report feeling under pressure than those working for an independent optician.

Similarly, the PDA 2021 Safer Pharmacies Survey[130] found that 46% of respondents stated that patient safety was placed above 'commercial or other operational considerations' only half the time or less.

Putting undue pressure on health professionals to meet commercial targets is likely to create a conflict between the demands of the employer and patient interests. While it should be clear that complying with professional standards must be the priority, it may be challenging for individual registrants to make this case, particularly where targets are set at a distance by a large corporation, and store managers may not be registrants and therefore not subject to the same professional standards.

As well as questionable practices among some high street providers of healthcare, there have been a number of reports and inquiries highlighting poor practice and profiteering in both the adult and children's social care sectors.The Winterbourne View serious case review found that profit was placed 'over and above decisions about the effective and humane delivery of assessment, treatment and rehabilitation'.[131] In South Wales the coroner ruling on the deaths of residents at Brithdir Nursing Home, due to neglect, stated that the owner was 'more concerned about his profits from the care home, than the well-being of the residents'.[132]

In addition, a recent CMA market study into children's social care found that the market was 'dysfunctional' and that large private sector providers were making unduly high profits.[133] There is no single professional

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regulator overseeing care sector workers,with practitioners coming from varying backgrounds, including nursing, medicine, occupational therapy, and social work. No professional regulators have powers over social care providers. However, regulators will clearly have an interest in business practices that may have a negative impact on registrants or service users in the care sector.

How much 'commercial practices' in the health sector should be overseen or regulated by healthcare regulators is a contested area. The CMA has the power to take action against company directors if they breach competition law, focusing strongly on the pharmaceutical sector.[134] However, the CMA is also conscious of the need not to over-regulate and has made it clear that competition is the key mechanism for driving down prices and promoting innovation.[135]

The healthcare professional regulators have generally steered away from commenting on commercial practices unless they pose a clear risk to patient safety. The GPhC, for example, states that it will 'not usually take action on matters that are purely commercial in nature and have no medicinal or practice-related element'.[136] However, the PDA has criticised this approach, particularly the decision not to be prescriptive around what constitutes a 'safe staffing level.'[137]

The GPhC set aside its hands-off approach to commercial practices during the pandemic when it signed a joint CMA letter on overcharging. In this instance, it made its decision to intervene on the basis of its duty to uphold public confidence. The GPhC stated that 'retail practice can impact on public perceptions of pharmacy – and public confidence' and expressed a willingness to take action where there are 'broader issues that would impact on public confidence.'[138]

All healthcare professional regulators have a duty to uphold public confidence in the profession as one of their overarching objectives.[139] Many of the business practices described above could impact on public confidence, which would bring them clearly into the professional regulators' territory.

While scrutinising individual practices such as 'hard sell' tactics may be tricky for regulators, this does not mean that they should shy away from engaging with them altogether. There is a clear risk that the widespread use of these practices could undermine public trust; not only in the professionals using these tactics, but in the profession as a whole. They also risk creating conflicts for registrants between the demands of the employer and those of regulators.

Regulators should tackle business practices that fail to put patients first, risk undermining confidence in the professions, or fail to allow registrants to exercise their professional judgement.

Businesses have an important role to play in the delivery of healthcare and we know many take patient safety extremely seriously.The Independent Healthcare Providers Network (IHPN) the membership organisation for a range of independent healthcare providers across the UK has led work by the sector on patient safety. This has included supporting the implementation of the recommendations from the Paterson inquiry and encouraging independent providers to appoint a Freedom to Speak Up Guardian.[140]

However, the inherent tension between profit and patient best interest should be monitored. Regulators will need to consider whether they need to be more interventionist in their approach where it is in the best interests of the public.

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Individual conflicts of interest – time to get tough?

> ‘MRI scans, PET, you name it, I have had every scan under the sun multiple times, because at the end of the day he [Ian Paterson] was raking in, Spire were raking in that money.’

Patient 69 treated at Spire hospitals, Report of the Independent Inquiry into the Issues raised by Paterson[141]

Conflicts of interest do not just occur within big businesses and corporate entities, they can just as easily arise between a single health or social care professional and the patient or service user in their care. Although they can occur across all health and social care sectors, the most high-profile cases often involve doctors, and there are several shocking examples of patients being harmed by doctors acting out of financial self-interest. While there are measures in place to mitigate risk, most notably professional codes and rules set by the CMA, these have been criticised for being both weak and poorly enforced. As a result there is a danger that patients are left exposed to an unacceptable risk of harm, which is only likely to grow as private practice continues to expand its share of the healthcare market and patients exercise their choice.[142]

It is estimated that around 17,500 consultants in the UK undertake some form of regular private work.[143] Arrangements vary but may involve them ‘renting a room’ in a private hospital or forming a joint venture business with a hospital. In the latter arrangement, consultants receive a share of the profits from treating patients in the form of a dividend, in addition to the fees they earn from treating individual patients.[144] A number of other arrangements made between private hospitals and consultants have been banned by the CMA within the past decade.[145] They include where consultants are required to refer their private patients to an individual hospital, or where financial rewards are based on the number of referrals they make.[146]

As consultants working in private practice may have opportunities to refer patients to that practice (to their own financial benefit) there is a clear risk of conflicts of interest arising. Healthcare professional regulators are alive to this risk, and in 2017 issued a joint statement making clear that professionals must put patients’ interests before their own and ‘ensure their professional judgement is not compromised by personal, financial or commercial interests…’.[147] Separate GMC guidance also states that ‘you must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients.’[148] It goes on to say that where a medical professional refers a patient to an organisation in which they have a commercial interest they must tell the patient and record it in their medical record.

In addition to the guidance issued by professional regulators, the CMA oversees and governs the financial interests of doctors in private practice across the UK. It has raised concerns about how the private healthcare market operates, and in 2014 introduced rules restricting the financial stake consultants are permitted to have in private hospitals. Consultants are now prohibited from owning more than a 5% share of a company where they refer or treat patients. Further, doctors and private hospitals must declare any such financial arrangements on the hospital website.[149] The CMA rules sit alongside NHS guidance that conflicts of interest should be declared.[150]

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However, these rules have been criticised for being insufficiently robust and poorly enforced, and there is evidence that financial conflicts of interest have led to patient harm in spite of them.

UK examples of patients being harmed by doctors apparently acting in their own financial interest include the cases of Mina Chowdhury, who falsely told parents their children had cancer and then referred them for private scans provided by his company,[151] Paul Miller, who inappropriately referred patients for treatment using a machine he owned,[152] and surgeon Ian Paterson who carried out hundreds of unnecessary surgeries from which he allegedly benefited financially.[153] Whilst such examples are thankfully rare they can nonetheless impact on many patients and have a significant impact on public confidence.

There is also substantial evidence of harm from countries with more developed private medical markets, such as the US. It has been found, for example, that doctors who received financial rewards for prescribing opioids prescribed substantially larger quantities,[154] contributing to the US opioid crisis. The CHPI cites further examples from the US of financial incentives in medicine subjecting patients to unnecessary treatment or other harm.[155]

Criticisms of the current system for managing conflicts of interest in medicine are twofold; firstly, that the rules which already exist are not properly enforced, and secondly that the rules themselves are inadequate.

In respect of the first point, research conducted by the CHPI has found that 'rules governing share ownership and the declaration of financial interests by private healthcare companies appear to have been breached… In some cases, [they] found that consultants own up to 20% of the private hospital facilities they work in, significantly more than the 5% limit imposed by the CMA'.[156]

The CHPI further asserts that 'there is no evidence that the CMA has dedicated any resource to monitoring or enforcing the law governing the use of financial incentives in the UK healthcare system'.[157] Commentators have also drawn attention to the fact that the GMC has declined to take action on breaches of the share ownership rules on the basis that no direct impact on patient care had occurred.[158]

While steps could be taken to ensure that existing rules are better enforced, would this, in itself, be sufficient to adequately manage the risks posed by conflicts of interest in medicine? There is a strong argument that such conflicts should in fact be banned where possible (accepting that some conflicts may be unavoidable). The US for example, with its long history of private medical provision, largely prohibits financial conflicts of interest, including physician ownership of facilities.[159]

David Rowland, Director of the CHPI makes this argument stating that merely requiring transparency about conflicts of interest, and then placing the onus on the patient to reach an informed decision, ignores the 'information asymmetries which exist between the patient and the doctor.'[160]

The predominance of the state sector in the provision of healthcare in the UK has meant that rules for managing conflicts of interest are relatively new and underdeveloped. However, the private healthcare market is expanding rapidly, with research conducted by the IInstitute for Public Policy Research (IPPR) finding that 'the UK is the G7 nation with the fastest rise in healthcare expenditure from out-of-pocket or voluntary insurance sources.'[161] For those who can afford it, private healthcare can offer a welcome and speedy alternative particularly when the NHS is going through a challenging period. However, the rapid growth of this sector means that issues arising from financial conflicts of interest are only likely to grow, and regulators must ensure they are equipped to deal with them robustly.

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This is also an issue for the NHS. In its 2019 report looking at financial incentives and conflicts of interest in the UK's private healthcare system, the CHPI identified 481 medical consultants with equity stakes in 34 different joint ventures with private hospital companies – 73% of these consultants are employed directly by the NHS. Over the six-year period covering 2015 to 2020 these 34 joint ventures generated £1.24 billion in revenue and recorded an operating profit of £258 million.[162]

CHPI notes that 'as the majority of the doctors with equity in joint ventures work primarily for the NHS, there is a potential conflict of interest when NHS Trusts contract with these companies'.

More recently the potential for conflicts of interest to arise from the new Integrated Care Systems being brought in on the back of the Health and Care Act 2022 has been highlighted with the argument being made that they could undermine transparency of local decision-making.[163]

Concerns about financial conflicts of interest in the UK medical sector have gained prominence in recent years, particularly in the light of Baroness Cumberlege's review of medicines and medical devices. The Review highlighted concerns around the financial and other links between hospitals and other organisations, and the pharmaceutical and medical device companies, as well as with individual clinicians. This included a recommendation requiring transparency of payments made to clinicians and hospitals and the full declaration by clinicians of all financial and non-pecuniary interests.[164] The Department of Health and Social Care is currently implementing this recommendation, which we welcome. However, whilst this planned increase in transparency is positive, it is unlikely to be enough to address the issues arising as a result of conflicts of interest.

The current situation, where rules exist but are routinely breached without consequence, risks both the safety and the confidence of the public.

As a first step, existing CMA rules governing financial conflicts of interest should be enforced more consistently and breaches dealt with appropriately.

In the longer term we believe that there should be a cross-sector review of the effectiveness of current arrangements to address financial conflicts of interest among healthcare professionals. Any harm caused to patients as a result of a conflict of interest not only represents a gross breach of trust by the individual medical professional involved, but also risks damaging patient and public confidence in the profession as a whole.

As these issues cut across the NHS and independent sector, there will be the need for collaborative working to tackle these problems. The work ongoing to implement the Paterson Inquiry recommendations may provide a positive model for collaborative action.

Cumberlege's review of medicines and medical devices highlighted concerns around the financial links between hospitals and the pharmaceutical and medical device companies



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Regulation fit for the future: regulating virtual healthcare and new technologies

> 'Innovation is a key enabler of improvements in health and social care. Many of the things we now think of as essential to high-quality care were once considered new and innovative, and today's innovations will be tomorrow's best practice.'

Care Quality Commission, 2018[165]

The delivery of healthcare in both the UK and globally is changing rapidly. Technological advances mean that a vast array of healthcare services can be delivered virtually, from primary care, to consultations with a pharmacist, to some hospital services. The Covid-19 pandemic has undoubtedly accelerated what was already a growing shift towards online provision, with research suggesting that the pandemic brought forward digital adoption by up to seven years.[166] For patients, being able to access services from home will make them more accessible and convenient. Putting services online is also likely to reduce costs for both patient and provider.[167]

It is not just care delivery that is changing. Technology is also transforming the very nature of healthcare, and the role of the healthcare professional within it. Machines, such as those utilising AI, can now assist with complex surgery, diagnose cancer and even estimate risk of suicide.[168] They can far exceed the capabilities of humans, especially in tasks that involve processing high volumes of complex data.[169] Some within the healthcare world now predict a future in which patient data is automatically analysed via algorithms, with machines providing the diagnosis and the role of the doctor being transformed into one of 'communicator'.[170]

The UK Government has signalled a clear intention to rapidly expand the use of technology across the NHS, with the recently announced merger of NHSX and NHS Digital with NHS England; all part of a plan to 'put digital transformation at the heart of the NHS.'[171] When he was Health Secretary, Sajid Javid pledged to 'use the power of digital to drive a new era of recovery and reform.'[172] If this were to go ahead, it would include increasing the use of clinical decision support software so that it becomes 'the expected norm for all clinicians' and the expanded use of 'virtual wards'.[173] In Scotland, the Government has pledged a £20 million investment in surgical robots,[174] and Wales has announced increased funding for robot-assisted surgery as well as the establishment of an 'All-Wales Robotic Assisted Surgery Network'.[175]

However, despite the benefits of online services and new technologies there are a number of risks to the quality and safety of care that require vigilance from regulators. There have been concerns across primary care, optical services, dentistry and pharmacy services that online providers often fail to meet basic standards, with the quality of care falling well below that achieved by physical providers.

