Witness Name: William Vineall
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INFECTED BLOOD INQUIRY

ELEVENTH WRITTEN STATEMENT OF WILLIAM VINEALL

I provide this statement on behalf of the Department of Health and Social Care in response to a request under Rule 9 of the Inquiry Rules 2006, dated 31 July 2023.

I, William Vineall, will say as follows: -

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Section 0: Introduction

0.1. My name is William Vineall. My professional address is 39 Victoria Street, Westminster, London SW1H 0EU and my date of birth is known to the Inquiry.

0.2. I am Director of NHS Quality, Safety and Investigations at the Department of Health and Social Care ("the Department"), and have held this post since 2016. This is my eleventh statement to the Inquiry, and I refer back to my previous statements for further information about my role, responsibilities and employment history. I gave oral evidence to the Inquiry on 21 May 2021.

0.3. I have been asked to provide the Department's perspective on various proposals for patient safety initiatives from different witnesses that have given evidence to the Inquiry. I have responsibility for DHSC's patient safety policies. I am not responsible for the NHS Patient Safety Strategy (see paragraph 2.4 below), its implementation or day to day interactions with the NHS on patient safety. These are the responsibility of NHS England. This division of labour reflects the distinction between the policy oversight of DHSC and the day to day operational responsibility of NHS England for the NHS. I do not have responsibility for medicines or medicines safety policy. I am duly authorised to make this statement on behalf of the Department. The contents of this statement are true to the best of my knowledge, information and belief.

Section 1: Background information

1.1. In this section I have aimed to set out why patient safety systems are necessary as well as some of the complex reasons why patient safety incidents occur.

1.2. Harm caused during the provision of healthcare can be devastating for patients and their families, and have long lasting consequences. Previous systematic studies and available data have estimated that each year in England there are about 11,000 adult deaths thought to be due to problems in care[1], and 33,000 patient safety-related disabilities[2]; and between 19,800 and 32,200 cases of significant harm in primary care[3].

1.3. The reasons for patient safety incidents are normally complex. They relate to a complex interplay of multiple factors such as the nature of tasks, equipment and consumables, the work and wider organisational environments, and the individuals working in those environments.

1.4. Examples of unsafe care practices and errors that contribute to patient harm include, but are not limited to, medication, diagnostic and communication errors, healthcare associated infections, problems with surgical procedures and the avoidable deterioration of patients.

1.5. Specific challenges to patient safety vary and include, but are not limited to, staffing, poor leadership, problems with IT systems, workload and demand, skills and capabilities, poor communication and lack of teamwork.

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[1] NHSE: The NHS Patient Safety Strategy (2019), building on Hogan et al Avoidability of Hospital Deaths and association with hospital wide mortality ratios: retrospective case record review and regression analysis (2015).

[2] NHSE: The NHS Patient Safety Strategy (2019), building on Hogan et al Avoidability of Hospital Deaths and association with hospital wide mortality ratios: retrospective case record review and regression analysis (2015).

[3] Avery et al, Incidence, nature and causes of avoidable significant harm in primary care England: retrospective case review (September 2020).

1.6. Key approaches that may contribute to reduce harm and improve safety include team working between staff (coupled with optimal working conditions and safety training), good communication, engaging leadership, openness and transparency, listening to and engaging patients, reviewing data to measure safety and ensuring adequate resources.

1.7. Various studies suggest that a significant proportion of medical errors can be prevented through comprehensive, systematic approaches to patient safety.

Section 2: Advancing patient safety

2.1. Given the questions asked by the Inquiry it may be useful to set out how the current patient safety system has evolved. Until around 1997, there was, in broad terms, less statutory oversight of quality and safety by Government bodies. Various high-profile cases of care failures (e.g. Bristol Royal Infirmary, 1998) then led to the Government of that day taking a more active approach from the late 1990s with the establishment of the National Institute for Health and Clinical Excellence ("NICE") in 1999 and the Commission of Healthcare Improvement (a predecessor form of the Care Quality Commission ("CQC")) in 2001.

