Witness Name: Aidan Fowler
Statement No: WITN7717001-
WITN7717008
Dated: 15 September 2023

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF AIDAN FOWLER

I, AIDAN FOWLER, National Director of Patient Safety in England within NHS England, will say as follows:-

Section 1: Introduction

1. My name is Aidan Fowler. I am based at NHS England at Wellington House, 133-135 Waterloo Road, London SE1 8UG. My date of birth is GRO-C 1966.

2. I, as NHS National Director of Patient Safety, lead the National Patient Safety Team in NHS England. This team is the centre of expertise in relation to patient safety science within the NHS. The team lead patient safety in the NHS from a clinical, policy, strategy, digital, leadership, governance, education/training and improvement perspective.

3. The team's leadership position derives from its responsibility to deliver key statutory patient safety duties across the NHS. These are:

a. collecting information about what goes wrong in the health service, in part by maintaining and operating the National Reporting and Learning System (NRLS) and its replacement, the Learn from patient safety events service: and

b. using that information to provide advice and guidance "for the purposes of maintaining and improving the safety of the services provided by the health service".

4. These duties require the remit of the patient safety team to encompass the whole healthcare system; primary care, urgent and emergency care, secondary care, tertiary care, health in justice, commissioning and independent care provision, as well as interaction with the nursing/care home sector.

5. I have not been a member, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference.

6. I make this statement in response to a Rule 9 requests from the Infected Blood Inquiry ("IBI") dated 17th July 2023, 2nd August 2023 and 29th August 2023.

7. In producing this statement on behalf of NHS England ("NHSE"), I have sought generic advice and information from NHSE colleagues and have sought specific advice relating to the Rule 9 from Dr Matthew Fogarty, Deputy Director of Patient Safety (Policy and Strategy) and Dr Tracey Herlihey, Head of Patient Safety Incident Response Policy.

Section 2: Background regarding Patient Safety

8. As set out in NHS England's "the NHS Patient Safety Strategy" document, dated July 2019 [WITN7717002][1], we consider patient safety to be about maximising success in healthcare and it is integral to the NHS's definition of quality in healthcare, alongside effectiveness and patient experience. Our vision is for the NHS to improve patient safety continuously. Safety is not an absolute concept and has neither a single objective measure nor a defined end point. It is also

[1] Updated in 2021 – see WITN7717003 and subsequent online updates

continuously changing as new ways to treat disease and other healthcare conditions emerge. What we consider to be success now will likely be different in a few years' time.

9. Patient Safety is a complex discipline, encompasses all aspects of healthcare; from the simplest primary care appointment; through complicated technical interventions like surgery or interventional radiology; to the holistic treatment needs and services required by our most complex patients with multiple co-morbidities and conditions.

10. Healthcare is delivered via complex sociotechnical work systems, with many factors interacting to produce outcomes. These factors include the tools and equipment used, the nature of tasks, clarity of guidelines and policies, the organisational context including workload, the working environment, and the behaviour of others. A 'systems approach' to safety considers all relevant factors and recognises that safety arises not from a single component, but from the interactions between them. The purpose of any patient safety-focussed response to a safety event is to explore what the event reveals about the healthcare system in which the event occurred. That insight then allows consideration of how system factors may be changed to increase the likelihood of the desired outcome being achieved in the future.

11. Central to the systems approach to patient safety is the idea that people are a critical part of any work system, and that the success of work depends on the extent to which that system supports the people working in it to perform as desired. It is also the case that people working in systems compensate for deficiencies in those systems.

12. This approach has implications for the way we engage people who are involved in patient safety events. It is a truism to say that the vast majority of people come to work to do a good job. Only in extremely rare cases are people deliberately malicious, or inappropriately depart from good practice. When that occurs, action should be taken by employers, professional regulators and/or the police to remove the individual from positions where they will cause further harm. In all other situations people will have behaved and acted in line with normal expectations.

The actions (and inactions) that people take in any particular circumstance will have made sense to them at the time. This is as true during normal work as it is during an event where in hindsight we can see that something has 'gone wrong'. If, looking back at the event, the actions people took don't make sense to us, that is because we do not yet understand the context in which they were operating. Only once we understand their context can we consider how to change that context, and that work system, to improve the chances of future success.