A 2018 report on online primary care by the CQC highlighted significant, potential patient safety issues. These included online providers failing to perform proper patient identity checks, being unable to identify whether the patient understood or consented to treatment, taking inadequate medical history, and failing to contact the patient's regular GP, including where medication was prescribed requiring monitoring or follow-up.[176] Of the 35 online providers inspected as part of the report, 30 did not fully meet the CQC's safety standards.[177]

In the pharmacy sector, both the GPhC and the CQC have raised concerns about online provision. The GPhC has revealed that online pharmacies are significantly overrepresented in fitness to practise cases, making up more than

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a quarter of the caseload, despite representing just 2.7% of pharmacies.[178] Recent inspection data shows that only 63% of online pharmacies meet the GPhC's standards, compared to the overall benchmark of 84%.[179]

Issues include allowing customers to effectively 'shop' for particular medicines, poor identity checking processes, and prescribing high risk medications through an online form. The GPhC has stated that of the online pharmacies it has taken action against, the majority were working with online prescribing services that were 'prescribing medicines which are liable to abuse, misuse and overuse to people, on the basis of an online questionnaire' and added that this 'puts patients at risk of serious harm or death.'[180]

In the recent case of Pharmacorp, an online pharmacy prosecuted by the CQC, the company was found to be posting prescription medication to patients based on an online questionnaire, with prescriptions issued by doctors based in Romania. The CQC stated that the service carried a 'real risk of misdiagnosis' and 'exposed patients to a significant risk of harm'.[181]

Regulators' ability to act against online providers is impeded by restrictions on their geographical jurisdictions. The CQC for example, only regulates providers based in England. This poses significant challenges when services are available in England but based outside, even if they are within the UK. The CQC describes the problem as follows: 'Regulators have limited opportunities to take action in response to harm by providers that are outside the scope of their legal powers. We are aware of the regulatory challenges arising from the easier delivery of cross-border health care… and the legal limits to our regulatory powers. We know there are challenges where organisations provide services online that are out of the scope of CQC's regulation.'[182]

The GPhC has highlighted the risks of online pharmacies working with prescribers who are not based in the UK and not registered with the relevant UK professional regulator, which they believe could 'create significant extra risks for patients and the public'.[183]

There are similar and longstanding concerns in the optical sector, with The Association of Optometrists having warned that unregulated online providers are selling unsafe and poorly fitting contact lenses, putting the public at risk.[184] While contact lenses should only be provided by a registered practitioner, websites run by companies based overseas are outside UK jurisdiction, allowing providers to circumvent UK rules.

The GOC has long been grappling with this issue, and have stated that both professional bodies and registrants have asked it to 'do more to protect the public from illegal online sales, both UK and non-UK.'[185] However, in practical terms the action they can take is limited, as they outlined in their 2022 call for evidence on the Opticians Act: 'The reality is that the enforcement of our legislation relating to sales – bringing a private prosecution in the magistrates' court – is not practicable for an organisation the size of the GOC or in relation to sales in a global online market. Moreover, it is not realistic to expect the GOC to achieve legislative reform that enables us to routinely act against non-UK sellers.'[186]

In the dental sector, the advent of 'remote' or 'direct-to-consumer' orthodontics has raised significant concern, with accusations that it may expose patients to risk of harm. A number of these services offer patients clear braces or aligners having assessed their suitability for treatment on the basis of a 'selfie' photograph uploaded online. Appliances are posted out without the patient ever having had a physical examination.[187] Many in the sector have warned that this can result in long-term damage to dental health.[188] The GDC has issued a statement reminding dental practitioners that 'clinical judgements about the suitability of a proposed course of orthodontic treatment must be based on a full assessment of the patient's

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oral health' and that 'there is no effective substitute for a physical, clinical examination as the foundation for that assessment.'[189] Both the GDC and the CQC have issued statements stressing the requirement for both professionals and providers to be registered with the regulators.[190,191]

Online provision is just one of the technological changes presenting challenges for regulators. The development of new technologies and innovations, including robotics and machine learning is just as significant. These include robot assisted surgery, AI, nanotechnology, the ability to grow organs and tissues in a laboratory,[192] wearables and implants, online symptoms checkers, virtual agents and even bionic organs.[193] Technological advances have the potential to vastly improve patient care and help address some of the workforce challenges facing the NHS; but technology is not a panacea and there are still issues to address, including, crucially, where responsibility lies when technology fails.

Cases such as that of the Da Vinci surgical system have brought some of these issues to the fore. The robot is used to perform complex heart surgery in conjunction with a human surgeon. The manufacturer of Da Vinci has faced thousands of lawsuits because the robot had malfunctioned, including cases where the machine has burnt patients and where parts of it have broken off inside them.[194] The first time the Da Vinci robot was used in the UK in 2005 it resulted in a patient's death, with the Coroner finding that it was caused in part by 'robotic assistance.'[195] In cases such as this, where humans work in conjunction with robots, the issue of liability and accountability can be unclear.

Liability for medical errors is even more difficult to determine where AI, or machine learning, is involved. AI can be defined as 'the capability of a computer program to perform tasks or reasoning processes that we usually associate with intelligence in a human being.'[196] It can be an incredibly powerful tool, but it is only as good as the data and algorithms that drive it. Numerous concerns have been raised about the potential for biased algorithms to result in incorrect diagnosis or inappropriate treatment. Algorithms may also disadvantage certain groups and exacerbate health inequalities between populations as referenced in the chapter on inequalities. Where this happens, it is unclear where responsibility and accountability lies; 'If diagnostic AI trained on data that over-represents white patients then misdiagnoses a black patient, it's unclear whether the culprit is the machine-learning company, those who collected the biased data, or the doctor who chose to listen to the recommendation.'[197] It had been suggested that practitioners themselves will need to understand 'where the underlying data come from and what biases might be embedded in the algorithms.'[198] However, expecting each individual healthcare practitioner to build up a detailed understanding of every AI tool they use may be unrealistic.

The recent Law Commission review of the regulatory framework for automated vehicles might provide a useful foundation for medical regulators to build on. The review recommends that, where a car is authorised as being 'self-driving' the human driver should not be held legally accountable for accidents, with liability falling instead on the vehicle developers.[199] This could be applied to robotics and AI within healthcare, if we were to develop a similar system for determining liability.

The MHRA has recently announced a work programme to provide a regulatory framework for software and AI in medicine which will require many applications to be regulated as medical devices.[200] The programme aims to ensure that software is safe and effective and that AI models are 'sufficiently transparent to be robust and testable or are otherwise properly validated'. A post-market surveillance system which includes the capture of 'adverse incidents,' is also in train. The MHRA hopes to complete this work by Summer 2023.and we hope that the programme will also provide

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greater clarity on where responsibility lies in relation to errors arising from the use of AI in healthcare.

AI also has the potential to redefine the role of the medical professional. Alastair Denniston, Consultant Ophthalmologist at University of Birmingham Hospital has asserted that 'AI and autonomous systems will have a much wider role in diagnostics and diagnostic support – we will increasingly get to a point where patient data is automatically analysed via algorithms increasing efficiency and accuracy – in this context the role of a doctor is more in communication of conditions and exploring different risk pathways for treating conditions with the patient.'[201]

This imagined future presents its own challenges as it involves health and care professionals ceding judgement and decision-making to robots. As one article notes, 'as AI improves, it gets harder for humans to go against machines' decisions. If a robot is right 99% of the time, then a doctor could face serious liability if they make a different choice.'[202] In this context, it is vital that we address the issue of the professional accountability of clinicians alongside these new technologies and communicate clearly about it with patients and service users, professionals and employers.

The Governments, regulators and registers should review how they will determine the lines of accountability for new technologies used in health and care.

The momentum of all these advances continues to build. Boots, which has been trialling online consultations since 2020, has recently announced a new training programme on digital healthcare for all its pharmacists,[203] and Amazon has registered its pharmacy operation.[204] Meanwhile technological solutions are still being rolled out across the NHS. On both fronts, regulators need to provide agile solutions to new problems and find ways of managing emerging risks proportionately. The current, ongoing review of regulatory powers will be an opportunity to close regulatory loopholes and address issues around jurisdiction.

The Governments should use the regulatory reform programme to ensure that regulators have the agility to address the challenges brought about by new technologies.

It will also be important for healthcare professional regulators, accredited registers, education providers, medical royal colleges and employers to ensure that education, training, and CPD for registrants adequately prepares them to interact with new technology, including robotics and AI.



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The future is now: our conclusions

Each issue we identify in this chapter, from the increasing role of for-profit providers and the conflicts of interest this presents, to the rise in online services, to the expansion of new and innovative models of care, represents a growing trend away from established models of provision. As the delivery of healthcare continues to evolve and change, regulators need to be able to respond agilely to meet the challenges head-on.

By and large, healthcare professional regulators are alive to the issues and already taking action to manage risks and protect the public. However, they are sometimes reluctant or unable to intervene (for example in matters relating to commercial practices) even where there is a legitimate case for doing so. This is partially due to the risk of challenge if there is no specific duty to act. They are also hampered by outdated and overly prescriptive legislation, and some lack the powers they need to best protect the public.

The Governments' current programme of regulatory reform may provide regulators with more agility to respond to emerging risks. It is also an ideal opportunity to look at some of these issues afresh and assess whether more action is needed to address them. Governments and regulators should strive to be ahead of the curve in respect of new delivery models, rather than constantly struggling to catch up.

Appropriate oversight and action are made more challenging by the number and range of bodies involved, with no one entity able to take a bird's-eye view of the emerging risks to patients and service users and identify possible solutions. We need more reliable mechanisms, for anticipating changes that open up public protection gaps across the sector – it should not be left to individual bodies within their limited remits. These mechanisms must be developed in partnership with patients and service users.

Recommendations

We recommend that:

- Governments use the current healthcare professional regulation reform programme to:
  - **a.** Review the adequacy and effectiveness of the powers of regulators with a role in regulating businesses
  - **b.** Consider whether there is a case for extending business regulation powers to all regulators whose registrants work in 'high street' practices
  - **c.** Ensure regulators have the agility to address the challenges brought about by new approaches to funding and delivering care, including the introduction of new technologies.
- Regulators tackle business practices that fail to put patients first, risk undermining confidence in the professions, or fail to allow registrants to exercise their professional judgement. A cross-sector review should be conducted of the effectiveness of arrangements to address financial conflicts of interest among healthcare professionals.
- Governments, regulators and registers review how they will determine the lines of accountability for new technologies used in health and care.

We have also identified a gap that would ideally be filled by the Health and Social Care Safety Commissioners referred to in the final section of this report. We recommend:

- The development of reliable mechanisms for anticipating changes in service provision that open up public protection gaps across the sector, and identifying ways to address them.

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Facing up to the workforce crisis and regulation's future role

> 'The UK health workforce needs to double, and care quadruple its growth over the next decade. At current rates of supply, there will be too few, too late.'

The Health Foundation, October 2021[205]

In this chapter we consider the scale and breadth of this problem across the UK, and ask how regulation can become an enabler rather than a barrier to addressing it.



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The UK needs over a million extra health and social care workers in the next decade but professional bodies and think tanks warn that this is unlikely to be achieved.[206]

In its 'immediate and essential actions', the Ockenden Review highlighted the issue of safe staffing and called for maternity and neonatal services in England to receive a multi-year settlement from NHS England to ensure the safe delivery of care.[207] Reporting on five year old Logan Mwangi's death, Prof Donald Forrester said, similarly, that the case highlighted critical issues affecting many children's social services in Wales; from social worker capacity and staffing shortages, to high and increasing numbers of children being taken into care.* Eight million operations a year are set to be cancelled or delayed due to consultant anaesthetist shortages across the UK.[208]

Workforce planning is shared among different bodies, and across the four countries of the UK. This has made it hard to keep track of vacancies, or forecast the number of training places needed. Each Government acknowledges that data and planning have not kept pace with demand, and while they are investing in more training places and improving data, it looks likely there will be significant shortages ahead.

Although there are now new ways into the regulated professions such as apprenticeships, widening the pool of potential applicants, the length of training generally remains constant. This time lag between demand and supply means there is a considerable risk that there will be too few people to provide the care needed, and that may compromise patient and service user safety.

At a time of global healthcare worker shortages, what can we do differently to grow our workforce, and adapt to new ways of working? What is the role of professional regulation and registration within this?



* Wales shares with other countries in the UK problems relating to child social worker shortages, with some councils reportedly having vacancy rates of up to 40% and heavily reliant on temporary staff. Wales has not yet undertaken a recent review of children's social care. Scotland's care review reported in 2020, Northern Ireland's launched in February, and England's is due to report in May (See: The Guardian, April 2022, Logan Mwangi's murder: major review of Welsh social care needed, says expert. Available at: https://www.theguardian.com/society/2022/apr/22/logan-mwangi-murder-welsh-social-care-review-needed)

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A compelling case for change

> 'The lack of attention given to all parts of both the health and care workforce means that the ability to integrate care to maximise quality and safety is inhibited.'

House of Commons Health and Social Care Committee evaluation of workforce commitments, Third Special Report of Session 2022–23[209]

A problem in breadth and depth

It is widely acknowledged that the UK has a workforce problem in health and care. It is worth restating some key statistics to illustrate the breadth of the issue.