2.2. The Shipman Public Inquiry in 2003 brought further focus on the oversight of medical activity. Independent medical scrutiny of deaths was recommended in the Inquiry's Third Report of 2003, and the HMG response in 2007 proposed to introduce medical examiners. A White Paper called "Good Doctors, Safer Patients" followed, as well as an equivalent for non-medical staff. This was followed by primary legislation in 2008 to reform the oversight of the professional regulators, change the standard of proof for fitness to practice investigations and other wide-ranging reforms. The serious failings at Mid Staffordshire NHS Foundation Trust from 2005 to 2009 led to a sharp focus on reinforcing the whole regulatory regime which had not detected and responded to early warning signs at the hospital[4]. The Government's response to the 2013 Francis Public Inquiry report on Mid Staffordshire led to an enhanced regulatory system for quality and safety in the NHS through to the present day.

2.3. Measures that the Department of Health and/or NHS England have taken over the last decade to create higher patient safety standards and to foster a transparent safety culture across the NHS include:

[4] See the first (non-statutory) inquiry chaired by Sir Robert Francis KC ('Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust January 2005 – March 2009') that reported in February 2010.

a) A more intelligence-driven model of CQC regulation informed by ongoing monitoring of the safety and quality of care (introduced 2013/14);

b) A statutory duty of candour which is enforced by the CQC to ensure that providers of NHS services tell patients if their safety has been compromised and apologise (since 2014). Professional regulators, such as the General Medical Council and the Nursing and Midwifery Council, also made the duty of candour a professional requirement for their registered members (since 2014);

c) From 2016, enhancing legal protections for whistle-blowers when they raise safety concerns, alongside Freedom to Speak Up Guardians in every Trust supported by a National Guardian to lead positive culture change in the NHS and make speaking up the norm;

d) Implementing substantial programmes within the first NHS Patient Safety Strategy (2019) led by NHS England to achieve continuous improvement in safety (see paragraph 2.4 below for further details);

e) Establishing the first Patient Safety Commissioner in 2022 to champion patient voice in relation to the safety of medicines and medical devices;

f) Establishing the Health Services Safety Investigations Body ("HSSIB") from October 2023 as a new arm's length body to conduct independent, expert-led national safety investigations, continuing the work of the current Healthcare Safety Investigation Branch ("HSIB") established in 2017. HSIB's maternity investigation programme, into each incident of early neonatal deaths and potential severe brain injury, as well as maternal deaths, will be hosted by the Care Quality Commission from autumn 2023; and

g) Beginning to implement medical examiners on a non-statutory basis from 2019 to provide independent scrutiny of the causes of all non-coronial deaths and engage with the bereaved about any of their concerns (the Government plans to place medical examiners and the Medical Certificate of Cause of Death on a statutory footing from April 2024).

2.4. The NHS Patient Safety Strategy, led by NHS England, is the first whole-NHS strategy designed to support the entire NHS system to achieve continuous improvement in safety and the reduction of patient harm by embracing an ethic of learning. Now in its fifth year of operation, the Strategy continues to change the way safety is approached in the NHS. Major delivery programmes include:

a) The new Learn from Patient Safety Events ("LFPSE") service to replace the National Reporting and Learning System ("NRLS"). LFPSE will improve the recording and analysis of patient safety event information to speed up identification of risks;

b) National Patient Safety Alerts issued by accredited national bodies that set out clear and effective actions to support providers to tackle safety critical issues and where failure to comply may lead to regulatory action by the CQC;

c) The Patient Safety Incident Response Framework ("PSIRF") to deliver a new approach for responding to patient safety incidents, anchored in the principles of openness, fair accountability, learning and continuous improvement;

d) The Framework for involving patients in patient safety, which required all NHS organisations to appoint 'Patient Safety Partners' on their safety-related clinical governance committees or equivalents from April 2021;

e) 'Patient Safety Specialists' in all NHS organisations to oversee safety activities; and

f) A first-ever Patient Safety Syllabus to support education and training for all health and care workers.

