Witness Name: Peter May
Statement No.: WITN7461001
Exhibits: WITN7461002 - WITN7461006
Dated: 25 November 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PETER MAY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 21 October 2022.

I, Peter May, will say as follows: -

Section 1: Introduction

1 Please set out your name, address, date of birth and any professional qualifications relevant to the duties you discharge on behalf of the Northern Ireland government.

1.1 My name is Peter May (DoB GRO-C 1965). I am the Permanent Secretary in the Department of Health in Northern Ireland and am based in Castle Buildings, Stormont Estate, Belfast. I am the principal policy advisor to the Minister of Health and am the Department's Accounting Officer.

2 Please outline your employment history and the positions that you have held.

2.1 I was appointed to the role of Permanent Secretary in the Department of Health NI on 4 April 2022. Prior to taking up my current post, I served as Permanent Secretary in the Department for Justice. Previous roles include Permanent Secretary in the Department for Infrastructure and Department of Culture, Arts and Leisure.

3 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.

3.1 I am not, and have not been, a member of any committee, association, party, society or group relevant to the Inquiry's Terms of Reference.

4 Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations or criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products.

4.1 I have not provided evidence to, or have been involved in, any other inquiries, investigations or criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products.

Section 2: Public Health Structures

5 Please outline the public health structures and systems in Northern Ireland. Please explain how these have developed, how effective they

are (and in particular whether there are any gaps) and set out the arrangements for coordination with the other nations of the UK.

5.1 The Department of Health (DoH NI) has a statutory responsibility to promote an integrated system of Health and Social Care (HSC) designed to secure improvement in:

- the physical and mental health of people;
- the prevention, diagnosis and treatment of illness; and
- the social wellbeing of people in Northern Ireland.

Under the Health and Social Care (Reform) Act (Northern Ireland) 2009[1], the Department is required to:

- Develop policies;
- Determine priorities;
- Secure and allocate resources;
- Set standards and guidelines;
- Secure the commissioning of relevant programmes and initiatives;
- Monitor and hold to account its ALBs, and;
- Promote a whole system approach.

The Department discharges its duties both by direct Departmental action and through its Arm's Length Bodies (ALBs). Exhibit **WITN7461002** shows the structure of Health & Social Care (HSC) in Northern Ireland.

Background – how public health structures and systems in NI have developed

5.2 The National Health Service (NHS) is the shared name of three of the four publicly funded health care systems in the United Kingdom. In reality, only the English NHS is officially called the National Health Service. There are separate entities entitled NHS Scotland and NHS Wales. The integrated system in Northern Ireland is unique and is officially called *'Health and Social Care (HSC)'* rather than the NHS. In Northern Ireland, health and social care

[1] 2009 c. 1 www.legislation.gov.uk/nia/2009/1/contents

(HSC) services have been integrated since 1973. Integration provides the opportunity for comprehensive assessment of both health and social care needs and allows the Department and commissioners to plan services on the basis of Programmes of Care (POC). A single budget has also promoted the coherent development of objectives within a unified strategic planning process, which spans acute and community-based care. Since 1973 there have been a number of restructuring exercises. These include:

- Merger of the previous four health and social services boards into a single Health and Social Care Board (HSCB) pursuant to the Health and Social Care (Reform) Act (Northern Ireland) 2009. The HSCB was a statutory body which commissioned health and social care services from the Health and Social Care Trusts for the population of Northern Ireland.

- Establishment of the Public Health Agency (PHA) in April 2009. The PHA is charged specifically with promoting improvements in the general health and wellbeing of the people of Northern Ireland and works closely with other public services such as education and local government in a local community planning process. The PHA is a multi-disciplinary, multi-professional body with a regional and local presence, whose role is to address the causes and associated inequalities of preventable ill-health and lack of wellbeing. Prior to the establishment of the Public Health Agency in 2009, responsibility for health protection sat predominantly with the four geographical health and social services boards (HSS Boards) in Northern Ireland. Two surveillance centres also had a specialist epidemiological function (epidemiology is a distinct part/element of health protection) as part of the regions overall health protection service; these were (i) the Communicable Disease Surveillance Centre (CDSC) which was located on the Belfast City Hospital site, operating as a standalone unit and (ii) the healthcare associated infection surveillance unit located in the Royal Victoria Hospital.

