

Module Code and Title:

LCHS7006 Quality Assurance and Service
Improvements

*Addressing a Systemic Quality Assurance Failure in a
Neonatal Unit: The Countess of Chester Hospital*

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1. Abbreviation

ANNP	Advanced Neonatal Nurse Practitioner
NHS	National Health Service
PDSA	Plan-Do-Study-Act
PESTLE	Political, Economic, Social, Technological, Legal, Environmental
SWOT	Strengths, Weaknesses, Opportunities, Threats

2. Introduction

The case at the Countess of Chester Hospital is one of the worst quality assurance issues in recent National Health Service (NHS) history (The Lancet, 2023). The unit experienced an unprecedented number of unexplained neonatal deaths and collapses between June 2015 and July 2016, which were later the subject of an investigation into a criminal case brought by the coroner against a former neonatal nurse, but also uncovered a broader issue of organisational, structural and cultural shortcomings within the trust (Lawrence and Conn, 2024). Criminalisation policies were the centrepiece of news coverage, but such a criminal-centred story also has the potential to miss an opportunity to learn more about and correct the systemic conditions that allowed harm to come free to vulnerable patients unchecked (Whiteing, 2023).

When the crisis occurred, the neonatal unit was in a building built in the 1970s, which had not been significantly modernised, despite the increase in clinical demand, and was classified as a level 2 unit, which should only be resourced to handle moderate-risk cases and, in practice, often had to perform level 3 intensive care beyond its resourcing (Harrison, 2025). Local transport and availability of specialist cots were not always available, despite national NHS policy advocating for the most vulnerable and extremely premature infants to be referred to regional tertiary centres, which led to the unit taking on more complexity than they could handle (Lawrence and Conn, 2024). Neonatal nurse staffing levels were chronically low - neonatal nurses were about 20% below the national standard, and there was no equivalent staffing for Neonatal

advanced Nurse Practitioner (ANP) posts (Bowie, 2025). Aside from a handful of senior consultants, there was very little presence in the evening, and all of the junior doctors covered a number of wards at night.

In this context, there was a significant increase in neonatal mortality, from an average of 4 neonatal deaths per year to 13 deaths over the thirteen-month index period before the number of deaths dropped again following the unit's formal downgrade of its acuity (Lawrence and Conn, 2024). However, when senior clinicians did raise concerns over a possible connection between the deaths and one member of staff, the hospital executives reportedly demanded that the consultants apologise, rather than investigate the matter formally, and this was not done until many months later (Kirkup and Titcombe, 2023). This response pattern of 'reputation' over 'patient safety concerns' is central to this quality assurance failure and is the response pattern explored in this report.