Section 3: Patient safety incident reporting

3.1. This section aims to set out a general overview of the current framework for patient safety incident reporting. However, I should make it clear that the detailed expertise relating to the operation of this framework, the analysis and learning generated by it, and the current initiatives for ongoing change and further development, lies with NHS England and its National Patient Safety Team.

3.2. One of the drivers of the increased focus on patient safety reporting was lessons learned from the aviation industry. For example, in the US, the Aviation Safety Reporting System is central to the safety record of the airline industry and the benefits to safety in this context are well described and its successes were admired and thought to have useful application in healthcare. The Institute of Medicine which is the American, national, non-governmental, advisory scientific body for medicine (now the National Academy of Medicine) recommended adopting patient safety reporting as an approach to gain understanding on patient safety risks in hospitals through collecting safety reports and solutions.

3.3. Patient safety reporting began to exist internationally throughout healthcare such as the Advanced Incident Management System run by the Australian Patient Safety Foundation in South Australia and the Danish Patient Safety Database. In the UK (England), the National Patient Safety Agency established the NRLS in 2003.

3.4. The National Reporting and Learning Service has been the largest single source of patient safety incident data in England, and one of the largest such databases in the world. It was introduced to collect patient safety incident reports from frontline NHS staff and has seen year on year increases in reporting with over 2 million incidents now reported annually.

3.5. Acute hospitals, mental health services, community trusts, ambulance services and primary care organisations have reported incidents to the NRLS where any patient could have been harmed or has suffered any level of harm. The level of harm experienced by the patient has been recorded, ranging from "no" or "low" harm, through to "moderate" or "severe" harm, or "death". It is mandatory for providers to report patient safety incidents to CQC which result in "severe harm" or "death" under the Care Quality Commission (Registration) Regulations 2009 (providers may fulfil this obligation by reporting their data to NRLS which CQC can access); see further below at Section 4. Other reporting is voluntary.

3.6. The vast majority of reported incidents are "no harm" (70%) or "low harm" (27%) events, but all represent opportunities to advance safety. 3% of events cause higher degrees of harm (including 0.3% resulting in severe harm and 0.3% in death).

3.7. The largely voluntary nature of reporting of the NRLS has been to encourage openness and continual increases in reporting to facilitate learning from error. Examples of the types of incidents voluntarily reported to the NRLS include instances of a patient slipping or falling while in a care setting, a patient developing a pressure ulcer, or an incorrect medication dosage being given to a patient.

3.8. The vast majority of NRLS data comes as a secondary use of what is already reported within providers' Local Risk Management Systems ("LRMS") and used within hospitals to manage and respond to safety and other issues. The value of data collection nationally has been the ability to undertake surveillance for new, emerging or under-recognised risks which might appear unique at a local level, but nationally can reveal important patterns.

3.9. A parallel system to NRLS, the Strategic Executive Information System ("StEIS"), has been operating as the main reporting mechanism under NHS England's Serious Incident Framework ("SIF") of 2015 [WITN4688084]. SIF governs how safety incidents are investigated. It should be clear from the SIF [WITN4688084] that there is a clear obligation to report and to investigate serious incidents, including ones that lead to unexpected or avoidable death, or unexpected or unavoidable injury resulting in serious harm. The successor to the SIF is the Patient Safety Incident Response Framework or PSIRF.

3.10. In summary NRLS and StEIS will be replaced by LFPSE when it is rolled out to all providers in autumn 2023. The current Serious Incident Framework or SIF will be replaced by the PSIRF in autumn 2023.

3.11. The PSIRF is being implemented across the NHS to provide updated guidance on how providers should respond to patient safety incidents and how and when an investigation should be conducted. PSIRF promotes a proportionate approach for responding to patient safety incidents by removing the requirement of the SIF for repeated investigations of similar incidents that yielded limited new learning. Compassionate engagement of those affected by patient safety incidents (patients, families and staff) is a core element of the PSIRF.

