Witness Name: Professor
Sir Stephen Powis
Statement No.: NHSE/4
Exhibits: SP/0344-0355
Dated: 24 July 2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF PROFESSOR SIR STEPHEN POWIS

I, Professor Sir Stephen Powis, will say as follows: -

1. I am the National Medical Director of NHS England and have held this position since 2018. This is my fourth statement in connection with the Thirlwall Inquiry ("the Inquiry") and is made by NHS England in response to the supplementary questions asked by the Inquiry in its Rule 9 letters dated 19 and 28 June 2024.

2. As with my previous statements, this statement has been drafted on my behalf by the external solicitors acting for NHS England in respect of the Inquiry, with my oversight and input. As the questions in the two further Rule 9 letters go beyond matters which are within my own personal knowledge, this statement is the product of drafting after communications between those external solicitors and senior individuals within NHS England in writing, by telephone and video conference.

3. As agreed with the Inquiry, the question relating to the risk register held on behalf of the North West Neonatal Operational Delivery Network will be addressed by Julie McCabe in her personal witness statement, as she has been asked the same question and is better placed to assist the Inquiry in this regard.

The 2006 Memorandum of Understanding between the NHS and police

4. The Inquiry has asked me to address a series of questions relating to a Memorandum of Understanding previously agreed between the Department of Health, Health & Safety Executive and the police in February 2006 ("the MoU"), governing the

circumstances in, and procedure by, which an NHS body should contact the police. I previously exhibited the MoU to NHSE/1 when explaining that the Regional Chief Nurse for the North region used this document as a guide when chairing an Incident Coordination Panel in response to the police launching Operation Hummingbird in relation to the events that took place at the Countess of Chester Hospital **[SP/0131, INQ0014686]**. The members of this Panel are described at paragraph 582 of NHSE/1.

5. The MoU, and the accompanying "Guidelines to the NHS", were developed by the Department for Health before the establishment of NHS England in 2012. NHS England therefore does not have any corporate knowledge of the reasons why the MoU was developed, the extent to which it was distributed to hospitals and what, if any, training was provided at the time.

6. I note that the MoU was referenced in the Serious Incident Framework published in 2015 by NHS England. The Serious Incident Framework makes clear that the MoU provides a "source of reference" for communication and management of a serious incident where an investigation is also required by the police. Hospitals would have been expected to make themselves familiar with the MoU and its requirements as a result, alongside ensuring their broader compliance with related statutory and regulatory duties (including those relating to safeguarding).

7. I note further that the 2015 Serious Incident Framework expressly states that the MoU was under review. Whilst NHS England is not in a position to confirm the precise reasons for this (as the MoU remained a policy area for the Department of Health), it is our understanding that the Association of Chief Police Officers was dissolved in 2015 and replaced by the National Police Chiefs' Council. This change in the national leadership arrangements for the Police is noted in the Williams Review as a factor supporting an update to the MoU. I have set out below at paragraph 10 my understanding of the Williams Review. The Department of Health will be able to confirm whether the MoU or the Guidelines to the NHS were ever officially "withdrawn".

8. From NHS England's perspective, although the MoU remained under review, it remained a helpful guide for how NHS bodies should work with the police in relation to criminal investigations, as explained in the Serious Incident Framework. The MoU's core principles of engaging the police early and keeping ongoing lines of communication open, without compromising a police investigation, were useful starting points. The 2015 Serious Incident Framework makes several references to

coordinating with the police where appropriate, and where an incident is subject to police investigation. Further, as noted above, the MoU recommends the establishment of an Incident Coordination Group, which is what NHS England's North regional team did following the launch of Operation Hummingbird.

9. NHS England is not aware that any alternative policy (other than the MoU) existed between the period January 2015 and December 2017.