- The children's social worker shortage in England is running at 16%, risking leaving families and vulnerable children without support and protection.[210] In the adult social care sector, the overall vacancy rate of 7.3% is equivalent to 112,000 vacancies, nearly three times higher than the wider UK economy estimated vacancy rate of 2.7%.[211]
- The British Medical Association (BMA) predicts England needs almost 50,000 additional full-time equivalent (FTE) doctors to put it on a standard comparable to today's Organisation for Economic Co-operation and Development (OECD) EU average of 3.7 doctors per 1,000 inhabitants.[212] By January this year, only 9,500 of 26,000 extra physiotherapists, pharmacists, mental health therapists and other clinical staff had been recruited to help GPs in England.[213]
- Scotland fares better than England for GPs, with 76 per 100,000, compared to 58, but still needs to recruit 800 more over the next decade to fill gaps.[214]
- There are major shortages in the nursing workforce as well, including over 4,000 vacancies in Scotland,[215] 1,719 in Wales,[216] 1,800 in Northern Ireland[217] and 39,652 within the NHS in England.[218] Over the past 10 years, only adult nursing and children's nursing have seen increases in FTE nurse numbers, while the numbers in community nursing, mental health nursing and learning disability nursing are all lower than they were in June 2010.[219]
- The UK Government aims to deliver 50,000 extra nurses by the end of this Parliament and reports that it is half-way there.[220] However, this target does not include non-NHS providers such as social care. The Government has acknowledged it will need to recruit well over 50,000 more to account for numbers leaving the profession and not being replaced.
- In March 2021, NHS England said it would recruit an extra 1,200 midwives as part of a £95 million investment. But the official NHS England workforce statistics show that the number of full-time midwives working in the NHS is falling, as a rolling average, with 326 fewer in September 2021 compared to the previous year.[221]
- Figures from Royal College of Nursing (RCN) Wales suggest that each week, nurses in Wales give the NHS extra hours to the value of 914 full-time nurses.[222]
- According to the British Medical Association (BMA) on average, each FTE doctor in the NHS does 1.3 FTE roles, 11-12 hours extra a week for each FTE doctor. This is about two hours above the working time regulations cap of 48 for average weekly hours and 13 hours more than the average hours of work for full-time workers.[223] Such Herculean efforts are obviously unsustainable in the long term.

Some of the inequalities affecting healthcare staff highlighted in chapter 1 may be another factor to explain why people are leaving the professions, and where they are amenable to influence by professional regulation we will advocate for change.

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Why we need a rethink

International recruitment has long been used to bolster UK supply. However, it is not without its complications; it can add to workforce shortages in the country of origin, exacerbating global health inequalities, and leaving the world at risk of future pandemics. This supply route is also vulnerable to changes in immigration policy, which is currently decided nationally for the whole of the UK.[224]

The Government is looking at alleviating some of the barriers to international recruitment, and has recently consulted on changes to make it easier for some regulators to adapt their requirements for registering overseas applicants.[225] It has also passed the Professional Qualifications Act which creates a new framework for recognising professional qualifications and experience gained overseas.[226] It is now working on reforms to health professional regulators' legislation to remove prescriptive detail and support a more agile approach to registration of international applicants.[227] We acknowledge these initiatives as helpful contributors to solving the problem, at least in part.

Technology may help to free up capacity too. As we describe in the previous chapter, this poses both opportunities and risks and will require clarity on the lines of accountability when using new technology.

However, the longer-term, more sustainable solution would seem to be to grow our own workforce. To do that quickly and safely, we think a different approach will be needed by professional regulators, governments, and others to educate and train the regulated professions, adapt to difference, and assure unregulated roles. The solution lies in:

- Training more regulated professionals faster – this would need regulators to agree to alter education requirements for entry to the register, or support more flexible career pathways by allowing earlier transition to other roles.
- Altering what people do and how – changing the scope of existing roles, creating new ones, or making better use of un-regulated roles.
- Reviewing existing barriers, such as funding and access, to consider where they may be alleviated.

Alongside this, to adapt to and support this agenda, a new regulatory approach is needed on two related fronts:

1. In the past, we have held the firm view that professional regulation should not be drawn into adapting standards to respond to workforce issues. We now view this stance as unsustainable; the shortages are so great that the lack of workers may pose a greater risk to patient and service user safety than any changes in standards. It may be justifiable to adapt regulatory approaches to allow more people into the workforce – cautiously, and with the appropriate safeguards. Naturally, such a change in policy would need to be implemented with extreme caution, and on the basis of robust risk-modelling.
2. We propose that these decisions should form part of a new strategy for the regulation of people, developed in partnership with patients, service users, providers, professionals and workforce bodies. It should sit alongside workforce plans and align with workforce and service change. A future regulatory framework must be agile enough to meet workforce needs while continuing to prevent harm.

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Training more regulated professionals faster

> ‘A regulated profession means that the access to or the pursuit of a professional activity or group of professional activities is restricted, by regulation, to people having specific professional qualifications. This also covers the use of professional titles which are restricted to holders of specific qualifications’.

Directive (EU) 2018/958[228]

The professional regulatory model is both a help and a hindrance to the workforce and its growth. As the quote from the directive shows, it ensures quality by specifying the qualifications needed and controlling entry to a role. The restriction is good for public safety, ensuring both competence and conduct. Setting it high though, and most are at under-graduate level or above, limits the pool of potential workers and restricts numbers coming into the workforce. It also carries with it the risk of restrictive practices and protectionism.

It is to some extent illusory since protection of title can be circumvented by simply giving a role another name. Thus, clinical psychologists are regulated, but psychologists are not. Both may be employed as experts in the family courts, offering opinions on which serious decisions are made about the welfare and custody of children.[229] The model does not, for the most part, restrict activities to titles either.

Nonetheless, it offers a mostly effective, well-established means of controlling risks of harm to the public. Statutory regulation supports the workforce through the holding of a register, which employers access as part of their employment checks; their revalidation processes help to ensure continuing competence by requiring registrants to keep their skills and knowledge up to date. Regulation also acts as a deterrent to misconduct through its standard setting and fitness to practise functions, helping to maintain standards in the workplace.

Statutory regulation helps registrants by giving them standards and guidance to follow and allowing them to resist, by reference to their regulatory standards, pressure to breach them, take undue risks or work in areas outside their competence.

The 10 regulators we oversee (who between them regulate 35 professions) and those set up under Scotland, Wales and Northern Ireland’s devolved powers for social workers and social care workers, each decide which qualifications registrants must have, and for the most part quality assure pre-registration education courses run by educational institutions. Their decisions directly affect the length and type of training and how quickly future practitioners enter the workforce.

Unlike some other jurisdictions, UK regulators do not have a statutory role of ensuring an adequate workforce supply. This is still right, in our view, as there is an inherent tension between ensuring adequate supply, and setting the bar for entry to a profession for reasons of safety; but, as we mention above, we must acknowledge the scale of the issue that the country is facing, and the trade-offs that may have to be made. Risks of safety and quality of care being compromised by workforce shortages may be greater than those resulting from a potential lowering of standards. Regulators should therefore critically re-examine their contribution. It may be that numbers can be increased without undue compromise on standards, but all options need to be considered.

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Although numbers on registers have steadily increased* workforce vacancy rates for these roles still remain high, with further shortages predicted. The number of students has not kept pace with rising demand because of gaps in workforce planning, lack of funding and investment, and limits on capacity of staff in the workplace to support training placements. The problem now, is that far higher numbers are needed to overcome the combined effects of high vacancy and attrition rates.

The BMA predicts it will take 25 years to achieve the 50,000 doctors needed at current rates of supply.[230] Despite the Scottish Government's commitment to fund 139 extra training places for doctors at a cost of £32 million,[231] Audit Scotland predicts that it will add just 19 doctors to the primary care workforce by 2027 – just 2% of the 800 target.[232] Training a doctor takes four to six years at medical school, two more years' foundation training to gain experience, and then several years of specialty training: three years for general practice, and around five to seven years for other specialties.[233] It is quicker for other professions but still takes five years to qualify as a pharmacist,[234] and three as a nurse, midwife, or physiotherapist.

Social work now has a wider range of entry routes than some other professions with undergraduate degree courses typically three years full-time, six years part-time. Postgraduate degree courses take between 14 months to two years full-time, and four years part-time. There are some fast-track programmes (including Frontline, Think Ahead and Step up to Social Work) which typically take 14 months. There are also undergraduate social work apprenticeship programmes which are three years full-time.

In 2020 there was a 23% increase in the number of students accepted onto nursing degree courses in England (relative to 2019) – the highest annual number of acceptances since 2011. However, the Health Foundation still predicts that the 50,000 target for nurses is too low to meet demand.[235] The RCN reports similar shortages in Wales, Scotland and Northern Ireland too.[236]

Something needs to change. There may be lessons we can build on from what happened during the pandemic – outlined in our 2021 *Learning from COVID-19 review.*[237] Amongst other changes the NMC introduced emergency education and training standards.[238] These allowed final year students to spend up to 100% of their time in clinical practice if their education provider deemed it necessary. Regulators also used online and simulated training to overcome difficulties in providing workplace-based experience.

Regulators, educators, and professional bodies might therefore explore whether there are opportunities for accelerating training safely. We recognise that there are likely to be risk trade-offs to be made here, but believe that those associated with workforce shortages may at least warrant a fresh look at training length, pace and delivery method. We also understand that the availability of training is in part dependent on staff being available to provide training and supervision – however,in some circumstances, technology may provide some solutions.

Regulators and registers should work together, and in partnership with key stakeholders including patients and service users, to identify opportunities to speed up workforce supply.

* The General Medical Council's register has grown by about 100,000 over the last decade and the Nursing and Midwifery Council's by about 80,000 in a similar period. Social Work England's register has increased from 97,684 in December 2019 to 98,4991.

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Speeding up statutory regulation when it's needed

Creating new roles with shorter training requirements and adding them to an existing statutory register is one way to increase workforce numbers more quickly, but it too may need to be achieved faster. For most of the regulators we oversee,*(1) once a government decides to regulate a role it can use secondary legislation under the Health Act 1999 to amend the regulator's legislation allowing them to regulate it. This is a relatively streamlined process, as legislative changes go. However, there is a lot of work that goes into preparing the ground for a new role, and the length of time it takes varies. Despite deciding to regulate Physicians Associates in October 2018, and planning to assign them to the GMC to regulate, the relevant legislation has not yet been passed.[239]

Having a clear policy and approach for introducing new roles and deciding how any risks they present will be controlled could help to standardise and speed it up. It could also help to contain some of the politics that can interfere with these sorts of decisions and processes. We welcomed a recent Government consultation on reform setting out a risk-based methodology for deciding whether and how a group should be regulated using our right-touch assurance methodology.[240] We also asked questions about how it would be put into practice, and are awaiting the outcome. As we see it, this kind of approach would form part of a new regulatory strategy.

Power to regulate new healthcare roles is devolved in Scotland, but not Wales or Northern Ireland. There is a longstanding four-country commitment to UK-wide regulation of healthcare roles though, and to date the only deviation has been for nursing associates, who are only regulated in England.[241] Decisions to regulate social care workers, however, are devolved. This has allowed these groups to be regulated in all UK countries except England. While this variation, may be helpful at a local level, this sort of fragmentation can potentially exacerbate workforce shortages by disrupting the free flow of workers around the UK. Careful thought needs to be given to the risks and benefits of consistency versus flexibility in this area – a point that we highlighted in our report for the Scottish Government on regulating a profession in fewer than all four UK countries.*(2)

There should be a clear process to guide the development of new health and care roles for each UK country, including:

- the scope and purpose of the role
- the process for deciding on the level of assurance required to control risk of harm
- the criteria for evaluating risks and benefits of deviating from a UK-wide approach.

* (1) With the exception of Social Work England and the Pharmaceutical Society of Northern Ireland.

(2) Different groups of social care workers are regulated in Scotland, Wales and Northern Ireland (see: Professional Standards Authority, 2018, *Regulating an occupation in fewer than all four UK countries Implications for policy-makers, the public, and practitioners. Advice for the Scottish Government*. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/policy-advice/regulating-an-occupation-in-fewer-than-all-4-uk-countries-2018.pdf?sfvrsn=ce3e7220_11)

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Making better use of the unregulated workforce

> ‘New solutions are required … to meet the changing needs of the population. This will need new ways of working, new roles and new behaviours.’

‘NHS Multi-professional framework for advanced clinical practice in England[242]

Planning the workforce is broader than it may seem. Delivery of health and social care depends on huge numbers of unregulated workers who support, supplement and service care. For example, for every four people working in general practice only one of them is a doctor. GPs cannot run their surgeries without practice managers, receptionists, counsellors, social prescribers, care navigators or community link workers, as well as nurses, pharmacists, and allied health professionals.[243]

Almost two thirds of the 4 million people employed in health and care are working in unregulated roles.[244] Some carry out tasks under the delegated authority of regulated professionals, others are supervised either by regulated professionals or employers. Some carry out high risk procedures, such as clinical physiologists*(3) or surgical care assistants. Others may work autonomously, often on their own, such as counsellors and psychotherapists.

The advantage of unregulated roles is that they are flexible, and employers and others can create, change, train and deploy them as they wish. However, when roles are created locally, whether within a country or organisation, the standards they work to and range of tasks they carry out may be different to a similar role, or even a role with the same name, elsewhere.This may make it harder for prospective employers to know what to expect when they recruit someone; for their colleagues to know what their role in the team will be, or what they are competent to do; or for patients to understand where they sit within the healthcare team.

For example, a ‘nurse’, may be a healthcare assistant, not a registered nurse.[245] A ‘sonographer’ may be a post-graduate radiographer or someone who has done a short training course to operate ultra-sound for a limited purpose such as scans in a baby clinic producing souvenir pictures.

Safe care depends on effective teamwork – and that needs familiarity, each member understanding their respective roles. Team members typically change frequently and at short notice. They may never have met before and yet they must make snap judgements about who will do what – sometimes while someone’s life hangs in the balance.

There is no readily accessible taxonomy of health and care roles, or common agreement on titles not protected by law. What people with similar names do may vary considerably. An advanced practice label can be attached to a regulated role, such as a registered nurse, or a nursing assistant. Health Education England (HEE) has worked with other stakeholders in England to develop a national framework for advanced practice, to ensure national consistency and understanding. Intended initially to cover regulated professions, HEE is working to wards extending it to unregulated roles, too.[246]

Technologies such as blood pressure monitors or extra corporeal membrane oxygenation equipment make it possible to delegate a wider range of tasks. In doing so, unregulated, or less highly qualified roles can take over areas of practice previously the domain of regulated

* (3) Clinical Physiologists use specialist equipment and advanced technologies to carry out vital procedures and investigations on patients to help in the diagnosis, monitoring and treatment of a wide range of disease processes. For example, cardiac procedures.

