Witness Name: Caroline Lamb
Statement No.: WITN7458011
Exhibits: WITN7458012-WITN7458049
Dated: 26 September 2023

INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF CAROLINE LAMB

I provide this statement in response to a request under Rule 9(1) and (2) of the Inquiry Rules 2006 dated 31 July 2023.

I, Caroline Lamb, will say as follows: -

Introduction

My name is Caroline Lamb and my address is care of St. Andrew's House, Regent Road, Edinburgh, EH1 3DG. My date of birth is GRO-C 1963. I am qualified as a chartered accountant.

I originally qualified as a chartered accountant in England and later moved to Scotland, where I worked as the Director of Finance and Corporate Resources in NHS Education for Scotland (NES) from 2004 to 2014. I then became Acting Chief Executive for NES, before being appointed into the role on a permanent basis in 2015.

In December 2019, I joined the Scottish Government as Director for Digital Health and Care. During the COVID 19 pandemic, I also took on other roles including leading on the COVID-19 related intensive care unit surge requirements from March

2020, acting as Portfolio Director for Test and Protect from May 2020 and becoming Delivery Director for the Extended Seasonal Flu and COVID-19 vaccination programmes from August 2020.

Since January 2021 I have been Director General for Health and Social Care in the Scottish Government and Chief Executive of NHSScotland.

Response to Questions

1. **You will see that Mr Bragg 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, and 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. Please set out your response, from the perspective of the Scottish Government, to this proposal. Please provide any further comments regarding Mr Bragg's proposals that you wish to provide.**

    1.1. There are a range of statutory and mandated obligations on staff and NHS Boards to report serious injuries or death.

    1.2. Medical practitioners working in NHS Scotland must ensure that reportable deaths are reported to the Crown Office and Procurator Fiscal Service's Scottish Fatalities Investigation Unit. The Scottish Fatalities Investigation Unit (SFIU) is a specialist team within the Crown Office and Procurator Fiscal Service (COPFS) that is responsible for most of COPFS's death investigation work. SFIU oversees all death investigations in the delivery of Health and Social Care except where there is evidence of a crime having taken place.

    1.3. These mandatory requirements are set out in guidance produced by the COPFS[1].

[1] WITN7458012

1.4. Reportable deaths are those that are sudden, suspicious, accidental or unexplained and fall within prescribed categories.

1.5. Deaths related to adverse drug reactions must be reported under the Medicines and Healthcare Regulatory Agency (MHRA) Yellow Card Scheme[2].

1.6. The prescribed categories referred to at 1.4 above include

- deaths which may be due in whole or part to natural causes but occur where death is the result of neglect/fault, which includes any deaths which may be related to a suggestion of neglect or where there is an allegation or possibility of fault on the part of another person, body or organisation;
- any sudden, unexpected and unexplained perinatal death, where the death may be categorised as a Sudden Unexpected Death in Infancy;
- any death of a child or young person under the age of eighteen years who is looked after by a local authority
- deaths from notifiable industrial/infectious diseases.

1.7. Reportable deaths include any death under medical or dental care, the circumstances of which are the subject of concern to, or complaint by, the nearest relatives of the deceased person about the medical treatment given to the deceased with a suggestion that the medical treatment may have contributed to the death of the patient.

1.8. Full details of the deaths reportable to COPFS are outlined at Annex A of my statement.

1.9. Deaths and injuries due to a work-related accident must be reported to the Health and Safety Executive as set out in the Reporting of Injuries,

[2] WITN7458013

Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)[3].

1.10. Events involving health, social care, estates and facilities equipment must be reported to the Incident Reporting and Investigation Centre (IRIC) within Health Facilities Scotland[4].

1.11. Events relating to blood must be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) through their Serious Adverse Blood Reactions and Events system, as required by the Blood Safety and Quality Regulations 2005[5] which implemented the EU Blood Safety Directive[6] across the UK.

1.12. Adverse events involving ionising radiation must be reported to Healthcare Improvement Scotland[7]. This can be done through a single national online portal.

1.13. Scotland has a National Hub for Reviewing and Learning from the Deaths of Children and Young People[8]. The National Hub aims to ensure that the death of every child in Scotland is subject to a quality review by developing a methodology and documentation to ensure all deaths of children and young people, that are not subject to any other review, are reviewed through a high quality and consistent process. It also seeks to improve the quality and consistency of existing reviews, improving the experiences and engagement with families and carers, and to channel learning from current review processes across Scotland that could direct action to help reduce preventable deaths. There is a single online national reporting portal and associated guidance. Annual Reports on the work of the National Hub are published[9].

