Witness Name: Dr Sean O'Kelly
Statement No.: WITN7624001
Dated: 12 January 2023

INFECTED BLOOD INQUIRY

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 of the Inquiry Rules 2006 dated 16 April 2021.

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

Section 1: Introduction

1. I am Dr Sean O'Kelly, of GRO-C Oxfordshire, GRO-C I was born on GRO-C 1960.

2. My professional qualifications relevant to the Inquiry are:
   - BSc (Psychology) from University of Bristol (1981)
   - MBChB, University of Bristol (1984)
   - MSc (Strategic Management) University of Bristol (2008)
   - Diploma in Child Health, Royal College of Physicians (1989)

- Fellow of the Royal College of Anaesthetists (by examination), Royal College of Anaesthetists (1991)

3. I am Chief Inspector of Hospitals, and Interim Chief Inspector of Primary Medical Services at the Care Quality Commission. I was appointed in 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.

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

5. I have no previous involvement 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

6. The Care Quality Commission ('CQC') is the independent regulator of health and social care in England. CQC was established by the Health and Social Care Act 2008 ('the Act'). CQC began regulating services in April 2009 and took on responsibility for regulating NHS hospital trusts in April 2010. Prior to this, varying responsibilities were held by CQC's predecessor bodies: The Commission for Healthcare Improvement (1999-2003), and The Healthcare Commission (2003-2010).

7. CQC makes sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage services to improve. CQC's role incorporates:

   - Registration of care providers
   - Monitoring, inspection and rating of services

- Taking action to protect people who use services
- Speaking with our independent voice, publishing our views on major quality issues in health and social care

8. People using health and care services have a right to expect that registered providers will securely maintain accurate, complete and contemporaneous records about their care and treatment. This is reflected in the Fundamental Standards that form the foundation of CQC's regulatory framework. CQC's statutory guidance describes what all registered providers should do to meet this standard and reflects the range of topics that providers should consider to ensure their practice is fit for purpose.

9. CQC's statutory guidance draws on and is applied alongside frameworks operated by other organisations. These include the health professions regulators and the Information Commissioner who all play complementary roles in regulating the storage, access and accuracy of patients' records. We have memoranda of understanding with these regulators to support effective working relationships in regulating medical records and information management.

10. We have reflected on the presentation prepared by Counsel to the Inquiry on the issues that have arisen from the written and oral evidence the Inquiry has received from the infected and affected, in respect of medical records (INQY0000378) and the questions posed against that background.

11. Without in-depth interrogation of our data sources and inspection records we do not feel able to offer a view on the sufficiency or otherwise of the overall current framework governing medical records (including storage of medical records, access to medical records and accuracy of medical records). Additionally, we are not able to comment on the approach taken by other regulators with responsibilities in this area across the UK or matters beyond our regulatory remit.

12. This statement seeks to provide an outline of the legislative basis of CQC's regulation of registered health and care providers' activity around medical records, and how the powers given to CQC are delivered in practice today.

13. We would be happy to expand on anything below for the benefit of the Inquiry.

Registered providers and Fundamental standards

14. The Act gives CQC powers to monitor, inspect and regulate health and social care providers when they carry out a Regulated Activity as described in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.[1]

15. When providers register with CQC they are required to comply with the fundamental standards set out in Part 3 Section 2 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 when it carries out a regulated activity.

16. Regulation 17(2)(c) sets a fundamental standard for registered providers around good governance of medical records. This states:

Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part.
Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to…
…maintain securely an accurate, complete and contemporaneous record in respect of each service user, including a record of the care and treatment

[1] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Available at: https://www.legislation.gov.uk/uksi/2014/2936/contents

provided to the service user and of decisions taken in relation to the care and treatment provided.

17. Alongside this explicit reference to medical records, other fundamental standards in Part 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 relate to the recording of information about a person's care and treatment, such as Person-centred care (regulation 9), Need for consent (regulation 11) and Safe care and treatment (regulation 12). For example, in delivering patient-centred care, registered providers must ensure the care and treatment of people using services is appropriate, meets their needs and reflects their preferences. Regulation 9(3)(g) requires the provider to provide the 'relevant person' with information they would reasonably need to understand their treatment choices and participate in decisions about their care, which could include access to medical records.