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professionals. Introducing blood pressure monitors meant registered nurses could delegate taking blood pressure to healthcare assistants for example. Extra corporeal membrane oxygenation may be carried out by a clinical perfusionist who whilst providing critical care, is also in an unregulated role.*(1)

This can create anxiety for regulated professionals who remain professionally responsible to their regulator for care delegated by them or provided under their supervision, whilst being unclear about supervisees' training, experience, and scope of practice.

They may worry that their role will be undermined, and that the public will be put at risk by people who are less well trained taking over some of their tasks. Regulators have provided guides to help them understand their responsibilities when delegating or accepting delegated tasks, but we appreciate that increasing pressures in the workplace may make it challenging to put them into practice.[247] Those in unregulated roles may also feel anxious if asked to take on tasks they do not think they are trained to do but feel unable to decline.[248] Unlike regulated professionals or those on Accredited Registers, they cannot fall back on their professional registration and requirement to practise within their competence as a reason for refusal.

From patients and service users' perspectives, our research amongst the public has shown that they generally assume anyone caring for them is subject to some form of regulation when this may not be the case.[249]

Broadening the regulatory model

Broadening the regulatory model to include a spectrum of controls rather than solely relying on statutory regulation would allow workforce planners greater flexibility and speed up growth. Having services embrace and make use of these controls would remove disincentives and obstacles, clearing the path for example, for new educational courses. It could also cause other barriers to development to be systematically re-examined and potentially removed.

As workforce planners get to grips with the challenge before them, health and care delivery changes, and roles evolve, services need a way to ensure they protect patients and service users from harm, for example: having workers join voluntary registers, sign up to codes, setting up professional bodies, and requiring certain qualifications or training. They also need a way to help other members of the teams they work with recognise and understand their role and what they can safely do.

Within England's mental health services, new roles are being developed such as psychological wellbeing practitioners and children's wellbeing practitioners who work alongside healthcare professionals to assess and support people with common but sometimes serious mental health difficulties. In Scotland, community link workers now work within GP practices to provide support with personal, social, emotional, and financial issues.

We need safe, proportionate ways to control the risks associated with such roles. One option being considered by NHS England is the use of voluntary registers under our accredited registers programme. Accreditation provides independent assurance that these voluntary registers operate effectively to protect the public. The Authority has recently accredited the British Psychological Society, and has interest from other related registers.

Licensing is another option, with Scotland and England both considering introducing it as an alternative form of control for non-surgical cosmetics.[250,251] While cosmetic surgery can only be carried out by a doctor, non-surgical but still invasive cosmetic procedures such as Botox or injectable fillers can be carried out by anyone.*(2)

* (1) In extracorporeal membrane oxygenation (ECMO), blood is pumped outside of your body to a heart-lung machine that removes carbon dioxide and sends oxygen-filled blood back to tissues in the body. ECMO is used in critical care situations, when your heart and lungs need help so that you can heal. It may be used in care for COVID-19.

(2) Botox must be prescribed by a clinician but can be administered by a non-registered person.

The advantage of licensing is that it can restrict one or more activities rather than an entire role. It can be used independently or along-side either statutory regulation or accredited registers, or both. The Authority accredits two Registers in this area, the Joint Council for Cosmetic Practitioners and Save Face, both of whom support the addition of licensing to strengthen controls.

With the Government's consultation on criteria for statutory regulation – based mainly on the Authority's right-touch assurance model[252] – the question of which roles should be regulated has come to the fore.[253] There has been ongoing debate for example about whether cosmetic practice, counselling and psychotherapy, and social care in England should be regulated. More recently the Ockenden Review has restarted the debate about whether health service managers should be regulated. In our view, not every role can or should be regulated by law, and it is for governments to decide which. The UK Government's recent consultation on regulating based on risk supports this view.[254]

We have previously put forward the idea of a 'continuum of assurance'.[255] The type and level of controls for different groups within health and care should be proportionate to the risk of harm arising from practice, and responsive to the nature of the risks.[256] There are many different ways to control risks ranging from employer controls, credentialing, accredited registration,*(3) and licensing through to statutory regulation for the riskiest occupations. Standard codes, common competencies, national units of learning, national frameworks like HEE, agreed qualification and training routes for entry to roles, and standard naming conventions are other ways to manage risks.

There are other ways too to mitigate risk and prevent harm. Good governance, effective management, making changes to the environment, adapting, or licensing equipment, requiring registration or inspection of premises, and ensuring that those inspecting workplaces check those aspects that are essential to supporting workers' competence, wellbeing and professionalism. Resolving risks requires careful analysis of the problem, using right-touch principles to decide the most appropriate way of controlling it, and collaboration between organisations to close safety gaps.

There should be an agile process for identifying risk, deciding and authorising the form of assurance needed, and firm government and service backing for using a spectrum of regulatory controls. The Authority developed Right-touch assurance to advise on how risks arising from unregulated occupations should be managed.[257] This involves creating a risk profile for each occupation we assess, taking account of the complexity of tasks, the context in which it is practised and the vulnerability of the patient or service user group. Making sure that regulatory measures strengthen public protection, rather than increase burden means understanding what types of controls are already in place. This may be different for roles within managed settings such as schools or the NHS, to those providing services in private homes.

New and changed roles offer us opportunities to address some of the workforce shortages and help relieve workplace pressures. We will need to adopt a proactive approach to addressing the safety gaps that emerge and provide active support for the spectrum of measures that are available to manage risk. This could, if our recommendations are taken forward, be part of the Commissioner role – and so protect patients and service users from harm. Acceptance by those used to operating within the statutory regulatory model that there are other, valid means of assurance will also be essential.

* (3) The creation of the Authority's Accredited Registers programme in 2012, and the legislation underpinning these powers of accreditation, was a big step in introducing alternative forms of assurance. For the first time, organisations that hold voluntary registers of roles in health and care could show they met a set of independently assessed Standards, under a statutory scheme. Since its introduction, the programme has expanded to 26 registers, more than 100,000 practitioners and improved the organisations accredited.

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Developing a regulatory strategy to support workforce expansion

> 'the people who run regulation struggle to provide coordinated or coherent oversight of the delivery of care, despite their valiant efforts, because its parts are not designed to work together well'

Professional Standards Authority 2015, *Rethinking regulation*[258]

We have outlined in this chapter why we think we need a broader regulatory model to address key pressures and ensure that risks to patients and service users are managed.

We see a strategy for the regulation of people (or 'regulatory strategy'), as a defined approach to managing risks of harm arising from the practice and behaviour of individuals through regulation in its broadest sense. It should set out regulatory objectives and how they will enable service needs. This basic framework should be the starting point for decisions and assurance mechanisms for new roles, based on risk and workforce trade-offs. It should be acknowledged, though, that while creating new roles can address existing risks, it can also create new ones.

It should be positioned within the Government's approach to other forms of regulation in health and care, and contemplate a wide range of possible assurance mechanisms. It should have the flexibility to be used in the development of as yet unknown future roles.

The strategy would be used in the early development stages for new roles. This would require active consideration from the outset about the likely risks and consequences and the options for averting them. It would support a more coordinated approach to ensuring that professionals have the skill sets required to adapt to the diverse needs of patients and service users, innovations in health and care, and emerging risks (as outlined in the chapters looking at inequalities, and business and technology).

Having a strategy for the regulation of people, to complement and support delivery of the workforce strategy for each UK country, would enable the thinking about how a role should be regulated to happen in tandem with that about new or evolving roles and developments in care. It would also bring transparency to the basis for these important decisions, and how they serve the public interest.

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The strategy would:

- Cover regulated and unregulated roles and make clear how risks will be controlled as the system adapts to meet workforce challenges.
- Look forward, supporting the development of specific roles where this is known, and where not, providing a basis for future risk-based decisions about appropriate means of assurance.
- Allow enough control to preserve safety, leave room for innovation, and take into account the impact of regulatory controls on supply.
- Include a visible way for employers and others to recognise and value all roles. For example, using quality marks or an agreed set of titles. This would give regulated professionals the confidence to delegate to and work alongside unregulated roles.
- Require a shared acceptance by workforce leaders, planners, regulators, and governments of a strategic approach that makes use of a spectrum of regulatory measures rather than relying solely on statutory regulation.
- Find a balance between where it is necessary or beneficial to take country-specific approaches, and where four-country coherence takes precedence.[259]

This final point hints at the complexity of making this work UK-wide, something we must acknowledge. Some decisions about which groups in health and care should be regulated are devolved, but many are not. There are benefits to UK-wide regulation, but also arguments for deviating from this model in certain circumstances.*

Whether we should aim for a UK-wide over-arching regulatory strategy with allowances for each country's specific circumstances, or four strategies with degrees of commonality, would need to be determined. What is certain is that close working between the four countries would be essential in establishing principles on which decisions about consistency and divergence could be made.

The workforce and regulatory strategies between them should provide clear pathways and processes for the creation of new roles to include decisions about how these roles and, potentially, activities would be regulated and assured. Those creating new roles should work with the regulators, accredited registers, and the Authority to identify which regulatory or assurance controls will best suit their situation.

The Authority would also use its oversight role, expertise and convening power to support the development of these strategies across the four countries.

* We have previously considered the issues that might arise from diverging from a UK-wide approach to professional regulation in our report: Professionals Standards Authority, 2018, *Regulating an occupation in fewer than all four UK countries Implications for policy-makers, the public, and practitioners, Advice for the Scottish Government*. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/policy-advice/regulating-an-occupation-in-fewer-than-all-4-uk-countries-2018.pdf?sfvrsn=ce3e7220_11

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Facing up to the workforce crisis and regulation's future role: our conclusions

The UK is facing a serious workforce shortage which it must address if care is not to suffer, and patients and service users come to harm. To address shortages in the statutorily regulated workforce, governments, regulators, and employers must succeed in retaining existing professionals, recruiting from overseas, creating new roles and training professionals in sufficient numbers. The latter may mean regulators challenging conventions about education and training, and governments setting up clear pathways. Another option may be to look at those working in unregulated roles and consider whether they, with appropriate safeguards, might offer a way forward.

Addressing these issues will not be easy. It takes time and money to train more health and care professionals and it may be hard to incentivise existing staff to stay or to recruit quickly enough to relieve the pressure. Alterations to training pathways take time to agree, change and assure.

A coordinated, coherent approach is also needed to up-skill the workforce to prepare them for developing models of care, providing care to diverse groups of patients and service users and to address emerging risks in healthcare provision; for example, through increased use of technology in health and care. These problems need addressing quickly, and safely – and regulatory arrangements should form a key part of this.

Recommendations

We recommend that:

- Regulators and registers work collaboratively to identify opportunities to speed up workforce supply, equip practitioners to deal with future challenges in how care is delivered, close safety gaps and protect patients and service users.
- There is a clear process to guide the development of new health and care roles including the scope and purpose of the role, the process for deciding on the level of assurance required.
- There should also be an agreed way of deciding when to deviate from taking a UK-wide approach based on a review of risks and benefits alongside consideration of the national context.
- Those involved in health and care workforce planning and delivery across the UK actively support additional and alternative means of assurance as a means of managing risks to patients and service users.
- The four UK Governments work together to develop a coherent strategy for the regulation of people, to support delivery of their national health and social care workforce strategies.

Recommendation that could form part of the Health and Social Care Safety Commissioner's role

- Identifying risks relating to workforce shortages and how practitioners are regulated. This would help to inform the regulatory strategies.

The Authority will:

- Use its oversight role, expertise and convening power to support the development of these regulatory strategies.

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Accountability, fear, and public safety

> ‘Fear is toxic to both safety and improvement.’

Don Berwick, A promise to learn – a commitment to act[260]

In this chapter we examine the apparent tension between professionals learning from their mistakes and taking responsibility for their actions. We explore what this means for regulation, and for its role in protecting the public.



It is widely accepted that health and care professionals practising in fear – of their regulator,[261] their colleagues, or their employer[262] – is a bad thing.[263] But when things go wrong, we also need people to take responsibility for their actions.[264] The extreme working conditions NHS and social care staff endured during the pandemic have brought this challenge for professional regulation into the spotlight.[265] Even before this, the case of Dr Bawa-Garba drew widespread criticism from doctors fearing that a single mistake could end their career. Fear is not just bad for professional wellbeing, with all the unsettling effects that has on recruitment and retention, it can also lead to defensive practice, or worse, cover-ups.

Alongside this, repeated, high-profile failings like those at Shrewsbury and Telford NHS Trust remind us how important accountability is when care goes wrong.

Having ways of holding individuals to account is clearly in the public interest. These include, where possible enabling a practitioner to address concerns about their competence or conduct, or removing the very small number of reckless, dangerous, dishonest practitioners from the workforce to prevent further harm.

By doing this, professional regulation shows the public that they can have confidence in the profession, while sending a message to other professionals about what is acceptable.

Are our accountability mechanisms working? How can regulation protect the public without undermining efforts to address toxic, fear-based cultures in health and social care? Conversely, how can we deliver cultural change in frontline care without undermining individual accountability?



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A deeper understanding of the causes of safety incidents in health and care

> 'We cannot change the human condition, but we can change the conditions under which humans work.'

James Reason, Human error: models and management[266]

Over the last two decades or so, national and local approaches to patient and service user safety have started to recognise how toxic fear can be in safety-critical work environments. These new approaches are based primarily on a more sophisticated understanding of how individuals function within systems, although implementation remains patchy.