[3] The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (legislation.gov.uk)
[4] WITN7458014
[5] The Blood Safety and Quality Regulations 2005 (legislation.gov.uk)
[6] WITN7458015
[7] WITN7458016
[8] WITN7458017
[9] WITN7458018

1.14. In November 2015 the Lord Advocate directed that the medical profession working in Scotland should be made aware that the Crown Office and Procurator Fiscal's guidance on reportable deaths was expanded to include a new section in relation to those who die while subject to compulsory treatment under the mental health legislation[10]. The new requirement was for mandatory reporting of d*eaths while subject to compulsory treatment under mental health legislation, that is of any death of a person who was, at the time of death detained or liable to be detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 or Part VI of the Criminal Procedure (Scotland) Act 1995; or subject to a community based compulsory treatment order or compulsion order under the above provisions.*

1.15. Health professionals regulated by professional regulators such as the General Medical Council, General Dental Council, Nursing and Midwifery Council, Health and Care Professions Council, General Optical Council or General Pharmaceutical Council must engage with adverse event recognition and reporting systems. All professional codes of conduct for such regulated health professionals set out specific professional duties relating to the professional conduct requirements for reporting adverse events and incidents relating to patient safety.

1.16. Section 37 of the Mental Health (Scotland) Act 2015 set out a requirement for Scottish Ministers to undertake a Review of the arrangements for investigating deaths of people who were in hospital for the assessment and treatment of a mental health condition or learning disability. The remit of this Review was subsequently extended to also examine the processes for investigating the deaths of people being compulsorily treated in the community. The Review's aim was to establish whether the current arrangements for investigating the deaths of people being treated for a mental health condition or learning disability are

[10] WITN7458019

adequate, and how well local organisations support and engage with the families and carers of people who have died.

1.17. The report of the Review was completed and submitted to the Scottish Parliament in December 2018[11]. Its main finding was that the deaths of people being treated for a mental health condition or learning disability were not being investigated consistently in a way that can be guaranteed to be independent.

1.18. The Review found that not all deaths are investigated, especially in cases where the deaths have not been recorded as 'unavoidable' or 'unexpected', despite the fact that the people who died may have spent long periods of time subject to orders under the *Mental Health (Care and Treatment) (Scotland) Act 2003 or Part VI of the Criminal Procedure (Scotland) Act 1995.*

1.19. The Review also found that there is wide variation in the time taken to carry out investigations – from a few weeks to as much as two years – and that families and carers are often excluded from the process.

1.20. The Review recommended that every death where the person was subject to an order under mental health legislation should be subject to a proportionate level of review. The investigation process should be timely, should have a sufficient element of public scrutiny, and should involve families, staff and carers.

1.21. The Scottish Government asked the Mental Welfare Commission for Scotland to develop a system for investigating all deaths of patients who, at the time of death, were subject to an order under either the Mental Health (Care and Treatment) (Scotland) Act 2003 or part VI of the Criminal Procedure (Scotland) Act 1995 (whether in hospital or in the community, including those who had their detention suspended). The Scottish Government stated that this process should take account of the

[11] WITN7458020

effectiveness of any investigation carried out by other agencies and should reflect the range of powers the Commission has to inspect medical records, carry out investigations, and hold inquiries (as set out in sections 11-12 and 16 of the 2003 Act). The Scottish Government further required that the design and testing of the new system should involve, and be informed by the views of, carers, families and staff with direct experience of existing systems. The system should include appropriate elements of public scrutiny and should involve staff, families and carers. The new system should have clear timescales for investigation, reporting and publication. The Mental Welfare Commission have tested a process for review and the Scottish Government is considering the actions required to support further implementation, as part of the response to the recommendations of the Scottish Mental Health Law review[12].

1.22. Following detection/recognition of a healthcare infection incident/outbreak all NHS Boards are required to undertake an initial assessment using the same national standardised assessment – the Healthcare Infection Incident Assessment Tool (HIIAT).

1.23. NHS Boards are required to report all HIIAT assessed Green, Amber and Red reports to ARHAI (Antimicrobial Resistance and Healthcare Associated Infection) Scotland using a national electronic outbreak reporting tool (ORT). ARHAI Scotland is responsible for the surveillance and monitoring of infections and antimicrobial resistance to assess their impact on health.

1.24. The national requirements and mechanisms for reporting are outlined in the National Infection and Prevention Control Manual[13]. This single channel of infection incident/outbreak assessment and information reporting is used internally within a NHS Board area and for reporting nationally to ARHAI Scotland and the Scottish Government.

[12]WITN7458021
[13]WITN7458022

1.25. The Healthcare Infection Incident Assessment Tool (HIIAT) is used by Infection Prevention and Control Teams or Health Protection Teams to assess every healthcare infection incident i.e. all outbreaks and incidents (including decontamination incidents or near misses) in any healthcare setting.

1.26. This supports a single channel of infection incident/outbreak assessment and information reporting both internally within a NHS Board area and externally to ARHAI Scotland and Scottish Government.

Healthcare Improvement Scotland

1.27. The Scottish Government issues directions to NHS Boards through relevant Chief Medical Officer and Director's Letters to ensure that the statutory and mandatory reporting requirements of NHS staff are clearly outlined[14].

1.28. Healthcare Improvement Scotland (HIS) was established in 2011 as a Health Body, constituted by the National Health Service (Scotland) Act 1978 (as amended by the Public Services Reform (Scotland) Act 2010) and the Public Bodies (Joint Working) Act 2014.