18. Prospective providers and managers must demonstrate to CQC that they will be able to meet the requirements set out in the fundamental standards when they register and that they will continue to meet them once registered.

CQC's statutory guidance

19. CQC publishes statutory guidance under regulation 21 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 to support providers' compliance with the standards. Registered providers must have regard to this guidance and CQC must take the guidance into account when making regulatory decisions (Section 25(1) of Health and Social Care Act 2008).

20. CQC's statutory guidance relating to Regulation 17(2)(c)[2] sets out details on how the fundamental standard can be met. This guidance sets expectations around the issues discussed in the Counsel's presentation to the Inquiry.

[2] Regulation 17. Good Governance. Available at: RLIT0001940

- *Records relating to the care and treatment of each person using the service must be kept and be fit for purpose. Fit for purpose means they must:*
    - *Be complete, legible, indelible, accurate and up to date, with no undue delays in adding and filing information, as far as is reasonable. This includes results of diagnostic tests, correspondence and changes to care plans following medical advice.*
    - *Include an accurate record of all decisions taken in relation to care and treatment and make reference to discussions with people who use the service, their carers and those lawfully acting on their behalf. This includes consent records and advance decisions to refuse treatment. Consent records include when consent changes, why the person changed consent and alternatives offered.*
    - *Be accessible to authorised people as necessary in order to deliver people's care and treatment in a way that meets their needs and keeps them safe. This applies both internally and externally to other organisations.*
    - *Be created, amended, stored and destroyed in line with current legislation and nationally recognised guidance.*
    - *Be kept secure at all times and only accessed, amended, or securely destroyed by authorised people.*
- *Both paper and electronic records can be held securely providing they meet the requirements of the Data Protection Act 2018.*
- *Decisions made on behalf of a person who lacks capacity must be recorded and provide evidence that these have been taken in line with the requirements of the Mental Capacity Act 2005 or, where relevant, the Mental Health Act 1983, and their associated Codes of Practice.*

- *Information in all formats must be managed in line with current legislation and guidance.*
- *Systems and processes must support the confidentiality of people using the service and not contravene the Data Protection Act 2018.*

21. The statutory guidance for Regulation 17(2)(c) refers to current legislation and nationally recognised guidance. At time of writing our Medical Care inspection framework[3] includes the following:
    - Records Management: code of practice for health and social care (2021)[4]
    - GMC guidance on keeping records [5]
    - NICE Quality Standards on patient experience in adult NHS services: Quality Statement 3 – Information exchange[6]

Registration, monitoring, inspection and regulation

22. CQC's registration and ongoing monitoring and inspection of providers is structured around five key questions that reflect what matters to people using services:
    - Is it safe?
    - Is it effective?
    - Is it caring?
    - Is it responsive?
    - Is it well-led?

23. Each key question is underpinned by a number of 'key lines of enquiry' (KLOEs)[7] and prompts. These help registration assessors and inspectors to form a judgement about the quality of the service and where relevant produce a rating for the service. This approach allows us to take a consistent

[3] NHS Core Services Framework: Medical Care. Available at: RLIT0001941
[4] Records Management Code of Practice for Health and Social Care. Available at: RLIT0001942
[5] General Medical Council. Ethical Guidance on Keeping Records. Available at: RLIT0001943
[6] NICE Quality Standards on patient experience in adult NHS services. Available at: RLIT0001944
[7] Key Lines of Enquiry for health services. Available at: https://www.cqc.org.uk/guidance-providers/healthcare/key-lines-enquiry-healthcare-services

approach to assessing how providers are meeting the fundamental standards of care set out through the Health and Social Care Act 2008.

24. Storage, accuracy and access to medical records feature in two KLOEs and prompts and we use these to monitor how providers maintain the quality and safety of their services:

    S3. Do staff have all the information they need to deliver safe care and treatment to people? This KLOE forms part of the assessment of the key question 'Is it safe?'. It is reported in the 'Records' section of inspection reports.

    W6. Is appropriate and accurate information being effectively processed, challenged and acted upon? This KLOE forms part of the assessment of the key question 'Is it well-led?'. It is reported in the 'Information Management' section of inspection reports.

