Witness Name: Stephen Powis
Statement No.: 2
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THIRLWALL INQUIRY

SECOND 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 second statement in connection with the Thirlwall Inquiry ("the Inquiry") and is made by NHS England to provide detail to the Inquiry in relation to the ongoing work the Chief Pharmaceutical Officer for England has been commissioned to undertake by the Minister for Mental Health and Women's Health Strategy ("the Minister") relating to the safe management of insulin on neonatal wards. It should be read alongside NHS England's corporate witness statement ("NHSE/1").

2. As acknowledged in NHSE/1, NHS England recognises that neonatal babies are particularly vulnerable to the improper use of insulin. Specific controls relating to the management of insulin have not previously been considered necessary. It is worth noting in this context that there has historically been a very low occurrence of accidental misuse of insulin, and there is a clinical need for it to be quickly administered to neonates with high potassium levels.

3. The ongoing work that has been commissioned by the Minister is discussed in more detail below. NHS England understands that the Ministerial commission came about after some of the families of the babies killed by LL raised specific concerns with the Minister about safeguards around insulin. The Chief Pharmaceutical Officer's team were invited to meet with the Minister, following which they were asked to support a rapid commission focused on the safe use of insulin in neonatal care.

4. NHS England supports the Minister's desire to understand how insulin is managed on neonatal wards, recognising that the appalling crimes committed by LL naturally raise questions around whether the controls and safeguards currently in place are sufficient. NHS England also recognises that this work now needs to form part of the wider consideration by NHS England of learnings arising from the events involving LL and this

could include any actions considered necessary forming part of NHS England's formal neonatal transformation governance.

The use of insulin by neonatal units

5. NHS England has not issued guidance on the clinical use of insulin in a neonatal context.

6. General guidance on the administration of insulin is issued by various bodies, including the National Institute For Health and Care Excellence, Royal Pharmaceutical Society, various NHS providers and Operational Delivery Networks across the country. One such example is the guidance issued by the Thames Valley and Wessex Neonatal Network Quality Care Group, which helpfully explains as follows why insulin is used specifically by neonatal units [**SP2/1, INQ0014554**]:

> *Insulin is a hormone secreted by beta cells in the pancreas, which causes increased glucose uptake by adipose tissue and muscles, and suppression of hepatic glucose release. In a healthy individual the body secretes insulin in two main cycles. Firstly through 'basal insulin' (a low and steady secretion of background insulin that controls the glucose continuously released from the liver) and secondly by 'meal-time bolus' insulin (secreted in response to glucose absorbed from food and drink).*
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> *In adults and children insulin is most commonly given to medicate for symptoms of the medical condition diabetes, which is a lifelong condition that causes a person's blood sugar level to become too high. There are two main types of diabetes; type 1, where the body's immune system attacks and destroys the cells that produce insulin. Or type 2 where the body does not produce enough insulin, or the body's cells are resistant to the effects of insulin.*
>
> *It is extremely uncommon for a neonate to have diabetes, however insulin infusions may be required to manage hyperglycaemia by lowering blood-glucose concentrations and helping to prevent associated microvascular, macrovascular and metabolic complications of hyperglycaemia.*
>
> *…*
>
> *Three types of insulin are available in the UK: human insulin, human insulin analogues, and animal insulin although animal insulins are no longer used for new patients. Insulin is inactivated by gastro-intestinal enzymes and must therefore be*

given by injection. The subcutaneous route is ideal in most circumstances, but soluble insulin administered intravenously is the most appropriate form of insulin for use in neonates with hyperglycaemia.

7. This guidance goes on to provide practical information in relation to how insulin should be prepared, ongoing care, discontinuing the infusion, the importance of keeping parents informed, staff training and audits.

8. Each NHS provider will also determine what policies and procedures to operationalise in relation to the use of insulin. For example, this may include separate guidance for the use of insulin as a treatment for hyperglycemia and hyperkalaemia in neonates **[SP2/2, INQ0014566] [SP2/3, INQ0014562] [SP2/4, INQ0014563].**

NHS England's role in relation to medicines management

9. All medicines, whether designated as a controlled drug or not, need to be appropriately handled. Medicines management is pivotal to good patient care. NHS England is one of several bodies that has a role in relation to the management of medicines. This role is described in detail in Section 3 of NHSE/1. In short, while NHS England provides guidance on best practice around the storage and handling of medicines, including through estates guidance, described below at paragraph 13, it has no overarching statutory role in relation to the *regulation* of controlled drugs per se.

10. There are two broad categories of medicines, those that are controlled drugs and those that are not. Controlled drugs are designated as such by the Home Office and NHS England has no statutory role in relation to whether a drug is classified as such (although it may contribute to stakeholder discussions around potential changes to designations).

