Witness Name: Lynsey Cleland
Statement No.: WITN7671001
Exhibits: WITN7671002 – 008
Dated: 14 June 2023

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF LYNSEY CLELAND ON BEHALF OF HEALTHCARE IMPROVEMENT SCOTLAND

I provide this statement in response to a request under Rule 9(1) and (2) of the Inquiry Rules 2006 dated 3 March 2022.

I, Lynsey Cleland, will say as follows: -

1. I am Director of Quality Assurance at Healthcare Improvement Scotland and am responsible for leading the organisation's external quality assurance of healthcare services in Scotland to secure measurable improvements in the safety and quality of care people receive. I have held this position since May 2021 and prior to that I was the organisation's Director of Community Engagement. As a director and member of the Executive Team, I fully contribute to and participate in the corporate management and governance of the organisation.

Section 1: Response to Evidence

1. **Please provide a brief outline of the role and responsibilities of Healthcare Improvement Scotland.**

2. Healthcare Improvement Scotland (HIS) is the national improvement agency for health and care in Scotland. The organisation's core purpose is to enable the people of Scotland to experience the best quality health and social care, with a specific focus on safety.

3. As outlined in the Operating Framework (WITN7671002) between HIS and Scottish Government, HIS was established in 2011 as a Health Body, constituted by the National Health Service (Scotland) Act 1978, as amended by the Public Service Reform Scotland Act 2010 and the Public Bodies (Joint Working) Act 2014. While HIS is not a special health board, it may be grouped with NHS special health boards in terms of Scottish Government initiatives such as shared services.

4. HIS's statutory functions are set out in the aforementioned legislation. Broadly, these include duties and powers to:

    a. further improve the quality of health and care
    b. provide information to the public about the availability and quality of NHS services
    c. support and monitor public involvement
    d. monitor the quality of healthcare provided or secured by the health service, and
    e. evaluate and provide advice to the health service on the clinical and cost effectiveness of new medicines and new and existing health technologies.

5. HIS is not a health care provider. Nor is HIS responsible for the performance management of any NHS or social care body which does provide care. We scrutinise and assure the safety and quality of NHS services in Scotland but we do not regulate them. Our regulatory function only applies to independent healthcare services in Scotland. NHS Scotland service providers are ultimately accountable to the Scottish Cabinet Secretary for Health and Social Care through established governance mechanisms, which is a different approach to scrutiny and quality assurance from that taken in England.

6. There is no equivalent organisation elsewhere within the UK, as HIS uniquely combines a range of statutory duties with several other functions and areas of work. HIS works with over 100 partner health and social care organisations, taking a quality management systems approach, in a range of different ways:

    a. to strategically redesign and continually improve services
    b. providing advice and sharing knowledge that enables people to get the best out of the services they use and help services improve, and
    c. providing quality assurance that gives people confidence in services and supports providers to improve.

7. HIS's main functions are the independent assurance of the quality of care in Scotland, national improvement and redesign support for health and care services, and independent assessment of evidence to underpin high quality care. We work in partnership with health and care staff, with citizens and communities at the heart of change. Specialist teams across the organisation deliver these functions, often with cross-organisational working, through an extensive work programme aligned with HIS's corporate strategy.

8. Ensuring that patients are kept safe within the healthcare setting is central to furthering improvements in the quality of patient care. A focus on safety is fundamental to our work and seen across our work programmes. This will facilitate a more regular and systematic approach to sharing advice, knowledge and intelligence for safety in the system at a national level as well as the prioritisation of improvements in the safety and effectiveness of care. Over the course of the Covid-19 pandemic we demonstrated our ability to pivot our scrutiny, improvement, evidence and engagement support at pace to respond to the needs of our system. We have also developed a strong reputation for delivering timely and relevant national learning systems which are able to capture key learning and spread it rapidly across the system.