1.29. HIS' key statutory duties are a general duty of furthering improvement in the quality of health care, a duty to provide information to the public about the availability and quality of services provided under the health service and, when requested by Scottish Ministers, a duty to provide to Scottish Ministers advice about any matter relevant to the health service functions of HIS.

1.30. HIS support, ensure, and monitor the quality of healthcare provided or secured by the health service, review and inspect the quality of healthcare in any service both in the NHS Scotland and the independent sector (based on intelligence and evidence and at a time and manner of

[14] WITN7458023

its choosing). HIS must have access to all relevant information held nationally and locally about the quality of health care and services, for the purposes of assurance, learning, enquiry and improvement.

1.31. All inspections and assurance activity undertaken by HIS is undertaken independently of the Scottish Government and its findings or recommendations are publicly presented.

1.32. In 2019, the Scottish Government published its Operating Framework with HIS, which sets out the framework within which HIS and the Scottish Government (SG) work together and defines the key roles and responsibilities which underpin the relationship. The Operating Framework between HIS and the Scottish Government describes three levels of escalation, the first being issuance of a formal letter of non-compliance to an NHS Board, the second escalation to Scottish Government officials and the third being direct escalation to the Scottish Ministers.

1.33. The Patient Rights Act (Scotland) Act 2011 and supporting legislation provides a specific right for people to make complaints, raise concerns, make comments and give feedback about the services they have received from NHSScotland. It places a duty on NHS Boards to encourage patients to exercise that right and to thoroughly investigate and respond to any concerns raised, to take improvement actions where appropriate and to share learning from the views they receive. Boards are required via Directions[15] to publish annual reports summarising the action which has been taken or is to be taken to improve services as a result of feedback, comments or concerns received and handled in that year, some of which might be related to instances of death or injury.

1.34. NHSScotland supports and encourages an environment where employees can raise concerns about patient safety and malpractice. The procedures for raising and handling whistleblowing concerns are detailed

[15] WITN7458024

in the National Whistleblowing Standards[16]. Where the employee remains dissatisfied, the concern can be escalated for external review to the Independent National Whistleblowing Officer[17].

1.35. The Cabinet Secretary for Health and Sport instructed Healthcare Improvement Scotland in September 2019 that all NHS Boards in Scotland must notify them when a Significant Adverse Event Review had been commissioned for a Category 1 adverse event[18].

1.36. The National Framework for Learning from Adverse Events through reporting and review[19] defines a category 1 adverse event to be an event that may have contributed to or resulted in permanent harm, for example unexpected death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity (likely to be graded as major or extreme impact on NHS Scotland risk assessment matrix, or Category G, H or I on National Coordinating Council for Medical Error Reporting and Prevention (NCC MERP) index).

1.37. The Scottish Fatalities Investigation Unit guidance on reportable deaths (referred to in my response above) requires that a death is reportable if the circumstances while receiving medical or dental care are likely to be subject to an Adverse Event Review (as defined by Healthcare Improvement Scotland). The reference to the requirements of the national adverse events framework in this way ensures that reportable deaths reported to the SFIU take account of those captured by the national adverse events framework guidance.

1.38. Since January 2020, all NHS boards have engaged fully with the new notification system for Category 1 events. Monthly notification data has been received from all organisations. Between January 2020 and October

[16] WITN7458025
[17] Independent National Whistleblowing Officer | INWO (spso.org.uk)
[18] WITN7458026
[19] WITN7458027

2021 Healthcare Improvement Scotland were notified of an average of 50 Significant Adverse Event Reviews having been commissioned for Category 1 Adverse Events per month[20].

1.39. Once a review has been completed, boards are asked to update the initial notification record, and submit the outcomes from the SAER process.

1.40. These reports are made to the Quality Assurance Directorate of Healthcare Improvement Scotland and considered as part of the Quality Assurance Framework used by Healthcare Improvement Scotland, a framework that is used to identify any follow-up activity or support that may be required[21].

1.41. The framework has seven domains, each with criteria against which quality indicators are provided to inform quality assurance assessments. The quality improvement domain sets out quality indicators for the criterion 'pathways, procedures and policies'. This includes the quality indicator that staff are aware of the process for raising or escalating concerns and feel confident to report things that go wrong, including near misses, and to communicate safety issues with their colleagues. The inclusion of this quality indicator reflects the arrangements to ensure that Healthcare Improvement Scotland, in addition to receiving all reports of Category I Significant Adverse Events Reviews that are commissioned, have integrated a range of associated indicators within their Quality Assurance Framework.

1.42. Specific guidance has been developed collaboratively with clinicians to support implementation of adverse event review reports in maternity and neonatal services[22].

[20] WITN7458028
[21] WITN7458029
[22] WITN7458030

2. **You will see from the statement of Ms Braithwaite that the Professional Standards Authority for Health and Social Care supports the establishment of a single body responsible for overseeing the safety system for health and social care. To the extent not already addressed above, please set out your response, from the perspective of the Scottish Government, to this suggestion.**

2.1 Healthcare Improvement Scotland provides public assurance about the quality and safety of healthcare through the scrutiny of NHS Scotland hospitals and independent healthcare services.

