Written evidence submitted by the Department of Health and Social Care (PSN0027)

Contents

Section 1: Maternity care and leadership

Recommendation 1

"There is no mechanism to scrutinise perinatal deaths or maternal deaths independently, to identify patient safety concerns and to provide early warning of adverse trends. This shortcoming has been clearly identified in relation to adult deaths by Dame Janet Smith in her review of the Shipman deaths, but is in our view no less applicable to maternal and perinatal deaths, and should have raised concerns in the University Hospitals of Morecambe Bay NHS Foundation Trust before they eventually became evident. Legislative preparations have already been made to implement a system based on medical examiners, as effectively used in other countries, and pilot schemes have apparently proved effective. We cannot understand why this has not already been implemented in full, and recommend that steps are taken to do so without delay."[1]

Has the recommendation been implemented? Or (in the case of a recommendation whose deadline has not yet been reached) Is the recommendation on track to be implemented?

Medical Examiners were introduced on a non-statutory basis from 2019/20.

In April 2023 the Government announced[2] that the statutory Medical Examiner system would commence from April 2024. This was dependent on DHSC and other government departments finalising the death certification reforms planned from April 2024, details of which were published in December 2023.[3]

Medical Examiners have now provided independent scrutiny of approximately 640,000 deaths in England since the programme started. They are providing independent scrutiny of almost all deaths in acute Trusts, and a growing number of deaths in non-acute settings; an estimated 34% of non-acute deaths were scrutinised in Q2 of 2023/24 (up from 30% in Q1 of 2023/24, 18% in Q4 of 2022/23, 14% in Q3 and 11% in Q2).

Once the new statutory process comes into force, all deaths in England and Wales will be independently reviewed, without exception, either by a medical examiner or a coroner. In terms of maternity and neonatal services this will include a review of neonatal and maternal deaths.

While this recommendation refers to trends identified by Medical Examiners and asks why they had not been introduced as of 2015, there are additional mechanisms for scrutiny and surveillance in maternity and neonatal care, largely established since 2015 and listed here chronologically:

Confidential Enquiry into Maternal Deaths

The Confidential Enquiry into Maternal Deaths is a national programme investigating maternal deaths in the UK. Since June 2012, the Confidential Enquiry has been carried out by the MBRRACE-UK collaboration.

Maternal deaths are reported to MBRRACE-UK by the staff caring for the women concerned, or through other sources including coroners and media reports. In addition, identification of deaths is cross-checked with records from the Office for National Statistics, Information

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1 From The Report of the Morcambe Bay Investigation, page 190

2 Written statements - Written questions, answers and statements - UK Parliament

3 An overview of the death certification reforms - GOV.UK (www.gov.uk)

Services Division Scotland and National Records of Scotland. Full medical records are obtained for all women who die, as well as those identified for the Confidential Enquiry into Maternal Morbidity and are anonymised prior to undergoing confidential review.

The anonymous records are reviewed by a pathologist, together with an obstetrician or physician as required to establish a woman's cause of death. Each woman's care is examined by between ten and fifteen multidisciplinary expert reviewers and assessed against current guidelines and standards (such as that produced by NICE or relevant Royal Colleges and other professional organisations). Subsequently the expert reviews of each woman's care are examined by a multidisciplinary writing group to enable the main themes for learning to be drawn out for the MBRRACE-UK report. MBBRACE publishes all reports, including specific thematic enquiries.[4]

Maternity and Newborn Safety Investigations programme – formerly Healthcare Safety Investigations Branch (HSIB) Maternity Investigations Programme

The HSIB Maternity Investigations Programme was established in April 2018 to take over the investigation of a specific set of maternity outcomes from NHS Trusts in England[5]. At this time eligible cases were those which met the criteria in *Each Baby Counts*[6] and direct or indirect maternal deaths as defined in *MBRRACE-UK's Saving Lives Improving Mothers' Care Report 2016*[7].

Since October 2023, the Maternity and Newborn Safety Investigations programme has been hosted by the CQC. It continues to have the same remit and purpose as the Maternity Investigations Programme and there has been no change to investigations of perinatal deaths as a result of the move to from HSIB. The programme has been and continues to be fully funded by DHSC to deliver this remit. The investigations it conducts are carried out by an investigator independent to the Trust and provide learning for the Trust and the wider system.