In his work on organisational safety, James Reason developed the concept of the 'just culture' – often contrasted with the 'blame culture'. In a 'just culture', it is understood that mistakes primarily result from organisational factors, and the priority is to identify what went wrong rather than who was responsible.[267] This approach has been embraced in the world of aviation to the extent that it is now enshrined in European law, and has been adopted in healthcare less formally.[268,269] For example, Suzette Woodward's thinking, building on Sidney Dekker and Eric Hollnagel's pioneering work on safety cultures, has explicitly influenced the patient safety strategy for the NHS in England.[270] The strategy document explains that:

'Blame is a natural and easy response to error. It allows the cause of mistakes to be boiled down to individual incompetence, carelessness or recklessness and asserts that the problem is the individual. Blame relies on two myths. First, the perfection myth: that if we try hard, we will not make any errors. Second, the punishment myth: if we punish people when they make errors, they will not make them again.'

In the wake of the Mid-Staffordshire NHS Foundation Trust Public Inquiry, Don Berwick advocated for the closely related concept of 'learning' cultures, inherent in systems and organisations that want to learn from their mistakes in order to improve. He wrote: 'when people find themselves working in a culture that avoids a predisposition to blame, eschews naïve or mechanistic targets, and appreciates the pressures that can accumulate under resource constraints, they can avoid the fear, opacity, and denial that will almost inevitably lead to harm.'[271] One sign of progress is the move to incorporate 'human factors' into patient safety approaches – 'enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture and organisation on human behaviour and abilities'.[272] The push towards 'psychological safety', – 'a shared belief held by members of a team that the team is safe for interpersonal risk taking' – is another.[273]

Unsurprisingly, social work is on a similar path. In 2011, the Munro Review of child protection in England identified that an overly bureaucratic, rules-based approach that aimed to remove all risk was disempowering social workers, and encouraging a blame culture. To counter this, the rules needed to be pared back to allow room for professional judgement, system learning, and an acceptance that people make mistakes: 'sometimes mistakes happen because people mess up. In child protection, it is very usual and easy to blame individuals when things go wrong. But blaming individuals each time something goes wrong can get in the way of seeing that the system was (also) at fault.'[274]

A more recent review of child protection in England, chaired by Josh McAlister, reported that little progress had been made, and that there is still 'a high level of anxiety when making decisions and social workers and organisations

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continue to feel vulnerable to public, regulatory and Government scrutiny if things do go wrong.'[275]

Alongside this, healthcare policy makers have been looking at the impacts of approaches to clinical negligence. Unlike some other countries, such as New Zealand and Sweden, the UK does not have 'no fault' compensation for clinical error. In our tort-based system, someone must be found to be liable in order for compensation to be awarded. This means that even though NHS workers are covered financially by NHS compensation schemes, which differ across the UK, the schemes tend to pay out on the basis of a healthcare professional having been found to be negligent.[276] Some see this as a barrier to more open, learning-based approaches to clinical error, because it encourages harmful, defensive practice,[277] and pits claimants, who have to make the case for negligence to a greater or lesser extent, against professionals and employers. The English system is currently being reviewed by the UK Government, as well as coming under scrutiny from the Health and Social Care Committee in Westminster.[278, 279]

Why individual accountability matters

> 'Justice is coming for every baby'
>
> **Julie Rowlings, mother who lost a baby due to poor care at Shrewsbury and Telford Hospitals NHS Trust**[280]

When care has gone wrong and people have died, or been left with life-changing injuries, victims and families typically want the truth about what happened. They want an apology, financial compensation, and to prevent the same thing from happening to others.[281, 282]

There are multiple systems involved in the aftermath of a serious care incident including:

- local statutory investigations
- local complaints frameworks
- system and professional regulators
- ombudsmen
- public redress agencies
- private insurers.

Even without public inquiries or criminal investigations, it is a complex, even baffling mix of investigations and responsibilities.[283] Much of it is aimed at identifying what went wrong, and learning from it to prevent future harm, although learning can be limited if professionals are not fully candid because they fear personal repercussions.[284]

We saw in the previous section how important it is to understand the role that systemic issues have played in failures of care. While this is undoubtedly true, establishing the part played by individuals is as important; they may be the primary cause of harm, through the original incident, or the cause of 'second harm' through a poor institutional response.

There is a long line of inquiries and reviews, most recently the Ockenden Review, that have documented not only failings in care, but also concerted efforts by institutions, and the individuals within them, to conceal the truth from patients, service users and families.[285] Attempts to improve safety that focus on systemic and institutional failings alone can obscure the responsibility of individuals (both regulated and unregulated) within that system, leaving them unaddressed. They also assume that none of the behaviour was in fact 'blameworthy'. While this is probably the case most of the time, the pattern of almost systematic lack of candour uncovered by public inquiries shows that these assumptions can be misplaced. It is also worth noting that a reduction in individual

accountability can have other unintended effects, such as impeding collaborative learning,[286] increasing risk-appetites,[287] and even lowering standards of behaviour.[288]

The Ockenden Review makes very little of the role of professional regulators – in line with the terms of reference.[289] This differs to the approach taken in, say, the Mid-Staffordshire Foundation Trust Inquiry,[290] or the Shipman Inquiry, which considered, the latter in forensic detail, how cases were handled by regulators, and made recommendations for change. There is little explanation of what action was, and was not, taken by professional regulators in relation to Shrewsbury and Telford, in respect of the professionals involved. It is not necessarily the case that any regulator was at fault in this instance, but it is more that the Review does not help us understand if they were or not – or if there are flaws in the regulatory model itself.

We recognise that terms of reference may need to vary between inquiries or reviews. However, when major variations aren't explained, big pieces of the puzzle may be missing, and weaknesses in the systems that exist to keep people safe can go undetected and unchallenged. We are also aware of differences in how reviews and inquiries are set up and run. For example, the legal status of statutory inquiries means they have legal powers to compel witnesses to give evidence, provide legal safeguards, and can set limits on the government's discretionary control of an inquiry. As the House of Commons Library Briefing points out, the threshold for establishing a public inquiry, 'matters of public concern' is open to wide interpretation.[291] From the healthcare perspective, it is unclear why Paterson, Cumberlege, and Ockenden were not set up as, or converted to, statutory inquiries, particularly given the scale of harm identified.

We do not make these points to lay blame about what has gone before; but to highlight a structural gap that appears to be hindering a more joined up, coherent approach to inquiries and reviews.

An independent, centralised mechanism for coordination, determining criteria and providing oversight of public inquiries should be introduced. [This would form part of the role of the recommended Health and Social Care Safety Commissioner.]

This would help to bring greater consistency and coherence of approach to the scope and rigour of inquiries. Picking up on points made in our inequalities chapter, such a framework would also give us a way of analysing the findings and recommendations to identify trends, for example the demographics of those affected, and ensure coordinated follow-up on recommendations.

To return to the key question posed in this section, why is individual accountability important?

It matters because, if it didn't exist, the resulting changes in behaviour could ultimately undermine safety and care. It also matters, fundamentally, because people can cause harm; and when that happens, it needs to be confirmed and addressed.

People who use services need to be confident that accountability mechanisms exist; public inquiries and reviews are one such mechanism, and professional regulation – our core focus – is another.

We need greater consistency and coherence of approach in the scope and rigour of inquiries

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Professional regulation – individual accountability when care goes wrong

> ‘Justice must not only be done, but must also be seen to be done.’

R. v Sussex Justices, Ex parte McCarthy [1924] 1 KB 256, [1923] All ER Rep 23

Professional regulation is part of the harm prevention framework. The over-arching objective of the regulators we oversee as well as our own,*[292] is the protection of the public. According to the law, this involves:

- protecting, promoting and maintaining the health, safety and wellbeing of the public
- promoting and maintaining public confidence in the professions regulated by the regulatory bodies
- promoting and maintaining proper professional standards and conduct for members of those professions.

While the first of these three objectives may seem to be the only one that relates to public safety, the second and third are indirect means of preventing wider harms. Losing confidence in a profession can affect people’s willingness to seek treatment, leading them to take risks with their care.

Declaring and upholding professional standards shows professionals and the public what is deemed unacceptable, which in turn can have a positive impact on other professionals’ behaviour, as well as on people’s willingness to seek care.

Case law in this field has established that decisions about individuals should be forward-looking, and not punitive. In essence:

- Does the way that you have behaved in the past, combined with what you may have done to address any past failings and any insight you have shown, lead us to believe that you will harm patients or service users again in the future?
- If not, did your past actions and behaviour fall so far short of what is expected of a professional that action needs to be taken to maintain public confidence or professional standards?

The second question can appear punitive because it acknowledges that it is not about the threat posed by the individual,[293] however it is an important and well-established part of the role of professional regulation that aims to prevent wider harms. In fact, the three objectives have parallels with the principle of justice needing to be both done and seen to be done, and apply in similar form to other parts of the patient and service user safety frameworks.

When a safety incident has occurred, regulators may have to investigate and take action relating to the individuals involved. The decisions that they have to make are complex and mainly case-specific, though there are a number of factors the regulators look at when weighing up whether a registrant’s fitness to practise is called into question. The sorts of considerations that inform their assessment of future risk of harm, impact on public confidence, and the need to declare and uphold professional standards include:

- Is the incident a one-off or repeated?
- How serious are the failings (as measured against established approaches), and how great a risk was the patient/service user exposed to as a result?
- Is this conduct that puts patient and service user safety at risk?
- Is there evidence that the professional has insight and has attempted to remedy their failings?

* With the exception of the PSNI.

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- Does the case raise any concerns about the professional's attitude (for example: were the actions deliberate? Was the professional negligent, or reckless? Was there dishonesty and/or a failure to be candid, such as an attempt to cover up or minimise the harm or their part in it? Did the professional ignore the concerns of colleagues or otherwise show a lack of aptitude for teamwork?)
- Were there mitigating factors such as challenging working conditions?

Some cases, where a patient or service user has been harmed, fall less obviously under the remit of professional regulators than others. Low-level failings that can be addressed by the registrant (known as remediation), and those where there is no evidence of serious attitudinal issues, are more clearly the responsibility of employers. This assumes of course that the registrant is employed, and that the employer has the mechanisms and resources to pick up on competence issues and address them.

The most serious concerns for regulators are often when a professional has also demonstrated deep-seated attitudinal issues, because these may be very difficult to remediate. This means they are likely to put patients at risk again in the future – as well as affecting public confidence.[294]

It can be harder to articulate the role of the regulator in cases where the failings are serious, but there are no outstanding competence concerns, and no evidence of attitudinal issues or of ongoing risk to patients. Mitigating factors relating to the difficult conditions the professional was working in can add further complexity – something that came to the fore at the height of the pandemic[295] – and the fact that his or her record was otherwise unblemished.[296]

However, we also need to recognise the value of the processes themselves. Where professional failings are sufficiently serious, knowing that the regulator will investigate and may refer to a hearing helps maintain public confidence, as well as being essential to establishing if action needs to be taken. In addition, while fitness to practise is a forward-looking exercise for most regulators, part of the analysis must include what has happened in the past, and that may be enough by itself to require an impairment finding and sanction.

We mentioned in our introduction, the case of Dr Bawa-Garba, a doctor who failed to spot the signs of sepsis in a child who died as a result. In summary:

- the doctor was found guilty of gross negligence manslaughter by the Courts
- the Medical Practitioners Tribunal Service (MPTS) decided that she should be suspended for 12 months
- the GMC appealed this, arguing that she should have been struck off
- the High Court agreed with the GMC
- on appeal by the registrant, the MPTS's original decision was reinstated by the Court of Appeal.

The Court of Appeal noted that the doctor's conduct had been found to be criminally negligent and had had a tragic outcome, but that it had been a single incident, and the environment on that day had been dysfunctional. It also took into account the fact that the doctor had subsequently remediated the concerns and practised safely for four years.*(1)

Clearly, the case was serious and the public interest compelled the regulator to take action, to maintain public confidence and professional standards. However, the way the GMC handled the case in appealing to have the doctor struck off, even after a panel had imposed a 12-month suspension – caused consternation among professionals, politicians and the wider public. It prompted two reviews of how gross negligence manslaughter/culpable homicide are handled in healthcare.[297, 298]

* (1) The full timeline is more complex. See: BMJ, The Bawa-Garba case. Available at: https://www.bmj.com/bawa-garba

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We should acknowledge that some of this concern may have been the result of misunderstandings. This was a complex case spanning several different legal processes – the regulator's fitness to practise decisions, as well as the criminal proceedings, and two appeals to the Courts.

Action against Medical Accidents (AvMA) argued that 'a lot of fear has been stirred up unnecessarily. A prosecution for gross negligence manslaughter, as happened to Dr Bawa-Garba, is incredibly rare. It was irresponsible of some to have suggested it can happen to any doctor who makes a simple honest mistake.'[299] This was perhaps symptomatic of a wider problem, that regulatory roles and processes are often not well understood by the general public, nor by the regulated professions themselves.[300, 301] For example, cases concerning clinical competence alone made up only 1.7% of GMC suspensions and erasures between 2012 and 2020.[302]

Ultimately, the legal challenges in Bawa-Garba, along with others where professionals appear to have been sanctioned for one-off failings,[303] help to explain the broader purpose of professional regulation. Health professionals and social workers are not robots, and by virtue of the high-risk work they do, can make mistakes that lead to permanent injury and even death. These mistakes are more likely to happen when professionals are under pressure, and working in challenging conditions.

It is the role of professional regulation neither to punish for past wrongdoing,*(2) nor to divorce professional failings from the context in which they occurred.[304] That said, there are discrepancies in the current system, as the GCC and GOsC both have outdated legislation requiring them to take action based on past misconduct, rather than current impairment – we hope that the current round of reforms will address this.

