Witness Name: Christine Braithwaite
Statement No.: WITN7523012
Exhibits: WITN7523013 – WITN7523015
Dated: 22 March 2023

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF CHRISTINE BRAITHWAITE ON BEHALF OF THE PROFESSIONAL STANDARDS AUTHORITY

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

I, Christine Braithwaite, will say as follows: -

Section 1: Response to Evidence

1. 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 Professional Standards Authority, to this proposal. Please provide any further comments regarding Mr. Bragg's proposals that you wish to provide.

1. We are asked to comment upon Mr Bragg's proposal to the Inquiry 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.

2. Mr Bragg suggests there should be a statutory duty to make a report when serious injury or death has occurred which might have been preventable. In our view, in line with the approach we set out in *Right-touch regulation (2015)* legislation should only be used when it is clear it is the best and only way to prevent harm. We also advise that care be taken to ensure any new measures do not duplicate or cut across existing legislation or policies but instead form part of a coherent safety system.

3. There are currently requirements on the NHS to report avoidable injury or death. In England this is set out in NHS England's Serious Incident Framework, which is due shortly to be replaced by their NHS England Patient Safety Incident Response Framework [WITN7523013]. Similar policies exist in the three other countries of the UK. It seems from our initial scan that systems also exist to analyse incident data for trends, but we will not comment further as this is not our area of expertise.

4. Several inquiries and those responding to our recent publication, *Safer Care for All* and our recent strategic plan consultation have highlighted the importance of positive workplace cultures that support open and honest internal reporting of incidents – on which any external reporting mechanisms depend. The Inquiry may, when considering Mr Bragg's suggestion to introduce a statutory duty to report, wish to take account of the existing legal duty of candour. Since 2014, organisations registered with the Care Quality Commission in England have a statutory duty of candour. Such organisations run the risk of criminal sanctions (fines and/or possible de-registration) if they fail to comply with the requirement to be open and honest when things go wrong. CQC is responsible for enforcing compliance with the duty.

5. Part of the duty is to report back to the patient or relatives if there has been a 'notifiable safety incident', defined as: *'any unintended or unexpected incident that … in the reasonable opinion of a healthcare professional could result in, or appears to have resulted in a) the death of the service user or b) severe harm, moderate harm or prolonged psychological harm to the service user'* The organisational duty does not include a requirement to tell the patient about 'near-misses', although this is recommended.

6. Scotland introduced a similar statutory duty for NHS bodies in 2018. Northern Ireland consulted on introducing a statutory duty on individuals also, but legislation is not yet in place; in Wales an organisational duty commences in April 2023.

7. The registrants of the regulators we oversee are also required to comply with a professional duty of candour, which has a lower threshold. The regulators issued a joint statement on the professional duty of candour to show that it applied equally to all regulated professionals [WITN7523014]. Whilst there are relatively few fitness to practise cases in which the duty of candour is mentioned, regulators do take action in cases involving lack of honesty and covering up.

8. It has become clear to us, both in relation to the legal and professional duty of candour, that healthcare professionals must feel psychologically safe to report, whether a legal duty exists or not – and that largely depends on workplace culture.

9. Mr Bragg has also proposed that the NHS should adopt the approach taken in other safety industries. That thinking has underpinned other initiatives in healthcare including the creation of HSSIB. Whilst we are not experts in those industries, I think it worth drawing out some of the factors in healthcare that may be relevant when considering the extent to which approaches in other industries are transferable.

10. Health care has few mandated safe staffing levels. Instead, staffing levels are decided depending upon the acuity and numbers of patients and resources available. This may vary day to day. Workforce shortages are acute and may impact the ability of staff to provide safe care. Capacity issues may also restrict choices on such measures as closing a site or service or re-directing patients to another location. By way of analogy, the aircraft can seldom be grounded.

11. Teams in the NHS are not static but dynamic. The composition of multi-disciplinary teams varies around the needs of groups of patients and around an individual patient. Workforce shortages and heavy reliance on agencies and locums mean that colleagues may not have met before, be unaware of

each other's skills and experience yet must make critical decisions fast. This may vary by shift.

12. That might suggest working to checklists and protocols is the safest way to proceed. However, healthcare involves multiple variables, not just in terms of the places, people, and products but also in the nature of diseases and conditions. The situations health professionals face daily are not fixed and certain but varied. Whilst a surgeon may have a relatively familiar caseload, staff in A&E or elderly care wards may face a variety of conditions and co morbidities. The ways in which clinical conditions manifest and patients respond to treatments is also variable, meaning health professionals must use clinical judgement, whilst taking account of existing guidelines, protocols, and pathways. The problem in the NHS is seldom absence of protocols and guidance but instead is reported to be too many.

13. Mr Bragg suggests that there should be a new body established with responsibility to collect serious incident information, to investigate them and to make sure that effective action has been taken. The NHS, which itself is made up of many organisations, is also overseen by multiple other bodies who may require data, inspect, and investigate. One research study found over 126 organisations exerted some regulatory influence over it, with overlapping functions and activities [WITN7523015]. However, we agree with Mr Bragg that there is a need for a body to check that the healthcare safety system is operating effectively, and serious review findings are implemented. We suggest that role might form part of the Health and Care Safety Commission role we recommended in *Safer Care for All* to help ensure a robust safety system and champion the patient and service user interest. Part of its role might be to ensure that the patient incident reporting systems already in place are operating effectively.

Statement of Truth

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

GRO-C

Signed:

Dated: 20 June 2023