9. **Scrutiny**: HIS provides public assurance about the quality and safety of healthcare through inspections and reviews of NHS hospitals and services, as

well as regulation of independent healthcare services. Our scrutiny activity covers inspection, regulation and review. In addition to our core programme of scrutiny activity, we may also be commissioned by Scottish Government to undertake ad hoc assurance reviews in areas of emerging and urgent need. We report and publish our findings on performance and demonstrate accountability of these services to the people who use them. This work includes:

a. **Inspecting care in Scotland**: By inspecting care we help to ensure that healthcare services are meeting the required standards of care, that good practice is identified and areas for improvement are addressed. Our inspectors undertake announced and unannounced inspections of healthcare services. These will involve a physical inspection of the clinical areas, and discussions with staff. This includes:

    i. Inspection of NHS hospitals and services
    ii. Inspection of mental health units, and
    iii. Joint inspections of care (including joint inspections of adult services, joint inspections of adult support and protection, inspecting the provision of healthcare to individuals within the criminal justice system, and joint inspections of services for children and young people).

b. **Regulating care**: We are responsible for the registration and regulation of independent healthcare services across Scotland. This includes inspecting services to make sure they are complying with necessary standards and regulations, investigating complaints, and where necessary taking enforcement action in accordance with our statutory powers. We also enforce the Ionising Radiation (Medical Exposure) Regulations (IRMER) in Scotland on behalf of the Scottish Government and inspect NHS and independent services to ensure they comply with the regulations.

c. **Governance, assurance and reviews of healthcare services**: We work to ensure that NHS boards have a clear and consistent approach to clinical governance in healthcare through a range of review programmes, and we make our findings public.

d. **The Death Certification Review Service**: Arrangements for death certification and registration in Scotland changed in 2015, at which point the Death Certification Review Service (DCRS), which is run by HIS, was established. The DCRS conducts random quality assurance checks on the accuracy of death certification and provides an advice service to those seeking to certify cause of death. The DCRS does not review the quality of care provided to the deceased prior to their death, nor suspicious deaths or deaths that should be reported to the Procurator Fiscal under the Inquiries into Fatal Accidents and Sudden Deaths etc. (Scotland) Act 2016.

e. **The Quality Assurance System**: Our Quality Assurance System (QAS) is an evolving approach to shaping our inspection, regulation, and reviews of services across Scotland. Our Quality Assurance Framework provides a consistent reference point for assessing services. The framework sets out what good care looks like, emphasising the importance of leadership and culture, vision and purpose, and the importance of co-designing services with people.

f. The **Adverse Events** team works with all NHS Boards supporting their adherence to the national framework for learning from adverse events. HIS has led the development of the national approach to learning from adverse events and is driving implementation through an improvement support programme. The Medicines and Pharmacy team works with the Adverse Events team in considering the implications of National Patient Safety Alerts (NPSAs) for NHS Scotland and cascading of any appropriate information to relevant parties. HIS does not provide scrutiny or assurance of boards' policies and procedures in relation to the management of adverse events.

g. HIS has a duty to respond to concerns raised by NHS Scotland staff (who wish to remain anonymous), or referred to us by another organisation, about the safety and quality of patient care, with the ultimate aim of helping to make care better. We have an organisation-wide **Responding to Concerns (RTC)** process which ensures that, regardless of the route through which we receive these concerns, our process for managing them is the same. We undertake an assessment of concerns in line with our established RTC process to determine how the concerns should be managed, what steps will be taken to seek assurance from the relevant NHS Board(s) in relation to the concerns, and analysis of evidence to determine any areas for improvement/further activity.

h. HIS is a member of the **Sharing Intelligence for Health & Care Group (SIHCG)**,(WITN7671003) a mechanism that enables seven national agencies to share, consider and respond to intelligence about care systems across Scotland, and in particular, care delivered by NHS Boards. The other group members are:

   i. Audit Scotland
   ii. Care Inspectorate
   iii. Mental Welfare Commission for Scotland
   iv. NHS Education for Scotland
   v. Public Health Scotland
   vi. Scottish Public Services Ombudsman

i. Our planned scrutiny activity for 2023-24 is outlined in our Scrutiny Plan. (WITN7671004)