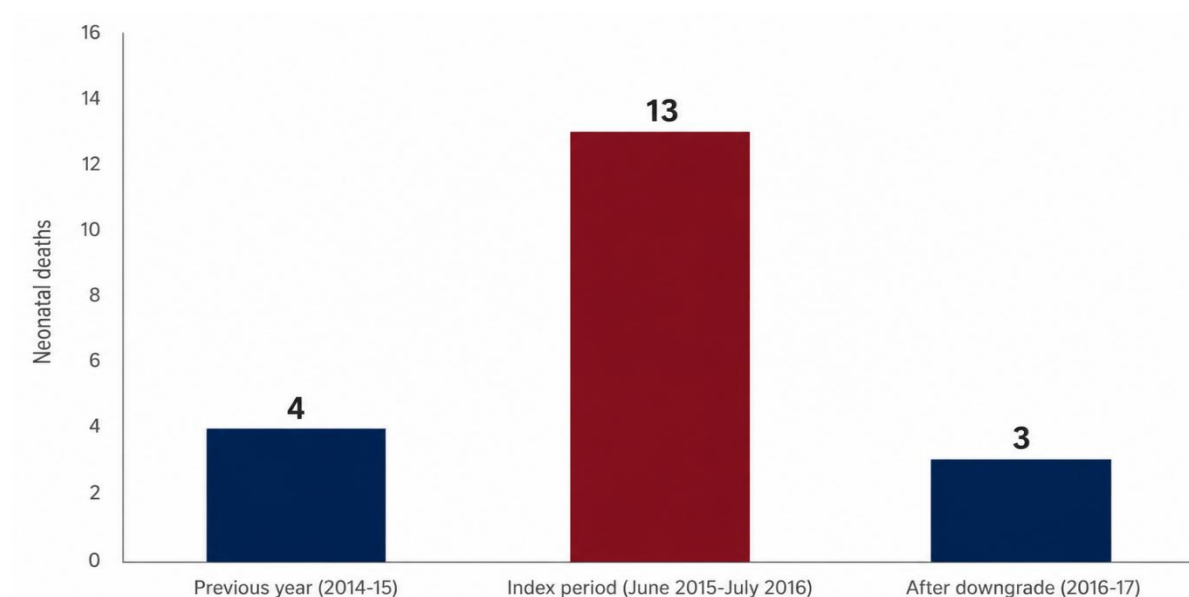


Figure 1: Neonatal mortality clustering, Countess of Chester Hospital (Lawrence and Conn, 2024)

This report is laid out in three parts: first, a theoretically informed root cause diagnosis, followed by an application of strategic analysis tools to appraise the internal and external position of the organisation, and lastly, an evidence-based, staged implementation strategy for ongoing improvement.

3. Root Cause Analysis: The Fishbone Diagram and 5 Whys

Fishbone, also known as the Ishikawa diagram, is one of the most popular methods to perform root cause analysis, which usually consists of people, process, environment and management and can include multiple contributing factors instead of the adverse event being considered a single point failure (Siddiqui, 2021). When applied to the case of the Countess of Chester, it becomes clear that it was not any one of these weaknesses that caused the elevated neonatal mortality, but several categories of weakness.

The unit was also chronically understaffed, with the ratio of advanced neonatal nurse practitioners per patient being one-fifth lower than the national benchmark, and fewer neonatal nurses than the same ratio as the national standard (Bowie, 2025). Escalation pathways for clinical concerns were inadequate under process, meaning that when consultants voiced concerns about the mortality trend, these were channelled through management layers, concerns were trivialised, and doctors were pushed into apologising, without their observations being investigated independently (Kirkup and Titcombe, 2023). The physical estate under the environment was dated to 1971 and had been impacted by sewage backups and contaminated water, which compromised control of infection (Harrison, 2025). The internal governance structures acted as a blockage to improvement in patient safety, rather than a facilitator, because a culture of focusing on institutional reputation over patient safety concerns continued to exist under management (Kirkup and Titcombe, 2023).

The following table illustrates how these categories relate to the central symptom – increased number of unexplained neonatal deaths – as illustrated by the application of the 5 Whys technique. If there is any increase in deaths, asking why brings up unrecognised patterns in deaths data; if there is any reason for the increase in deaths to remain unrecognised, it brings up weak escalation processes; if the escalation processes are weak, it brings up a management culture that did not encourage challenge; if it did not encourage challenge, it brings up a lack of external accountability

mechanisms; and if there are no external accountability mechanisms, it brings up systemic gaps in the wider NHS governance architecture, a recurring feature identified in trusts which do not investigate, learn and improve (Ockenden, 2022). The importance of the 5 Whys is that it can help to shift the focus of analysis from a superficial description of events to a deeper examination of the underlying conditions within the organisation that allowed the event to happen, reflecting the overall enterprise of the 5 Whys and in the healthcare field, a tendency for the system to view safety incidents as isolated events rather than indicators of latent weaknesses within the system (Jesudason, 2023).