NHS Resolution's Maternity Incentive Scheme (MIS) supports the delivery of safer maternity care through an incentive element to trust contributions to the Clinical Negligence Scheme for Trusts. The MIS, developed in partnership with the national maternity safety champions at the time, rewards Trusts that meet 10 safety actions designed to improve the delivery of best practice in maternity and neonatal services. Safety action 10 of the Maternity Incentive Scheme[8] requires that all qualifying cases are referred to MNSI (and previously HSIB) for investigation. Trusts that can demonstrate they have achieved this, and the other nine safety actions, will recover the element of their contribution to the CNST maternity incentive fund and will also receive a share of any unallocated funds. The percentage of Trusts meeting each safety action for each year the scheme has been running is published on NHS Resolution's website.

Perinatal Mortality Review Tool (PMRT)

The PMRT was released in January 2018 and is funded and commissioned by the Health Quality Improvement Partnership on behalf of DHSC.

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4 Reports | MBRRACE-UK | NPEU (ox.ac.uk)

5 The Care Quality Commission (Maternity and Newborn Safety Investigation Programme) Directions 2023 (publishing.service.gov.uk)

6 Each Baby Counts | RCOG

7 MBRRACE-UK Maternal Report 2016 - website.pdf (ox.ac.uk)

[8] Maternity incentive scheme - NHS Resolution

The aim of the PMRT is to support objective, robust and standardised local reviews of care when babies die. This is to provide answers for bereaved parents and their families about whether the care that they and their baby received was appropriately safe and personalised and whether different care may have changed the outcome.

An additional aim is to ensure that review findings result in learning at both the local and national level in order to improve care, reduce safety-related adverse events, and prevent future baby deaths. The PMRT is designed to support the review of baby deaths from 22 weeks' gestation onwards, including late miscarriages, stillbirths, and neonatal deaths.

Guidance for the use of the PMRT recommends the involvement as part of the multidisciplinary review team of a member who is external to the Trust or Health Board with relevant clinical expertise. This is intended to bring 'fresh eyes' to the review and to provide robust challenge where complacency or 'group think' in service provision could potentially predominate. MBRRACE-UK publishes an annual report on PMRT.[9]

Both the PMRT and the Maternity and Newborn Safety Investigations programme provide the opportunity for parents' involvement in the investigation of certain categories of stillbirths, which is essential to help provide answers for bereaved parents.

Additional work to improve surveillance and data use in maternity care

- The NHS Perinatal Quality Surveillance Model (PQSM) was established to provide consistent and methodical oversight of maternity services. This acts as a mechanism to ensure concerns are identified early, addressed and escalated where appropriate. The details of the model are publicly available and published online. The guidance was published in 2020.[10] Engagement with the PQSM is stated as an expectation of Trusts in NHS England's Three Year Delivery Plan[11].
- NHS England are implementing a data coordination group that will bring together mechanisms for improved access to and use of data, including patient reported experience measures. As part of this NHS England's Maternity and Neonatal Outcomes Group, established in 2023, is leading a programme of work to further improve the use of data in maternity services in response to a recommendation from Dr Bill Kirkup's report into maternity and neonatal services in East Kent. The group is developing an early warning surveillance tool using more timely outcome data to identify potential issues at an early stage, to enable Trusts, including Trust Boards, to identify and crucially take action in relation to services which require support. It is intended that the tool will be
  operational by the end of 2024.
- Work is underway to deliver more frequent and timely data around births in order to better track progress and trends in outcomes. The Office for National Statistics is planning to move to publishing quarterly provisional births data.

Progress following the consultation on coronial investigations of stillbirths in 2019

In December 2023, DHSC and the Ministry of Justice published a factual summary of responses to the 2019 consultation regarding proposals to introduce coronial investigations of term stillbirths. DHSC is working closely with the Ministry of Justice to give full consideration to next steps in this area and how the Government will respond.

