Witness Name: Dr Sean O'Kelly
Statement No.: WITN7624002
Exhibits: WITN7624003 - WITN7624018
Dated: 15 June 2023

INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF
DR SEAN O'KELLY ON BEHALF OF THE CARE QUALITY COMMISSION

I provide this statement in response to a request under Rule 9(1) and (2) of the Inquiry Rules 2006 dated 3 March 2022 and further to my statement of 12 January 2023.

I, Dr Sean O'Kelly, will say as follows: -

Section 1: Introduction

1. I am Dr Sean O'Kelly, of the Care Quality Commission ('CQC'). I have been the Chief Inspector of Healthcare since June 2022. In my roles I oversee the outcomes of regulatory inspection activity and provide strategic guidance to CQC leadership. I am also CQC's Caldicott Guardian.

2. I declare no membership of committees, association, parties, societies or groups relevant to the Inquiry's Terms of Reference.

3. I have no previous involvement in any other inquiries, investigations or criminal or civil litigation in relation to human immunodeficiency virus ("HIV") infections and/or variant Creutzfeldt-Jakob disease ("CJD") in blood and/or blood products.

Section 2: Response to Evidence

Q1. Please provide a brief outline of the role and responsibilities of the Care Quality Commission.

1. In relation to an outline of CQC's role and responsibilities, I refer you to my written statement dated 12 January 2023 [WIT7624001].

Q2. 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 Care Quality Commission, to this proposal. Please provide any further comments regarding Mr. Bragg's proposals that you wish to provide.

2. Mr Bragg proposed:
   a. "A statutory responsibility be created to require all employees within the NHS to formally report when serious injury or death has occurred during the treatment of an individual which may have been preventable"
   b. A new organisation is created with the responsibility to collect, investigate and take action with respect to the new statutory responsibility to report preventable serious injury or death.

3. Given the proposal stipulates a statutory responsibility on **individuals**, it is suggested that Professional Standards Authority and / or the individual professional body regulators are contacted for their views on this proposal, including the extent to which is it is currently included in their codes of practice. However, this will only relate to registered healthcare professionals, as opposed to all staff.

4. CQC is the independent regulator of health and social care in England and as such regulates **registered persons** (i.e. registered providers and registered managers) of health and social care services, as opposed to the individuals employed within them (see: WITN7624003). There are provisions within CQC's regulations regarding the reporting and investigation of incidents where there is significant overlap with the witness's proposal. Paragraphs 6-9 describe the existing responsibilities for the reporting of incidents. Paragraphs 10-12 cover the existing responsibilities for the investigation of, and learning from, incidents.

5. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014[1] set out fundamental standards that apply to all registered persons (providers and managers) registered with the CQC that carry on regulated activities. The intention of Regulation 12: Safe Care and Treatment is to prevent people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm. It states:

   12(1) Care and treatment must be provided in a safe way for service users; including:

   12(2)(a) Assessing the risks to the health and safety of service users of receiving the care or treatment

   12(2) (b) Doing all that is reasonably practicable to mitigate any such risks

6. CQC guidance on 12(2)(b) [WITN7624004] states:

   a. Incidents that affect the health, safety and welfare of people using services must be reported internally and to relevant external authorities/bodies. They must be reviewed and thoroughly investigated by competent staff, and monitored to make sure that action is taken to remedy the situation, prevent further occurrences and make sure that improvements are made as a result. Staff who were involved in incidents should receive information about them and this should be

[1] [SI 2014/2936]

shared with others to promote learning. Incidents include those that have potential for harm.

b. Outcomes of investigations into incidents must be shared with the person concerned and, where relevant, their families, carers and advocates. This is in keeping with Regulation 20, Duty of candour

   The duty of candour requires registered providers and registered managers to act in an open and transparent way with people receiving care or treatment from them. The regulation also defines 'notifiable safety incidents' [WITN7624005] and specifies how registered persons must apply the duty of candour if these incidents occur.

c. There must be policies and procedures in place for anyone to raise concerns about their own care and treatment or the care and treatment of people they care for or represent. The policies and procedures must be in line with current legislation and guidance, and staff must follow them.

7. There are specific statutory notifications that all providers must make to CQC in relation to certain events and incidents. For NHS trusts and NHS foundation trusts some of these notifications can be made via a national reporting system (currently known as the National Reporting and Learning System (NRLS) but transitioning to a new system known as Learning from Patient Safety Events (LFPSE)). The national patient safety team at NHS England are the data controllers of these systems.

