Witness Name: Judith Richardson
Statement No.: WITN7421001
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WITN7421004
Dated: 5 October 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF JUDITH RICHARDSON

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 14 September 2022. I understand from the request that the Inquiry is currently gathering evidence relevant to recommendations which the Chair may be asked to make and it is in that context that this statement is sought and provided.

I, Judith Richardson, will say as follows: -

Section 1: Introduction

Q1. Please set out your name, address, date of birth and any relevant professional qualifications relevant to the role you currently discharge as Acting Director of Health and Social Care, National Institute for Health and Clinical Excellence (NICE).

1. My name is Judith Richardson, of GRO-C Manchester, GRO-C GRO-C I was born on GRO-C 1962.

2. I am the Acting Director of Health and Social Care at the National Institute for Health and Care Excellence ("NICE") of Level 1A, City Tower, Piccadilly Plaza, Manchester, M1 4BT.

3. I hold the qualifications of: Bachelor of Medicine, Bachelor of Surgery (MB BS); Master of Public Health (MPH); Membership of Royal College of General Practice (MRCGP); and Fellow of the Faculty of Public Health Medicine (FFPHM).

4. These are all relevant to my role as Acting Director of NICE, a post I have held since 1 April 2020.

Q2. Please describe, in broad terms, your role and responsibilities as Acting Director for Health and Social Care at NICE.

5. In order to answer this question I first set out an overview of the legal framework in which NICE operates and NICE's relevant functions.

The role of NICE

6. NICE (in its present incarnation) was established by section 232 of the Health and Social Care Act 2012 ("the 2012 Act"). NICE's general duties are set out in section 233 of the 2012 Act as follows:

> "(1) In exercising its functions NICE must have regard to—
>
> a) the broad balance between the benefits and costs of the provision of health services or of social care in England,
>
> b) the degree of need of persons for health services or social care in England, and
>
> c) the desirability of promoting innovation in the provision of health services or of social care in England.
>
> (2) NICE must exercise its functions effectively, efficiently and economically."

7. NICE's functions are set out in Part 8 and Schedule 16 of the 2012 Act and in the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 (SI 2013 No 259) ("the 2013 Regulations"), made under that Act.

8. Of relevance, section 234 of the 2012 Act enables the Secretary of State ("SoS") to direct NICE to prepare statements of standards (referred to as "quality standards") in relation to the provision of public health services or social care in England and enables NHS England to direct NICE to prepare quality standards in relation to the provision of NHS services in England. NICE must establish a procedure for the preparation of quality standards and consult those it considers appropriate in establishing that procedure, and has done so in its Quality standards process guide (July 2021). The SoS and NHS England must have regard to NICE quality standards when discharging their duties as to improvement in quality of services (sections 1A(4) and 13E(4)(b) of the NHS Act 2006). There is no statutory duty for other NHS bodies such as trusts to have regard to NICE quality standards, but they nevertheless often take them into account.

9. NICE may also supply (and make appropriate adjustments to) a quality standard to a devolved authority or other person (regulation 4 of the 2012 Regulations).

10. NICE also has advisory functions under section 237 of the 2012 Act, which provides:

> "(1) Regulations may confer functions on NICE in relation to the giving of advice or guidance, provision of information or making of recommendations about any matter concerning or connected with the provision of
>
> a) NHS services,
> b) public health services, or
> c) social care in England…"

11. Accordingly, the 2012 Regulations provide for NICE to give advice or guidance, provide information or make recommendations about any matter concerning or connected with the provision of NHS services, public health services, or social care in England (regulation 5), and NICE does so in various ways including the production of NICE Guidelines and Clinical Guidelines, among other types of guidance. Advice under regulation 5 is non-mandatory but public bodies are likely to (and NICE expects that they will) take it into account as a relevant factor.

12. The 2012 Regulations also provide for NICE to make "technology appraisal recommendations" (regulation 7) and "highly specialised technology recommendations" (regulation 8). There is a statutory duty on commissioners to "comply" with a positive single technology appraisal or highly specialised technology appraisal recommendation.

13. The 2012 Regulations require NICE to establish procedures for providing such advice and guidance and to consult those it considers appropriate in establishing those procedures.

14. NICE has long recognised that involving patients, service users, carers and the public adds value to the discussions of the independent committees and working groups that develop NICE guidance. Its processes therefore provide for patient and public involvement in different ways.

The role of Acting Director for Health and Social Care

15. In my role as Acting Director for Health and Social Care at NICE I am responsible for leading the implementation support for the guidance and quality standards referred to above across health, public health and social care. The aim of NICE implementation support is to encourage and promote uptake of NICE guidance in line with the 4 themes of our implementation strategy, these being: identifying implementation challenges during the

development of guidance; working in collaboration and partnership with organisations beyond NICE; delivering campaigns on health and care system priorities; using data to assess uptake and impact of guidance.