9 Reports | PMRT | NPEU (ox.ac.uk)

10 NHS England » Implementing a revised perinatal quality surveillance model

11

The landscape of maternity investigations has changed significantly since the consultation; as outlined above, the Maternity and Newborn Safety Investigations programme is now in place, and the Perinatal Mortality Review Tool supports standardised perinatal mortality reviews across NHS maternity and neonatal units in the UK. Additionally, DHSC officials are working to improve the information available to families regarding these investigative processes that may be taken forward following a stillbirth.

Has there been specific and adequate funding to enable the recommendation to be implemented?

Yes, the Medical Examiner system is centrally funded in England and Wales and this will continue to be the way the statutory Medical Examiners system will be funded. Costs are detailed in a combined impact assessment for the Health and Care Act 2022.[12]

Has there been a positive impact on patients and people in receipt of social care as a result of the recommendation being implemented?

The Medical examiners system gives bereaved people an opportunity to ask questions and raise concerns about care. It will also allow trends in deaths to be observed. Feedback from bereaved people has been overwhelmingly positive. Further information is available in the Medical Examiner National reports.[13] Additional information on scrutiny of maternal and perinatal deaths is available in published reports from MBRRACE and MNSI.[14][15][16]

Was the Government's interpretation and implementation of the recommendation appropriate?

Yes, once the new statutory Medical Examiner process comes into force, all deaths in England and Wales will be independently reviewed, without exception, either by a medical examiner or a coroner.

In addition to the recommendation, the mechanisms for scrutiny of stillbirths described above provide the tools for independent review and surveillance.

Recommendation 2

"A common code of ethics, standards and conduct for senior board-level healthcare leaders and managers should be produced and steps taken to oblige all such staff to comply with the code and their employers to enforce it."[17]

Has the recommendation been implemented? Or (in the case of a recommendation whose deadline has not yet been reached) Is the recommendation on track to be implemented?

The recommendation has been implemented.

A range of reviews and initiatives around NHS Leadership have been introduced since publication of the Mid-Staffs NHS Foundation Trust Public Inquiry recommendations. This

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12 Health and Care Act 2022: combined impact assessments - GOV.UK (www.gov.uk)
13 National Medical Examiner's report 2022 (england.nhs.uk)
14 Reports | MBRRACE-UK | NPEU (ox.ac.uk)
15 Reports | PMRT | NPEU (ox.ac.uk).
16 Home (mnsi.org.uk)
17 From The Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, page 108

included a Secretary of State commission in 2013 to the Professional Standards Authority to produce a series of standards for senior board-level leaders and managers.[18]

In February 2023, NHS England published a new code of governance[19] for NHS provider organisations (updating the previous code published in 2014). This sets out a common overarching framework for the corporate governance of Trusts, reflecting developments in UK corporate governance and the development of integrated care systems. It is designed to help NHS providers deliver effective corporate governance, contribute to better organisational and system performance and ultimately discharge their duties in the best interests of patients, service users and the public.

In 2018, the Government commissioned Tom Kark KC to review the scope, operation and purpose of the Fit and Proper Persons Test as it applied under Regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The Kark review[20] was a rapid review. It was published in February 2019 and made seven recommendations on how to improve the operation and effectiveness of Regulation 5.

In response, NHS England in August 2023 published a Fit and Proper Person Test Framework for board members[21]. This introduces a standardised reference system and a means of retaining information regarding background checks for individual directors which will help prevent directors who have been involved in or enabled serious misconduct or mismanagement from joining a new NHS organisation. The new Framework came into effect on 30 September 2023 and all boards are now expected to have started work on implementing the new Framework. By 31 March 2024, organisations will need to have fully implemented the Framework. The Framework is accompanied by resources to support current and aspiring board members within the NHS to further develop their skills and careers, including information on development programmes and peer support networks to develop and share good practice.

Following recommendation in the Kark Fit and Proper Persons Review, NHS England is developing a Board Leadership Competency Framework, anticipated for launch in February 2024. The framework builds on Our Leadership Way and the People Promise and will set out six competency domains with actions and behaviours expected of NHS board members. The framework has undergone extensive stakeholder engagement and will underpin board appraisal processes, which are currently under development.

Beyond the steps already taken by NHS England, the Government is currently exploring whether further mechanisms are needed to hold NHS managers accountable. This will be considered alongside the actions recommended by General Sir Gordon Messenger's review of leadership published in June 2022.[22]

Has there been specific and adequate funding to enable the recommendation to be implemented?

