Witness Name: Briege Donaghy
Statement No.: WITN7673001
Exhibits: None
Dated: 20 June 2023

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF BRIEGE DONAGHY

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

I, Briege Donaghy, will say as follows: -

Section 1: Introduction

Please set out your name, address, date of birth and any professional qualifications relevant to the duties you discharge in the Regulation and Quality Improvement Authority (Northern Ireland).

1. Full Name: Briege Donaghy DOB: GRO-C 962

2. Address: Regulation and Quality Improvement Authority,
   James House, The Gasworks, Belfast, BT7 2JA

3. Professional Qualifications – No clinical qualifications

Please outline your employment history and any relevant positions that you have held.

4. Joined RQIA on 1 July 2021 as Chief Executive. Previously worked in health and social care across Northern Ireland since graduating from Queens University

Belfast in 1983 in Physics, and later MA in Health Informatics from Manchester University.

5. Prior to my appointment to RQIA, I worked within the Northern Health and Social Care Trust for 14 years where I held a number of Director positions, including most recently Director of Integrated Care and Partnership from October 2019

Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement.

6. None

Section 2: Response to Evidence

Please provide a brief outline of the role and responsibilities of the Regulation and Quality Improvement Authority (Northern Ireland).

7. The Regulation and Quality Improvement Authority (RQIA) is the independent regulator for Health and Social Care (HSC) in Northern Ireland (NI). RQIA's role and functions are set out in The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003[1](the 2003 Order), The Mental Health (Northern Ireland) Order 1986, The Health and Social Care (Reform) Act (Northern Ireland) 2009[2] (the 2009 Act) and the Mental Capacity (Northern Ireland) Act 2016[3]. Under section 5 of the 2009 Act the 2011 Department of Health Framework Document[4] describes the roles and functions of the various health and social care bodies and the systems that govern their relationships with each other and the Department.

[1] The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003. Cited: April 2021. Available from: https://www.legislation.gov.uk/nisi/2003/431/contents/made
[2] Health and Social Care (Reform) Act (Northern Ireland) 2009. Cited: April 2021. Available from: https://www.legislation.gov.uk/nia/2009/1/contents
[3] The Mental Capacity Northern Ireland) Act 2016
[4] Department of Health, Social Services and Public Safety (DHSSPS) Framework Document (September 2011). Cited: April 2021. Available from: https://www.health-ni.gov.uk/publications/dhssps-framework-document-september-2011

8. Under the 2003 Order, RQIA's mandate is to provide the NI Health Minister, through the Department of Health (DoH), with ongoing independent assessment of the quality, safety and availability of health and social care services in Northern Ireland services, and to encourage improvement in those services. It does so by registering, inspecting, reporting upon, and where necessary enforcing compliance with standards set by the Department of Health in respect of a range of health and social care services, provided by independent and in some cases (e.g. children's homes; care homes) statutory health and social care providers.

9. RQIA undertakes a range of responsibilities for people with mental ill health and those with a learning disability. Under the Mental Health Order, the RQIA has the duty of keeping under review the care and treatment of patients (as defined in the Order) and the exercise of the powers and the discharge of the duties imposed by the Order. In particular, RQIA has a role in safeguarding people against improper detention.

10. Given this role, RQIA has been designated as a part of the national preventive mechanism (or NPM) by the UK Government.

    It should be noted that RQIA does not (outside of the exceptions noted above) **register** providers of statutory Health and Social Care services in NI; and so does not have the enforcement powers which flow from registration in respect of statutory Health and Social Care providers.

11. In addition to RQIA inspection programmes, conducts a programme of reviews under Article 35 of the 2003 Order: following a Direction from the NI Health Minister in 2014, RQIA conducts a programme of unannounced Acute Hospital Inspections, and reports on these.

12. This Reviews Programme is an important mechanism by which RQIA carries out its core duty of keeping the DoH informed as to the quality, safety and availability of HSC services, and encouraging improvement in their quality.

13. RQIA assesses HSC services against minimum standards set by the DoH taking into consideration RQIA's four domains: whether services are Well Led; Safe; Effective; and Compassionate.