2.2 Healthcare Improvement Scotland has led the development of a Quality Management System, and has developed a Quality Management System (QMS) Framework[23]. This supports health and social care organisations to apply a consistent and coordinated approach to the management of the quality of health and care services. This requires senior leadership support and a balanced focus across all the components of quality management.

2.3 Healthcare Improvement Scotland have also developed an Excellence in Care Framework for nursing and midwifery staff[24].

2.4 The Quality Management system outlines the following components:

2.5 Quality planning: Understanding the needs of the people and communities served, often through services providing reports through the Board's governance processes on an annual basis.

2.6 Quality assurance: Checks that good care is being provided, meeting minimum standards and identifying gaps, developing action plans and rechecking to ensure compliance.

[23] WITN7458031
[24] WITN7458032

2.7 Quality control: Monitoring of service quality in real time, through team safety huddles and daily review of data at the point of care.

2.8 Quality improvement: Systematic process to improve performance and improve quality, involving those closest to the issue, often focused on solving a problem where the answer is not known or where new actions are tested to tackle what matters most to people receiving care.

2.9 The QMS includes a learning system focused on measurement that enables learning about what is and isn't working (qualitative and quantitative), implementation of processes in place that support the appropriate use of evidence, learning networks of people learning together on similar challenges and a system for identifying bright spots and learning that can be generalised within and across organisations.

You will see from the statement of Dr Benneyworth that the Healthcare Safety Investigation Branch in England supports the operation of safety management systems and towards this the aggregation of data regarding patient safety collected by local, regional and national organisations to inform the identification of patient safety priorities. To the extent not already addressed above, please set out your response, from the perspective of the Scottish Government, to this suggestion.

2.10 The Second Edition of the Blueprint for Good Governance in the NHS in Scotland was published in December 2022[25]. This outlines the assurance information system to be implemented by NHS Scotland Boards and sets out that this should be designed to provide frequent and informative performance and financial reports to assure the Board that it is delivering safe, effective, patient-centred, affordable and sustainable services. This system should deliver relevant, accurate and timely information on a wide range of activities, including service delivery and safety and quality standards.

[25] WITN7458033

2.11 The concept of "active governance" is key to our approach. This means NHS bodies ensuring that the appropriate issues are considered by the right people, the relevant information is reviewed in the most useful format at the right time, and the level of scrutiny produces rigorous challenge and an effective response. This should include the drawing in of any external scrutiny (including for example HIS inspections) as well as information flows from within the organisation, such as clinical governance reports. Taking this approach allows the board to triangulate data and seek assurance on the safety and effectiveness of the system. The Scottish Government will shortly commence a programme of structured self-assessments by health boards on the effectiveness of their governance systems. In the future, this will also be underpinned by external review of board governance arrangements.

2.12 The NHS Scotland Performance Management Framework[26] provides five stages of a Ladder of Escalation that provides a model for intervention by the Scottish Government when there are concerns about a NHS Board's ability to deliver the expected standards, targets and governance.

2.13 The Performance Management Framework is overseen by the National Planning and Performance Oversight Group (NPPOG), a sub-group of the Health and Social Care Management Board. The Oversight Group considers various forms of intelligence and data and makes subsequent recommendations to the Health and Social Care Management Board on escalation, de-escalation and/or the provision of enhanced support for NHS Boards.

2.14 One example of where significant outcomes were achieved through the use of patient safety data was where the NPPOG considered the findings of a series of HIS inspections at NHS Forth Valley, which had highlighted several patient safety concerns, with a lack of learning and improvement evidenced on the part of the board between inspections. Following

[26] WITN7458034

unsatisfactory responses from NHS Forth Valley senior management to their inspection visits, HIS had escalated their concerns to their sponsor team in Scottish Government, in accordance with the agreed escalation process outlined in the published Operating Framework referred to at paragraph 1.32.

2.15 Following discussion and consideration at NPPOG, the decision was reached in mid-November 2022 to escalate NHS Forth Valley to Stage 4 on the SG escalation framework, in relation to governance, leadership and culture. An improvement plan was subsequently developed, based on and informed by the Blueprint for Good Governance, and improvement and progress against the plan was closely monitored and kept under review by NPPOG. Future development of the Blueprint itself will be informed through feedback on its application through this and other similar pieces of work.

2.16 The Scottish Government supports the proposals to improve safety culture, support candour and accountability in a manner that includes patients, service users and families, professionals and regulators. In 2018 the statutory organisational duty of candour legislation for providers of health services, care services and social work services in Part 2 of the Health (Tobacco, Nicotine etc and Care) (Scotland) Act 2016 came into force[27]. The statutory obligations for NHS Boards are set out in the 2016 Act and the Duty of Candour Procedure (Scotland) Regulations 2018[28]. These set out the requirements in respect of notification, apologising to relevant people, involvement of relevant persons, conducting a learning focused review as well as support and training for staff.