Yes. NHS England invests nationally in initiatives to support board effectiveness. Local Trusts make their own decisions on board level investment.

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18 Standards for NHS boards and CCG governing bodies in England | PSA (professionalstandards.org.uk)

19 NHS England » Code of governance for NHS provider trusts

20 Kark review of the fit and proper persons test - GOV.UK (www.gov.uk)

21 NHS England » NHS England fit and proper person test framework for board members

22 Health and social care review: leadership for a collaborative and inclusive future - GOV.UK

(www.gov.uk)

Has there been a positive impact on patients and people in receipt of social care as a result of the recommendation being implemented?

This is difficult to quantify, but there is good evidence that strong and effective leadership equates to good patient care and outcomes. As Michael West has set out in his research "from frontline leadership in wards, primary care and community mental health teams to board leadership in trusts to national leadership in overseeing bodies – is influential in determining organisational performance" (West et al, 2015). However, seeing the longer- term impact on patients and staff, their experiences and outcomes, will take time and is factored into ongoing evaluation of the work.

Was the Government's interpretation and implementation of the recommendation appropriate?

The Government's interpretation and implementation of the recommendation was appropriate, but work continues to further strengthen leadership across the NHS. The section below touches on some of these issues.

Section 2: Training of staff in health and social care

Recommendation 1

"Targeted interventions on collaborative leadership and organisational values. [including] A new national entry-level induction for all who join health and social care."[23]

Has the recommendation been implemented? Or (in the case of a recommendation whose deadline has not yet been reached) Is the recommendation on track to be implemented?

The recommendation is in the process of being implemented.

The former Secretary of State, Sajid Javid commissioned Sir General Gordon Messenger to review leadership across the NHS and social care. The Messenger Review was published in June 2022. It identified an 'institutional inadequacy' in the way that leaders and management are trained, developed and valued across the NHS and social care. The review set out the need for a more standardised and systematic approach to training and talent management. The review also stressed the importance of reinforcing the right culture, values and behaviours from first taking on managerial responsibility, advocated a step change in diversity and inclusion, the need to address geographical variations in the quality of leadership, and sough to professionalise leadership and management so it was on an equal footing to clinical roles and careers.

The review set out 7 recommendations, all of which were accepted by the Government with implementation being taken forward by NHS England and Skills for Care. The first recommendation is focused on 'Targeted interventions on collaborative leadership and organisational values'. There are two parts to this. The first is the need for national entry level induction for all who join the NHS and social care. The second is a national mid-career programme for managers across the NHS and social care.

NHS England and Skills for Care aim to launch a new induction framework for all those joining the NHS and social care in Spring 2024. The aim of this programme is to introduce new starters to the culture and values that are expected within services and to foster a sense of belonging wider than the immediate organisation. The scope of this recommendation is broad to capture the breadth of those who enter a role in the NHS and social care. In the NHS, around 196,000 (latest data required) staff joined or took up new roles between September 2020 and September 2021 with social care seeing approximately 490,00 staff joining or taking up new roles in the financial year 2020-21.

The content of this programme is being co-created by partners across health and social care, including NHS England, DHSC, Skills for Care, local government, staff networks and patient representatives. The framework will include a number of elements, namely : materials which introduce the sectors, made available before commencing employment if staff are new to the sectors and wish to learn more but with no expectation that activity will be undertaken prior to commencement; a structured pathway that can then support individuals through their first 3-6 months of employment; manager resources to enable then to induct well and complement their arrangements for local induction; a set of resources to enable a collaboration activity at place level in systems; a resource library. The framework will be nationally set but collateral will be customisable allowing for local variation so that organisations can align with any arrangements already in place to support induction. There is scope to build on the Care Certificate standards (a Francis recommendation) which

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23 From Leadership for a collaborative and inclusive future

already sets out the introductory knowledge and skills that are important for those in non- regulated roles.

At the end of the defined induction period, the new induction introduces a review point which in time will align to messenger recommendation 4 on the new appraisal framework for all staff.