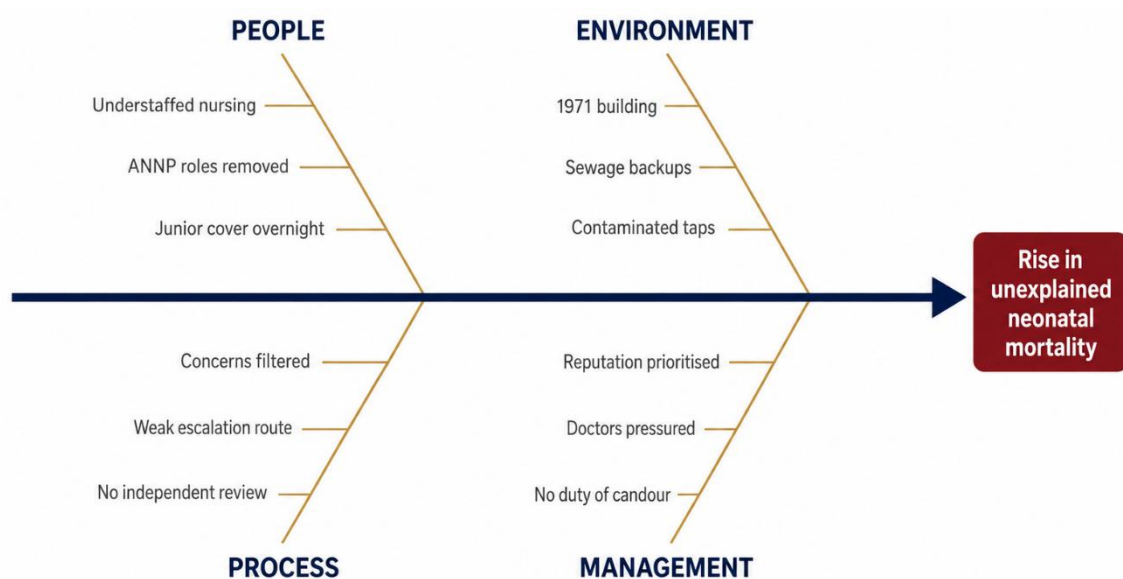


Figure 2: Fishbone (Ishikawa) diagram of contributory causes at the Countess of Chester neonatal unit (Siddiqui, 2021; Bowie, 2025; Kirkup and Titcombe, 2023)

4. The Donabedian Model: Structure, Process and Outcome

The Donabedian model continues to be one of the classic models for assessing healthcare quality, which includes three components: structure (the physical and organisational resources used to provide care); process (the activities carried out to provide care); and outcome (the effect of care on patients), and stresses that these three parts are not separate stages but are interdependent (Tossaint-Schoenmakers et al., 2021). The structural deficiencies, along with an ageing estate, understaffing and equipment that was over the acuity, directly affected the care processes that relied on these processes. Senior consultant cover was often not provided outside of hours, leading to junior doctors at times being called to look after multiple wards for an overnight period, with the effect that at times clinical decisions were not made in a timely and reliable manner, particularly during periods of high risk (Harrison, 2025).



Figure 3: Donabedian Structure-Process-Outcome framework applied to the Countess of Chester case (Tossaint-Schoenmakers et al., 2021)

These structural and process failures led to outcome-level harm the neonatal death rate was almost quadruple in the index period than the previous year, but decreased again after the unit was placed in a lower acuity of care (Lawrence and Conn, 2024). The Donabedian framework is useful because it doesn't blame outcomes and encourages people not to become 'over individualised' and assume that an outcome is only the fault of one member of staff and that the system in which they operate made it easy to hide harm, or it was a 'few bad apples' (Dobson, 2023). Studies of the application of the model have been positive with respect to the association between a strong structure and a sound process, and between a sound process and a good outcome, this is the same relationship that was not present at Chester, as described by Tossaint-Schoenmakers et al. (2021). The implication for service improvement is that service improvement must happen at all three levels at once: structural investment alone will not fix the poor process of escalation; improving process alone will not compensate for a poorly resourced structure; and improving process while the structure remains under-resourced will not allow the system to sustain itself in the long run.