- Creation of the new Strategic Planning and Performance Group (SPPG) within the Department in April 2022 following closure of the HSCB on 31 March 2022. The SPPG has largely undertaken the majority of the former functions of the HSCB. Working in conjunction with the PHA, SPPG commissions services to meet assessed need and promote general health and wellbeing. Exhibit **WITN7461003** shows the structures pre and post HSCB closure.

5.3 In October 2020, the then Health Minister Robin Swann approved a programme of work on the development of an Integrated Care System (ICS) model in NI[2]. This provides a blueprint for the future of planning and managing HSC services in Northern Ireland. This model aims to promote and enable improved integration, partnership working and collaboration both within and outside traditional HSC boundaries and allow us to tackle wider determinants of health and wellbeing. Once implemented it will deliver care on a population health-based needs approach with the person at the centre of the model.

Governance and accountability

5.4 Within the Department, the Resources and Corporate Management Group is responsible for (i) the allocation of finance to the health and social care bodies; and (ii) the implementation of organisational governance arrangements required in line with the DoF guidance and '*Managing Public Money Northern Ireland'* (MPMNI)[3].

5.5 In line with MPMNI requirements each HSC body has a Management Statement / Financial Memorandum (MS/FM) which details the framework of strategic control used by DoH NI to oversee its operations, financing and accountability and control, including the conditions under which any government funds are provided to it. As part of a Northern Ireland review of

[2] Future Planning Model - Targeted Stakeholder Consultation | Department of Health (health-ni.gov.uk)
[3] Managing Public Money Northern Ireland - Chapters (finance-ni.gov.uk)

ALB relationships undertaken by the Department of Finance these are due to be replaced with partnership agreements.

5.6 All of the HSC bodies, including the PHA, are accountable to the NI Assembly and, in my role as Permanent Secretary of the Department, I am responsible to the Minister and accountable to the NI Assembly for the Department's use of resources in carrying out its functions. I am supported by the Departmental Board, whose role is to advise me on the effective operation of the Department which includes the implementation of the ALBs assurance and accountability arrangements[4] within the Department.

5.7 In my role as Departmental Accounting Officer (defined within MPMNI), I am provided with an additional level of scrutiny by the Department's Audit and Risk Assurance Committee (DARAC) which advises, through the Departmental Board, on the quality of assurances it receives about strategic processes for risk management, governance, internal control and the integrity of financial statements. This Committee includes a number of members external to, and independent from, the Department.

5.8 Along with the ongoing engagement with HSC bodies, mid year and end year accountability review processes ensure both the robustness of the assurances provided and hold the bodies to account.

5.9 Aside from the formal processes, my officials and I have ongoing engagement with each of the bodies on various levels and I am confident that the arrangements in place provide effective governance and oversight. The system allows for prompt escalation of issues and efficient dissemination of information and we have strong productive relationships with each of our HSC bodies.

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4 www.health-ni.gov.uk/sites/default/files/publications/health/doh-code-conduct-accountability-hsc-bodies.pdf

Public Health Agency Reshape and Refresh

5.10 In March 2022, the then Health Minister Robin Swann gave approval to proceed with a review of the Public Health Agency (PHA), building on the work of the Hussey Review [exhibit **WITN7461004**] to enable it to fulfil its critical role to secure health improvement and health protection for the population of Northern Ireland, as well as contributing professional public health advice and the necessary professional leadership to the new and developing integrated process for commissioning care. The Report on the review *'Final Report - Programme to Reshape and Refresh the Public Health Agency (Phase 1)'* [exhibit **WITN7461005**] was finalised in September 2022. The findings of the review identified opportunities for improvement across five key themes: (i) functions and structure, (ii) governance and accountability, (iii) people and development, (iv) culture and communications and (v) data and Innovation. Phase 2 of the review (implementation of the recommendations) has been approved to begin in mid-November 2022, with funding secured to complete the first phase (Phase 2a) which is of 6 months duration. Subject to securing the remaining required resource, the entire implementation phase is anticipated to take approximately 14 months to complete.

Four nations coordination

5.11 As health and social care are devolved matters, the extent to which the Department aligns policy with the other UK nations is at all times a decision for the NI Health Minister.