The NHS Patient Safety Syllabus training[24] is building knowledge, capability, and capacity in 'systems-thinking' and patient safety science through the creation of the first system-wide standardised approach to training and education in patient safety across the NHS.

Level 1 and Level 2 are available for all staff via the E-learning for Health platform, including a module for Boards and Senior Leaders.

The strategy's ambition is for all NHS staff to undertake Patient Safety Syllabus Level 1 (essentials) training. Level 2 (access to practice) is designed for those who have an interest in understanding more about patient safety and/or want to access the higher levels of training.

An independent organisation, RSM UK Consulting LLP, were commissioned to undertake an evaluation of Level 1 and 2 with positive feedback. The evaluation led to changes to improve functionality and accessibility and introduced certificates of completion. Sector specific sessions covering acute care, maternity, primary care, mental health, and management
and administration were also added in April 2023.

Earlier this year, a robust procurement process was undertaken to appoint a provider to deliver Level 3 and 4 NHS Patient Safety Syllabus training for all the registered Patient Safety Specialists. As a result of that tender exercise, Loughborough University, have been commissioned to deliver training to 820 colleagues, primarily Patient Safety Specialists, but also including Medical Device Officers, Medicines Safety Officers, Maternity Safety Champions and Digital Safety Officers across the NHS. The contract with Loughborough University commenced during September 2023 and will run until October 2024. During this time Loughborough will deliver Level 3 and 4 Patient Safety Syllabus training to 820 Patient Safety colleagues, using a blended learning approach.

Has there been specific and adequate funding to enable the recommendation to be implemented?

Specific and adequate funding has been available for this recommendation to be implemented. Funding to develop the component product has been sufficient to develop product that can be expanded and built upon. Costs have been kept to a minimum, utilising internal expertise and partnership working in health and social care.

Has there been a positive impact on patients and people in receipt of social care as a result of the recommendation being implemented?

An evaluation plan is being developed to track usage and satisfaction with the induction framework. It is expected that it will positively impact early attrition from NHS and social care roles by providing consistent support and information for new joiners.

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24 NHS Patient Safety Syllabus training - elearning for healthcare (e-lfh.org.uk)

Was the Government's interpretation and implementation of the recommendation appropriate?

We do not anticipate any unintended consequences. Investing in leadership and management remains a priority as reflected in the recent NHS Long Term Workforce Plan which reinforced the ambitions of the Messenger review.

Section 3: Culture of safety/whistleblowing

Recommendation 1

"Culture of safety: Every organisation involved in providing NHS healthcare, should actively foster a culture of safety and learning, in which all staff feel safe to raise concerns.

Action 1.1: Boards should ensure that progress in creating and maintaining a safe learning culture is measured, monitored and published on a regular basis.

Action 1.2: System regulators should regard departure from good practice, as identified in this report, as relevant to whether an organisation is safe and well-led."[25]

Has the recommendation been implemented? Or (in the case of a recommendation whose deadline has not yet been reached) Is the recommendation on track to be implemented?

Safety and learning Action

1.1

Significant work is underway to implement this recommendation. In relation to Action 1.1, the NHS Patient Safety Strategy (2019) [26] highlighted the importance of a patient safety culture, including a just culture[27] in which no-one fears inappropriate blame, alongside the need for openness and transparency and commitment to continuous improvement. Several steps were set out in the Strategy to support improvement in safety culture alongside a range of other initiatives. Safety culture is recognised as being difficult to measure because mechanisms for Boards to measure, monitor and publish progress in creating a safe learning culture are multi-faceted. As part of its focus on patient safety culture, NHS England have worked across healthcare sectors, including primary care, to develop guidance on what works well including publishing *Safety culture: learning from best practice*[28]. NHS England subsequently developed *Improving patient safety culture: a practical guide*,[29] which has also been well received.

Staff are critical to the safety of healthcare and its culture. A positive patient safety culture and a healthy organisational culture are two sides of the same coin. NHS England have been working alongside the *NHS Long-Term Workforce Plan*[30] to define work that will support cultures in which staff are valued, supported and engaged in their work. The People Promise[31] also describes what good staff experience should look like. NHS England have also been exploring how a focus on staff safety can support patient safety and are developing the Person-centred Safety Improvement Plan. This aims to identify and enable the alignment between the NHS Patient Safety Strategy and the NHS Long-Term Workforce Plan to improve the health, wellbeing and experience of staff, patients, service users, families and carers along with improvements in safety culture and patient safety.