10. **Improvement**: HIS, through its Improvement Hub (ihub), provides practical support for quality improvement across the integrated health and social care space with extensive expertise in both redesign and continuous improvement. The ihub supports services to: understand their high impact opportunities for

improvement; design processes, care models and systems that will improve outcomes; implement changes that will lead to improvement; and evaluate the impact of changes, embed change and spread learning. All work is co-designed, co-owned and co-delivered with our partners with the aim of building local improvement capacity to meet local need. The ihub runs several portfolios of work across acute care, primary care, community care, dementia, mental health, housing and homelessness in healthcare, frailty, MAT Standards, and residential rehabilitation pathways, as well as the Scottish Patient Safety Programme (SPSP), a national quality improvement programme that aims to improve the safety and reliability of care and reduce harm. Since the launch of SPSP in 2008, the programme has expanded to support improvements in safety across a wide range of care settings including acute and primary care, mental health, maternity, neonatal, paediatric services and medicines safety.

11. **Evidence:** HIS is the national authority for the development of evidence-based advice, guidance and standards for health and care professionals to provide safer, more effective care. Working with experts from around the world, we identify, develop and share evidence to improve health and social care and help resolve the issues and challenges facing NHS Scotland. Our work reflects the experiences and opinions of the people of Scotland, and our advice lets them know about the quality of care they can expect to receive regardless of where they are in the country. We support the early assessment and adoption of innovative technologies and processes and assess the clinical and cost effectiveness of newly licensed medicines. Together, our resources support advancement in practice, sustainable service delivery and the reduction of health inequalities. This work includes the following:

    a. **Scottish Health Technologies Group (SHTG)**: a national health technology assessment (HTA) agency. We provide evidence support and advice to NHS Scotland on the use of new and existing health technologies which are not medicines and which are likely to have significant implications for people's care.

b. **Scottish Intercollegiate Guidelines Network (SIGN)**: looks to improve the quality of health care for patients in Scotland by reducing variation in practice and outcome, through the development and dissemination of national clinical guidelines containing recommendations for effective practice based on current evidence.

c. **Scottish Medicines Consortium (SMC)**: provides advice to NHS Scotland about the value for patients of new medicines. Once a new medicine has been licensed by the relevant regulatory authority, SMC assesses its clinical and cost-effectiveness on behalf of NHS Boards. Most new indications and formulations of established medicines are also assessed. Before a medicine can be prescribed routinely in Scotland, it has to be accepted for use by SMC.

d. **Standards and indicators**: are developed to support health and social care organisations improve the quality of care and support they deliver. Standards are statements of levels of service performance that people should expect from health services. They are based on evidence relating to effective clinical practice, feasibility and service provision that is responsive to patients' needs and views. Our indicators are tools for quality improvement and can be used to support service standards.

e. **Scottish Antimicrobial Prescribing Group (SAPG)**: works closely with clinical staff in NHS boards to promote the safe and effective use of antibiotics across hospital and community settings.

f. **Rapid responses**: these are generally based on published literature. They aim to define and answer a specific question relating to health and care, rather than broad health system issues, which may be used to inform further review. These reports summarise the type and quantity of evidence available, its general quality and main conclusions.

12. **Engagement**: HIS – Community Engagement (HIS-CE) has a role to provide advice, support and assurance to NHS boards and health and social

care partnerships on their statutory duties for public involvement. Although part of HIS, HIS-CE has a separate governance committee, which is responsible for agreeing the overall strategic direction and assuring the legal equality responsibilities of HIS. HIS-CE works with policy makers and service providers to ensure that people and communities are involved in the planning and development of local health and care services. Previously known as the Scottish Health Council, HIS-CE has a role for promoting:

a. best practice for engaging with individuals and communities to shape local services and influence national policy
b. equality and human rights to ensure everyone's voice is heard
c. collaborating and working in partnership, and
d. sharing learning on public engagement and involvement

13. **Medical and Nursing, Midwifery, and Allied Health Professionals (NMAHP):** The Medical directorate is responsible for ensuring clinical quality and governance across HIS's work in relation to medical and pharmacy professionals. The Medicines & Pharmacy team works with all external organisations in Scotland and the UK who have a responsibility for governance of medicines and the pharmacy profession. The team proactively and reactively responds to emerging Scottish Government policy and HIS organisational work related to medicines and pharmacy. The Nursing, Midwifery and Allied Health Professionals (NMAHP) directorate provides professional support and leadership, stimulating improvement in care and collaboration with multidisciplinary teams in HIS and the wider health and care system. Its primary role is to provide professional advice and assurance to HIS for the development, effective implementation and evaluation of strategy, policy and legislation. In addition, we provide professional advice and guidance to our key stakeholders that support the capacity and capabilities of the NMAHP and Health and Social Care workforce to meet policy priorities, changing health needs and public expectations, having the right people with the right skills in the right places.