Maintaining public confidence and upholding professional standards can require regulators to take action where the professional no longer presents a risk to public safety. Action must be balanced and proportionate, and take the registrant's rights, mitigations, and any public interest in keeping competent professionals in the workforce into account.[305] These concepts are complex and may not even have an agreed meaning.*(3) They are further complicated by the fact that the circumstances of each case are different and must all be weighed to reach an appropriate decision; and, as the Bawa-Garba case showed, there is often scope for legitimate disagreement as to the appropriate sanction.

There is also the question of consistency of approach across the regulators. As the Williams Review identified, there are perceived inconsistencies in the way that regulators deal with apparently similar cases, leading to perceptions of unfairness.[306] This was compounded by the lack of understanding about the basis on which outcomes were determined on public confidence grounds.

Regulators should do more, both individually and collectively, to clarify and explain their approach to cases where a professional has been involved in a patient or service user safety incident, with reference to their thresholds for referral into and through the fitness to practise process.

(2) Sir Anthony Clarke, Master of the Rolls, in Meadow v. General Medical Council [2007] 462 at [32] said: "In short, the purpose of FITNESS TO PRACTISE proceedings is not to punish the practitioner for past misdoings but to protect the public against the acts and omissions of those who are not fit to practise. The FPP thus looks forward not back. However, in order to form a view as to the fitness of a person to practise today, it is evident that it will have to take account of the way in which the person concerned has acted or failed to act in the past."

(3) We reported in our advice on public confidence that: 'There is a limited consensus on the types and seriousness of behaviours which are likely to damage public confidence and the public have different views in relation to different professions.' See: Professional Standards Authority, 2019, *How is public confidence maintained when fitness to practise decisions are made? Advice to the Secretary of State*. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/how-is-public-confidence-maintained-when-fitness-to-practise-decisions-are-made.pdf?sfvrsn=c8c47420_0

This would help to dispel myths and reduce unnecessary stress on professionals, it would reduce fear, and promote positive working environments, as well as increasing confidence in the process and its outcomes. For this to be effective, regulators need to communicate information clearly and through the right channels, for example working with employers and other partners to limit unwarranted referrals and disseminate clear information about decisions that have been made against registrants, and how they fit with their policies on thresholds for referral.

As part of this, regulators still need to work on understanding and describing public confidence, and its importance in regulation, more clearly. It is a key element of decisions where a professional has seriously failed, but no longer poses a risk to the public.

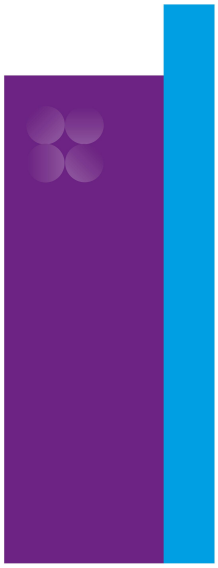
A review we conducted in 2019 told us that public confidence was not well understood and was applied differently in fitness to practise across the regulators.

We will consider how we use our policy and research function in this area, as part of our commitment to supporting the actions outlined in this report.

In addition, while fitness to practise is the regulatory function causing much of the fear, it is necessarily reactive, and slow. Cases in fitness to practise can be concluded years after the event. Regulators have more proactive tools at their disposal to support registrants practising in challenging circumstances.[307] They can work with other bodies to raise concerns about difficult working conditions that are compromising registrants' ability to provide safe care. Regulators also have what is sometimes referred to as preventative, or upstream powers such as setting standards, providing guidance, setting revalidation/CPD requirements, and influencing training curricula. These can all be used to equip registrants with a better understanding of how to navigate difficult working conditions using sound judgement.[308]

Employers can also do much more to reduce the need for referrals to the regulator, both by providing a more supportive, learning environment, and by resolving performance, quality and safety issues locally, where appropriate. This could involve building in more time for self-reflection for individuals and teams, and there are many models of good practice in this area. But as we highlighted in the chapter on inequalities, this kind of support may not be accessible to everyone equally, and employers should ensure that everyone can benefit from them.

Regulators have proactive tools at their disposal to support registrants practising in challenging circumstances



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Building trust while maintaining independence

> 'We need to look beyond the actions of an individual and understand the role of other people, the culture and environment they were working in when something went wrong. Only then can we identify what needs to happen to keep people safe in the future – even if we're not the ones who can take that action.'

NMC guidance, Taking account of context [309]

The regulators we oversee are broadly aware of the counter-productive effects of fear on their registrants, and are making efforts to keep pace with moves in the sector away from 'blame cultures'. Overall, we support these approaches where they are about understanding and communicating their role more clearly, increasing compliance and promoting learning when harm has occurred:

- The GOsC was one of the first regulators in our sector to identify the counterproductive nature of a relationship between regulator and regulated based on fear.[310]
- The GMC's response to the Bawa-Garba case includes incorporating a 'Supporting a profession under pressure' strand in its corporate strategy, 'to address the issues that have been raised with us about the environments in which doctors work, and the impact of systems pressures on medical practice'.[311]
- As well as focusing on support for its registrants in its strategy, the NMC has developed a framework for taking context into account in fitness to practise decisions, supporting learning rather than assigning blame; echoing thinking on just and learning cultures.[312]
- A major collaborative report on the concept of seriousness in fitness to practise published this year compares approaches across the regulators.[313] It should help regulators better understand and communicate the factors affecting decisions about the seriousness of professional misconduct, and bring greater consistency across bodies.
- Several regulators have now developed employer liaison functions to support employers (who refer a large proportion of cases to regulators), to identify the right sorts of cases for referral. This could also help address over- or under-referral of groups with particular protected characteristics.

We should sound a note of caution, however. There is a fine line between cultivating trust, and getting too close to the profession; the latter comes with the risk of becoming a less effective regulator, insufficiently focused on all three limbs of public protection. The Authority and the regulators we oversee will need to stay vigilant to ensure that the cumulative effect of these initiatives does not compromise our ability to protect the public effectively.

In addition to the regulators' work, the Governments' proposals to extend the use of consensual approaches to fitness to practise without a tribunal (accepted outcomes) could also help to alleviate the fear of action by the regulator.[314] While these measures are not designed to change the sorts of situations in which regulators can take action, the final decision-making process should be less daunting, and take less of a toll on professionals.

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These benefits will only be realised if regulators are transparent about the basis for their decisions, in support both of just cultures, and of maintaining public confidence.

Accepted outcomes, where decisions are taken in private, are, by their nature, less transparent than any decisions made by a tribunal. It will therefore be all the more important that regulators publish good, clear explanations for the public and the profession about accepted outcomes processes and decisions.

As we can see, tackling the problems presented by fear of regulatory consequences is well underway. We welcome this shift in approach, which can and should be compatible with the three aims of professional regulation set out in the previous section, provided it focuses on clarifying and communicating the role of the regulator, and increasing compliance.

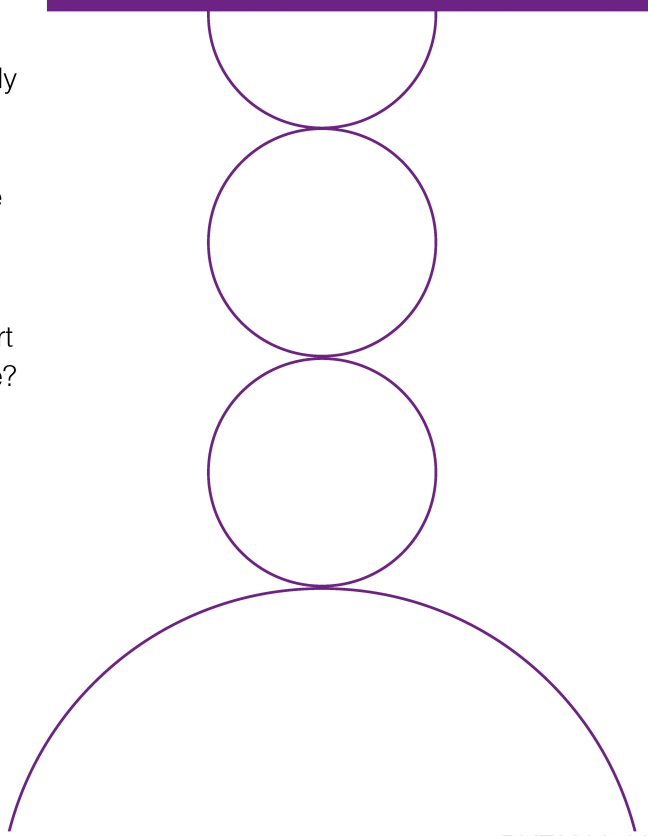
Will it lead to improvements? In our view there are three priority areas to review:

1. Fitness to practise policy: do the regulators' policies and guidance support fair decision-making that takes context into account while maintaining the three limbs of public protection?
2. Fitness to practise communication: are regulators sufficiently clear in their communications about the factors that are likely to lead to action on registrants when there has been a safety incident? Are they working with professionals, employers, patients and service users to ensure their role is understood?
3. Standards, guidance, and training for registrants: do regulators do enough to support registrants to do the right thing under pressure?

Taking these steps forward piecemeal will limit their value. That is why it is essential that regulators work together to develop a coherent approach to dealing with harmful mistakes in health and social care.

We must be realistic about what can be achieved in this way. Professional regulation involves apportioning responsibility for errors to individuals, and holding them to account for their actions. It is almost inevitable that it should be feared to an extent. What it can aim for – and what we want to help it achieve – is a more trusting relationship with the people it regulates, and policies and partnerships that support, rather than obstruct the development of just and learning cultures in the workplace. But as we will see in the next section, it is also important that these developing approaches to patient and service user safety support fair and just individual accountability.

Regulators need to be transparent about the basis for their fitness to practise decisions



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Healthy work cultures that support professional accountability

> 'When things do go wrong and cause harm, it is very rare that this is because individuals deliberately depart from good practice or act maliciously. However, if that were the case, the individuals would need to be held to account.'

AvMA, A vision of what a 'just culture' should look like for patients and healthcare staff [315]

While it is certainly not the intention, could there be unintended consequences for patient and service user safety, and for the wider public interest, of a move to a 'no blame' approach at local or national level?

The Just Culture Guide provided by NHS England, but used in other parts of the UK too,[316] describes just culture as a way of evaluating the actions of staff involved in a patient safety incident. Unsurprisingly, given that it has the support of regulators and patient safety bodies, it is not about shielding individuals from personal responsibility. It stresses that the priority of a patient safety investigation is 'to identify underlying causes that need to be acted on to reduce the risk of future incident.' It also makes clear that it is essential to establish the roles played by individuals in any incident. However, this must be done fairly and transparently, in a way that is readily understood by those involved – for example, asking questions about the particular context for the professional's actions and whether another professional would have acted in the same way in those circumstances. Interesting approaches have also developed locally, like the Restorative Just and Learning Culture espoused by Mersey Care NHS Foundation Trust,[317] which has gone on to be adopted by other providers.[318]

These encouraging policies show that just cultures do not only coexist with individual accountability frameworks – but also that a fair and transparent approach to individual accountability is an integral part of a just culture.

But local patient safety investigations sit alongside multiple national mechanisms, each of which fulfils a different societal benefit – providing financial redress, assessing criminal liability, and protecting patients from future harm.

We mentioned above some of the thinking on no-blame approaches to redress and compensation. There is some criticism though that they can, in fact, reduce levels of accountability and in doing so actually have a negative impact on patient safety. A 2015 study comparing approaches to indemnity in medicine found that 'Despite the seductive nature of the no-fault system – the absence of the spectrum of guilt and accusation, the decrease of confrontation, the possibility to compensate more patients – it must be acknowledged that it also presents serious flaws, including the almost complete absence of accountability, […] and the potential degradation of the standard of conduct of health professionals.'[319] This paper concludes that no-fault approaches are more flawed than tort-based systems, and that efforts should be focused on improving the latter rather than trying to move to the former. We are not in a position to assess the merits of this particular finding; but it is certainly interesting that the benefits to patient safety of a no-fault approach may not be as clear-cut as some have suggested; precisely because it could cut across the mechanisms that identify fault at individual level.

The Safe Spaces policy embraced by the English Healthcare Safety Investigation Branch (HSIB) for its national investigations and recently placed on a statutory footing by the Health and Care Act epitomises our concern about national approaches.[320] It is undoubtedly true that people can be put off speaking up if they are

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concerned about what this might mean for them or their career,[321] (illustrated by the Ockenden and Mid Staffordshire NHS Foundation Trust inquiries), and that creating 'safe spaces' where people can raise concerns without fear of the consequences can help.

We welcome the fact that the safe spaces policy would not apply to local investigations as was originally planned,[322] and has never been extended to the statutory maternity investigations that will continue to be conducted by HSIB until the creation of a dedicated Special Health Authority.[323] We nonetheless question whether the benefits of the safe spaces approach, even when limited to national investigations, will outweigh the drawbacks. This may depend to some extent on how it is implemented.

Our main point is that evidence of concerns about the conduct or competence of an individual or organisation, may not be shared with the appropriate parties, stopping those best placed to assess if there are fitness to practise concerns from taking action.

It is hard to say how often this kind of situation might arise, but the problem is that the policy itself appears flawed – it creates an information silo by design, when there is ample evidence that the free flow of information is essential to safety.[324] Exemptions to the safe spaces policy, as drafted in the current Health and Care Bill, do little to address this issue because they place responsibility for deciding whether the threshold for sharing is met with the body holding the information.