2.17 The 2016 Act requires all NHS Boards to publish an annual report on the organisational duty of candour, publish this in a publicly accessible place and notify Scottish Ministers. This annual report outlines the number and nature of incidents where the duty of candour procedure has been

[27] WITN7458035
[28] WITN7458036

activated, the way which the procedure was followed, information relating to any changes to policies and procedures that have been identified following the activation of the duty of candour procedure and the support that is available to staff and relevant persons affected by the unintended or unexpected incident. The legislation is supported by non-statutory guidance which is currently under review by the Scottish Government to ensure it is fit for purpose. A revised version of the guidance is due to be published in Spring 2024.

2.18 In 2018 the Scottish Government commissioned NHS Education for Scotland and Healthcare Improvement Scotland to work together in supporting NHS Boards to increase the quality and credibility of incident investigation, to increase the quality or organisational and national learning, explore opportunities for patient/carer involvement in healthcare improvement, openness and learning and decrease the potential of adverse event recurrence[29].

2.19 Since January 2020 all health boards in Scotland have had to report to Healthcare Improvement Scotland when they have commissioned a category 1 Significant Adverse Event Review. This will allow Healthcare Improvement Scotland to identify the most reported harms and create a standardised list and definitions that can be implemented across NHS Scotland. Healthcare Improvement Scotland is now taking forward a programme of work on adverse events, which is focussed on standardisation of reporting, robust SAER reviews and national dissemination of learning. The ongoing revision of Learning From Adverse Events Through Reporting and Review – A National Framework[30] will support this work, as the revised version will emphasise both meaningful engagement with patients, families and care givers, and the importance of learning and follow-up of actions and recommendations.

[29] WITN7458037
[30] WITN7458038

2.20 HIS is working with the Adverse Events Network to produce a standardised version of the learning summary that should be produced following a SAER review. HIS has established the Adverse Events Community of Practice as the new internal national mechanism for sharing this information, and the place where NHS boards will upload learning summaries. The community of practice is being piloted with three NHS boards, with a further roll out to all NHS boards expected to take place later this year. A search engine is being developed to allow NHS boards to search the site for learning summaries related to particular areas of interest. The site also contains Adverse Event toolkits, information on related work by partner organisations, and a discussion forum where network members can ask questions and share information on their reviews.

2.21 A study reported in the BMJ in 2022 - Adverse event reviews in healthcare: what matters to patients and their family? A qualitative study exploring the perspective of patients and family[31] – concluded that an open, collaborative and person-centred approach which listens to, and meaningfully involves patients and their families can lead to improved outcomes for patients, families and the health services.

As part of this, please set out your views as to the appropriate body or bodies who should be responsible for identifying patient safety priorities from aggregated data about patient safety?

2.22 Identification of patient safety priorities and effective collaboration and co-ordination of a range of organisations with an interest is essential. The Scottish Sharing Intelligence for Health & Care Group was established in 2014, comprised of seven national agencies meeting together to share, consider, and respond to intelligence about care systems across Scotland (in particular NHS boards).

[31] WITN7458039

2.23 The seven national agencies, each of which has a Scotland-wide remit, are Audit Scotland, the Care Inspectorate, Healthcare Improvement Scotland, the Mental Welfare Commission for Scotland, NHS Education for Scotland, Public Health Scotland and the Scottish Public Services Ombudsman.

2.24 In 2022 the seven group members joined with nine professional regulators to form a network that would more formally consider emerging concerns about health and care safety and quality. The nine regulators are the General Medical Council, General Dental Council, Nursing and Midwifery Council, Health and Care Professions Council, General Pharmaceutical Council, General Optical Council, Scottish Social Services Council, General Osteopathic Council, and General Chiropractic Council.

2.25 The Scottish Government is committed to strengthening the existing infrastructure with delivery partners on patient safety. The Patient Safety Commissioner for Scotland Bill[32] is approaching its third and final stage in the Scottish Parliament, having received widespread support at Stages One and Two[33].

2.26 The Scottish National Audit Programme provides a health intelligence service which plays a key role in promoting safe, effective and person-centred healthcare in Scotland. It works in partnership with stakeholders to audit clinical care. A wide range of national clinical audits are implemented, many of which are speciality-based and involve clinical, government and voluntary sector stakeholders[34]. Quality assurance and patient safety are an integral part of the range of these national clinical audit programmes.

2.27 The establishment of a Patient Safety Commissioner for Scotland will promote and improve patient safety by amplifying the patient voice within

[32] WITN7458040
[33] WITN7458041
[34] WITN7458042

the patient safety system, develop a system-wide view of the healthcare system and use it to identify wider safety issues, and promote better coordination across the patient safety landscape in responding to concerns about patient safety.

2.28 The proposals to establish a Patient Safety Commissioner for Scotland will, if passed by the Scottish Parliament and when implemented, significantly improve the needs identified for a national approach to support improved coherence where relevant data are considered, aggregated, trends identified, and actionable recommendations made. The establishment of a Patient Safety Commissioner will also significantly assist in the work required to enhance and develop many of the existing processes in place but drawing all of the available information together.