5.12 There are a number of mechanisms, both formal and informal, that allow for the sharing of information, co-ordination, and shared approaches to a range of public health issues at the policy level. At official level, four-nations groups have facilitated productive working relationships on public health issues such as substance use, tobacco control, obesity, sexual health, inequalities, suicide and self-harm prevention. From briefing provided by departmental policy leads, I have noted that there has been effective four-nations co-operation on

health protection and food safety regarding the use of certain additives to food, such as folic acid and on emergency preparedness, resilience and response, as well as UK-wide collaboration on tackling Anti-Microbial Resistance (AMR). Departmental officials have reported that in recent years there has been good co-operation across the four UK nations on policy matters such as blood safety, screening and vaccinations and immunisations policy. Whilst these arrangements are informal, they have formed around the various expert committees - National Screening Committee, Advisory Committee on the Safety of Blood, Tissues and Organs (SABTO) and the Joint Committee on Vaccinations and Immunisations (JCVI). There is a formal service level agreement (SLA) on vaccine procurement. Four-nations collaboration continued throughout the COVID-19 pandemic.

5.13 The UK Health Security Agency (UKHSA) facilitates constructive four-nations coordination in relation to specific policy areas where it operates on a UK-wide basis. Depending on the policy area, UKHSA may chair these meetings or in some cases there will be a rotating chair. A new UKHSA Devolved Government (DG) Strategic Board has been established at the request of the Devolved Administrations to provide a strategic overview of the entirety of UKHSA's work insofar as it relates to the DAs. This Board, which had its first meeting in November 2022, will further ensure that there are opportunities to consider collaboration on a four-nations basis across UKHSA's remit.

5.14 Prior to the establishment of UKHSA, the Joint Biosecurity Centre (JBC[5]) provided a forum for meaningful four-nations collaboration throughout the COVID-19 pandemic. Close working relationships between the four-nations has enabled product development engagement and understanding in key areas of public health interest, such as collaboration on wastewater, which allowed the sharing of approaches and early findings and learning as each nation developed its surveillance systems. In addition, Agency Agreements between each (DA and JBC allowed JBC to access and use DA data to produce a UK-wide Alert level for the pandemic which the four CMOs reviewed and agreed. The role of JBC has now been subsumed within

[5] www.gov.uk/government/groups/joint-biosecurity-centre

UKHSA and the Agency Agreements have been extended to allow this important data-sharing arrangement to continue.

5.15 At a ministerial level there are regular UK Ministerial summits on drug use to which both the Health and Justice Ministers are invited, so that Ministers can share ideas and knowledge across the four administrations. There is an Inter-ministerial Group on Health and Social Care which can be used as a forum to discuss escalated UKHSA-related issues. The British-Irish Council (BIC) includes a specific workstream on alcohol and drugs, which is chaired by the Irish Government and allows all member administrations to learn from the experience and good practice of others.

5.16 With the UK's exit from the EU, it was recognised that there was risk of policy and legislative divergence across the UK as a result of certain common EU obligations falling away or remaining in place in NI due to the NI Protocol. As a result, a number of 'Frameworks' were established to provide a formal mechanism to manage potential divergence. The Blood Safety and Quality Common Framework [**WITN7306004**[6]] was agreed to facilitate structured discussion across the UK, with an extant four-nations blood safety group used as the forum for discussion. The Health Protection and Health Security Common Framework[7] was established primarily to replace EU legal obligations for all nations to share certain information on infectious diseases of international concern. With the EU legislation revoked[8], there was a need to legislate centrally on devolved areas to ensure that the Department for Health and Social Care (DHSC) in London had legal certainty to negotiate on behalf of the UK to access certain EU databases and to meet the UK's obligations under the International Health Regulations 2005. The legislation establishes the Health Protection Committee to, among other things, supervise the operation of the Framework. The Committee is led by the Four-Nations' Health Departments, supported by their public health agencies.

6

7 Public Health Protection and Health Security Framework Outline Agreement

8 The Health Security (EU Exit) Regulations 2021 (legislation.gov.uk)

5.17 As Permanent Secretary for the Department of Health in Northern Ireland, I reached out to my counterparts on taking up post and held individual virtual meetings with each of them and have followed that up with further engagement with my counterparts in Scotland and Wales on specific issues.