The concern is threefold: that the regulator should be able to make its own judgement as to whether information raises concerns that may be of relevance to its role; that the generic threshold set in the HSIB legislation is unlikely to match that of the regulators; and that in any case, the evidence held by HSIB may not on its own suggest a serious concern (and therefore meet the threshold for sharing), but may do so when combined with pieces of evidence held elsewhere. This is particularly relevant at a time when other regulatory bodies are recognising the importance of effective information-sharing to identify risk to the public, for example via the CQC's Emerging Concerns protocol.[325]

It is worth noting that HSIB safe spaces are primarily necessary where local workplace cultures are causing people to fear repercussions – but they work around the symptom without attempting to address the cause. This approach should not be a distraction from the more fundamental task of tackling toxic cultures.

As long as local ways of working allow for full and candid accounts to be shared with patients, service users and families, and for appropriate action to be taken, they are to be welcomed. The problem with the HSIB approach is that, almost by design, it imposes a model that seems to cut across both these things.

There is another issue too, of a slightly different order, which is that this information silo could undermine the professional duty of candour. This is a duty that requires professionals to be open and honest with patients, service users and families when care has gone wrong, and sits alongside the statutory organisational duty, where it is in place.[326] It seems hard to reconcile this duty with a framework that prevents information about patient safety incidents from being shared by law – and yet we see that catastrophic failings in care are often accompanied by a lack of candour.

The fact that the HSIB is a body for England only adds more complexity. The above issues would apply to patient safety incidents in England, but not Wales, Northern Ireland or Scotland. On the other hand, the health professional regulators that cover England also cover other parts of the UK, creating a complex patchwork of different approaches to patient safety incidents.

The HSIB was created in response to the very real concerns about the effect of blame on the willingness of professionals to speak up, and the ability of the system to learn from mistakes.

It is still possible that the lessons learnt from this approach may result in greater public protection benefits overall. But the UK Government should proceed with caution with the 'safe spaces' approach for England, building in a review to ensure that it is addressing more risks than it is creating. The review should also check that it is not cutting across the duties of candour, or otherwise having a negative impact on transparency. It should consider the possibility that the safe spaces policy may be so fundamentally flawed that it should be set aside in favour of more transparent mechanisms.

Additionally, if the Government has to make trade-offs, patients and the public should be told, openly.

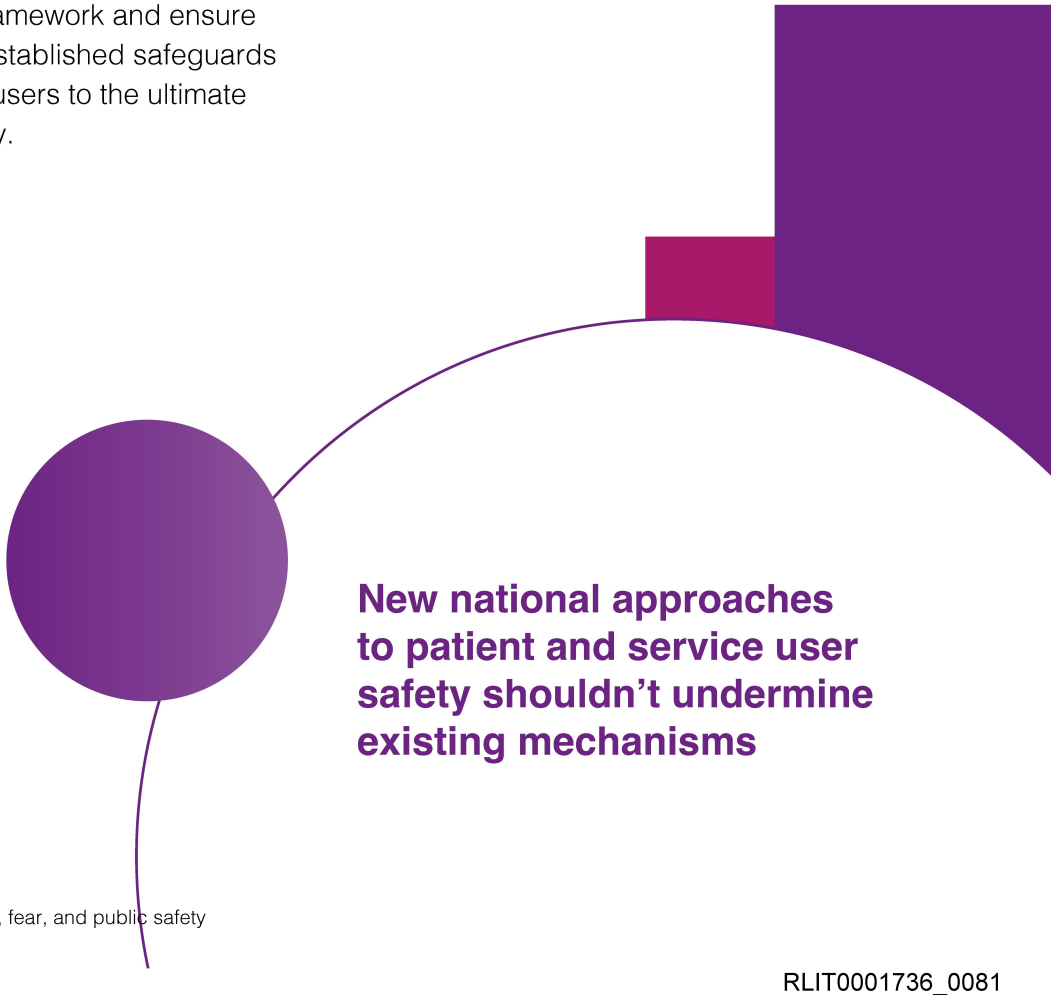
The UK Government should ensure that the 'safe spaces' investigation approach being implemented in England does not cut across the duty of candour or otherwise negatively impact on transparency or accountability.

These new powers for HSIB highlight the absence of a coherent review stage for new policy initiatives to consider how they fit within the existing legislative framework and ensure they do not undermine established safeguards for patients and service users to the ultimate detriment of public safety.

Policy checks should be introduced to ensure that any new national approaches linked to patient and service user safety are coherent with, and do not undermine, existing mechanisms. This would form part of the role of the recommended Health and Social Care Safety Commissioner.

While we have made recommendations throughout this chapter that may go some way to alleviating some of the tension between accountability and just, learning cultures, we recognise the limits of the work we have been able to do on this. To do justice to the complexity – and urgency – of this issue, we need an open, sector-wide conversation, with input from patients and service users, professionals, employers, and many others.

The Authority will bring stakeholders together to find ways for the 'safe spaces' approach of the Healthcare Safety Investigations Branch (HSIB) England, and other local and national initiatives for improving safety culture, to support candour and accountability.



New national approaches to patient and service user safety shouldn't undermine existing mechanisms

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Accountability, fear, and public safety: our conclusions

The theme of this section is, fundamentally, about how to make individual accountability work in a system that learns from mistakes and is safe for patients and service users, and fair to professionals.

We conclude that:

- Individual accountability plays a key part in keeping people safe in health and care, and professional regulation is integral to this framework. Inquiries and reviews investigating major failings should understand this.
- Professionals' fear of being unfairly blamed is, to an extent, inevitable, but we believe that it is sometimes driven by misunderstandings about the role of the regulator.
- Actions by regulators need to be fair and transparent, with clear explanations of how and why decisions are taken, with reference to the three limbs of public protection.
- Employers have a key role in communicating and acting on regulators' expectations, referring members of staff to the regulator only where concerns are sufficiently serious, in line with the regulator's own guidance.
- The safe spaces approach taken by HSIB for England appears to cut across the professional duty of candour and individual accountability mechanisms.
- Professional regulation is neither the cause of, nor the solution to, toxic workplace cultures – this is the preserve of the employer. But it does need to do more to become part of a just culture without compromising safety.

Recommendations

We recommend that:

- Regulators should do more, both individually and collectively, to clarify and explain their approach to cases where a professional has been involved in a patient or service user safety incident.
- The UK Government should ensure that the 'safe spaces' investigation approach being implemented in England does not cut across the duty of candour or otherwise negatively impact on transparency or accountability.

Recommendations that could form part of the Health and Social Care Safety Commissioner's role:

There should be an independent mechanism for centralised coordination and oversight of public inquiries.

- Policy checks should be introduced to ensure that any new national approaches linked to patient and service user safety are coherent with, and do not undermine, existing mechanisms.

The Authority will:

- Bring people together to find ways for the HSIB England's 'safe spaces' approach, and other initiatives for improving safety culture, to support candour and accountability. This will include patients, service users and families, professionals, regulators, and many others.

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Safer care for all: looking beyond professional regulation

> 'There is a whole jigsaw of organisations involved in regulation to keep patients safe, but despite numerous organisations and substantial resource, there was a failure to keep patients safe in the case of Paterson.'

Report of the Independent Inquiry into the Issues raised by Paterson[327]

In this chapter we reflect on how some of our conclusions have exposed structural and functional gaps in patient and service user safety. We propose a way to fill them through one overarching recommendation.



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Professional regulation – just one piece of a big jigsaw

Almost more than anything else, this report illustrates what a fragmented landscape we operate in – health, social care, four countries, and within these, complex patient and public safety mechanisms spanning numerous different bodies. Successive public inquiries continue to shock the four countries of the UK. Most recently, Donna Ockenden's report into maternity failings raises so many of the issues we have considered in this publication: calls for individuals to be held to account, calls for more safe spaces, the challenges created by workforce shortages, and the need to tackle inequalities in healthcare.

Meanwhile, changes to the way services are delivered and funded are creating risks that can go unnoticed, although these too have been brought to the fore by recent inquiries. This includes the Paterson Inquiry, cataloguing public and private healthcare's failure to prevent Ian Paterson from harming hundreds of patients, and the Cumberlege Review which identified barriers to recognising and addressing system wide issues: 'The healthcare system, and DHSC in its oversight role, has failed to demonstrate it can both recognise system-wide shortcomings and remedy them. Far more is needed to sharpen the linkages between the system's constituent parts to deliver system wide responses to patient safety concerns that are adequate, robust and timely.' [328]

We said we would ask difficult questions in this report:

- Why are we still seeing failings on the scale of those at Shrewsbury and Telford Hospitals NHS Trust?
- Using inquiries as a crude metric,[329] why does it appear that patient safety is not improving?
- Why do inequalities persist?

For too long, individual organisations with different and specific remits have been expected to work together to address workforce and patient and service user safety issues. This approach is structurally flawed as there is generally no accountability for joint working and collaboration; bystander apathy and differing organisational priorities also present significant barriers. Everyone understandably looks at the problem through the lens of their own remit, but no one has the overview.

This applies to inquiries too. Focusing on the most serious cases, inquiries are a key driver for change. The Inquiries into failures in children's heart surgery at Bristol Royal Infirmary[330] and the Shipman murders[331] transformed the way professional regulation works, and while the current system is imperfect, it is much improved from the previous professionally-dominated framework. But as we have outlined in the Accountability chapter, inquiries are a mixed bag of statutory and non-statutory, with significant variations in remit that are often unexplained. From a professional regulation perspective, some have a strong focus on regulators' actions (Shipman, Mid-Staffordshire) while others do not (Paterson, Ockenden).

In this report we set out to describe the big safety issues in health and care affecting professionals and their practice. We also wanted to give a view on how effectively professional regulation is responding to these challenges, and the gaps and issues that remain.

We have considered a range of problems; some of which are already being widely debated, while others may be slipping under the radar.

There are some specific ways professional regulation, including the Authority itself, could help to address these problems and we have highlighted them in our recommendations. And although our work on the model for reform of the professional regulators we oversee is well underway, there will still be opportunities to respond to some of the concerns we have raised here, particularly those on business regulation.

Our most significant observation, perhaps, is that looking at problems through the lens of professional regulation has its limits. It presupposes that the answer lies in changes to the way we regulate individuals, because that is what we do – a problem that is replicated across the sector through different lenses.

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Solutions beyond professional regulation: Health and Social Care Safety Commissioners

As we see it, the only solution to some of the key challenges affecting patent and service user safety is to create frameworks spanning organisational and sectoral boundaries. We recommend that:

- Each UK country should have a Health and Social Care Safety Commissioner, or equivalent function, with responsibility for identifying, monitoring, reporting, and advising on ways of addressing patient and service user risks.

This is ultimately a recommendation for the four UK Governments because it sits above everything else.

Moves are already afoot to create a Patient Safety Commissioner in England and Scotland. It is our view that this role could be introduced in all parts of the UK, and should take on a broader remit than just medicines and medical devices, as this would only increase fragmentation and exacerbate remit frustration.

A number of stakeholders, including patient organisations such as Patient Safety Learning, the Harmed Patients Alliance, AvMA and the Patients Association have made this point in response to the proposals for a Patient Safety Commissioner and called for the role to have a broader remit.

We need a body that can look across the system through the eyes of the patient and service user

Why another body?

We are conscious of the risk that calling for the creation of another body will simply add to the complexity that we have described. However, with no overarching patient and service user safety body, all efforts, short of a government initiative, inevitably focus on the remit of the bodies identifying them.

While many organisations have a role in patient safety, all of them have responsibility for a specific piece of the jigsaw. This means the majority are unable to look across the system through the eyes of the patient and service user and bring about the necessary action across organisations.