2.29 The Commissioner will advocate for systemic improvement in the safety of health care (which includes forensic medical examinations) in Scotland and promote the importance of the views of patients and other members of the public in relation to the safety of health care. As set out in the Bill (Bill as amended at Stage 2 (parliament.scot)[35] and explanatory notes[36], it is envisaged the Commissioner will gather information through a number of means, including directly from patients and families with regard to their experience; through consideration of existing published data; and through using their powers to require information from providers of healthcare, and to require information from anyone in the context of a formal investigation. Based on their consideration of this data, the Commissioner will make recommendations for systemic improvements in safety.

The Scottish Patient Safety Programme

2.30 Scotland has followed a nationwide approach to quality improvement and learning. The Scottish Patient Safety Programme (SPSP) was established to create the conditions to support learning and implementation of strong

[35] WITN7458043
[36] WITN7458044

evidence-based interventions to reduce avoidable harm in healthcare settings[37].

2.31 The programme, which is led by Healthcare Improvement Scotland (HIS), has played a central role in improving the safety of care since its launch in 2008. Aiming to improve the reliability of care and reduce harm, it supports people to apply quality improvement methods to key safety issues, capturing progress and learning through iterative cycles of testing, and then sharing that knowledge in order that others can improve.

2.32 The SPSP work in acute hospital care has focused on improving critical care outcomes through reducing mortality, infections and other adverse events, reducing infections, crash calls, pressure ulcers, adverse events related to detection of acute deterioration in clinical condition, reducing adverse drug events and through reduced peri-operative adverse events.

2.33 Hospital Standardised Mortality Ratios reduced in Scotland by 14% from 2011 to 2018, there was a 27% reduction in cardiac arrests between 2013 and 2018 across 17 NHS Scotland hospitals, a 25% reduction in pressure ulcers between 2015 and 2018 for 22 NHS Scotland hospitals, a 23% reduction in stillbirth between 2013 and 2015.

2.34 Many of the issues raised in Mr Bragg's evidence were addressed through the SPSP (for example his reference to the work of Atul Gwande on checklists informed SPSP work to improve reliability of the implementation of bundles of actions which if implemented consistently reduced the likelihood of adverse events). The SPSP's current focus on Essentials of Safe Care addresses the points made of the importance of creating the conditions for safe care for every person within every health and care setting.

SPSP current priorities

[37] WITN7458045

2.35 In 2020 the national team led an in-depth engagement exercise involving organisations, services and teams working across health and social care to identify the key safety priorities for the system. The following core themes were developed from this and formed the next phase of SPSP, which was launched in 2021:

- SPSP Essentials of Safe Care
- SPSP Programme Specific Improvements
- SPSP Learning System

2.36 Essentials of Safe Care describes the core elements that provide the foundations of safe care, including person-centred approaches and behaviours, culture that promotes safety, good communication between teams, and the reliable delivery of evidence-based clinical and care processes. This foundation has now been embedded within the design and delivery of each of the SPSP programmes.

2.37 The current programmes are:

- **SPSP Acute Adult**: aims to reduce harm and enhance the experience and outcomes for people in acute care;
- **SPSP Perinatal**: aims to improve safety for women, birthing people and babies;
- **SPSP Paediatric**: aims to improve safety for children and families;
- **SPSP Mental Health**: aims to ensure everyone in adult mental health inpatient wards experiences high quality, safe and person-centred care;
- **SPSP Primary Care**: aims to reduce the number of events which could cause avoidable harm from care delivered in any primary care setting.

2.38 A range of resources to support improvement activity have been published including:

- **Falls change package and measurement framework.** These resources support NHS boards to make improvements to support the reduction of falls and falls with harm by focusing improvement activity around change ideas and gathering data to understand whether a change has led to an improvement.
- **Deteriorating Patient change package and measurement framework**. These resources support NHS boards to improve the recognition and response to deterioration and associated reduction in cardiac arrest rate.
- **Pressure Ulcer change package and measurement framework.** These resources, supported by evidence-based guidance, support the prevention of acquired pressure ulcers by focusing on change ideas and gathering data to understand whether a change has led to an improvement.
- **Serial Prescription toolkit**. A serial prescription is a prescription for medicine(s) needed to treat a long-term condition. It looks like a normal prescription but allows for up to 56 weeks of supply of medication. Transferring suitable patients to serial prescriptions ensures medicines-related activity is dealt with by the right member of the pharmacy team, at the right time, safely and efficiently. The serial prescription toolkit was developed in collaboration with 53 GP practices to support the set up and implementation of serial prescription services and has supported the use of serial prescriptions across Scotland.
- **Acute Prescribing toolkit**. The Acute Prescribing Toolkit was developed within a learning network that worked with 75 GP practices and pharmacotherapy teams across Scotland. The toolkit aims to help primary care multi-disciplinary teams, including pharmacotherapy

services, use quality improvement methodology to safely improve their acute prescribing processes, and share learning across Scotland.