2. **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 be preventable, and that there should be a new, single organisation with responsibility to collect such information, investigate incidents and make sure that effective action has been taken. Please set out your response, from the perspective of Healthcare Improvement Scotland, to this proposal. Please provide any further comments regarding Mr. Bragg's proposals that you wish to provide.**

14. HIS believes that it is imperative that where something goes wrong with the treatment or care people receive, there are effective, consistent and transparent processes in place to review and learn from this to improve the safety of our health and care system for everyone.

15. In considering Mr Bragg's proposals it is important to take account of existing statutory and professional duties of candour, as well the systems and process in place in each of the healthcare systems across the UK to review and learn from adverse events. This will help ensure that any new proposals complement and strengthen existing arrangements and do not inadvertently duplicate any existing provisions in one or more of the UK nations.

16. A statutory organisational duty of candour legislation for all health, care and social work services came into force in Scotland on 1 April 2018. The Health (Tobacco, Nicotine etc and Care) (Scotland) Act 2016 and the Duty of Candour Procedure (Scotland) Regulations 2018 set out the procedures that organisations providing health services, care services and social work services in Scotland are required to follow when there has been an unintended or unexpected incident that results in death or harm, or where additional treatment is required to prevent injury that would result in death or harm. Organisations are also required to set out in an annual report the way the duty of candour procedure has been followed for all the cases they have identified. Further information about the organisational duty of candour can be found in guidance produced by the Scottish Government (WITN7671005).

17. This statutory organisational duty of candour is in addition to professional duties of candour placed on registered health and care professionals by their professional regulatory bodies.

18. In addition to existing statutory and professional obligations to be open and honest when something has gone wrong, HIS has a national role in supporting learning from adverse events which seeks to ensure that no matter where an adverse event occurs in Scotland the affected person receives the same high quality response.

19. The aims of our Adverse Events programme of work are to:

    a. learn locally and nationally to make service improvements that enhance the safety of the care system for everyone
    b. support adverse event management in a timely and effective manner
    c. support a consistent national approach to the identification, reporting and review of adverse events, and allow best practice to be actively promoted across Scotland
    d. present an approach that allows reflective review of events which can be adapted to different settings
    e. provide national resources to develop the skills, culture and systems required to effectively learn from adverse events to improve health and care services across Scotland, and
    f. provide a central database of all Category 1 Significant Adverse Event Reviews (SAERs) commissioned in Scotland from the first of January 2020. (Category 1 SAERs are events that may have contributed to or resulted in permanent harm).

20. Our national work is intended to cover all care being provided throughout Scotland including:

    a. acute care and managed community services

b. primary care (GP practices, dental practices, community pharmacies and optometrists)
c. social care
d. employees and independent contractors, and
e. clinical and non-clinical events (including information governance, health and safety at work, adverse publicity and finance).

21. A phased approach has been taken towards supporting implementation, with an initial focus to date on acute care, although the principles encompass all care settings.

22. As part of this work we have developed a national framework to support NHS Boards to standardise processes for managing and learning from adverse events (Learning from adverse events through reporting and review - A national framework for Scotland: December 2019 (healthcareimprovementscotland.org) (WITN7671006). Work is currently ongoing to update this framework in collaboration with NHS Boards and other partner agencies in Scotland.

23. We have also implemented an Adverse Events Notification System which receives information from NHS Boards regarding all Category 1 commissioned SAERs. Responsibility for investigating and implementing the learning from SAERs rightly remains with the NHS Board where the incident occurs, but our notification system is intended to enable analysis of adverse event data at a national level to drive learning, improvement and consistency of approach across Scotland. However, analysis of the data we receive has proved challenging to date due to the different ways NHS boards categorise and report adverse events. Work is therefore underway on a national approach to standardise all levels of adverse event data reporting in Scotland. This work is being taken forward in collaboration with the Adverse Events Network which has representation from all NHS Boards in Scotland. Included in this work is standardisation of events which lead to a SAER in order to ensure a consistent approach across the country.