14. RQIA publishes its findings in inspection and review reports which are publicly available on its website. [Note: historically Reports in respect of Children's Services have not been published. This is in the process of change, following a public consultation.]

Please set out your response, from the perspective of the Regulation and Quality Improvement Authority (Northern Ireland), to this proposal. Please provide any further comments regarding Mr. Bragg's proposals that you wish to provide.

15. At the outset, the Regulation and Quality Improvement Authority RQIA would like to express its sincere sympathies to Mr Bragg and the other patients and families across the UK, who have been sadly impacted by the administration of infected blood or blood products. RQIA will consider any learning derived by the Infected Blood Inquiry that is relevant to our work as a regulator as we endeavour to secure the safety of HSC services in NI and drive continuous improvement in these services.

16. RQIA has considered Mr Bragg's proposals to create

(a) "a statutory responsibility for all employees in the NHS to form a report when serious injury or death has occurred which might have been preventable"; and
(b) "a new organisation within government who has responsibility to collect this information, to investigate incidents and to make sure that effective action has been taken".

17. In Northern Ireland Serious Adverse Incidents within Health and Social Care Services are reported and reviewed through the regional Serious Adverse Incident (SAI) process. This Regional guidance for the reporting and follow-up of SAIs in Northern Ireland has been in place since 2004 and sets out the circumstances which meet the criteria for a Serious Adverse Incident. Any

adverse event that meets the criteria for an SAI should be reported to SPPG (formerly Health and Social Care Board) within the Department of Health, within 72 hours of being discovered. These include adverse events where death or serious harm has occurred.

18. Deaths, which may have been preventable, may also be subject to a Coronial investigation; those which meet the threshold for Coronial referral are reported to the Coroner's Service in accordance with Section 7 of the Coroners Act, 1959 (Northern Ireland). In the circumstances of a work-related death, incidents are reported to the Health and Safety Executive for Northern Ireland (HSENI). Where there is suspicion of criminal wrongdoing in relation to an imprisonable offence, under the Criminal Law Act (Northern Ireland) 1967 there is a legal duty to inform the Police Service of Northern Ireland (PSNI). A DoH Memorandum of Understanding (MOU) Circular HSS (MD) 8/2013 is in place to support interagency liaison in circumstances of unexpected death or serious untoward harm requiring investigation by the PSNI, Coroners Service for NI or HSENI separately or jointly; the MOU promotes effective communication between the relevant organisations.

19. The SAI process is intended to review cases of harm, identify learning and make recommendations to avoid similar harm occurring in the future. Regional guidance for the reporting and follow-up of SAIs in Northern Ireland has been in place since 2004. SAI reviews are undertaken at a number of levels: Level 1, Level 2, Level 3. The level is assigned according to the complexity and extent of deficit in care and degree of system learning anticipated.

    · Level 1 SAI reviews are Significant Event Audits which are overseen solely at HSC Trust level.

    · Level 2 SAI reviews are Root Cause Analysis reviews undertaken by the HSC Trust but chaired by a chair who is independent of the service.

    · Level 3 SAIs are independent reviews which are chaired by individuals external to the HSC Trust.

20. Level 2 and Level 3 SAIs are overseen by a Designated Review Officer (DRO) working at regional level, either within the Strategic Planning Performance Group (SPPG) at DoH in NI or within the Public Health Agency.

21. As set out in Regional guidance for the reporting and follow-up of SAIs in Northern Ireland, there are SAIs which must also be notified to RQIA:

"- All mental health and learning disability SAIs reportable to RQIA under Article 86.2 of the Mental Health (NI) Order 1986.
- Any SAI that occurs within the regulated sector (whether statutory or independent) for a service that has been commissioned/funded by a HSC organisation."

22. Under the Provisions of Articles 86(2) of the Mental Health (NI) Order 1986, the Regulation & Quality Improvement Authority (RQIA) has a duty to make inquiry into any case where it appears that there may be ill treatment or deficiency in care or treatment in relation to a 'patient' (as defined in the Mental Health Order) suffering from Mental Disorder. Information from, and the findings/ recommendations of, an SAI may inform this role and our broader role under the 2003 NI Order at a system or service level.