10. NHS England is aware that one of the recommendations made by the Williams Review Panel was that a new MoU should be developed to set out the respective roles of the police, Crown Prosecution Service, Health & Safety Executive and health service bodies (such as the Care Quality Commission, the Healthcare Safety Investigation Branch and healthcare professional regulators) in investigating unexpected deaths in healthcare settings in order to ensure that patient safety lessons can be understood and acted upon. However, we also note that the Williams Review Panel did also acknowledge that the principles of the MoU and the relationship it described between the police and local safety investigations remained as relevant in 2018 as they did in 2006. NHS England's former Head of Maternity, Children and Young People was a member of this panel.

11. NHS England understands that the Department of Health are working on developing a new MoU in response to the recommendation made by Williams review and that this work remains ongoing.

Other arrangements between the NHS and police relating to safeguarding

12. The Inquiry has requested copies of any national policy, protocol or MOU between the police and the DH/DHSC or NHS England in relation to safeguarding children which existed during the period between January 2015 and December 2017. I have previously set out in NHSE/1 (at paragraphs 733-760) how NHS England complies with its statutory duties and seeks to promote good safeguarding practice. I have expanded on those paragraphs below to address the Inquiry's supplementary question.

<u>NHS England guidance</u>

13. As set out in paragraph 750 of NHSE/1, NHS England has developed and published the "Safeguarding children, young people and adults at risk in the NHS Safeguarding

Accountability and Assurance Framework". During the period between January 2015 and December 2017, the March 2013 version, "Safeguarding Vulnerable People in the Reformed NHS Accountability and Assurance Framework" **[SP/0182, INQ0014618]** and July 2015 version, "Safeguarding Vulnerable People in the NHS Accountability and Assurance Framework" **[SP/0183, INQ0014623]**, were in place. Both the March 2013 version (at page 12) and July 2015 version (at page 21) provide that Clinical Commissioning Groups require appropriate systems to be in place to discharge their safeguarding duties, which included effective inter-agency working with local authorities, the police and third sector organisations. NHS England also provided additional safeguarding training and support for via the primary care safeguarding toolkit (see page 28).

14. Further, NHS England and NHS Improvement published "Managing Safeguarding Allegations Against Staff: Policy and Procedure" in March 2014, which was later updated in 2019 [**SP/0344, INQ0107001**]. This document details in particular the responsibilities of the Nominated Safeguarding Senior Officer in each NHS England and NHS Improvement region, which include reporting to and liaising with the police if the allegation is of a criminal nature (pages 7 and 21).

15. In addition, as explained earlier in this statement at paragraph 6 above, the 2015 Serious Incident Framework **[SP/0048, INQ0009236]** makes extensive and repeated reference to coordinating with the police where an incident is subject to police investigation.

Working Together guidance

16. As set out in paragraphs 737 and 738 of NHSE/1, the main statutory safeguarding duty is found in section 11 of the Children Act 2004, which requires certain bodies (including NHS England, other NHS bodies and the police) to make arrangements for ensuring their functions, and any services they commission, are discharged having regard to the need to safeguard and promote the welfare of children. In discharging this duty, these bodies are required to have regard to guidance given by the Secretary of State for Education, namely the Working Together Guidance. During the period between January 2015 and December 2017, an earlier version of the Working Together Guidance was in place, "Working Together to Safeguard Children: A guide to inter-agency working to safeguard and promote the welfare of children", published in March 2013 (the "2013 Working Together Guidance") [**SP/0345, INQ0106979**].

17. Chapter 5 of the 2013 Working Together Guidance dealt with Child Death Reviews and set out the procedure to be followed in the event of an unexpected death of a child and the roles and responsibilities of both health professionals and the police (see pages 79 – 84 of the 2013 Working Together Guidance). As noted in paragraph 558 of NHSE/1, Child Death Overview Panels also play a key safeguarding role. These panels comprise a multiagency group of professionals and are set up to review the deaths of all children normally resident in their area (and, if appropriate, deaths in their area of non-resident children) in order to learn lessons and share any findings for the prevention of future deaths. The panel usually comprises health and social care professionals and the police and is arranged by the senior professionals who have primary responsibility for the child. Child death reviews are part of the wider framework relating to the safeguarding of children, with the learning from child death reviews being shared with the National Child Mortality database, with a view to identifying trends in, or similarities between deaths (see paragraph 839 of NHSE/1). The output from programmes like the National Child Mortality Database provide valuable information to enable lessons to be learned and improvements in the quality of maternity, neonatal and perinatal services across the NHS.