13. The regulatory and supervisory landscape in Healthcare in England is complicated.

14. Different parts of the regulatory and oversight system play different roles and it is important to consider those roles and why they exist. An article written by Oikonomou et al entitled "Patient safety regulation in the NHS: mapping the regulatory landscape of healthcare" in July 2019 provides a relatively recent and comprehensive overview of this landscape and describe the roles of various regulators [WITN7717004].

15. We note there is reference within the evidence before the Inquiry to adding to the regulatory landscape through the creation of a single overarching 'Health and Social Care Safety Commissioner' (in particular in the statement from Christine Braithwaite at WITN7523001). The current intention appears to be for this to oversee professional regulation, service regulation and indeed ''all other health and care organisations, spanning public as well as private provision'' (RLIT0001837). This concept is interesting, although we also note the creation of another regulator will add to the complexity of the system and would create multiple additional interfaces with partner organisations.

16. Another strategy to support coordinated and effective safety action in the healthcare system could be to provide organisations and teams with a period of stability in remit and function. Allowing time for the current arrangement of organisations and teams to cement relationships and develop effective ways of coordinating their work could promote familiarity between organisations, allowing them to identify and plug gaps in functions and support improvement through long term planning.

17. The National Patient Safety Team recognises the importance of coordinating activity across organisations, which is why we host the National Patient Safety Committee that brings together teams from across the national healthcare bodies to consider shared challenges and coordinate work.

18. The National Patient Safety Team also works with the Devolved Administrations in a number of ways. The Devolved Administrations ("DAs") are observers on the external stakeholder panel which supports the National Patient Safety Team in its decision-making regarding how we respond to identified risks and issues, specifically when we issue National Patient Safety Alerts. This means that DAs are sighted on our work at an early stage and have access to the data and analysis generated by the National Patient Safety Team in support of this work. Typically the DAs will use the information relating to our response to the risk/issue, particularly where we believe an Alert is indicated, to understand if it is applicable to their country.

19. Our team collaborate with the DAs on a range of ad hoc issues as appropriate. For example, we recently led a programme of work to consider previously issued resources and information. As a result of this, we are working with DA colleagues to update several medicines information resources to ensure they are applicable across UK to provide clarity to users.

20. Ad hoc interactions also include the sharing of soft intelligence between the countries, particularly at the early stages of considering the response to an emerging risk.

21. The National Patient Safety Team is a member of the Cross UK Patient Safety Management Network. The purpose of the Network is to debate mutual interests in patient safety management to promote sharing of best practice and the development of new strategies, tools and approaches. The Network is an advisory and support structure, facilitating collaboration and learning between agencies to promote and improve the management of patient safety. The Network has membership from all four UK nations.

22. Discussions have also been held with all three DAs regarding their potential involvement in the Learn from patient safety events service. All three have considered participating in the service, although, as things stand, we believe the Welsh Government have elected to create their own standalone incident reporting system. Scotland and Northern Ireland are still welcome to participate, but that is a decision for their respective Administrations.

23. NHS England is leading significant work to improve both locally-led and nationally commissioned safety learning responses, in order to improve the effectiveness of inquiries, reviews and investigations.

24. At a local level, NHS England is introducing the Patient Safety Incident Response Framework. PSIRF represents a new approach to patient safety incident response focussed on learning and improvement and based on safety science approaches from other high-risk industries. PSIRF has four key aims:

    a. Compassionate engagement and involvement of those affected by patient safety incidents

    b. Application of a range of system-based approached to learning from patient safety incidents

    c. Considered and proportionate responses to patient safety incidents

    d. Supportive oversight focused on strengthening response system functioning and improvement

25. PSIRF was tested and independently evaluated with 24 early adopters, with the evaluation finding that PSIRF was the right thing to do (see the evaluation report at WITN7717005). It is now being implemented across all NHS trusts. PSIRF has been broadly welcomed, not only because of its core focus on compassionate engagement and involvement of those affected by patient safety incidents be they patients, families, and staff, but also because it appears to be changing cultures, supporting more openness, transparency and learning, leading to harm reduction

26. At national level, we would also agree with statements made to the Inquiry in relation to the potential to lose institutional expertise with the continuous disbanding of Inquiry support teams/secretariats and the need to 'reinvent the wheel' every time a new inquiry, investigation or review is required. Having recognised this, last year we created the first National Patient Safety Independent Investigations Team ("NPSIIT").

