Witness Name: Peter May
Statement No:WITN7461007
Exhibit: WITN7461008
Dated: 13th September 2023

INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF PETER MAY

I provide this second statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 31 July 2023.

I, Peter May, will say as follows: -

Section 1: Response to Evidence

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 Department of Health in Northern Ireland, to this proposal. Please provide any further comments regarding Mr Bragg's proposals that you wish to provide.**

Response

1.1 Several public inquiries have made reference to the importance of workplace culture to support openness and reporting, in particular when things go wrong. Paragraph 6 of my previous statement to the Inquiry [WITN7461001] outlines the current position in relation to duty of candour and references the ongoing work of the Department of Health in Northern Ireland to develop proposals for a '*Being Open*' framework. This approach was the policy direction set by the last Minister of Health, Robin Swann MLA. Key aims of the '*Being Open*' framework include helping to ensure that Health and Social Care (HSC) staff will be fully empowered to exercise candour and openness, and to further assist organisations to have in place the necessary support and systems required to enable and realise a truly open culture.

1.2 The current procedure for the reporting and follow-up of Serious Adverse Incidents [WITN7461008] provides guidance to the Health and Social Care (HSC) system in Northern Ireland on the reporting, management, follow-up and learning following a Serious Adverse Incident (SAI). SAI reviews are conducted to identify learning from incidents that led, or could have led, to unintended and/or unnecessary harm, and to deliver system improvements.

1.3 Recommendations arising from several recent Inquiries and Reviews have provided a strong evidence base underpinning the need to refresh and redesign the current approach to learning following adverse and serious adverse events or incidents. As such, the Department is currently taking forward a project to review and refresh the current approach, which will take account of relevant Inquiry recommendations. This project will see the introduction of a new HSC policy framework to deliver learning and improvement from health and social care incidents across the HSC and will consider necessary oversight and assurance mechanisms at regional level.

1.4 While not a statutory requirement and, as such, a lower threshold than that proposed by Mr Bragg, HSC staff who are registered with professional regulators are already required to comply with a professional duty of candour.

1.5 The Inquiry will appreciate that Northern Ireland is currently operating without a NI Executive or a Minister of Health. Decision making is determined by reference to Westminster legislation in the form of the Northern Ireland (Executive Formation etc) Act 2022 and its successor.

In the absence of a Minister I am not able to offer a view on the likelihood of a health minister asking to promote this recommendation in future primary legislation.

Primary legislation is not possible in the absence of a NI Assembly, save in cases where the UK Parliament chooses to legislate and these have been highly unusual events to date.

The introduction of any statutory duty, such as that proposed by Mr Bragg, would be of such significance as to require referral to the Northern Ireland Executive under the Ministerial Code. This would require the NI Executive to be restored. Similarly, the creation of a new organisation charged with responsibility to collect, investigate and take action with respect to any new statutory responsibility such as that described would require referral to the NI Executive for consideration.

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 Department of Health in Northern Ireland, to this suggestion.

Response

2.1 There are currently a number of organisations which have a role or function in overseeing and assuring safety in relation to the health and social care system in Northern Ireland. These include for example Health and Social

Care (HSC) Trusts which are subject to a statutory duty of quality in relation to the service they provide to the public (The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003; Article 34). Other organisations which have a role or function in overseeing safety include professional regulators (such as the General Medical Council or Nursing and Midwifery Council); the system regulator (the Regulation and Quality Improvement Authority); other bodies (such as Medicines and Healthcare products Regulatory Agency who oversee the safety of medicines and medical devices; and the Health & Safety Executive who oversee safety in the workplace including healthcare premises) and the Department of Health.

2.2 We recognise that there may be some synergy between the recommendation for a Health and Social Care Safety Commissioner, referred to in Ms. Braithwaite's statement, and that from the Baroness Cumberlege in relation to a Patient Safety Commissioner [RLIT0001379] - with the former (Health and Social Care Safety Commissioner) having a wider proposed remit beyond medicines and medical devices. We note that it would be critical to be clear from the outset the remit of such a single body to ensure clarity and to avoid the risk of duplication and overlap.

2.3 The Department of Health's work to consider Baroness Cumberlege's recommendation for a Patient Safety Commissioner has been delayed due to the COVID-19 pandemic response and recovery. There is no existing policy endorsed by our last Minister.

2.4 Any recommendation made by the Inquiry to consider the creation of a single body responsible for overseeing the safety system for health and social care will be considered fully by the Department of Health. As previously set out, any final policy decision would require referral to the NI Executive under the Ministerial Code. This will require the Northern Ireland Executive to be restored.

3 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 Department of Health in Northern Ireland, to this suggestion. 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.

Response

3.1 In line with the SAI Process managed by the Strategic Planning and Performance Group (SPPG) within the Department of Health NI, working jointly with Public Health Agency (PHA), there is oversight of SAIs across Northern Ireland. Data from this process are collected by SPPG and recorded on the DATIX Risk Management system. This information is used by the Department of Health NI and the Public Health Agency (PHA) to identify patterns, clusters and trends using the DATIX Common Classification System to facilitate the identification of regional learning and continuous improvement efforts.

3.2 The Department via SPPG working jointly with PHA, disseminates regional learning from this process through various methods including learning letters, reminders of best practice, learning matters newsletters and learning events. Prior to a learning letter or reminder of best practice letter being issued, the appropriate level of assurance is agreed in relation to actions required by provider organisation and the timescale for providing this assurance to the Department via SPPG. On receipt, these assurances are reviewed by relevant professional officers within the Department and PHA to ensure they are adequate. When a safety alert circular is issued by a policy branch within the Department, the letter may also advise provider organisations of the need to provide the Department via SPPG with the required level of assurance within a required timescale.

3.3 Further investigations would be required to determine the extent to which these arrangements meet the approach put forward by Dr Benneyworth and whether they do so fully or partially. In the event that it is established that there is a need for something substantially different or additional, the Department would be likely to be supportive of this approach, but decisions which would likely require new investment would need to be considered alongside other spending commitments. These would normally be decisions for a Minister of Health to take.

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

Signed GRO-C: Peter May

Dated 13/09/2023

Exhibits

Title / Description	Exhibit number
Procedure for the reporting and follow up of Serious Adverse Incidents - 2016	WITN7461008