Other relevant guidance and reports

18. As set out in paragraph 744 of NHSE/1, the Intercollegiate Document applies across the UK. During the period between January 2015 and December 2017, the revised 2014 version of the Intercollegiate Document, "Safeguarding Children and Young People: roles and competencies for health care staff" [**SP/0346, INQ0106986**], was in place. The 2014 Intercollegiate Document (at pp 61-62) provides that one of the key responsibilities of a Board Executive Director lead is to work in partnership with other groups including commissioners/providers of health care (as appropriate), local authorities and police to secure high quality, best practice in safeguarding/ child protection for children. Furthermore, all named professionals are responsible for advising local police, children's social care and other statutory and voluntary agencies on health matters with regard to safeguarding/child protection.

19. Some of the regulators and professional bodies have also produced their own guidance. For instance, the General Medical Council's "Protecting Children and young people: The responsibilities of all doctors" [**SP/0347, INQ0107006**] (as mentioned in paragraph 746 of NHSE/1) came into effect in September 2012 (updated in May 2018). This guidance explains that doctors are expected to work with and

communicate effectively with the police (paragraph 29) and tell an appropriate agency, such as the local authority children's services, the NSPCC or the police, promptly if there is concern that a child or young person is at risk of, or is suffering, abuse or neglect unless it is not in the child's best interests to do so. My understanding is that whilst the Nursing and Midwifery Council also now have a safeguarding toolkit, this was not first published until after the period in question (in 2018).

20. The Royal College of Paediatrics and Child Health (RCPCH) published in November 2016 the "Sudden unexpected death in infancy and childhood Multi-agency guidelines for care and investigation" (the "Kennedy Guidelines") [**SP/0348, INQ0106989**]. The Kennedy Guidelines emphasised that a multi-agency approach was key to the effective investigation of an unexpected death and support for the family. Section 2 of the Kennedy Guidelines set out the responsibilities of the lead health professional, including ongoing liaison with the police, and actions to be undertaken by the police. Appendix 1 of the Kennedy Guidelines outlines the principles of the police investigation in response to infant death.

21. The Government's "Information Sharing Advice for practitioners providing safeguarding services to children, young people, parents and carers" [**SP/0349, INQ0106980**] also sets out information sharing protocols for health practitioners and explains the circumstances in which information should be shared with the police.

22. Finally, I note that the Home Office's Safeguarding Unit produced a report in 2017 in order to better understand the specific circumstances in which the police need health information for safeguarding purposes [**SP/0350, INQ0106998**].

<u>Recent developments</u>

23. The Inquiry' supplementary question is focussed on national policies, protocols or MOUs between the NHS and the police from the period between period January 2015 and December 2017 but, for completeness, I refer the Inquiry to the following additional documents, in case they are useful in understanding the relationship between the police and the NHS more recently:

    a. In February 2018, a consensus document was agreed between, amongst others, the Association of Police and Crime Commissioners and NHS England

about working together to protect and prevent harm to vulnerable people [**SP/0351, INQ0107000**];

b. The College of Policing has produced a practical guide to facilitate local collaboration between the police force and NHS [**SP/0352, INQ0107002**];

c. As mentioned at paragraph 746 of NHSE/1, in 2021 the Royal College of Nursing published its guidance on "Safeguarding Children and Young People - Every Nurse's Responsibility" [**SP/0353, INQ0107003**]. This document provides that in the event of an allegation or concern that an employee or volunteer has behaved in a way that has harmed, or may have harmed, an appropriate response may include the police investigation and nurses based in England are required to follow the national Working Together guidance.