NI Public Health Structures and Systems

5.18 The Health and Social Care system in Northern Ireland is under considerable stress. The structures and systems are broadly effective, but all systems under constant pressure face increased risks of significant failures. Every effort is being made to mitigate those risks using the mechanisms described above.

Section 3: Statutory Duty of Candour

6 The Inquiry understands that Justice O'Hara in the Hyponatraemia Inquiry Report made a recommendation for a statutory duty of candour. Please outline the Department of Health Northern Ireland's response to this.

The Inquiry into Hyponatraemia-related Deaths

6.1 In January 2018, the report of the Inquiry into Hyponatraemia-related Deaths (IHRD)[9] recommended the introduction in Northern Ireland of a statutory duty of candour for healthcare organisations and everyone working for them, with criminal sanctions attached for breach. There were also recommendations regarding the guidance, support and protection that should be provided for staff to create a more open culture.

6.2 As part of the IHRD implementation programme established by DoH NI, the Duty of Candour Workstream, and its Being Open Sub-Group, were set up to

[9] http://www.ihrdni.org/inquiry-report.htm

take forward the recommendations relating to candour and openness. Significant work has been taken forward, including public engagement.

6.3 DoH NI is continuing to develop the policy for a *'Being Open Framework'* for our HSC system. Initial work on the *'Being Open Framework'* is focusing on the development of a pilot exercise in a HSC Trust.

6.4 DoH NI officials are also carrying out further study on how a duty of candour might work in practice, including additional analysis of the impact of such a duty on the health and care service, both legally and in workforce terms.

7 Please also set out your understanding as to why such a statutory duty has not yet been implemented in Northern Ireland, given that it is in place in England and Scotland.

7.1 The introduction of any statutory duty of candour would be of such significance as to require referral to the Executive under the Ministerial Code. This will require the Northern Ireland Executive to be restored.

Section 4: Health and Social Care

8 Please explain the purpose of *'Quality 2020 - a ten-year strategy to protect and improve quality in health and social care in Northern Ireland'* [DHNI0001507] and set out where the strategy has had a measurable impact on patient safety.

8.1 *'Quality 2020'* has been the strategic driver for improving Quality, Safety and Experience of HSC in Northern Ireland since 2011. In line with the implementation of the Strategy, all activity under the following strategic goals was considered as a contributor to improving safety and quality of care:

- transforming culture;
- strengthening workforce;

- raising standards;
- measuring improvement, and;
- integrating the care.

8.2 Each HSC body publishes a yearly Quality Report. These reports highlight the initiatives within each organisation which improved quality and safety of care and ultimately the associated impact on patient safety.

8.3 Throughout the lifespan of the strategy a number of key tasks have been undertaken which have also had a measurable impact on patient safety in Northern Ireland. Some examples include:

- the development of the Quality 2020 attributes framework and subsequent alignment of quality improvement programmes, which created a systematic Quality Improvement training programme for Northern Ireland which through its delivery ultimately increased professional leadership and focused on improving patient safety, and;
- the human factors and simulation-based education task group, which improved patient safety through establishing a collaborative network (Northern Ireland Simulation and Human Factors Network) which encouraged open discussion, provided support and shared learning and best outcomes across institutional and professional boundaries. As part of its work programme members piloted a number of multi-disciplinary training programmes relating to debriefing and human factors and delivered training to HSC staff.

8.4 Whilst no formal evaluation of the Q2020 Strategy has yet been undertaken, it has succeeded in encouraging quality improvement initiatives to take place where it is most needed and as a result improve treatment, care, safety and service quality for service users.

Section 5: Patient Safety and Involvement

9 Please outline the Northern Irish Government's response to Baroness Cumberlege's recommendation for a Patient Safety Commissioner [RLIT0001833].

9.1 While the focus of Baroness Cumberlege's report *'First Do No Harm'* was on the healthcare system in England, in July 2020 the then NI Health Minister confirmed that DoH NI would consider each of the recommendations in the local context. A written Ministerial Statement on progress of work undertaken up to February 2022 on the recommendations of this report was provided to the Northern Ireland Assembly in February 2022[10].

9.2 The Department of Health's work on the recommendation for a Patient Safety Commissioner has been delayed by its necessary work in responding to the COVID-19 pandemic.

10 How are patients involved in (i) the development of healthcare policies and (ii) in the way in which healthcare services are delivered, in Northern Ireland? Please explain how this is achieved, and how effective this is. How well, in practice, does patient involvement shape policy and services in Northern Ireland?