16. I am also responsible for NICE's patient and public involvement function. This means involving people who use services, carers and the public in the development of NICE guidance to ensure that the guidance is focused around the people most directly affected by our recommendations

Q3. 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.

17. I have been a Fellow of the Faculty of Public Health since 2008 for whom I examine and am an external assessor.

18. I am a member of the Royal College of General Practice by examination.

19. I am a subscription member of the British Medical Association.

Q4. 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. Please provide details of your involvement and copies of any statements or reports which you provided.

20. I have not provided evidence to, nor 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: Shared Decision Making

Q7. Was NICE's work in drawing up guidance and tools for shared decision making part of the Government response to the Review, or was it work that was being undertaken in any event? If the latter, what prompted this work?

21. For clarity I respond to this question in parts, as set out below.

What is shared decision making?

22. NICE's guideline on shared decision making provides the following definition:

> "Shared decision making is a collaborative process that involves a person and their healthcare professional working together to reach a joint decision about care. It could be care the person needs straightaway or care in the future, for example, through advance care planning.
>
> It involves choosing tests and treatments based both on evidence and on the person's individual preferences, beliefs and values. It means making sure the person understands the risks, benefits and possible consequences of different options through discussion and information sharing.
>
> This joint process empowers people to make decisions about the care that is right for them at that time (with the options of choosing to have no treatment or not changing what they are currently doing always included)."

What work has NICE undertaken in respect of drawing up guidance and tools for shared decision making?

23. NICE published a shared decision making guideline [NG197] (17 June 2021) [WITN7421002]. This was commissioned by NHS England as part of NICE's overall guideline commissioning process in 2018. The guideline explains that it:

> "covers how to make shared decision making part of everyday care in all healthcare settings. It promotes ways for healthcare professionals and people using services to work together to make decisions about treatment and care. It includes recommendations on training, communicating risks, benefits and consequences, using decision aids, and how to embed shared decision making in organisational culture and practices."

24. Shared decision making (SDM) had previously been referenced in other NICE guidelines (such as NICE's guideline on medicines optimisation [NG5], NICE's clinical guideline on medicines adherence [CG76] and NICE's clinical guideline on patient experience [CG138]). In addition, it is worth noting that for many years all NICE guidelines have carried the following wording, indicating an expectation for our guidance to be used in the context of SDM:

> 'The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.'

25. The SDM guideline is accompanied by a number of tools which can be used to support the embedding of SDM in clinical practice. These include:

- a resource impact report,
- a baseline assessment tool,
- a learning package co-produced between NICE and Keele University,
- recommendations for future research, and
- a standards framework for use by people developing or using SDM tools such as patient decision aids.

26. Recommendation 1.3 of the SDM guideline recommends that healthcare professionals use patient decision aids as one part of an overall 'toolkit' to support shared decision making alongside the other skills and interventions outlined in the guideline.

27. To support SDM in practice, patient decision aids (PDAs) are produced by a number of organisations, including NICE. PDAs support SDM by making treatment, care and support options explicit. They provide evidence-based information about the associated benefits and risks of surgical procedures and medical interventions and help patients to consider what matters most to them in relation to the possible outcomes, including doing nothing. PDAs can be online, apps, computer programmes or printed.

28. NICE has produced several PDAs to support decision making in the context of its own guidance. These PDAs are available on the NICE website - https://www.nice.org.uk/about/nice-communities/nice-and-the-public/making-decisions-about-your-care/patient-decision-aids. They cover a range of clinical areas including surgery, medicine, prevention, and treatment. These PDAs are developed according to a formal process which includes the direct participation of patients and, where appropriate, carers.

29. NICE is also enhancing its practical support for SDM by developing a ‘how to’ guide in relation to its standards framework for SDM tools (to be published at the end of 2022).

30. NICE is in discussion with NHS England and the DHSC in relation to its potential future role in the development of additional decision support tools, and the development and maintenance of a quality assured repository of such tools.

31. Finally, NICE also hosts a Shared Decision Making (SDM) Collaborative (established in 2015) [WITN7421003]. This is a group of organisations and individuals committed to thinking collectively about the role of shared decision making in UK health systems, drawing on international experience. It comprises a range of organisations from the statutory and charitable sector, patient and voluntary sector organisations, and academia.

Was this work part of the Government response to the Review, or was it work that was being undertaken in any event? If the latter what prompted this work?

32. The SDM guideline was commissioned by NHS England in 2018 and published in June 2021. Therefore, its inception, production and publication predate the Government's response to the report of the Independent Medicines Devices Safety (IMMDS) Review (published 21 July 2021).