National Reporting and Learning System and the Strategic Executive Information System

24. The Inquiry has asked me to address some supplementary questions relating to the evidence provided in NHSE/1 concerning the National Reporting and Learning System and the Strategic Executive Information System. We have previously described at paragraphs 357-358 and Annex 2 of NHSE/1 the way in which these systems operate; their purpose; what data is collected; and how it is analysed. In summary:

    a. The **National Reporting and Learning System** is the national database to which incident reports made at Trust level on local risk management systems are exported and uploaded as further described below. The primary purpose of NRLS is to enable the detection or rare, new or under-recognised patient safety risks and to share learning across the system via patient safety alerts to prevent them happening elsewhere. The analysis of data reported to the National Reporting and Learning System does not routinely respond to individual reports of known major patient safety risks. However, where data suggested that a service or practitioner was unsafe, these concerns would be escalated if it was unclear that appropriate action was not already underway. The National Reporting and Learning System was not designed to be used to support performance management or regulatory oversight of providers.

b. **The Strategic Executive Information System** was the mechanism for NHS provider trusts to report incidents that had been formally declared as serious incidents or never events. In contrast to the National Reporting and Learning System, the Strategic Executive Information System could support performance management by commissioners of providers and regulatory oversight. However, the effectiveness of the Strategic Executive Information System was strongly dependent on appropriate identification and reporting of incidents by providers.

25. The Inquiry has requested that I set out the mandatory and voluntary elements in relation to the National Reporting and Learning Systems and the Strategic Executive Information System.

26. Regulation 16 and 18 of the Care Quality Commission (Registration) Regulations 2009 require certain events, including those equivalent to patient safety incidents resulting in severe harm or death, to be reported to the Care Quality Commission. NHS Trusts and NHS Foundation Trusts could satisfy their mandatory Care Quality Commission reporting requirements in relation to patient safety incidents by reporting those incidents to the National Reporting and Learning System. This was a practical arrangement to minimise the number of platforms through which NHS Trusts and Foundation Trusts had to report. If the National Reporting and Learning System was not used, then I understand that a provider could report the matter directly to the Care Quality Commission.

27. More broadly, while NHS providers funded under the NHS Standard Contract were and are expected to be able to report patient safety incidents to the National Reporting and Learning System (and now its replacement the Learn from Patient Safety Events service), NHS England did not specifically mandate the reporting of all patient safety incidents via the National Reporting and Learning System. NHS England's National Patient Safety Team does not believe that mandated reporting of all patient safety incidents (outside of that required by the Care Quality Commission) is feasible, enforceable or useful – and indeed believe this would likely have significant negative consequences should attempts be made to mandate all incident reporting. Instead, it has been the aim to encourage the development of a culture of open reporting, which is considered more effective.

28. Most patient safety incident data was uploaded onto the National Reporting and Learning System via manual batch extraction and upload of incident reports made to local risk management systems. In practice, what this means is that an individual working in an NHS Trust or NHS Foundation Trust (this could be a clinician but did not have to be) could raise a local patient safety incident report about concerns on a unit or where they considered that a patient safety risk existed via their local risk management system. Such a report is often referred to as a "Datix report" because Datix is one of the risk management information systems commonly used at a local provider level.

29. These Datix reports were then uploaded on a regular basis to the National Reporting and Learning System. Local risk management teams would usually review these local patient safety reports for accuracy prior to upload. My understanding is that this could sometimes mean that local reports, upon risk team review for consistency and other things, were downgraded or resolved and would not always as a result be included in the upload to the National Reporting and Learning System. This is one of the points of difference between the National Reporting and Learning System and the new Learn from Patient Safety Events service. The Learn from Patient Safety Events service enables real-time access to local risk management systems so the National Patient Safety Team have access to all reports raised at a local level.

