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.

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.

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]

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.

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.