3.12. NRLS data about incidents causing severe harm and death (approximately 10,000 a year) has to date been reviewed manually by a small group of clinicians to characterise new, emerging or under-recognised risks, and determine how they might be addressed. This has resulted in various actions, of which the most-high profile is a National Patient Safety Alert which instructs providers to take specific action by a set date to reduce risks (5-10 alerts are issued each year, and non-compliance can lead to enforcement action by CQC). For every alert, 20 other issues are managed through specialist networks, professional associations and industry partners. Data is also routinely shared with national organisations with responsibility for patient safety

(e.g. CQC, MHRA and HSIB) who use it alongside other data to fulfil their statutory functions. Data is also shared with others (e.g. Royal Colleges to support speciality-specific learning with universities and research institutions) and via ad-hoc requests.

3.13. The aim of LFPSE is to provide a better centralised system to record information about patient safety events and across all settings. LFPSE will significantly enhance the NHS's capabilities for processing and analysing records of patient safety events, building upon manual evaluation. LFPSE will allow:

a) NHS organisations and staff to record details of patient safety events, and access their data to better understand local recording practices and culture, supporting local safety improvement work; and

b) NHS England to scan more effectively and efficiently for new and under-recognised risks, and to contribute insights to national learning initiatives.

3.14. LFPSE aims to make it easier for staff to report incidents and will use new technologies, such as AI/machine learning, to provide more detailed analyses to support improvements.

Section 4: The Inquiry's questions

4.1. Having laid out the current patient safety landscape and referred to the new LFPSE which comes online in autumn 2023, I now turn to the specific questions raised by the Inquiry.

4.2. I have been referred to the evidence of Mr Andrew Bragg, who proposes that there should be a statutory responsibility for all employees in the NHS to make a report when serious injury or death has occurred which might have been preventable. He also proposes that there should be a new, single organisation with responsibility to collect such information, to investigate incidents and to make sure that effective action has been taken.

4.3. With regards to the first part of this proposal, a statutory responsibility for all NHS employees to make a report, in substance, this already exists. In particular, under Regulation 16 of the Care Quality Commission (Registration) Regulations 2009, regulated providers must notify the CQC of deaths that cannot be attributed to the course which that individual's illness or medical condition would naturally have taken if that individual was receiving appropriate care or treatment. In addition, under Regulation 18 of the Care Quality Commission (Registration) Regulations 2009, regulated providers must notify CQC of all incidents short of death that affect the health, safety and welfare of people who use services. The definition of the incidents that must be reported is set out in Regulation 18(2) and is both detailed and wide, but it encompasses serious injury.[5] The notification requirements are not limited to injuries or death that might have been preventable. All providers must send their notifications directly to CQC unless the provider is (relevantly) a health service body, local authority or provider of primary medical services and it has previously notified NHS England (i.e., using the NRLS). CQC can prosecute for a breach of this regulation. The reason that reports are not required to be made to the CQC if

[5] It should be noted that if a death (of whatever sort) occurs when an individual is detained under the Mental Health Act 1983, regulated providers must notify the CQC under Regulation 17 of the Care Quality Commission (Registration) Regulations 2009.

notification has been made to NHS England is that data is shared routinely between NHS England and the CQC in order to avoid duplicate reports having to be made by providers. Providers within the independent sector, as well as within the NHS, may be subject to CQC regulation and thus to these obligations.

4.4. The reporting obligation under the Regulations to the CQC and also to NHS England is further underpinned by reporting requirements contained in the NHS Standard Contract. The NHS Standard Contract 2023/24 with Providers – Service Condition 33 – Patient Safety – provides as follows:

> 33.1 – *"The Provider must comply with the arrangements for notification of deaths and other incidents: to CQC, in accordance with CQC Regulations and Guidance…"*
>
> 33.4 – *"The Provider must ensure that it is able to report Patient Safety Incidents to the National Reporting and Learning System and to any system which replaces it."*

4.5. In addition, as the Inquiry will be aware, there is a statutory duty of candour placed on health service bodies under Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3). This is a duty owed to patients and their families or carers, rather than to a regulatory or similar body, so I have not outlined it further. But the Inquiry has received evidence upon it from its own experts: see for example [EXPG0000047/EXPG0000048], the 'Expert Report to the Infected Blood Inquiry: Public Health and Administration', in the Chapter on 'The duty of candour, transparency, accountability and redress when mistakes are made', pages 50-67. See also [EXPG0000128], the 'UK Infected Blood Inquiry – PHA Expert Group, Long Form Report in response to LoI Q36-Q38: Duty of Candour'. This document also discusses how the duty of candour is underpinned, for regulated healthcare staff, by the requirements of their regulators.

