1. I am David Wyndham Alexander Milligan and I was lead reviewer for the invited review by the Royal College of Paediatrics and Child Health (RCPCH) of neonatal services at Countess of Chester Hospital (COCH) in 2016. I have been asked to prepare a statement describing my involvement in the review. In accordance with RCPCH advice I did not keep any documentation relating to the review once it was completed and the content of this statement is based on my memory of events. My curriculum vitae is attached as a separate document.

DWAM/1 [INQ0102062]

2. Before taking up a post as a reviewer for the RCPCH I had had extensive training and experience through my work for the national clinical assessment service (NCAS) of interviewing technique, forensic case note review and structured and cross-referenced report writing. I did not receive any didactic training for the post of RCPCH reviewer because, for reasons which I do not recall, I was unable to attend the training day to which I was invited. I did however shadow an experienced reviewer before taking on any reviews myself. Prior to the Chester review I had led several other reviews the precise details of which I do not clearly remember but the RCPCH will have records of these.

3. I was approached by Sue Eardley, head of the RCPCH invited reviews service, to ask if I was available to take part in the Chester review. I confirmed that I was. I remember seeing some preliminary correspondence with some draft terms of reference which included a mention of an increased and as yet unexplained death rate of babies in the neonatal unit. There had been a review of the deaths led by a neonatologist from Liverpool Women's Hospital which I think had included an examination of the case notes and which had not found any obvious common cause for the deaths. To protect against the possibility that the deaths may have been the result of a combination of lack of experience and low staffing levels activity in the unit was temporarily restricted to caring only for the more mature babies.

4. At some point in the early documentation there must have been mention that doctors had raised the possibility that at least some of the deaths could have been attributable to poor practice or even malign interference by a nurse because I remember seeing a list of seven or eight unexplained deaths together with the names of nursing staff who had been present on shift at the time of the deaths. I observed that Lucy Letby (LL) was present for all but one or two of the deaths although she was not necessarily the nurse assigned to the care of the individual baby who died. I remember writing to Sue Eardley with this observation although I cannot remember precise wording or her response. At this stage my understanding was that the primary focus of the review was to assess whether the unit was adequately staffed for its workload, that there was appropriate clinical competence and that up to date guidance was in place and was being followed. I do not remember any discussion about escalation within the RCPCH system although with hindsight this might have been the correct course of action to take before the review went ahead (see my comments in para 12)

5. The review body consisted of myself, a consultant paediatrician from Glasgow, a senior nurse with extensive nursing and managerial experience and a lay person also with extensive experience of reviewing practice in the NHS. The review was organised and administratively led by Sue Eardley. It was common practice in other reviews in which I had been involved for there to have been a preliminary exploratory visit by the administrative and clinical leads to discuss relevant issues and firm up

terms of reference with the chief executive or medical director. I do not remember that I was personally involved in a preliminary visit for this review.

6. I do not clearly remember all the details of the review process. I recall the room in which the interviews took place and some details of the preliminary meeting with the neonatal clinicians one of whom had worked with me as a registrar in Newcastle. We learned from them that their suspicion that LL had been involved in, and was possibly responsible for, some of the deaths had led to her suspension from clinical duties. The majority of the review focused on the questions around the policies and practice of the unit together with staffing ratios and staff experience and competence. We presumably would have interviewed some senior nurses although I do not recall any detail.

7. I remember that at some point quite late in the interview process we had a discussion about whether we should interview Lucy Letby and that we agreed that she should be interviewed by the senior nurse and lay representative because of their expertise and because they were both women which might have been less threatening than bringing her before the complete interview panel the remainder of which anyway needed the time to complete the other interviews. I also remember a meeting with the medical director at the end of the interview process during which the possible involvement of LL was discussed. I recall that we asked him if he thought the police should be involved and that he said he preferred to handle the issue internally for the time being (or words to that effect).

8. Our conclusions at the end of the review were that there were a number of system issues which needed to be addressed and that the unit should for the time being continue to restrict activities to the care of the more mature babies only. We agreed that, so far as LL's involvement was concerned, the most important thing was to conduct a forensic examination of the case notes of the unexplained deaths by two independent and experienced neonatal clinicians. I remember pointing out at some stage that we needed to know if chest Xrays had been taken soon after death and whether blood samples had been taken for electrolyte and sugar levels and for any toxicology tests.

9. It was normal practice following a review that Sue Eardley drafted a report which was then circulated to review body members for their comments and any changes they wished to make. That procedure was followed in this case and after several iterations a final draft was produced. So far as I recall this was before we had heard any outcome from the case note review. It was also normal practice for the final draft to be sent to an independent paediatrician (?two) working within the RCPCH review system for quality assurance and I believe this practice was followed although I do not recall any specific details of comments that may have been made. Any final report would have been sent to the medical director at COCH and, when they had agreed its content, it would have remained their property.

10. We later learnt that the case note review had been undertaken by only one paediatrician (Dr Jane Hawdon) and that she had not found any systematic irregularity in any of the deaths. I do not think that I ever saw her report. I recall being disappointed that two people had not been involved but I had considerable respect for Dr Hawdon's opinion and by this time several months had gone by since the review body's visit.

11. As far as I recall I had no further involvement with the report until I was informed of some press comments. Subsequently I was interviewed as part of the Crisp report.

12. ***Reflections***

95. Was a service review an appropriate means of investigating an increase in unexpected deaths in circumstances where doctors had suspicions of potential criminality by a nurse?
In retrospect probably not unless this had been cleared with the RCPCH board before the review started. I do not know whether this was the case
96. Do you consider you properly discharged your duties as lead reviewer?
In general yes but in retrospect I should have recognised the potential hazards of conducting a review where potential criminality had been raised as an issue and taken a more proactive stance in ensuring that this had been cleared by the board. I should also have ensured that the case note review was carried out by two people as planned
97. Was the process of agreeing the terms of reference, and the terms themselves, appropriate?
Yes I think so
98. Should the review of been aborted when concerns of potential criminality were raised during interviews at the visit?
The interview process was not the first time at which we were made aware of concerns around potential criminality and any steps to abort the review, if this were indeed appropriate, should have been made at an earlier stage. If LL had been responsible for some of the deaths that danger had been removed as she had been suspended from any clinical work and there were other important issues to explore which may have contributed to the excess deaths such as staffing, workload and clinical competence
99. Was it appropriate for Letby to be interviewed by the review team?
We discussed this and on balance decided that it was (I think so long as the medical director agreed)
100. Do you consider it was appropriate for two versions of the report to be produced?
I do not remember that this was the case
101. Was there sufficient feedback of matters arising during the review to the RCPCH board?
I do not recall the process for this
102. Should the review team and/or the RCPCH have escalated the issues raised during the review, whether to the police or other external agency?
My understanding was that referral to an external agency was the prerogative of the COCH Trust board. The normal threshold of preventing harm to patients had been raised or abolished by LL's suspension from clinical practice
103. Should there have been follow up, or further follow up, with COCH and/or its paediatricians following provision of the report?
This would have been normal practice although I do not remember whether it occurred in this case
104. What, if anything, would you have done differently if any of the following had been in place at the time of the COCH review:
a. Escalation process and guidance March 2023 ***[INQ0012813]****.*
b. Handbook for reviewers undertaking invited reviews November 2023 ***[INQ0010213]****.*

I have not seen these documents but I imagine that the guidance given would have been uppermost in our minds and that we would have followed it

Signed 2024 **Personal Data**

Date …May 16th