24. Learning from adverse events is another crucial area of improvement for our Adverse Events programme. A new national community of practice has been launched and is currently in testing phase with NHS Boards. Revised national learning summaries following SAERs are also being redesigned in partnership with NHS boards and partner organisations such as COSLA and the Mental Welfare Commission for Scotland. Discussions are also underway with the Crown Office and Procurator Fiscal service (COPFS) regarding sharing learning from Fatal Accident Inquiries and significant case reviews and how SAERs can assist with these processes.

25. An update report on our adverse events work can be found at Adverse Events Notification System: Update Report: January 2022 (healthcareimprovementscotland.org) (WITN7671007).

26. In addition, HIS has been working with NHS Education for Scotland (NES) on a joint commission from Scottish Government on Safety, Openness and Learning. Research work, "Adverse Event Reviews in healthcare: what matters to patients and family?" completed as part of this the joint commission team and recently published in the British Medical Journal (Adverse event reviews in healthcare: what matters to patients and their family? A qualitative study exploring the perspective of patients and family) (WITN7671008). Following this, a review led by NHS Boards on patient and family engagement in SAERs concluded that there are varied arrangements in place across Scotland at this time. A national process to support a consistent approach is now being developed to ensure patients and families are at the heart of initiatives to improve patient safety within NHS Scotland. Compassionate communications training for NHS staff has also been developed by NES.

27. Following work with NHS staff members to understand what skills and expertise is required to lead reviews and investigate patient safety events, a programme of work to further enhance staff skill with a focus on Human Factors is also being developed by NES. The piloting of this patient safety curriculum for staff begins in April 2023.

3. **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 Healthcare Improvement Scotland, to this suggestion.**

28. Ensuring that patients are kept safe within the health and care settings is central to furthering improvements in the quality of care and as detailed in my response to question 1, a focus of safety is fundamental to our work.

29. A number of organisations in Scotland, including HIS, have defined statutory functions in relation to safety and quality of care. In addition, the Scottish Government has recently introduced a Bill detailing proposals for a Patient Safety Commissioner for Scotland. This Bill is working through the parliamentary process and has recently being subject to a series of evidence session which HIS participated in. Information regarding the Bill can be found here.

30. We recognise the combined strength of the respective skills and expertise that each of the organisations with a role to play in safety and quality of care in Scotland currently bring, but also understand the vital importance of these organisations working together to share, consider and respond to intelligence about health and care systems, as demonstrated by our membership of the Sharing Intelligence for Health & Care Group (SIHCG) and the secretariat support we provide for this.

31. We would have a strong interest in any proposals to further strengthen the safety of the health and care system in Scotland, but believe that detailed consideration needs to be given to the existing landscape, including the proposals for a Patient Safety Commissioner, in order to ensure that any new arrangements are evidence-based and do not inadvertently duplicate, complicate or dilute existing provisions. Such a situation could be both costly and inefficient, and act against the purpose and goals of the various

organisations working in the wider safety landscape. HIS would be happy to contribute to any further discussion that the Scottish Government and others may wish to take forward in respect of this.

Statement of Truth

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

Signed GRO-C

Dated 14 June 2023

Table of exhibits:

Date	Notes/ Description	Exhibit number
October 2022	Operating Framework: Healthcare Improvement Scotland and Scottish Government	WITN7671002
November 2021	A framework for sharing intelligence with health and care regulators in Scotland	WITN7671003
April 2023	Healthcare Improvement Scotland Scrutiny Plan 2023-2024	WITN7671004
March 2018	Organisational Duty of Candour guidance	WITN7671005
December 2019	Learning from adverse events through reporting and review	WITN7671006
January 2022	Adverse Events Notification System: Update Report	WITN7671007
May 2022	Adverse event reviews in healthcare: what matters to patients and their family? A qualitative study exploring the perspective of patients and family	WITN7671008