Background

10.1 Under section 19(2) of the Health and Social Care (Reform) Act (NI) 2009, the Department and HSC bodies must have published their own consultation scheme setting out what arrangements they have in place to ensure that the Patient and Client Council (PCC) and the public are involved in, and consulted on, policy matters relating to the planning and delivery of HSC services. The Department published its *'Personal and Public Involvement Consultation Scheme'* [exhibit **WITN7461006**] in 2015 and it sets out how the Department

[10] Department of Health - The Independent Medicines and Medical Devices Safety Review (niassembly.gov.uk)

will involve and consult patients, clients, carers and the PCC about policies and strategies which it develops, implements, and reviews.

10.2 In 2018, the Department launched the Co-Production Guide *'Connecting and Realising Value through People*[11]*'.* This guide sets out co-production ambitions, benefits and pathways to achieve them and looks to the next stage of evolving and embedding the partnerships and processes that will create the conditions for collaboration and inclusiveness within the HSC system.

10.3 There are numerous ways service users and carers can become involved. Some examples are:

- Patient Client Council (PCC) Membership Scheme
- Public Health Agency (PHA) Engage website
- Northern Health and Social Care Trust
- Belfast Health and Social Care Trust
- South Eastern Health and Social Care Trust
- Western Health and Social Care Trust
- Southern Health and Social Care rust
- Northern Ireland Ambulance Service
- Regulatory and Quality Improvement Agency
- NI Blood Transfusion Service

10.4 There are also different mechanisms for patient feedback including *'Care Opinion'*[12] which was launched in 2020 and *'10,000 more voices'* [13]*.*

10.5 Some recent examples of service users and carers being involved in Departmental policy workstreams either as members of the workstream or performing the role of co-chairs are:

- The Cancer Strategy;
- IHRD workstreams;

[11] Co-Production Guide for Northern Ireland - Connecting and Realising Value Through People | Department of Health (health-ni.gov.uk)
[12] Northern Ireland | Care Opinion
[13] 10000 More Voices (hscni.net)

- Enhancing Clinical Care in Care Homes project;
- Intermediate Care (Phase 1 Regional Model);
- Integrated Care Systems.

10.6 The Department funds PPI and Partnership working officers in the PHA, the PCC and the Trusts to support patient and carer involvement in decisions being made about Trust service provision and redesign of services. The Department has also funded training courses to help build capacity for service users and carers to contribute at a strategic level. This can be accessed via the PCC and PHA.

10.7 In January 2017 Queen's University Belfast carried out a piece of research called '*Personal and Public Involvement (PPI) and its impact*'[14] which outlines ten key recommendations to further support service user and carer involvement.

10.8 There are a set of standards for PPI and an associated monitoring framework. The Public Health Agency was tasked by the Department in 2012 via a PPI circular to take forward the monitoring of PPI within HSC and provide assurance to the Department in respect of the Trusts complying with their statutory responsibilities in regard to PPI.

10.9 The Department plans to carry out a review of PPI policy. This had been due to begin in 2020 however has been deferred due to Covid-19.

Section 6 – other relevant information

11 Other information you may have that is relevant to our Terms of Reference.

11.1 I note that the Expert Report on Public Health and Administration [**EXPG0000048**] makes some observations regarding the role of the Private Office and the extent to which Private Office civil servants decide which

[14] Personal and Public Involvement (PPI) and its impact | HSC Public Health Agency (hscni.net)

submissions are referred to the Minister for decision. Whilst this may be a practice in Whitehall Departments, it is not the case in the Department of Health, where standard practice is that the Minister sees all submissions sent from Departmental policy leads to the Private Office whether the matter is for decision or simply to note.

Statement of Truth

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

Signed GRO-C

Dated __25/11/22_____

Annex A

Table of exhibits

Title / Description	Exhibit number
Structure of Health & Social Care (HSC) in Northern Ireland	WITN7461002
Structures of HSC in NI pre and post HSCB closure	WITN7461003
Hussey Review (Dec 2020)	WITN7461004
Final Report - Programme to Reshape and Refresh the Public Health Agency (phase 1) (Oct 2022)	WITN7461005
Personal and Public Involvement Consultation Scheme (Jan 2015)	WITN7461006