27. This team's role is:

    a. to ensure standardisation and consistent governance of all NHS England-commissioned independent investigations, maintaining a current and accurate status of progress on each investigation;

    b. to strengthen the insight gained from national independent investigations to support improvements; and

    c. to ensure there is a robust structure in place to support the operational delivery of an independent investigation.

28. The team works with colleagues in other organisations, including DHSC, to support their functions as well.

29. The NPSIIT are also linking with other processes that generate safety insight; the incident reporting systems we describe below, information from coroners' inquests, information from HSIB's investigations and other sources, to enable triangulation of themes and trends.

30. The NPSIIT and the wider patient safety team take interest in the quality and impact of safety recommendations. When looking at why recommendations generated by previous inquiries have not irreversibly transformed the healthcare system for the better, we need to think beyond this just being a challenge of implementation and look at whether previous inquiries have had impact but that failures occur regardless. Where recommendations have not completely prevented failure, we would look at whether this relates to the nature of the recommendations or the capability of the system to implement them.

31. We believe, based on the evidence from other high-risk industries and within healthcare, that taking the systems approach to learning from safety events generates more effective insight for improvement. We have also specifically examined how to make effective recommendations based on the insight generated from systems-based learning approaches and have created a new framework for designing effective recommendations that we will be incorporating into the work of our new National Patient Safety Independent Investigations Team.

32. In terms of data collection, which allows trends to be spotted, the NHS is a highly data rich organisation with huge amounts of information collected that relate to patient safety and wider quality. Specific to patient safety, the NHS has the largest and most effective national patient safety incident reporting database of any country in the world which is operated by the National Patient Safety Team. This is called the National Reporting and Learning System (NRLS). Launched in 2003/04, the NRLS collects patient safety incident records uploaded from local risk management systems that are operated by healthcare provider organisations. Having run for 20 years, the NRLS now collects over 2.3 million patient safety incident records each year and in total holds almost 30 million patient safety incident records. Each of these is a report of a patient safety incident that includes information about the level of harm caused, and the type of incident. We are unaware of any other healthcare system with this size of database receiving data from every sector of healthcare nationwide.

33. We are currently replacing this with a successor system, the Learn from patient safety events service (LFPSE).

34. Using the national patient safety team's NRLS and LFPSE services, and by taking a birds' eye view of risks across the NHS, the national patient safety team identify new and emerging risks and implement national mitigation action. We use the insight derived from this work to craft strategies to reduce well-recognised risks to safety as well, saving hundreds more lives and tens if not hundreds of millions of pounds each year. The NRLS has enabled reductions in a wide range of risks, and in some cases virtually eliminating of specific hazards, as detailed on our relevant webpages (see for example https://www.england.nhs.uk/patient-safety/patient-safety-alerts/ and https://www.england.nhs.uk/patient-safety/using-patient-safety-

events-data-to-keep-patients-safe/how-we-acted-on-patient-safety-issues-you-recorded/). We estimate each year this work saves around 160 lives, eliminating over 480 severe harm incidents and avoiding £13.5m in care costs (see appendix 1 to WITN7717002). This means over the course of its operation, the NRLS is likely to have supported work that has saved thousands of lives, prevented tens of thousands of incidents leading to severe harm and saved hundreds of millions of pounds. The existence of the NRLS and its successor LFPSE require a national patient safety team to exist to extract value from it, meaning indirectly, NRLS and LFPSE support the existence of all national patient safety work in the NHS.

35. There is specific focus within the National Patient Safety Team on collecting and using information on healthcare inequalities more effectively. This is aligned with NHS England's wider Core20Plus5 programme. Further information about the Core20Plus5 extracted from NHS England's website is at WITN7717006, which describes Core20PLUS5 as a national NHS England approach to inform action to reduce healthcare inequalities at both national and system level. The approach defines a target population – the 'Core20PLUS' – and identifies '5' focus clinical areas requiring accelerated improvement. The programme is led by Dr Bola Owolabi, NHS England Director of Health Inequalities and is separate to, but works with, the National Patient Safety Team.