25. We are currently updating our regulatory model and developing a single assessment framework that will apply to all registered providers from 2023. Our KLOEs will be replaced by quality statements, written from a provider's perspective to help them understand what we expect from them. The fundamental standard reflected in Regulation 17(2)(c) will be reflected through quality statements focused on the need for safe systems of care supporting continuity and transition between services, and good governance.

26. Our inspectors may access medical records during on-site inspections. This is to assess the quality of care and to corroborate what we are told by staff and patients. We have set out in guidance what our powers are in these circumstances, and how and when this would occur.[8]

Reporting our findings

[8] Accessing medical and care records. Available at: RLIT0001953

27. Through our inspection work we have identified and highlighted inconsistencies in registered providers' approaches and compliance with our regulatory framework. We address these individually with providers. We use insight from our registration, inspection and monitoring activities to help drive wider improvements in quality and to protect people from poor care through publication of reports on major quality issues in health and social care.

28. Inspection reports are publicly available through our website (www.cqc.org.uk). For acute hospitals, core services we inspect will be given a rating (outstanding, good, requires improvement, inadequate) for each of the five key questions. We will also give the service an overall rating.[9]

29. Our inspections can identify poor practice around the storage, access and accuracy of medical records, such as incomplete and missing records, records not stored securely, records not reviewed in a timely manner, and entries that were not legible or complete. When indicated by our findings, our reports also identify actions that providers must take to comply with their legal obligations or actions they should take to improve services or compliance with a regulation.

    Examples of findings of substandard practice

    - *Staff did not always keep detailed records of patients' care and treatment and records were not always clear.*
    - *Records were not always clear and up-to-date.*
    - *We found gaps in risk assessments and nursing records.*
    - *Records were not always clear, up to date, stored securely and easily available to all staff providing care.*

    Examples of actions a provider is required to take to comply with legal obligations:

[9] Ratings characteristics. Available at https://www.cqc.org.uk/guidance-providers/healthcare/key-lines-enquiry-healthcare-services

- *The service must maintain securely an accurate, complete and contemporaneous record in respect of each service user, including a record of the care and treatment provided to the service user and of decisions taken in relation to the care and treatment provided. Regulation (17) (2) (c).*

Deregistration

30. CQC does not have power to enforce compliance with the fundamental standards if a provider is not registered with CQC to carry on a regulated activity. We could require a provider to put plans in place around future records management ahead of deregistration, as described in legislative and national guidance such as the Records Management Code of Practice for Health and Social Care, but do not have powers to enforce compliance with such plans following deregistration. Provider deregistration from CQC would not impact other regulatory and legal frameworks that would continue to apply around storage and access to medical records.

Responding to concerns from people who use services

31. People who use services can share feedback with CQC about a registered provider. If CQC receives concerns about a provider's approach to storage, access, or accuracy of medical records, this would be considered as part of our ongoing monitoring of a provider. CQC cannot investigate individual complaints under its registration functions (Chapter 2 of the Act). Our powers also do not extend to obtaining records on behalf of the service user (our powers are only engaged to the extent that we require information for the exercise of our own regulatory functions), nor do our powers extend to requiring the provider to disclose records. Anyone wishing to make a formal complaint about a service should approach the service provider.

32. We are aware of the value and significance of accessible medical records to the delivery of safe, high quality, person-centred care and would support recommendations that the Inquiry make may to drive improvements in this area.

Statement of Truth

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

Signed GRO-C

Dated 12 January 2023

Table of exhibits:

Date	Notes/ Description	Exhibit number
	Inquiry Presentation Note on the Destruction and Retention of Medical Records	INQY0000378
30/12/2022 (web accessed)	Regulation 17. Good Governance	RLIT0001940
	NHS Core Services Framework: Medical Care	RLIT0001941
08/2021	Records Management Code of Practice for Health and Social Care	RLIT0001942
	General Medical Council. Ethical Guidance on Keeping Records	RLIT0001943
	NICE Quality Standards on	RLIT0001944

	patient experience in adult NHS services	
09/2018	Accessing medical and care records	RLIT0001953