23. Unlike in England, there is no discrete body such as Health Safety Investigation Branch (HSIB) to review Serious Adverse Incidents[5]. Whilst SPPG has oversight of the Terms of Reference, timescales and outputs of Level 2 and Level 3 SAI reviews, they are not involved in conducting the review. The Northern Ireland Adverse Incident Centre (NIAIC) operates as a function of the Department of Health (DoH) with the objective of taking all reasonable action within its remit to safeguard the health of HSC service-users and staff through the provision of a regional centre for the voluntary reporting and investigation of those adverse incidents involving medical devices, non-medical equipment, plant and building elements and for providing relevant safety guidance in relation to these items. It does not deal with clinical care and treatment adverse incidents.

[5] Health Safety Investigations Body (HSIB). Available at: https://www.hsib.org.uk/what-we-do/maternity investigations/

24. Over the last decade, the SAI process established in Northern Ireland, and its implementation, has come under significant scrutiny. The Donaldson Report in 2014 highlighted concerns around the reporting of adverse incidents, ineffective processes for review, lack of expertise amongst reviewers (particularly in relation to human factors) and a failure for learning to translate into improvements in systems and patient safety. Donaldson also outlined a need for a 'just culture' for healthcare staff participating in SAI reviews, in addition to a need for candour and openness with patients and families.

25. In 2018, Justice O'Hara published his report on the Inquiry into Hyponatraemia-related Deaths (IHRD) in Northern Ireland. It called for statutory duties of candour, with criminal sanctions for breach, for both organisations and for individuals. It made a number of recommendations in relation to reporting, investigating and sharing of learning from SAIs, including a need to increase the involvement of families in these processes. This served to further highlight a need for a review of the regional procedure for SAI investigations in Northern Ireland.

26. In April 2018, the RQIA was commissioned by the Department of Health (DoH) to examine the effectiveness of the current procedure for the Reporting and Follow-up of Serious Adverse Incidents (SAIs) (November 2016) and its implementation within Health and Social Care services and make recommendations for improvement. A final Terms of Reference for this work was agreed with the DoH in October 2019 and fieldwork on this review concluded in January 2021.

27. The Review of Systems and Processes for learning from SAIs in NI was published in July 2022. The Expert Review Team concluded that the current practice for investigating and learning from SAIs in Northern Ireland was failing to deliver on the intended purpose of the current regional policy.

28. The Report made five strategic recommendations:

1: The Department of Health should work collaboratively with patient and carer

representatives, senior representatives of Trusts, the Strategic Performance and Planning Group, Public Health Agency and Regulation and Quality Improvement Authority to co-design a new regional procedure based on the concept of critical success factors. Central to this must be a focus on the involvement of patients and families in the review process.

2: Health and Social Care organisations should be required to evidence they are achieving these critical success factors to the Department of Health.

3: The Department of Health should implement an evidence-based approach for determining which adverse events require a structured, in-depth review. This should clearly outline that the level of SAI review is determined by significance of the incident and the level of potential deficit in care.

4: The Department of Health should ensure the new Regional procedure and its system of implementation is underpinned by 'just culture' principle and a clear evidence-based framework that delivers measurable and sustainable improvements.

5: The Department of Health should develop and implement a regional training curriculum and certification process for those participating in and leading SAI reviews.

29. These recommendations aim to support significant reform and improvement in how the HSC system is learning from SAIs. Such reform will require a concerted commitment to both the co design of the regional procedure, and the how it is applied in practice. The development of the new process must be based on a collaborative approach that involves patients, families, victims, their families and the wider communities, given the importance of the SAI process as the learning tool for health and social care services, and for its role in giving families and others impacted by the event both an opportunity to be heard, and to understand fully what happened. It will also require a new approach embedded in 'just culture' principles, and both encourage and require openness and transparency.