30. Incidents reported via local risk management systems could be categorised as no harm, low harm, moderate harm or severe harm or death/fatal. All reports that referenced a harm level of severe, or death/fatal, would be clinically reviewed by the NHS England national patient safety team. As set out in paragraph 11(a) of Annex 3 in NHSE/1, that analysis of data reported to the National Reporting and Learning System does not routinely respond to individual reports of known major safety risks. The primary purpose of the review was the detection of themes and new or under recognised patient safety issues. However, where data reviewed by the national review team suggested a safety issue in a service that was not being appropriately addressed at local level, these concerns could be escalated.

31. Where there was a patient safety incident recorded as having resulted in severe harm or death via the National Reporting and Learning System, and the report suggested that an individual practitioner, ward/unit or practice presented a current and ongoing risk to patient safety, the national review and response team within the Patient Safety

team would look for evidence of escalation of concerns. If there was no evidence of escalation/management of the issue the national team would seek assurance via NHS England regional teams that someone other than the individual reporting the incident was aware. It should be noted that this is done rarely, perhaps only a handful of times a year because in most cases it is clear that there is action being taken and/or oversight of the incident and its investigation. In the case of Serious Incidents reported via the Strategic Executive Information Management System, there was a requirement for it to be declared via the clinical governance team and for the commissioners to be notified, so no further action would be taken by the national team to check local management of an incident that had been declared as a Serious Incident.

32. Reporting of Serious Incidents on the Strategic Executive Information System was mandated for incidents that were declared as Serious Incidents. This requirement was set out in NHS England's Serious Incident Framework: Supporting learning to prevent recurrence (updated version published on 27 March 2015 **SP/0048, INQ0009236**), compliance with which was mandated via the NHS Standard Contract. The Framework provided guidance on Serious Incidents, but the interpretation of which incidents constituted a serious incident was for local determination (operating in accordance with the guidance contained within the Framework).

33. A death, in itself, did not constitute a Serious Incident. It is the act or omission in the delivery of healthcare that results in an unexpected or unanticipated death or severe harm that would lead to a Serious Incident being declared. This determination could involve the local Clinical Commissioning Group, working with the provider to ascertain whether an incident met the threshold of a Serious Incident.

34. Once a Serious Incident had been declared, it had to be logged on the Strategic Executive Information System but responsibility for overseeing completion of the required actions primarily rested with the relevant local Clinical Commissioning Group. NHS England's role in relation to Serious Incidents is described in NHSE/1, at paragraphs 479-481 in particular. In NHSE/1, I also described how the North Regional team became aware of the Serious Incidents reported by the Countess of Chester Hospital on 30 June 2016 and of a further Serious Incident report on 7 July 2016. The National Patient Safety Team also clinically reviewed information reported onto the Strategic Executive Information System in order to identify new and under-recognised issues, but would not normally follow up serious incident reports on the Strategic Executive Information System with regions, clinical commissioning groups or providers

unless there was a need to clarify an issue to support that national identification of new and under-recognised risks.

Reports made by the Countess of Chester Hospital

35. In Annex 3 of NHSE/1 I described the rapid review that was carried out in the Summer of 2023 (prior to the verdict) by the National Patient Safety Team and which involved reviewing incident data relating to incidents reported by the Countess of Chester Hospital during the period January 2015 to December 2016. Reports made to either the National Reporting and Learning System and/or the Strategic Executive Information System were considered as being "in-scope" for review. In summary, the results of that review were as follows:

    a. A total of 335 incidents were reported by the Countess of Chester Hospital on the National Reporting and Learning System in 2015-2016.

    b. The number of these incidents within the neonatology sub-speciality field on a per month basis did not show any particular spike or trend for the Countess of Chester during the period June 2015-June 2016 (see Figure 1 at paragraph 13 of Annex 3).

    c. This data also showed that the Countess of Chester hospital was not an outlier amongst trusts with neonatology speciality units (see Figure 2 at paragraph 14 of Annex 3).