8. In relation to the witness' proposal, whilst the route of notification may vary between NHS trusts / NHS foundation trusts and other providers, under the Care Quality Commission (Registration) Regulations 2009 [WITN7624006] **all** registered providers must notify CQC of the following incidents.

   Regulation 16 – Notification of death of service user (NHS trusts and NHS foundation trusts can notify via NRLS)

- Registered persons must notify CQC without delay of the death of a service user whilst services were being provided in the carrying on of a regulated activity; or which has, or may have, resulted from the carrying on of a regulated activity.

Regulation 17 – Deaths and unauthorised absences of peopled detained or liable to be detained under the Mental Health Act 1983. [WITN7624007]

- Registered persons must notify CQC without delay of the death of a service user detained (or liable to be detained) under the Mental Health Act 1983.

Regulation 18 - Serious injuries to people who use the activity [WITN7624008] (NHS trusts and NHS foundation trusts can notify via NRLS)

- Registered persons must notify CQC about:

(a) Any injury to a service user which, in the reasonable opinion of a healthcare professional, has resulted in:
    i. An impairment of the sensory, motor or intellectual functions of the service user which is not likely to be temporary
    ii. Changes to the structure of a service user's body
    iii. The service user experiencing prolonged pain or prolonged psychological harm or
    iv. The shortening of the life expectancy of the service user

(b) Any injury to a service user which, in the reasonable opinion of a healthcare professional, requires treatment by that, or another, healthcare professional in order to prevent:
    i. The death of the service user
    ii. An injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a)

9. As set out in CQC's guidance for Regulation 12: Safe care and treatment, the registered provider has responsibility to investigate incidents. The national

patient safety team at NHS England are the owner of the frameworks that NHS trusts and NHS foundation trusts must comply with in this regard. Currently, trusts are transitioning from the Serious Incident Framework (SIF) [WITN7624009] to the Patient Safety Incident Response Framework (PSIRF) [WITN7624010]. PSIRF is a contractual requirement under the NHS Standard Contract and as such is mandatory for all services provided under that framework – including NHS funded care provided by an independent organisation. Primary care providers may also wish to adopt PSIRF, although it is not a requirement at this stage.

10. In addition to the investigations carried out by providers, in April 2015 CQC assumed additional responsibility for enforcement in respect of health and safety related serious incidents concerning people using services in health and social care settings in England. Regulation 22 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 [WITN7624011] makes it an offence for a registered person to fail to comply with Regulations 12 (1), 13 (1)-(4) or 14 (1) where such failure results in:
(a) Avoidable harm (whether of a physical or psychological nature) to a service user; or
(b) A service user being exposed to a significant risk of such harm occurring

Criminal enforcement can arise from a single specific incident where the incident and resulting harm provides evidence of a serious breach of a prosecutable regulation by the Registered Person / Provider. It is a defence for the registered person to provide that they took all reasonable steps and exercised all due diligence to prevent the breach.

11. The Healthcare Safety Investigation Branch (HSIB) carry out national investigations [WITN7624012] designed to improve patient safety on a national level across the NHS. These national investigations do not replace local investigations within trusts. However, if HSIB feel that a serious incident ('reference event') presents a wider safety risk across the NHS, then they can investigate the incident in depth. Safety recommendations are made at a national level.

HSIB also carry out maternity investigations [WITN7624013], carrying out approximately 1,000 independent investigations a year. All NHS trusts and NHS foundation trusts with maternity services in England refer incidents to HSIB for investigation. From October 2023, the maternity investigations programme will be hosted by the CQC. This is to ensure the continuation of the maternity programme and maintain the independence of maternity investigations within the NHS.

HSIB should be contacted for further information on these programmes and the transformation programme to become the Health Services Safety Investigations Board (HSSIB), with powers set out under the Health and Care Act 2022.

Q3. 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 your response, from the perspective of the Care Quality Commission, to this suggestion.

12. The witness statement discusses the need for the establishment of a single body responsible for overseeing the safety system for health and social care. This consists of three elements:
    a. A function for coordinating the setup, collating the outputs, and following up on the recommendations of public inquiries and investigations,
    b. A function for collating and reviewing risk data gathered by other organisations,
    c. A function for making recommendations for addressing identified risks in patient safety systems and gaps in gathering data.