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25 From Freedom to speak up: an independent review into creating an open and honest reporting culture in the NHS, page 24

26 NHS England » The NHS Patient Safety Strategy

27 NHS England » A just culture guide

28 NHS England » Safety culture: learning from best practice

29 NHS England » Improving patient safety culture – a practical guide

30 NHS England » NHS Long Term Workforce Plan

31 NHS England » Our NHS People Promise

The launch of the new Patient Safety Incident Response Framework (PSIRF) and supporting guidance[32] in 2022 for provider Trusts, with gradual implementation within primary care from 2024, embodies the systems approach. PSIRF moves the system from a solely retrospective focus on 'past harm' to a more balanced approach that considers proactive risk mitigation alongside examining what has already happened. It also encourages NHS England to understand what happens in normal work. This includes a requirement for Boards to publish Patient Safety Incident Response Plans. Early adopters of PSIRF are reporting a positive impact on their safety cultures.

Staff feeling safe to speak up and for their concerns to be listened to and acted upon is an essential component of advancing patient safety and a safety culture. In 2016, the Government established an independent National Guardian with a remit focussed on driving positive cultural change across the NHS and healthcare providers, so that speaking up becomes business as usual. In addition to driving cultural change in the NHS. The National Guardian is providing support and leadership to a network of over 1,000 local Freedom to Speak Up Guardians throughout healthcare in England. The role of Guardians is to help and support staff who want to speak up about their concerns. In 2018, the Government enhanced legal protections available for whistle blowers to prohibit discrimination against job applicants on the grounds that they have spoken up in the past. This complements longstanding legal provisions within the Public Interest and Disclosure Act 1998 that protect workers against detrimental treatment for speaking up.

NHS England have published a national Freedom to Speak Up policy,[33] which provides the minimum standard for local Freedom to Speak Up policies across the NHS. NHS organisations are asked to adopt this new policy no later than 31 January 2024. Supporting guidance[34], co-produced with the National Guardian's Office (NGO), supports leaders to encourage a 'Speak Up, Listen Up, Follow Up' culture. NHS England and the NGO have also developed a self-reflection and planning tool[35] to be used by Boards in conjunction with the guidance to help senior leaders identify strengths in themselves, their leadership team and their organisation, and any gaps that need to be addressed.

Freedom to Speak Guardians are expected to present regularly in person to their board or equivalent, sharing their data and themes. They also report anonymised data about the cases they handle both locally and to the NGO, which is one of several metrics that boards or their equivalent should use to assess the effectiveness of their speaking up culture, including the culture of safety and learning. The NGO has delivered information sessions for Guardians on the effective use of data and anticipate publishing comprehensive standalone guidance in this area in 2024/25. At a national level, data can also be derived from the annual NHS Staff Survey to measure workers' perceptions of speaking up culture.

Other important NGO work to improve speaking up in the NHS includes:

- Speak Up reviews[36] to identify potential barriers to speaking up. In 2022/23, the NGO carried out a Speak Up review of NHS ambulance services in England,[37] prompted by consistent findings that ambulance Trust workers reported considerably low feelings of safety and confidence in speaking up. The NGO's report explored

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32 NHS England » Patient Safety Incident Response Framework and supporting guidance

33 NHS England » The national speak up policy

34 B1245_ii_NHS-FTSU-Guide-eBook.pdf (nationalguardian.org.uk)

35 B1245_iii_Freedom-To-Speak-Up-A-reflection-and-planning-tool_060422.docx-RC_RW_Final_Arial12.docx (live.com)

[36] Speak Up Reviews - National Guardian's Office

[37] Listening-to-Workers-Speak-Up-Review-of-Ambulance-Trusts.pdf (nationalguardian.org.uk)

possible reasons for this disparity and recommended remedial actions for CQC, NHS England, and others.

- Work with CQC to develop the dedicated Freedom to Speak Up quality statement,[38] which is an integral component of CQC's revised single assessment framework.