    d. During 2015-2016 period, 16 incident reports with the word "neonatology" had been extracted and reviewed at the time by the national patient safety team as per the routine monitoring and review of data uploaded onto the National Reporting Learning System. The overall conclusion reached following the subsequent rapid review of these 16 cases was that there was no evidence of any clear themes in these incidents that occurred in sufficient volume to provide early warning of an issue via reported incidents on the National Reporting and Learning System. There was also little evidence that new or under recognised issues were identified in incidents which could have alerted NHS England via the current clinical review processes. In addition, a targeted analysis revealed that none of the incidents that are now known to involve criminal activity resulting in death or severe harm were reported to the National

Reporting and Learning System with a degree of harm of death or severe harm until the final murders which occurred in late June 2016. Learnings drawn from the rapid review of these 16 cases described are set out at paragraph 16 in Annex 3 of NHSE/1.

e. There were 4 Serious Incident reports on the Strategic Executive Information System which related to neonatal fatalities.

36. The Inquiry has asked that I set out what reports were specifically made by the Countess of Chester Hospital in relation to any of the babies named on the indictment, to the National Reporting and Learning System and/or the Strategic Executive Information System, and when such reports were made. The Inquiry has also asked that I explain whether the information provided was the level of information that we would expect to be provided and what learning was gained as a result of those reports.

37. Incident reports made to either the National Reporting and Learning System and/or the Strategic Executive Information System are made in an anonymised format and we were not able, from this data alone, to reliably identify which of the reports made to either or both System relate to any of the babies named on the indictment. Reports made to the Strategic Executive Information System are summary reports only, with the detail being contained in the Serious Incident report, access to which is at a local level (i.e. the relevant Clinical Commissioning Group as was in 2015-2016 and, in the case of neonatal services, the relevant NHS England regional specialised commissioning team).

38. However, the rapid review described in Annex 3 of NHSE/1 included cross referencing incident reports pulled from both Systems with incident report reference data provided by the Countess of Chester Hospital and this enabled us to identify the cases that we considered correlated with the incident report references they provided and which they considered related to babies named on the Indictment.

39. I have exhibited [**SP/0354, INQ0107009**] to this Statement a log that shows all incident reports held by the National Patient Safety Team that meet the following criteria:

a. The word “neonatology” was included;

b. The incident report had been submitted by the Countess of Chester Hospital; and

c. The incident was reported in the period January 2015-December 2016.

40. In summary, there were 16 reports made to the National Reporting and Learning System, and 4 reports made to the Strategic Executive Information System, that we matched with the data provided by the Countess of Chester Hospital and which the Patient Safety team consider are therefore likely to relate to one of the babies named on the indictment. These have been highlighted in yellow on the exhibited incident report log for ease. For completeness, the full log has been provided to enable review by the Inquiry of other incident reports made by the Countess of Chester Hospital.

41. NHS England's Patient Safety team are of the view that the level of information included within the incident reports made by the Countess of Chester is consistent with what would have been expected and generally submitted by other Hospitals.

42. Finally, the Inquiry has asked me whether, for any baby named on the indictment who was not reported by the Countess of Chester Hospital to the National Reporting and Learning System and/or the Strategic Executive Information System, should it have been? In responding to this question, it is important to remember that, while incident reports can be raised at any time, it would be unusual for incident reports to be retrospectively made once there were other external reviews underway and, in particular, once the Police had commenced an investigation.

43. However, NHS England understands that in July 2015, Dr Stephen Brearey, the head consultant on the neonatal unit at the Countess of Chester Hospital, carried out a review of three unusual deaths that occurred in June 2015 in the unit. NHS England's solicitors have provided the Patient Safety team with copies of some of the materials disclosed to Core Participants by the Inquiry. These show that consideration was given in relation to the death of Child A as to whether this should have been declared a Serious Incident and reported via the Strategic Executive Information System (**INQ0000016**). Similarly, Child E's death was also reviewed to determine whether it should be declared a Serious Incident and reported via the Strategic Executive Information System (**INQ0000194**). I understand that neither death was ultimately

declared a Serious Incident. It is not possible to determine from the National Reporting and Learning System data how either of these panels came to their decision so we could not offer a view on whether this decision was reasonable or not.