13. We agree that the landscape of safety oversight of healthcare is fragmented, with many bodies having a specific legal or regulatory remit. There is likely to

be significant overlap of the proposed functions of a Health and Social Care Safety Commissioner with these existing roles and responsibilities. As set out in part 2 of this response for example, in relation to incidents, professional regulators take the lead in terms of individual responsibilities, CQC in terms of reporting and HSIB (at least for NHS funded care) in terms of systemic recommendations.

14. There would need to be consideration given to the value of adding another organisation into this landscape, as opposed to improving and strengthening coordination and clarification of existing responsibilities. This should include consultation with stakeholders, and the identification and appraisal of different options to the issues identified. It would need to be clear exactly how a new organisation could address the issue highlighted in Safer Care for All [WITN7624014] that *"the approach of individual organisations with specific remits being expected to work together to address safety issues is structurally flawed as there is no accountability for joint working and collaboration".*

15. In relation to the proposals made around intelligence and data, consideration should also be given to issues – other than the lack of a single overarching body – that impact on data sharing. For example, recommendation 11 of the report of the independent inquiry into the issues raised by Paterson [WITN7624015] was:

We recommend that the government should ensure that the current system of regulation and the collaboration of the regulators serves patient safety as the top priority, given the ineffectiveness of the system identified in the inquiry.

This recommendation was accepted by DHSC and, as part of the response to the recommendation [WITN7624016]a shared data platform was developed by CQC, GMC and NMC to identify potential concerns based on pooled data. However, this platform, for legal and contractual reasons, can only be accessed by the above three organisations.

16. Safety oversight and support are very much focused on NHS funded healthcare, with research identifying 126 organisations who exert some regulatory influence on NHS provider organisations [WITN7624017]. However, there is less oversight and support outwith CQC for independent healthcare, and less again for adult social care services. This is reflected in the commitments set out in the Safety through Learning ambition of CQC's Strategy [WITN7624018]:

"It's crucial that all health and care services have consistent access to the right support and insight to help them build strong safety cultures, learn from safety and safeguarding incidents, and improve their practice. We'll work with others to develop solutions to ensure that all services have support and leadership during difficult times, and they have the right tools to always provide safe care. We'll need to understand where this oversight is best placed and develop the right frameworks as needed."

CQC are currently developing a programme of work to:

a. provide a comprehensive outline of the support and insight available to all health and case service to help them build strong safety cultures, learn from safety and safeguarding incidents, and improve their practice.
b. set out how CQC will use its influence to help fill the gaps identified.

The impact of the proposed new role across the entirety of the Health and Social Care would therefore also need careful consideration.

Statement of Truth

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

Signed GRO-C

Dated __15 June 2023__

Table of exhibits:

05/2022	The Scope of Registration	WITN7624003
13/06/2023 (web accessed)	Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 12	WITN7624004
13/06/2023 (web accessed)	Duty of candour: notifiable safety incidents	WITN7624005
13/06/2023 (web accessed)	Care Quality Commission (Registration) Regulations 2009	WITN7624006
13/06/2023 (web accessed)	Regulation 17 – Deaths and unauthorised absences of people detained or liable to be detained under the Mental Health Act 1983	WITN7624007
13/06/2023 (web accessed)	Regulation 18 – Serious injuries to people who use the activity	WITN7624008
05/04/2023 (web accessed)	Serious Incident framework	WITN7624009
13/06/2023 (web accessed)	Patient Safety Incident Response Framework	WITN7624010
13/06/2023 (web accessed)	Regulation 22 of the Health and Social Care Act 2008 Reg 2014	WITN7624011
13/06/2023 (web accessed)	National Investigations	WITN7624012
13/06/2023 (web accessed)	Maternity Investigations	WITN7624013
13/06/2023 (web accessed)	Safer Care for All – solutions from professional regulation and beyond	WITN7624014
13/06/2023 (web accessed)	Report of independent inquiry into the issues raised by Paterson	WITN7624015
13/06/2023 (web accessed)	Government response to independent inquiry to the inquiry reports into the issues raised by former surgeon Ian Paterson	WITN7624016
13/06/2023 (web accessed)	Patient safety regulation in the NHS: mapping the regulatory landscape of healthcare	WITN7624017
13/06/2023 (web accessed)	A new strategy for the changing world of health and social care – CQC's strategy from 2021	WITN7624018