- **Acute Prescribing Quick Guide**. The quick guide helps primary care multidisciplinary teams, including pharmacotherapy services, to get started on any of the seven change ideas to safely improve acute prescribing processes, in line with the Essentials of Safe Care.
- **Mental Health Safety** climate resources, which include tools for measuring individual staff and patient safety climates.

2.39 SPSP was hibernated for a brief period during the early stage of the COVID-19 pandemic, however the development of Essentials of Safe Care and subsequent design and delivery of programmes has seen renewed and increasing participation and engagement from all NHS Boards in Scotland.

SPSP significant achievements

2.40 Each of the SPSP programmes are at differing stages of design or delivery. Some significant achievements over the past five years include the following.

2.41 As of August 2023, a reduction in falls in seven acute hospitals and a reduction in falls with harm in four acute hospitals. These improvements range from 15% to 33% in falls in acute hospitals. Core to this work is the support provided to boards through the SPSP Acute Adult learning system. The learning system supports and accelerates sharing of learning and improvement work through a range of engagement and learning opportunities, including:

- access to evidence-informed resources[38] and publications to support improvement;

[38] WITN7458046

- a falls, deteriorating patient and pressure ulcer network to support relationship building and cross organisational working across NHS Scotland;
- events such as webinars and project surgeries; and
- support with measurement and evaluation through tailored improvement coaching including in-person and virtual site visits.

HIS is also responding to the needs of the system by leading on work to standardise the definition of a fall and a fall with harm.

2.42 The impact of this work will ultimately be to improve patient and staff experience and reduce the length of hospital stays.

2.43 One NHS board and two hospitals are demonstrating a reduction in cardiac arrest rate. All boards are focusing on recognising and responding to deteriorating patients, where the SPSP is supporting boards through workshops and/or tailored support to map the structured response to deterioration of their local teams, and to identify local improvement aims.

2.44 Since December 2020 the proportion of items dispensed from a serial prescription[39] has been increasing twice as quickly in practices participating in the SPSP Primary Care Pharmacotherapy collaborative, compared to the rest of Scotland. These prescriptions ensure that patients receive an annual person-centred review of their medications.

2.45 The Pharmacotherapy quick start programme continues to work directly with teams to safely test changes to prescribing processes. Prescribing projects in 2022/23 included:

- A practice from NHS Lothian, which introduced an online form for safely reviewing HRT prescriptions.[40] This increased the number of

[39] WITN7458047
[40] WITN7458048

completed reviews per month threefold, resulting in more patients having safe access to their medication.

- A practice from NHS Ayrshire and Arran created a new procedure to manage antidepressant prescriptions.[41] Their pharmacist reported that having a SOP (Standard Operating Procedure) in place allows the safe prescribing and regular reviews of patients on antidepressants.

Statement of Truth

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

Signed GRO-C

Dated 26 September 2023

Table of exhibits:

Unique ID	Description
WITN7458012	Reporting Deaths - COPFS
WITN7458013	The Yellow Card scheme: guidance for healthcare professionals, patients and the public
WITN7458014	Safety of health, social care, estates and facilities equipment: NHS Board and local authority responsibilities
WITN7458015	DIRECTIVE 2002/98/EC - Setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

[41] WITN7458049

WITN7458016	The Ionising Radiation (Medical Exposure)(Amendment) Regulations 2018
WITN7458017	National Hub for Reviewing and Learning from the Deaths of Children and Young People
WITN7458018	National Hub for Reviewing and Learning from the Deaths of Children and Young People, Overview Report: Year 1 (Implementation year)
WITN7458019	Reporting Deaths to the Procurator Fiscal Guidance
WITN7458020	Review of the arrangements for investigating the deaths of patients being treated for mental disorder
WITN7458021	Scottish mental health law review: our response
WITN7458022	National Infection Prevention and Control Manual: Chapter 3 - Healthcare Infection Incidents, Outbreak and Data Exceedance
WITN7458023	Guidance for doctors completing Medical Certificates of the Cause of Death (MCCD) and its quality assurance
WITN7458024	The Patient Rights (complaints procedure and consequential provisions)(Scotland) Amendment Regulations 2016 and the Patient Rights (feedback, comments, concerns and complaints)(Scotland) Directions 2017
WITN7458025	National Whistleblowing Standards
WITN7458026	Adverse events management within NHS Scotland
WITN7458027	Learning from adverse events through reporting and review - A national framework for Scotland
WITN7458028	Adverse Events Notification System: Update Report