Every major healthcare failure prompts further well-meaning efforts at collaboration between organisations to prevent future harm; but there is no-one to follow up on organisations' commitments and actions and, where necessary, hold to account. As the Cumberlege Review stated when describing the proposed Patient Safety Commissioner role: 'We are calling for a public spokesperson with the necessary authority and standing to talk about and report on, to influence and cajole where necessary without fear or favour on matters related to patient safety.'[332]

We also believe that there is a major gap in responsibility with regard to public inquiries. Anyone reading the Ockenden Review would have been struck by the parallels with previous maternity reviews such as the Morecambe Bay Investigation carried out by Bill Kirkup in 2015. However, despite the urgent recommendations made in this report the CQC found, just last year, that the Morecambe Bay NHS Foundation Trust remains 'inadequate' with over half of maternity services in England falling into this category.[333]

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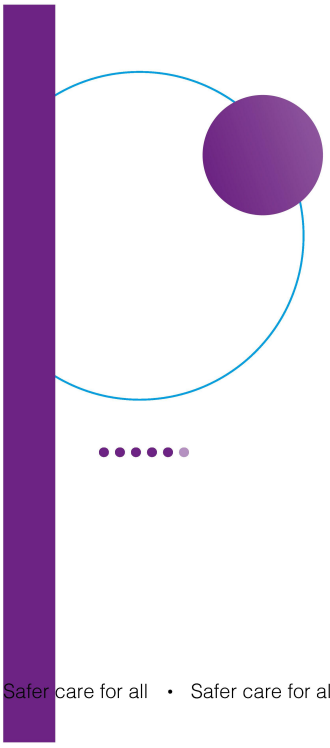
With further maternity Inquiries underway in East Kent and Nottingham it is clear that problems remain widespread. However, as we have touched on, as well as the lack of a mechanism to ensure recommendations are addressed promptly, there is also no way of standardising the terms of public inquiries to ensure that they provide sufficient analysis of all the factors contributing to the harm in question. This should include the failures of the regulatory frameworks which are meant to keep patients safe.

We are not the first to have concerns here – the Institute for Government has highlighted the lack of guidance on how to set up and run a statutory inquiry, and the lack of follow-up on implementation.[334]

We must find a way of breaking this cycle and have come to the conclusion that there must be a role with steely and unblinking focus on safety across the system and the necessary influence and remit to bring about change. It must be developed in partnership with users of care services, and become a champion of patient and service user partnership as a means of identifying risks and solutions.



What would the Commissioners do?

The Commissioners would sit above all other health and care organisations, spanning public as well as private provision. They would also be independent of Governments, and transparent in both their approach and outputs. In this unique position of oversight, and working closely with key stakeholders including service users, they could fulfil the following roles:

Risk intelligence

- Review risk data produced by other organisations to identify trends either nationally or locally
- Carry out meta-analyses of inquiry findings to identify trends
- Report specifically on any inequalities concerns arising from safety data.

Expertise

- Make recommendations for addressing risks identified through the intelligence function
- Identify gaps in the patient and service user safety landscape, and make recommendations for addressing them
- Identify gaps in data collection and make recommendations for addressing them
- Recommend ways in which data collection can be improved and harmonised across the sector
- Signpost people making complaints to the correct organisation (and take notes of concerns as part of the intelligence function)
- Carry out policy checks to ensure that any new national approaches linked to patient and service user safety are coherent with, and do not undermine, existing mechanisms to the ultimate detriment of patient safety.

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Inquiries secretariat

- Coordinate inquiries and reviews into health and care failings to bring greater coherence to terms of reference and approaches
- Report on progress against inquiry recommendations.

What wouldn't they do?

What this role would not be is another regulator, another layer of checks or a burden on an already over-stretched system.

While we believe the role can and should absorb responsibilities around public inquiries (a function currently not fulfilled by any organisation) the most important function would be to provide the bird's-eye-view across the system and prompt the relevant organisations to take action on behalf of patients. To quote from the Cumberlege Review: 'This person would be the golden thread, tying the disjointed system together in the interests of those who matter most.'[335]

The role would need tailoring to the heath and care contexts, we draw parallels with existing roles such as that of the Victims' Commissioner for England and Wales; who first and foremost is intended to be 'the voice of victims' of crime.[336]

We thought carefully about whether such a role should have an advocacy function in relation to the quality of health and social care services, but ultimately concluded that this could conflict with the role of existing organisations and patient representative groups. It would also make it more difficult for the role to fulfil a distinct function within the landscape of each of the four countries of the UK. For example, in Wales the new Citizen Voice Body will represent public views of services, helping ensure that their experiences 'shape the design and improvement of services'.[337]

Geographical scope of roles

While there would be advantages to creating a UK-wide Commissioner, we recognise that the differences between UK countries would make it difficult, and could make the role unmanageable. There might be resistance to the creation of a UK-wide role and, potentially, the need for individual Commissioner's roles and responsibilities to fit within the health and care contexts and infrastructures of the different countries of the UK.

To accommodate this, we recommend the creation of a Consortium of UK Safety Commissioners for Health and Care to ensure coordination across all four countries.

The Authority has already embarked on a programme of work under the 'Bridging the Gap' banner looking at ways to bridge the gaps in information flows and shared risk management across the health and care sectors.[338] As part of this, we intend to reflect upon, and work up, this proposal in more detail.

Why a Commissioner?

We recommend a Commissioner model to fulfil this function partly because we see similarities with the issues identified by the Cumberlege review, and we do not want to add complexity though duplication. It also appeals because commissioner roles of this type are often intended to be a voice for groups who collectively may lack one, such as victims of crime, or children – not an advocate as such, but a role with a single, undiluted purpose that gives it licence to look across the system. This would address our observation that the current framework is failing because each body involved in safety is focused on its own, necessarily narrow remit.

Ultimately, what is most important is that the functions we set out above are fulfilled, whether by a commissioner, or another body. We would not want the substance of this recommendation to be discounted because of opposition to or complications with setting up the Commissioner role in this way.

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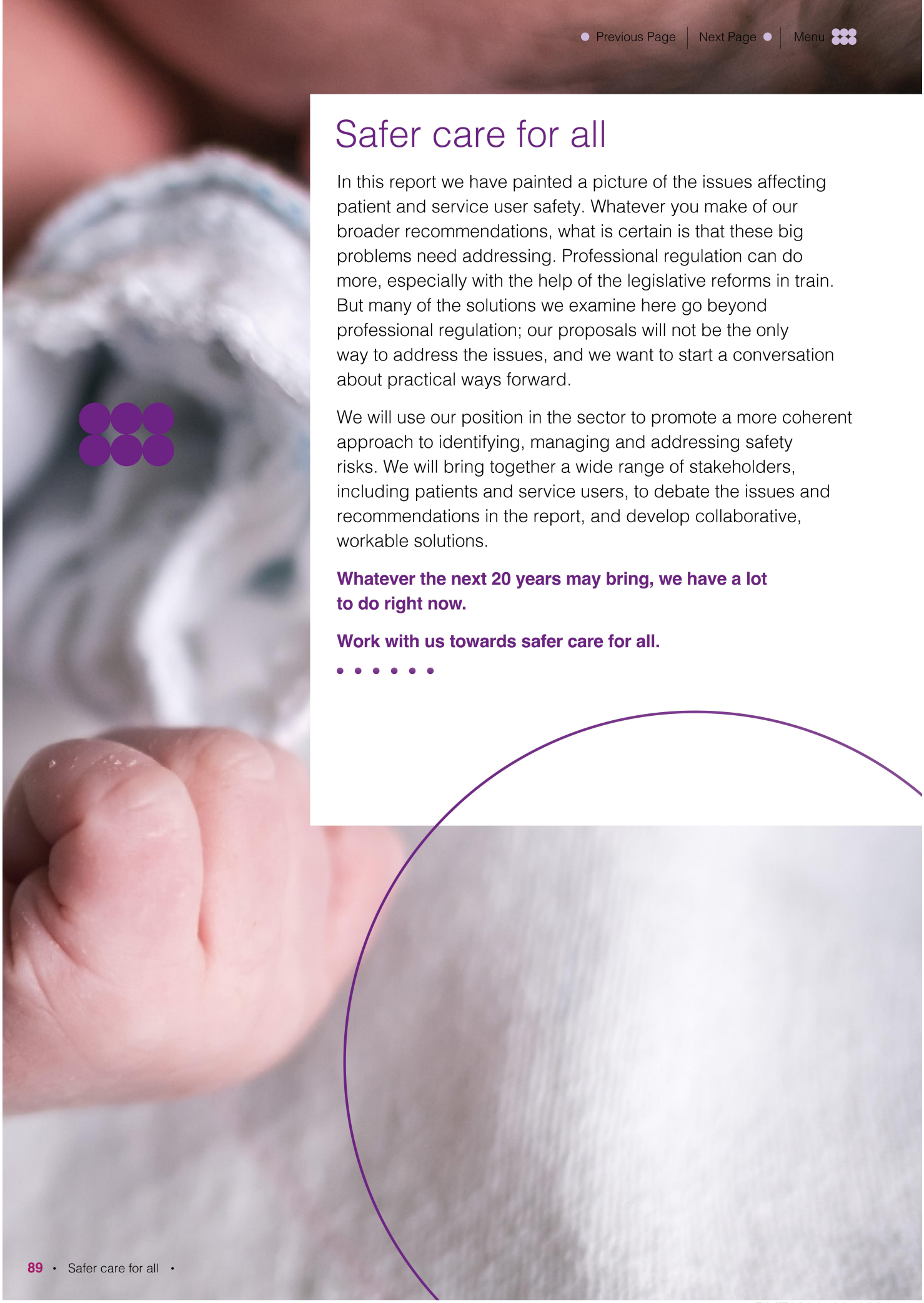
Safer care for all

In this report we have painted a picture of the issues affecting patient and service user safety. Whatever you make of our broader recommendations, what is certain is that these big problems need addressing. Professional regulation can do more, especially with the help of the legislative reforms in train. But many of the solutions we examine here go beyond professional regulation; our proposals will not be the only way to address the issues, and we want to start a conversation about practical ways forward.

We will use our position in the sector to promote a more coherent approach to identifying, managing and addressing safety risks. We will bring together a wide range of stakeholders, including patients and service users, to debate the issues and recommendations in the report, and develop collaborative, workable solutions.

Whatever the next 20 years may bring, we have a lot to do right now.

Work with us towards safer care for all.



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Appendix: All our recommendations and commitments

	What?	Who?	Chapter
1	Each UK country should have a Health and Social Care Safety Commissioner, or equivalent function, with broad responsibility for identifying, monitoring, reporting, and advising on ways of addressing patient and service user risks. *(See text for details of actions we recommend are taken forward by the commissioners.)*	The four UK Governments	5
2	Regulators and registers work collaboratively to improve the diversity of fitness to practise panels, other decision-makers and senior leadership to ensure they reflect the diversity of the community more closely.	Professional regulators and Accredited registers	1
3	Regulators and registers work with other health and care bodies to gain a better understanding of the demographic profile of complainants and reduce barriers to raising complaints for particular groups.	Professional regulators, Accredited Registers, and other health and care sector bodies	1
4	Regulators and registers review how their fitness to practise processes and guidance address allegations of racist and discriminatory behaviour.	Professional regulators and Accredited registers	1
5	Demographic data on complaints made to the health and care services across the UK is recorded and made available for all bodies to use.	UK Governments/health and social care services	1
6	Governments use the current healthcare professional regulation reform programme to: Review the adequacy and effectiveness of the powers of regulators with a role in regulating businesses. • Consider whether there is a case for extending business regulation powers to all regulators whose registrants work in 'high street' practices • Ensure regulators have the agility to address the challenges brought about by new approaches to funding and delivering care, including the introduction of new technologies.	UK Governments	2
7	Regulators tackle business practices that fail to put patients first, risk undermining confidence in the professions, or fail to allow registrants to exercise their professional judgement. A cross-sector review should be conducted of the effectiveness of arrangements to address financial conflicts of interest among healthcare professionals.	Professional regulators	2
8	Governments, regulators and registers review how they will determine the lines of accountability for new technologies used in health and care.	UK Governments, professional regulators and Accredited registers	2
9	Regulators and registers work collaboratively to identify opportunities to speed up workforce supply, equip practitioners to deal with future challenges in how care is delivered, close safety gaps and protect patients and service users.	Professional regulators and Accredited registers	3

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	What?	Who?	Chapter
10	There is a clear process to guide the development of new health and care roles including the scope and purpose of the role, and the process for deciding on the level of assurance required.	UK Governments and education and workforce bodies	3
11	There should be an agreed way of deciding when to deviate from taking a UK-wide approach based on a review of risks and benefits alongside consideration of the national context.	UK Governments	3
12	Those involved in health and care workforce planning and delivery across the UK actively support additional and alternative means of assurance as a means of managing risks to patients and service users.	UK Governments, health social care services, employers, education and workforce bodies	3
13	The four UK Governments work together to develop a coherent strategy for the regulation of people, to support delivery of their national health and social care workforce strategies.	UK Governments	3
14	Regulators should do more, both individually and collectively, to clarify and explain their approach to cases where a professional has been involved in a patient or service user safety incident.	Professional regulators	4
15	The UK Government should ensure that the 'safe spaces' investigation approach being implemented in England does not cut across the duty of candour or otherwise negatively impact on transparency or accountability.	The UK Government	4
16	The Authority will ensure that the application of our EDI standards for regulators is stretching and stimulates continuous improvement.	The Professional Standards Authority	1
17	The Authority will work to ensure a consistent approach across both regulated and unregulated practitioners through our Accredited Registers programme and will be introducing clearer requirements for registers on EDI later this year.	The Professional Standards Authority	1
18	The Authority will look at its own processes to ensure that we are not reinforcing or exacerbating inequalities in the regulatory system.	The Professional Standards Authority	1
19	The Authority will use its oversight role to encourage co-operation, collaboration, and coherence on EDI issues across the system, noting the inherent challenges in trying to address safety concerns when it is so fragmented.	The Professional Standards Authority	1
20	The Authority will use its oversight role, expertise and convening power to support the development of regulatory strategies by the UK Governments.	The Professional Standards Authority	3
21	The Authority will bring people together to find ways for the HSIB England's 'safe spaces' approach, and other initiatives for improving safety culture, to support candour and accountability. This will include patients, service users and families, professionals, regulators, and many others.	The Professional Standards Authority + stakeholders	4

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