36. The data we collect via NRLS and LFPSE are shared with CQC to support organisational regulation, HSIB to support national investigation work, and MHRA to support healthcare products and medicines regulation. The data is also used to support national and international research into patient safety via academic, industry, clinical and policy bodies.

37. There is no one single report which sets out the many ways that this data is used, but NHS England's most recent national patient safety incident report data commentary can be found at WITN7717007. The data is very deliberately anonymised so is not of direct use to professional regulators, but we work with those regulators on wider policy development to improve safety as evidenced for example by the work to coordinate cross-system support for our Just Culture Guide [see WITN7717008].

38. The NHS also holds some of the world's most comprehensive national datasets relating to clinical diagnoses, outcomes, procedures, prescriptions and other data. Work to create outcomes registries for longitudinal assessment of the safety and efficacy of implanted devices is underway and already exists for various areas of healthcare such as hip replacement implants.

39. There is more that could be done to pool and examine safety related data, but that is more of a challenge of resource, than organisational structure.

40. We note the Inquiry is interested in patient safety incident reporting and the suggestion that there could be a legal duty to report incidents involving serious injury or death and that there should be a body to collect such incident records, to investigate and ensure action is taken. However, all these elements already exist.

41. It is a condition of CQC registration that healthcare organisations report all patient safety incidents leading to severe harm and death to them. NHS Trusts do this by reporting to NHS England's incident reporting systems (NRLS and LFPSE). This information is shared in its entirety with CQC (as well as MHRA and HSIB). This legal requirement to report is placed on the organisation and not the individual and this is entirely appropriate. People should not be punished if they work in an organisation that does not support them to report incidents. The duty is currently on the organisation and rightly so.

42. Around 20,000 such incidents are recorded each year. It is unfeasible to expect one organisation to investigate all such incidents. The responsibility for learning from such incidents rests primarily with the provider organisation in question. Occasionally investigation is led by the commissioner of the care or NHS England, or HSIB depending on circumstances. The NHS's current policy for guiding the responses that organisations take to incidents is, as described earlier, the Patient Safety Incident Response Framework which is being implemented in 2023. This is associated with incident response standards including training requirements. Responsibility to act in response to the findings of an investigation sits with the leadership of that organisation and is already regulated by CQC.

Section 3: Specific questions from the Inquiry

43. The background set out above provides important context for the research commissioned by NHS England referred to in paragraph 36 of Dr Rosie Benneyworth's statement [WITN7689001].

44. Safety Management Systems are an organised approach to managing safety which are widely used in different industries. The fundamental activities in a Safety Management System (SMS) are fully integrated and consist of;

    a. Identification of safety hazards

    b. Improving the management of known safety risks

    c. Monitoring safety performance

    d. Evaluation of safety interventions

    e. Training and education for safety

    f. Promotion of safety

45. Such SMSs were originally adopted by the chemical industry in the 1980s and have since been widely adopted in other safety critical industries including aviation.

46. All of these activities also exist in healthcare, although it is fair to say that they are not always termed 'safety management systems' and the extent to which they are fully integrated with each other and with wider business processes is variable. They will also vary in their implementation at different levels of the system, from the frontline provision of care to patients, to the national strategic leadership of the healthcare system. For example, under the NHS Patient Safety Strategy, working with Health Education England and the Academy of Medical Royal Colleges, we have created the NHS's first Patient Safety Syllabus and associated training and education resources. Similarly work to identify and manage safety hazards is a well embedded process at all levels of the healthcare system, from frontline incident reporting and risk management, through to the national work we lead to collect and analyse patient safety incident reports from across the NHS and to mitigate those risks amenable to national response.

47. As described above, in 2023 the Patient Safety Incident Response Framework (PSIRF) is being implemented in the NHS. PSIRF is part of the NHS National Patient Safety Strategy published in 2019 that sits alongside and supports the NHS Long Term Plan. PSIRF represents a complete redesign of how the NHS manages patient safety incident response. The new framework describes an approach to safety management that aims to enable both reactive and proactive approaches to safety and balances resources dedicated to learning from events (i.e., acquiring new knowledge and insight) with those dedicated to improvement (transforming insight into action and monitoring impact).