5. Strategic Analysis: SWOT and PESTLE

4.1 SWOT Analysis

If the cause(s) of a problem are identified, strategic tools are required to turn this diagnosis into a viable improvement direction. SWOT analysis is a strategic planning tool that has long been used to assess an organisation's internal strengths and weaknesses, and external opportunities and threats and is a tool that has been widely adopted for the healthcare sector for structuring improvement planning, SWOT (Siddiqui, 2021). Internal strengths applied to the neonatal service at the trust were that there was a skilled clinical staff who were not afraid to raise concerns, evidenced by an experienced team of consultants, who worked tirelessly to raise the mortality trend despite the resistance of the institution; and a renewed focus on patient safety after the case, which was reflected in the new regulatory requirements. Internal weaknesses are the lack of a national benchmark to match staffing, understaffing in general and the long-standing poor escalation culture, as well as ageing physical estate. International opportunities are increasingly present, such as regional neonatal transport networks and partnerships with tertiary centres, if appropriately resourced, that could help to alleviate local pressures, as well as a more assertive national patient safety agenda, since similar maternity and neonatal reviews (Ockenden, 2022). There are external risks too, such as ongoing national pressures of specialist neonatal nurses and financial pressures in the wider NHS estate and the potential for the public to remain disaffiliated with the service long after any structural changes have been made (Dyer, 2023).

4.2 PESTLE Analysis

A complementary PESTLE analysis situates these findings within the wider policy environment. In a political sense, the case has drawn attention to the governance of the NHS and the need for the statutory duty of candour to be enforced on those who are not frontline clinicians, but rather senior managers (Kirkup and Titcombe, 2023). From an economic perspective, there is a wider pressure on NHS budgets on sustainable investment for neonatal infrastructure, and so improvement plans need to show not only safety benefits but value. Socially, families and the public are now demanding transparency and genuine engagement in the redesign of services after a

service failure or incident of harm, which was reiterated during the national maternity and neonatal failures reviews (Dobson, 2023). At the technological level, there are opportunities to improve mortality surveillance, for example, by introducing a data system that provides greater capacity for detecting statistical anomalies than does individual clinical vigilance. The case has done much to strengthen legal duties for whistleblower protection and mandatory reporting of incidents. At an environmental level, meaning the physical setting for care, the state of the ageing NHS estates, such as the infection control failures found at Chester, is a known risk factor for the quality of care across the whole country (Harrison, 2025).

6. Recommendations and Implementation Strategy

The root causes highlighted above, structural under-investment, weak escalation processes and a defence culture of management, indicate a recommendation set that needs to be implemented in an iterative way, not as one event. The PDSA (Plan-Do-Study-Act) cycle, widely promoted by NHS improvement organisations as the main way to trial and implement change at a manageable scale, is the vehicle that is suitable for this. (The Health Foundation, 2021). To avoid disrupting and disengaging clinicians, rather than trying to reorganise in one go, a staged PDSA approach can be adopted so that each intervention can be piloted, safety and quality measures are pre-defined, and the intervention is refined before being rolled out to a wider group of patients.

5.1 Plan

The first is to set up an independent, board-level escalation process, where any concern a clinician might have regarding a statistical mortality anomaly is automatically sent to an external panel in a predetermined time frame, so that all earlier concerns are not ignored and suppressed by the management. (Kirkup and Titcombe 2023) Time-to-escalation and time-to-independent-review should be used to help measure success and should be piloted on the neonatal unit before wider extension.

5.2 Do

At the same time, the staffing configuration of the unit should be aligned with the national neonatal nursing standards, with advanced neonatal nurse practitioner (ANNNP) positions reinstated, and consultant cover provided out of hours, rather than by junior staff (Bowie, 2025). Before adopting a guaranteed consultant on call cover on a long-term basis, it should be trially assessed to determine if there is any measurable difference in response time to deteriorating patients.