30. RQIA recognises the importance of embedding a safety culture which encourages and supports staff to reports incidents of harm and near misses. A just and learning culture is essential to foster the openness and transparency required to maximise engagement of staff in incident reporting and review processes, ensuring that optimal learning is derived and, importantly, that the necessary steps are taken to improve the systems for delivery of care. This requires culture and behavioural change.

31. RQIA considers that a stepped approach should be considered in implementing measures which ensure mandatory reporting of incidents. Robust governance processes, underpinned by a strong safety culture where staff feel encouraged and supported to report incidents ("Being Open") may seem swifter and easier to implement than legislative requirements, the RQIA points to Justice O'Hara's conclusion that current measures (including requirements for candour in professional Codes) had proven ineffectual, and that statutory requirements for candour backed by criminal sanctions for breach were therefore necessary.

32. The Independent Hyponatremia Inquiry Implementation Programme, led by the DoH, considered both the Duty of Candour and the closely related "Being Open" recommendations; and an extensive consultation process was held during 2021 (https://www.health ni.gov.uk/consultations/duty-of-candour). This is referred to further below.

33. RQIA acknowledges the absolute importance of reporting and reviewing preventable serious harm, injuries and deaths. Deliberate under-reporting or mis-reporting cannot be tolerated; and the role of service regulation must be developed so that it encourages and supports honesty and openness from staff.

34. RQIA considers that reporting incidents is a first step in learning, and in preventing similar incidents occurring in future. It is essential that organisations and individuals are open and honest about the nature and extent of harms caused, any contributory factors, and the outcome of any processes undertaken to review or investigate the harms. The Inquiry into Hyponatraemia-related Deaths in NI drew into question the honesty of individual clinicians who gave

evidence. In his IHRD inquiry report, Justice O'Hara's recommended that there should be a statutory duty of candour in Northern Ireland. This lead to the DoH holding a public consultation on policy proposals for a Duty of Candour and also for a Being Open framework, as referred to earlier. These proposals for Duty of Candour included options for a statutory duty of candour for organisations and a statutory duty of candour for individuals, with criminal sanctions where those duties are breached.

35. Candour is essential in effective system regulation and in delivery of safe, effective care. In its response to the public consultation, RQIA indicated support for a statutory duty of candour for organisations and for the implementation of a Being Open Framework; noting that the approach to regulation in the health and social care system in Northern Ireland is based on a presumption of candour and honesty. RQIA also noted that that appropriate planning, training and resourcing is required. In relation to proposals for a Statutory Duty of Candour for Individuals, with criminal sanctions, RQIA's position was that this is a finely balanced decision that must first consider the ability to secure candour through already existing or enhanced processes and arrangements prior to resorting to the introduction of legislation. Other jurisdictions have opted not to introduce a statutory duty on candour for individuals on the basis that clinicians already have an ethical duty to be honest under their professional code of conduct, overseen by professional regulatory bodies, (although the efficacy of these arrangements is questionable) and that there may be unintended adverse consequences arising from the introduction of statutory requirements that attach criminal sanctions, although this is unproven.

36. In summary, RQIA considers that effective oversight and regulation for the purposes of reducing avoidable harm requires robust arrangements for incident reporting and incident review in order to derive system learning and implement improvement. All of these are best supported by the underpinning principles of openness, fairness and learning which underpin a just and learning culture. Any statutory requirement for reporting of incidents placed on individuals should be carefully considered in terms of necessity, practicality and impact on existing systems.

37. The establishment of a separate government body to collate information, investigate incidents and ensure that effective action has been taken may provide a degree of rigour, independent scrutiny, assurance and accountability for implementation of improvements. However, in Northern Ireland, preparatory work is underway to reform the SAI process in Northern Ireland, based on the recommendations of the SAI Review published by RQIA in 2022, was part of the Independent Hyponatremia Inquiry Implementation Programme. The reformed systems and processes will be required to be in drawn up collaboration with patients, families, victims, their families, staff and with the wider involvement of stakeholders. RQIA support this co-produced approach to determining the specifics of any new and effective system for the SAI process in Northern Ireland, including the supporting infrastructure and oversight aspects.

Statement of Truth

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

Signed GRO-C

Dated 20 June 2023