4.6. I note that the proposal from Mr Bragg is framed in terms of a statutory duty on employees rather than employers. The statutory obligations outlined above are imposed on health service providers (the employers) rather than directly on individual employees. Individual providers are responsible for seeing that the statutory obligations are complied with, throughout their organisation, by the actions of individual staff members. They are expected to have policies clarifying the operational requirements of the patient safety framework and Regulations, which staff must adhere to.

4.7. The Inquiry has also received evidence of how the professional duty of candour (introduced in 2014) is underpinned by the requirements of professional regulators; these duties are imposed on the individuals who are registered with each professional regulator. Further, whilst this statement does not purport to set out an account of how each regulator addresses the issue of reporting matters relating to patient safety, the ethical guidance from regulators on this topic is unlikely to be limited to the issue of the duty of candour towards patients only. See for example the GMC's Guidance on "Raising and acting on concerns about patient safety", which is focussed on patient safety concerns more broadly [WITN4688085].

4.8. The second part of Mr Bragg's proposal is that of a new single organisation, outside of the NHS, to investigate such incidents. The Department's view is that the National Patient Safety Team within NHS England is appropriately responsible for the ensuring that the learning and investigations suggested by Mr Bragg take place. In particular, the aim of the LFPSE is to streamline the NHS reporting system that is already in place to make it work better and more effectively.

4.9. I have also been asked whether the Department supports the establishment of a single body responsible for overseeing the safety systems for both health and social care. As I have made clear in this statement, there is already 'single body' oversight in the form of the CQC, and the incident reporting obligations to NHS

England have been outlined above. I note the views of Dr Rosie Benneyworth of HSIB, who has outlined some of the challenges that such a proposal would face and has stated that *"...creating a single body for safety may be over simplistic"* [WITN7689001].

4.10. Finally, I have been asked for the Department's perspective on a suggestion from HSIB that patient safety data collected by local, regional and national organisations should be aggregated to inform the identification of patient safety priorities. I have been asked which body should be responsible for identifying patient safety priorities from aggregated data about patient safety.

4.11. As set out in the account at Section 3, my understanding is that this aggregation of patient safety data does already happen, via the NRLS in particular (and soon, its replacement in the form of the LFPSE). NHS England's National Patient Safety Team is in overall charge of this extensive programme. There are mechanisms to ensure data sharing with other interested bodies such as the MHRA and the CQC.

4.12 Finally, I have been asked to comment further on paragraph 35 of Dr Rosie Benneyworth (HSIB)'s statement. This sets out the case for a "*much more structured approach to development of a health and safety management system across the health and care landscape, comparable to best practice in other industries".* The example of the airline industry is given, as well as a brief outline of a system's elements.

4.13 Focussing on the landscape of healthcare and the NHS (which I understand to be the Inquiry's focus), I have briefly set out above, in this statement, an account of the development of safety systems across the NHS in the last 20 years or so, including the use of learning from the airline safety industry (para 3.2 above). I have referred to the NHS Patient Safety Strategy (2019) led by NHS England, which aims to achieve continuous improvement in safety, and to NHS

England's recent launch of the Learn from Patient Safety Events service to replace the National Reporting and Learning System, as well as the Patient Safety Incident Response Framework (see paragraph 2.4 above).

4.14 These represent a Safety Management System. For example, the new PSIRF requires both proactive and reactive approaches to safety, and balances resources dedicated to learning from patient safety events with those assigned to improvement. There is a continuing process of exploration and development to secure improvement in safety management. But as explained at paragraph 0.3 of this statement, the further development of policy proposals in this area is led by NHS England. Finally, I note that HSIB organised roundtable discussions with relevant parties re a Safety Management System during the summer of 2023.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated.....13/10/2023.....