Action 1.2

CQC's previous assessment framework used five Key Questions when making judgements about providers: are services safe, effective, caring, responsive and well-led? In that assessment framework system CQC rated services separately for each of these key questions. As its inspection programme has progressed over the last eight years, the CQC has recognised the importance of leadership, culture and governance in the delivery of consistently high-quality services. The well-led Key Question has consequently become central to its assessment of NHS services.

The five Key Questions will remain in the CQC's new single assessment framework. However, CQC is developing clear Quality Statements (based on what people should expected from services) and evidence requirements (based on the standards to expect) for each key question. Furthermore, in line with CQC's strategy, it will strengthen its focus in key areas: safety culture, reflecting and responding to people's experiences and expectations, addressing health inequalities, accelerating improvement and partnership working in health and social care services.

Has there been specific and adequate funding to enable the recommendation to be implemented?

The NGO is staffed by 16 people with an annual budget of £1.58m in 2023/24. The number of Freedom to Speak Up Guardians that the NGO leads, trains and supports has increased from approximately 700 to over 1,000 and the number continues to grow.

Has there been a positive impact on patients and people in receipt of social care as a result of the recommendation being implemented?

There are some positive signs of progress but there is more work to be done to make this recommendation a reality across the NHS. Freedom to Speak Up Guardians have handled over 100,000 cases since the NGO first started collecting data in 2017. This represents over 100,000 opportunities for learning and improvement. Guardians ask workers whether, in light of their experience, they would speak up again and in 2022/23, 82.8% of workers who responded answered 'Yes'. In comments provided alongside data submissions, Freedom to Speak Up Guardians also told the NGO about work that is being done to address worker safety concerns that have been raised through Speaking Up, for example, the application of zero-tolerance to violence policies.

More generally, there is interest in the NGO's training and support for Freedom to Speak Up Guardians across other sectors including the Metropolitan Police, Fire and Rescue services and Crown Dependencies.

38 Freedom to speak up - Care Quality Commission (cqc.org.uk)

Was the Government's interpretation and implementation of the recommendation appropriate?

The interpretation and implementation of the recommendation was appropriate, but work continues to further ensure the NHS embraces a culture of safety and learning, in which all staff feel safe to raise concerns.

Recommendation 2

"Primary Care: All principles in this report should apply with necessary adaptations in primary care.

Action 19.1: NHS England should include in its contractual terms for general/primary medical services standards for empowering and protecting staff to enable them to raise concerns freely, consistent with these Principles.

Action 19.2: NHS England and all commissioned primary care services should ensure that each has a policy and procedures consistent with these Principles which identify appropriate external points of referral which are easily accessible for all primary care staff for support and to register a concern, in accordance with this report.

Action 19.3: In regulating registered primary care services CQC should have regard to these Principles and the extent to which services comply with them."[39]

Has the recommendation been implemented? Or (in the case of a recommendation whose deadline has not yet been reached) Is the recommendation on track to be implemented?

Action 19.1

The importance of primary care staff being able to raise concerns so they can be addressed is clear, and contractual terms for primary medical services include protections for staff wishing to raise concerns, as recommended in Action 19.1 of the Freedom to Speak Up Review. GPs on all contract types have been protected by the Public Interest Disclosure Act (PIDA) 1998 since 2013. The General Medical Council (GMC) are one of the prescribed workers under the Prescribed Persons Order 2014 who can be approached by a GP wishing to speak up.

The National Health Service (General Medical Services Contracts) Regulations 2015 includes provision at Regulation 79 which states the processes that a GP providing primary medical services must have in place in relation to complaints. The regulations state that the contractor must establish and operate a complaints procedure to deal with complaints made in relation to any matter that is reasonably connected with the provision of services under the contract. The complaints procedure must comply with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009. These regulations go onto explicitly state the meaning of cooperation with an investigation to leave no room for doubt.

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 specify Terms of Service that all pharmacy contractors providing NHS services must comply with. The clinical governance provisions within the Terms of Service

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39 From Freedom to speak up: an independent review into creating an open and honest reporting culture in the NHS, page 28

specifically mandate community pharmacy contractors to establish arrangements, including having a written policy in place, to ensure that all staff, including locums, can make a 'protected disclosure' within the meaning given in section 43A of the Employment Rights Act 1996 and have the rights afforded in respect of such disclosures by that Act.