33. As previously stated, NICE had produced some PDAs but did not do so universally for all its guidelines before the IMMDS review was announced in February 2018. Of note we did not have a PDA for the guideline on urinary incontinence (published in 2006). During the IMMDS review a pause was put in place on the use of mesh for pelvic organ prolapse (POP) and urinary incontinence. One of the conditions for lifting the pause was that NICE should update the guideline on urinary incontinence and produce one on POP, published in 2019 as Urinary incontinence and pelvic organ prolapse in women: management. NICE agreed with the Department of Health and Social Care (DHSC) to produce a PDA for the treatment of urinary incontinence and POP and this was published in April 2019 with the guideline before the IMMDS review was published on 8 July 2020. Therefore, whilst not

part of the government's formal response to IMMDS published 21 July 2021, NICE's work on POP and urinary incontinence (described above) was informed by the work of the IMMDS review.

34. After the publication of the IMMDS review on 8 July 2020:

    a. NICE produced a decision tool for use by those considering mesh removal in specialised centres being set up by NHSE. This was in response to work being done to respond to the recommendations in the review.

    b. In response to recommendation 2.22 of the IMMDS review the NICE Board stated that NICE would consider how to facilitate the production of a single and collaboratively produced "patient decision aid" for each surgical procedure and medical intervention. It was recognised by the NICE board that this is a potentially complex and resource intensive task needing consideration of the methods for the production of the aid, its quality assurance, how it is optimally presented and how best it might be validated.

Q8. Please explain what shared decision making is.

35. See paragraph 22 above.

Q9. What impact do you anticipate the guidance and tools will have?

36. Our ambition for the SDM guideline is that it results in patients (by which we mean the broadest possible group of people who might use services, or carers or advocates for those who do) being as fully informed about their choices for treatment and care as they wish to be, and to be an equal partner with their practitioners in decisions about that treatment and care.

37. Evidence shows that patients and clinicians consistently underestimate risk and overestimate benefit and therefore we hope that the guideline's recommendations will result in honest conversations about benefits and risks, and clarity about any uncertainty in the evidence base.

38. Benefits derived from implementing the guideline may include:
    - better health outcomes and care experiences
    - discussion of benefits of treatment against the risks associated with the treatments and enable users to avoid procedures they would not have agreed to if they had full information
    - reduction in harm from potential adverse effects and associated costs, for example, litigation costs
    - reduction of some unnecessary routine practices (both overuse and underuse) and in some situations, by extrapolation, costs.

39. The benefits or savings are likely to accrue across both primary and secondary care settings.

Q10. Do NICE have a plan for assessment of the effectiveness of the guidelines and tools?

a. If not, how will their effectiveness be assessed?

40. NICE does not currently have a plan to specifically assess the effectiveness of its SDM guideline or other tools (i.e. the PDAs). This would be very difficult methodologically and beyond the resources of NICE.

41. We do use routinely available data to assess the uptake and impact of guideline recommendations where that data exists.

42. When updating guidelines, NICE gathers views from stakeholders on the extent to which a guideline has been implemented and these views may help determine the focus of an updated guideline.

43. While we take the above steps, it's important to note the responsibility for implementation of NICE's guidelines does not rest with NICE and it requires a system wide approach to ensure our guidelines are implemented.

b. If so, please give details.

Q11. What more can be done to embed shared decision making in clinical practice?

44. The SDM guideline is accompanied by a number of tools which can be used to support the embedding of SDM in clinical practice as set out above (see response to question 7).

45. In addition to the work described above (see response to question 7 above), other initiatives aiming to embed SDM in clinical practice have been undertaken by other bodies that comprise the SDM Collaborative, for example, the General Medical Council's revised consent guidance states that SDM is fundamental to good medical practice [RLIT0001426].

46. More could be done to raise awareness of SDM. For example, it is possible that some clinicians, and certainly some patients, may be unaware of the High Court ruling in the Montgomery case. This states that doctors must provide information about all material risks; they must disclose any risk to which a reasonable person in the patient's position would attach significance.

Q12. Are there any further steps that need to be taken in your view, to ensure that these tools are effective in contributing to patients' understanding of risk, the obtaining of informed consent from patients and patient safety? Please give details.

47. The integration of SDM in NHS practice may require cultural shifts from both clinicians and patients. The clinician needs to be comfortable with sharing power and the patient needs to be comfortable making decisions. Joseph-Williams et al outline some of the key barriers to implementing SDM in the NHS in their paper "Implementing shared decision making in the NHS: lessons from the MAGIC programme" (published in the BMJ) [WITN7421004].

48. Despite changes in clinical education at under and post-graduate level to incorporate training on SDM, the practicality for clinicians of dealing with high volumes of patients in a limited time may not always allow for clarity when communicating risk and uncertainty to patients, and help people to make and own decisions about their care.

Statement of Truth

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

Signed GRO-C

Dated 28th October 2022