11. NHS England does have a supervision duty under the Controlled Drugs (Supervision of Management and Use) Regulations 2013, which require NHS England and other 'designated bodies' such as NHS providers to appoint Accountable Officers for Controlled Drugs and requires those Accountable Officers to ensure safe systems are in place for the management and use of controlled drugs. Non-controlled drugs are not regulated in the same way as controlled drugs and, as a result, NHS England has no specific statutory role in relation to medicines that are not controlled drugs.

12. All organisations within a region are required to report controlled drug incidents and concerns to the Accountable Officers. The regional leads are then required to set up Controlled Drugs Local Intelligence Networks to share concerns and good practice

within their area. As insulin is not a controlled drug, it would not currently be 'in scope' for these supervisory structures.

13. As noted above and described in more detail of Section 3 of NHSE/1, NHS England has also issued guidance (Health Building Note 14-02) relating to the storage of medicines in clinical areas and best practice on storage facilities for medicines, including (but not only) controlled drugs in clinical areas. There is no separate Health Building Note relating to neonatal and maternity units specifically in the context of the management and use of drugs.

14. Although insulin is not a controlled drug, this does not mean that appropriate safeguards are not required to be applied by NHS providers. NHS England considers the management and use of controlled drugs to in effect be additional requirements in relation to what is otherwise considered to constitute the safe and secure handling and use of medicines and good governance. Whilst there are therefore no specific statutory obligations in relation to the management and use on non-controlled drugs, the guidance of the Royal Pharmaceutical Society and principles in the National Institute For Health and Care Excellence guidance referred to above (and addressed in detail in NHSE/1) remain applicable. The Care Quality Commission's regulatory oversight would also look more broadly at medicines management (i.e. not just in relation to controlled drugs).

15. In summary, therefore, all providers must demonstrate (including when inspected by the Care Quality Commission) that they have sufficient medicines management arrangements in place for all categories of medicine and this expectation is reinforced through the NHS Standard Contract, under which providers of NHS services are required to comply with relevant statutory, regulatory and guidance requirements.

The initial insulin survey

16. On 8 November 2023, a meeting was arranged between NHS England officials and the Minister to explore potential ways in which there could be improved safeguards around the use of insulin in hospitals generally. During the meeting it was agreed to narrow this specifically to the use of insulin on neonatal units as the tighter control of insulin generally could negatively impact most patients with diabetes. The meeting was attended by NHS England's Hospital Pharmacy Modernisation Lead (who reports to the Chief Pharmaceutical Officer) and the National Speciality Advisor for Diabetes. **[SP2/5, INQ0014565]**

17. By way of context, the Chief Pharmaceutical Officer is a joint appointment across both the Department of Health and Social Care and NHS England. As such, the Chief Pharmaceutical Officer supports the Department of Health and Social Care in relation to pharmacy and medicines use in the NHS.

18. Specifically, the Chief Pharmaceutical Officer's team was asked by the Minister following the meeting to provide:

    (1) An assessment of how frequently insulin is used in neonatal wards and, if possible, for what purpose.

    (2) An assessment of the level of variation in NHS Trust approaches to the safeguards they implement around the use of insulin on neonatal wards.

    (3) Given (1) and (2), what action we could take to increase safeguards of insulin on neonatal wards. This should include options for:

        a. Additional safeguards that could be introduced on neonatal wards around the use of insulin. Here, she has previously sighted the safeguards used for concentrated potassium as an example we could explore, though she will be interested in other proposals.

        b. Doing more to standardise approaches to safeguards across NHS trusts, ensuring that everyone adheres to best practice (including any interventions identified under the 3a).

19. This commission led to the Chief Pharmaceutical Officer's team developing a survey regarding the use of insulin across a selection of neonatal units in England. The Chief Pharmaceutical Officer's team considered the survey to be the best tool to collect the information requested by the Department for Health and Social Care given that it does not itself hold data on the use of insulin for the reasons explained at paragraphs 9-15 above and no other national database collects such information. The survey questions were designed specifically to address the Minister's three questions set out above and had two aims: (1) to provide insight into these issues; and, (2) to develop a survey for a potentially wider (complete) assessment across all units.

20. The Care Quality Commission, Chair of the Chief Paediatric Pharmacist's Group, and NHS England's National Clinical Director for Neonatal care, Neonatal lead nurse, and Clinical Improvement Lead for Medicines Safety were all consulted on the survey questions **[SP2/6, INQ0014561]**. Given the nature of the commission and the requested response timeframe (with the Minister requesting a response by 23 November 2023),

this engagement was necessarily targeted and in the overall context of a commission focused on insulin as a medicine in neonatal units.