The General Pharmaceutical Council (GPC) regulates all pharmacies and registered pharmacy professionals in Great Britain, sets standards for pharmacy professionals and monitors compliance. Standard 8 mandates pharmacy professionals to speak up when they have concerns or when things go wrong. GPC guidance explains how to raise concerns and what respective responsibilities both professionals and employers have and where to seek further advice.

Action 19.2

The Review also recommends that primary care services have policies and procedures in place in addition to these contractual terms that provide staff with clear routes to raise concerns. The Freedom to Speak Up guide and improvement tool[40] and the updated national Freedom to Speak Up policy[41] referred to in the previous section also apply to primary care. The Learn From Patient Safety Events (LFPSE) Online Service[42] has been available to all of Primary Care since July 2021, and supports staff, both clinical and otherwise, to record patient safety incidents or concerns through a webform. NHS England use all data inputted to LFPSE (whether from primary care, acute providers etc) to monitor for new and under- recognised risks and undertake learning and improvement activities.

In addition, further work has been done to support staff within the specific primary care context. In 2019, the NGO began a two-year project working with primary care providers to understand how the Freedom to Speak Up Guardian role could be introduced in primary care and integrated settings. The NGO's 2021 report, *Exploring Freedom to Speak Up: Supporting the introduction of the Freedom to Speak Up Guardian role in Primary Care and Integrated Settings*[43] illustrated the challenges and benefits of implementing Freedom to Speak Up in different primary care settings whilst showing that the universal nature of the promoters and barriers to speaking up requires universal principles[44] to provide a consistent approach.

In July 2022, the NHS introduced 42 Integrated Care Systems in England, and in June 2023 NHS England and the NGO published guidance[45] to ensure there are speaking up routes available for all workers in NHS healthcare providers across the Integrated Care System. By the end of January 2024, Integrated Care Boards must also ensure their own staff have access to routes for speaking up, including Freedom to Speak Up Guardian(s), and associated arrangements. The NGO is starting a dialogue with Integrated Care Board Guardians via a roundtable to determine their support requirements and whether an Integrated Care Board network would be of value. NHS England are also developing a new Primary care-specific Patient Safety Strategy.

Action 19.3

This recommends that CQC have regard to these principles when regulating primary care services. As referred to in the response to Recommendation 1, the NGO have worked with

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40 NHS England » The guide for the NHS on freedom to speak up
41 NHS England » The national speak up policy
42 NHS England » Learn from patient safety events (LFPSE) service
43 Exploring-Freedom-to-Speak-Up-Primary-Care-Integrated-Settings.pdf (nationalguardian.org.uk)

[44] Principles for Responding to Speaking Up - National Guardian's Office

[45] Guidance for Integrated Care Boards - National Guardian's Office

CQC to develop the dedicated Freedom to Speak Up quality statement, part of CQC's revised single assessment framework.

Has there been specific and adequate funding to enable the recommendation to be implemented?

Primary care structures have changed with the introduction of Integrated Care Boards and the disbanding of Clinical Commissioning Groups. While there was an initial allocation of funding for the NGO to explore the roll out of Freedom to Speak Up in primary care, there has not been any additional funding to support the roll out and to address the particular challenges in this area around speaking up routes and access to Guardians.

Has there been a positive impact on patients and people in receipt of social care as a result of the recommendation being implemented?

As of December 2023, there are 135 trained and registered primary care Guardians on the NGO's directory. These Guardians support over 400 primary care services (ranging from individual GP practices to Primary Care Networks).

Most Freedom to Speak Up cases reported to the NGO are from NHS Trusts. In 2022/23 less than one per cent (0.7%, or 166) of the 25,382 cases reported to the NGO were from Primary Care although 10% of Freedom to Speak Up Guardians registered on the NGO directory supported Primary Care services. Despite national guidance, these organisations are less likely to submit data. The NGO is aiming to improve data reporting compliance across all sectors, including primary care, during 2023/24.

Was the Government's interpretation and implementation of the recommendation appropriate?

The interpretation and implementation of the recommendation was appropriate, but work continues to deliver Freedom to Speak Up within primary care services.

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