WITN7458029	Quality Assurance Framework
WITN7458030	Maternity and neonatal (perinatal) adverse event review process for Scotland
WITN7458031	Quality Management System
WITN7458032	Excellence in Care Framework
WITN7458033	NHS Scotland - blueprint for good governance: second edition
WITN7458034	NHS healthcare standards: Board performance escalation framework
WITN7458035	Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016
WITN7458036	The Duty of Candour Procedure (Scotland) Regulations 2018
WITN7458037	Joint Commission for Safety Openness and Learning
WITN7458038	Learning From Adverse Events Through Reporting and Review – A National Framework
WITN7458039	Adverse event reviews in healthcare: what matters to patients and their family? A qualitative study exploring the perspective of patients and family
WITN7458040	Patient Safety Commissioner for Scotland Bill
WITN7458041	Stage 1 Report on the Patient Safety Commissioner for Scotland Bill
WITN7458042	Overview - Scottish National Audit Programme (SNAP)
WITN7458043	Patient Safety Commissioner for Scotland Bill

WITN7458044	Patient Safety Commissioner for Scotland Bill - Explanatory notes
WITN7458045	The Scottish Improvement Journey: a nationwide approach to improvement
WITN7458046	SPSP Acute Adult programme updates
WITN7458047	Serial Prescription Toolkit
WITN7458048	Online form for safely reviewing HRT prescriptions
WITN7458049	New procedure to manage antidepressant descriptions

Annex A Categories of death to be reported as per the 'Reporting deaths to the Procurator Fiscal. Information and Guidance for Medical Practitioners' (COPFS, 2015).

Unnatural cause of death:

Any death which cannot be entirely attributed to natural causes (whether the primary cause or a contributing factor) including:

- Suspicious deaths – i.e., where homicide cannot be ruled out
- Drug related deaths - including deaths due to adverse drug reactions reportable under the Medicines and Healthcare Products Regulatory Agency (MHRA) (Yellow Card Scheme)
- Accidental deaths (including those resulting from falls)
- Deaths resulting from an accident in the course of employment
- Deaths of children from overlaying or suffocation
- Deaths where the circumstances indicate the possibility of suicide

Natural cause of death:

Deaths which may be due in whole or part to natural causes but occur in the following circumstances:

(a) Any death due to natural causes where the cause of death cannot be identified by a medical practitioner to the best of his or her knowledge and belief

(b) Deaths as a result of neglect/fault

Any death:

- which may be related to a suggestion of neglect (including self-neglect) or exposure
- where there is an allegation or possibility of fault on the part of another person, body or organisation

(c) Deaths of children

Any death of a child:

- which is a sudden, unexpected and unexplained perinatal death
- where the body of a newborn is found
- where the death may be categorised as a Sudden Unexpected Death in Infancy (SUDI)
- which arises following a concealed pregnancy

Any death of a child or young person under the age of eighteen years who is 'looked after' by a local authority, including:

- a child whose name is on the Child Protection Register
- a child who is subject to a supervision requirement made by a Children's Hearing
- a child who is subject to an order, authorisation or warrant made by a Court or Children's Hearing (e.g., a child being accommodated by a local authority in foster care, kinship care, residential accommodation or secure accommodation)
- a child who is otherwise being accommodated by a local authority

(d) Deaths from notifiable industrial/infectious diseases

Any death:

- due to a notifiable industrial disease or disease acquired as a consequence of the deceased's occupation in terms of column 1 of Part 1 of Schedule 3 to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (see http://www.legislation.gov.uk/uksi/1995/3163/schedule/3/made and Section 10 of this guidance)

- which poses an acute and serious risk to public health due to either a Notifiable Infectious Disease or Organism in terms of Schedule 1 of the Public Heath (Scotland) Act 2008 (see http://www.legislation.gov.uk/asp/2008/5/schedule/1) or any other infectious disease or syndrome,

(e) Deaths under medical or dental care (see Section 9 below)

Any death:

- the circumstances of which are the subject of concern to, or complaint by, the nearest relatives of the deceased about the medical treatment given to the deceased with a suggestion that the medical treatment may have contributed to the death of the patient.

- the circumstances of which might indicate fault or neglect on the part of medical staff or where medical staff have concerns regarding the circumstances of death

- the circumstances of which indicate that the failure of a piece of equipment may have caused or contributed to the death

- the circumstances of which are likely to be subject to an Adverse Event Review (as defined by Healthcare Improvement Scotland)

- where, at any time, a death certificate has been issued and a complaint is later received by a doctor or by the Health Board, which suggests that an act or omission by medical staff caused or contributed to the death

- caused by the withdrawal of life sustaining treatment or other medical treatment to a patient in a permanent vegetative state (whether with or without the authority of the Court of Session). (See Section 13 below)

- which occurs in circumstances raising issues of public safety.

(f) Deaths while subject to compulsory treatment under mental health legislation

Any death of a person who was, at the time of death:

- detained or liable to be detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 or Part VI of the Criminal Procedure (Scotland) Act 1995; or

- subject to a community based compulsory treatment order or compulsion order under the above provisions.

(g) Any death not falling into any of the foregoing categories where the circumstances surrounding the death may cause public anxiety.

Deaths in legal custody:

Any death of a person subject to legal custody. This includes (but is not restricted to) all persons:

- detained in prison
- arrested or detained in police offices
- in the course of transportation to and from prisons, police offices or otherwise beyond custodial premises e.g. a prisoner who has been admitted to hospital or a prisoner on home leave