44. The incident relating to Child C was also reported on the National Reporting and Learning System and categorised as Expected or Unexpected death with a harm level of 'no harm' but no information was provided as to whether this was referred to panel.

45. We also understand that a subsequent thematic review was ordered by Dr Brearey in February 2016 (**INQ0003217**), which looked to identify any common themes in the care provided to nine babies who had died since June 2015. The National Patient Safety Team have also now had the opportunity consider this review. The review identifies four themes and three other "suggestions for improving practice". The National Patient Safety Team would not generally expect themes from this sort of review to be reported on either the National Reporting and Learning System or Strategic Executive Information System as both are incident recording systems, not repositories for the outcomes from reviews – although the incidents underpinning these reports might well be considered to be patient safety incidents (and indeed some of the issues identified were captured on Datix).

46. As reflected above, the reporting of incidents is a matter of clinical judgment made at the local provider level where the full clinical picture is known. NHS England's Patient Safety team were therefore not in a position during the rapid review (or subsequently) to decide conclusively whether any particular incident ought to have been reported. NHS England notes, however, that the Countess of Chester did report the overall increased mortality rate in July 2016 as a serious incident and (as noted at paragraph 508 of NHSE/1) it is unclear why this was not done at any earlier point in 2016 following Dr Brearey completing his review in light of the concern about the (then) unexplained spike in mortality.

Update on results of insulin survey

47. In my second statement I set out the ongoing work the Chief Pharmaceutical Officer for England had been commissioned to undertake by the then Minister for Mental Health and Women's Health Strategy relating to the safe management of insulin on

neonatal wards. This work encompassed a survey sent out on 17 January 2024 to facilitate an in-depth assessment of the current safe and secure handling procedures regarding the use of insulin across all neonatal units. We committed in my second statement to keep the Inquiry updated in relation to any analysis of the results of this survey.

48. The Chief Pharmaceutical Officer's team have now analysed the 107 responses received and I have exhibited a copy of the team's report to this statement [**SP/0355, INQ0107008**]. The results were consistent with the initial assessment conducted in December 2023, namely:

    a. Insulin use in the neonatal patient population is infrequent; however, it remains a medication that needs to be readily available on neonatal units for use in an emergency.

    b. The results did not demonstrate any systemic failures that require a change in practice.

    c. Overall, there was good practice in the safe and secure handling of insulin in neonatal units in England, with some expected variation in practice based on the type and size of unit, patient acuity levels and the number of babies admitted at any one time.

    d. There was consistent practice in the use of insulin by neonatal units in the following areas:
        i. ordering of insulin
        ii. storage and disposal of insulin
        iii. preparation of insulin, and
        iv. second checking of insulin at both preparation and administration stages.

    e. There was some variation between the neonatal units in the following areas of practice:
        i. use of digital management systems including electronic prescribing
        ii. availability of neonatal specific policies, guidelines, and training
        iii. pharmacy staffing levels, and

iv. the use of ready to administer and/or standard concentration of insulin infusions.

f. There is no direct link between the frequency of incident reporting and safer handling of medicines, including for insulin. However, a positive learning culture and the improvements that result from incident reporting are key to controlling risks around medicine use and improving patient safety.

g. No recommended changes to practice were apparent on the basis that these would also increase the risk of harm to patients from restricted or delayed access.

h. Neonatal units should therefore at present continue to follow national and local policies and guidelines on the safe and secure handling of medicines, including insulin, and to audit local practice regularly.

49. As indicated in my second statement, NHS England will keep these results under review and will consider any further evidence that comes to light, including during the course of this Inquiry, any recommendations that may be made by the Inquiry concerning the safe management of insulin on neonatal wards, in relation to its ongoing neonatal transformation work.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: **Personal Data**

Dated: ________24 July 2024______________