21. On 17 November 2023, this initial survey was sent to the 20 chief pharmacist members of the Acute Provider Pharmacy Advisory Group **[SP2/7, INQ0014556] [SP2/8, INQ0014559].** It was also cascaded by the Chair of the Chief Paediatric Pharmacist's Group (who is also a member of this advisory group) to their member chief pharmacists of children's hospitals. The Acute Provider Pharmacy Advisory Group had previously been set up in June 2023 to allow the Chief Pharmaceutical Officer's team to engage directly with pharmacy professional leaders at the frontline of acute trust patient care to drive improvement and innovation, understand common challenges and seek feedback on proposed policy, amongst other things [**SP2/9, INQ0014555**]. The establishment of this group was unrelated to the Ministerial commission relating to insulin.

22. The initial distribution list was chosen to ensure a range of responses from different types of unit. 20 responses were received by the 22 November 2023 deadline.

23. The Chief Pharmaceutical Officer's team analysed the results and reported the outcome back to the Minister, by way of a written report sent to the Minister on 6 December 2023 [**SP2/10, INQ0014560**]. The report set out the findings as follows:

    a. Insulin is used rarely in the neonatal units sampled, with mostly zero to two babies receiving insulin at any one time but it remains a medication that needs to be available urgently to prevent patient harm. Only a small number of units estimated four to six babies on insulin at any one time. Two main indications for insulin administration by infusion were identified: (1) all units who used insulin used it for the treatment of hyperglycaemia (high blood glucose level); and (2) a number of higher acuity units indicated they also used insulin for the treatment of hyperkalaemia (elevated level of potassium in the blood).

    b. Some variation in practice was identified in areas such as staffing models, insulin infusion preparation, use of double checking and other safe and secure handling practices in neonatal units. For example:

        (i) nineteen out of the twenty hospitals sampled mandate a double-checking procedure for insulin preparation and administration and that standard concentration insulin infusions are used at nine of the twenty hospitals;

(ii) There were also differences in the availability of neonatal unit specific local policies and/or guidelines for insulin use and handling - only six of the hospitals sampled reported having specific guidance for the use of insulin on their neonatal unit; and

(iii) There were variations in the staffing of neonatal units and more investigation was needed to be done to understand if the staffing on a unit has any impact on safeguarding in this context.

24. The clinical view of the Chief Pharmaceutical Officer's team was that the variation in responses was not unexpected given differences in the size and nature of the units selected (for example, some smaller units may only use insulin very rarely).

25. As a result of the above analysis, the Chief Pharmaceutical Officer's team identified that there was the potential for standardisation to improve safety and control of insulin use in neonatal units. However, in order to consider appropriate actions and assess the expected impact, the Chief Pharmaceutical Officer's team recommended to the Minister that a further investigation across a larger sample size was required to better understand:

a. The difference in practice and potential impact of change between the three levels of national units;

b. Variation in staffing models in relation to the type of unit in the context of national safe staffing guidance and specifically insulin safe and secure handling; and

c. The optimal formulation(s) and method of preparation for insulin infusions in neonatal units.

26. On 18 December 2023, the Department confirmed the Minister's agreement that a wider survey was warranted [**SP2/11, INQ0014564**].

The wider insulin survey

27. As a result, in late December 2023, the Chief Pharmaceutical Officer's team commenced work on drafting a wider survey to facilitate a more in-depth assessment of the current safe and secure handling procedures regarding the use of insulin across all neonatal units. Again, the team consulted with selected NHS England and external pharmacy, neonatal and patient safety leads **[SP2/6, INQ0014561]**.

28. This survey was sent out on 17 January 2024 with a deadline of 15 February 2024 **[SP2/12, INQ0014558], [SP/13, INQ0014557]**. It was resent on 1 February 2024 to all

acute trust chief pharmacists and neonatal Operational Delivery Networks to ensure engagement.

29. In terms of next steps, there are two related strands of work to complete this analysis. The first is for the Chief Pharmaceutical Officer's team to complete the process of analysing the 107 responses received. As part of completing this process, the analysis will be shared with the NHS England officials who have been involved to date, following which the outcome and any potential next steps for consideration will be shared with the Minister and reported in tandem to relevant NHS England executives. The Chief Pharmaceutical Officer's team currently anticipate completing this stage later in Spring 2024.

30. Second, as set out at the start of this statement, and notwithstanding NHS England's limited statutory role in relation to the management of medicines, NHS England will ensure that any relevant actions arising from this analysis form part of its wider consideration of learnings arising from the events involving LL, including any actions relating to its ongoing neonatal transformation work.

31. NHS England appreciates that any such actions are relevant to the Inquiry's work and it will keep the Inquiry updated in this regard.

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 in its truth.

Signed: Personal Data

Dated: 21 March 2024

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