48. While the PSIRF brings a significant change in safety management to the NHS it is only a part of what might be considered an SMS. While all the other elements of an SMS approach also exist in the NHS, to date the NHS has not made a concerted effort to integrate these with wider processes at all levels. This relates, in part, to the complexity of the NHS which is some orders of magnitude greater than other high-risk industries. Understanding how SMSs might be conceived and applied in a healthcare setting is an integral step for informing further policy developments.

49. This is not about establishing something new in the NHS and we would caution against the tendency to adopt a new phrase or framework such as SMSs and suggest this is the solution to all the challenges the NHS faces. However, it is right to ask what more the NHS could do in this space and what more we could learn from other industries.

50. NHS England, in collaboration with the Department of Health & Social Care and the National Institute for Health & Care Research, are therefore in the process of scoping a research project/plan to develop the evidence base in this area and inform future policy decisions. This work is ongoing, so we are not able to provide full details at this point.

51. However, by way of illustrating the possible focus of future research, NHS England have developed three high level policy research questions:

    a. <u>What are the key attributes of a successful SMS for the NHS in England?</u>

'Off the shelf' SMSs from other safety critical industries such as rail transportation, aviation and oil and gas are available. However, while it is important to 'borrow' questions from these industries (e.g., how can we structure safety management?), we should not immediately adopt the solutions without ensuring they meet the unique needs of the NHS.

The PSIRF brings with it a huge shift in safety management in the NHS, and yet only deals with a part of what might be considered an SMS. Further research is needed to understand how SMSs might be conceived and applied into a healthcare setting including, exploring:

- the key components of SMSs across industries
- the system factors that support an SMS to flourish
- what should a healthcare SMS be designed to do?
- who should a healthcare SMS be designed for (e.g., regulators, ICBs, and/or providers) to allow consistency in governance approaches?

b. <u>What are the links between an SMS and a Quality Management System?</u>

Neither safety nor quality happens without a management plan. Both strive for continuous improvement and depend on monitoring and involving all functions and people across an organisation. Harmonious integration is crucial, but there are also important differences. A Quality Management System (QMS) aims to provide consistent services that meet regulatory requirements. A QMS also identifies ineffective processes and procedures that should be redesigned for efficiency and effectiveness. The objective of an SMS is to identify safety-related hazards and control risks to an acceptable level.

More work is needed to ensure alignment between safety and quality management for efficient use of resources and to avoid duplication.

c. What are the next steps for safety management in the NHS in England?

Many aspects of an SMS are already part of day-to-day work in the NHS. For example, risk assessment and patient safety incident investigation already form part of the NHS's approach to managing safety.

PSIRF provides a framework, standards, and competencies for the design of a patient safety incident response system that moves the NHS closer to SMSs in other safety critical industries.

This policy question will explore how systems and processes implemented as part of PSIRF can be improved and/or adapted to make further progress in safety management.

52. As noted above, we are at the early stages of developing a research plan/project that will address the policy questions covered above. Opportunities for such research to inform policy will remain valid regardless of when the research may be commissioned and/or completed. While updates to the patient safety strategy are provided on an annual basis, updates to incident response policy have historically been made every 2-7 years.

53. Organisations are anticipated to transition to PSIRF in autumn 2023. Based on learning from our early adopter programme it is likely to take a further 2-3 years for the policy to become fully embedded. At which point we can start to integrate further work regarding systematic safety management.

54. This autumn we will bring together stakeholders from across the system (including CQC, NHSR, HSIB) to meet for the first time to discuss coordinate all ongoing work and thinking related to safety management systems. The intention is that this group will help to steer the direction of the research and work collaboratively on how to take any findings forward to ensure an aligned approach.

55. As the research plan is at such an early stage, we have not yet chosen a methodology for the research, nor do we have any interim results or conclusions to share.

Statement of Truth

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

Signed: GRO-C

Dated: 15th September 2023