5.3 Study

The Fishbone and Donabedian analyses should identify root cause indicators and process indicators, which should then be monitored, tracked and reviewed monthly on a rolling dashboard, with an independent quality assurance committee (Ockenden, 2022; Dobson, 2023), and with family representation, as highlighted in the Ockenden review. This recommendation is backed by lean methodology principles of making

problems visible, and eliminating delay in the flow of information in the organisation: mortality and safety data should go through the organisation as quickly as possible, not filtered through layers of managerial review to reach decision makers (Rathi, Vakharia and Shadab, 2021).

5.4 Act

Where a PDSA cycle indicates that improvement is being seen, for example, when a measurable difference in escalation delay has been achieved, any changes should be formally incorporated into trust policy and implemented in other similar units, as per the PDSA principles that any changes should be based on tested evidence and not assume that they will be effective (The Health Foundation, 2021). If a cycle fails to yield improvement, it should not be eliminated, but instead modified and retested, in order to maintain the cycle of learning and non-punishment which is so strikingly missing at Chester.

Embedding Six Sigma Discipline

The data-driven components of this strategy can be complemented by Six Sigma principles. Since Six Sigma methodology involves structured measurement of variation and defects, a Six Sigma-informed audit of neonatal mortality and morbidity data would set up scale-based statistical control limits, and if the scale-based control limit were violated, it would be reviewed automatically rather than relying on individual clinicians noticing and believing the reduction in mortality and morbidity. (Rathi, Vakharia and Shadab, 2021). In the healthcare sector, the findings show that this integration of Lean's emphasis on wasteful delay reduction with Six Sigma's statistical approach is best implemented when it is part of an organisation's cultural and value system, rather than simply a toolbox, reinforcing the need for a structural and cultural approach to be taken simultaneously (Rathi, Vakharia and Shadab, 2021).

National Policy Alignment

National policy must also be given attention at a strategic level. Increased national expectations for extremely premature infants to be transferred to tertiary centres, coupled with the local absence of transport and cots at Chester, demonstrate a nationalistic expectation versus local capacity mismatch (Lawrence and Conn, 2024).

The regional commissioners should thus be accountable for publishing and tracking tertiary transfer capacity versus demand and implementing escalation steps when the local units are routinely transferring patients to higher acuity facilities than they are intended for.

Sustaining Leadership Commitment

Finally, it takes leadership commitment and visibility to maintain the improvement. The Ockenden review's core message – services do not work when they do not investigate, do not learn, and do not improve – is true for Chester and any trust that is trying to change. The central theme of the Ockenden review – services do not work when they do not investigate, do not learn and do not improve – is applicable to Chester and to any trust seeking to improve (Ockenden, 2022). The PDSA cycles outlined above should be overseen by a standing implementation board, co-chaired by clinical and executive leadership, which should also include families who are affected by the PDSA cycles. These implementation boards should ensure that lessons are not only taken, but visibly put into practice.

Stage	Action	Success Measure
Plan	Independent board-level escalation pathway for mortality anomalies	Time from concern raised to independent review
Do	Restore ANNP posts; guarantee consultant out-of-hours cover	Nurse-to-patient ratio; response time to deterioration
Study	Monthly dashboard reviewed by committee with family representation	Trend in mortality/morbidity indicators
Act	Embed successful changes trust-wide; revise and re-test unsuccessful ones	Sustained improvement across repeated cycles

Table 2: Summary of PDSA implementation plan mapped to identified root causes

7. Improvement

The independent, board-level escalation pathway that streams clinical concerns to an external panel (without management filters) is relevant for Chester and any trust aiming to put an end to the suppression of clinical concerns (Kirkup and Titcombe, 2023). The structural gap highlighted at the heart of the unit's failure to manage its burden safely – the presence of advanced neonatal nurse practitioner (ANNP) staffing and consultant out-of-hours cover – is relevant to Chester and any trust looking to bridge the structural and process gap (Bowie, 2025). The monthly, family-focused mortality dashboard – which provides safety data in real time, without having to go through layers of managerial review – could be applied to Chester, and to any trust that wants to investigate, learn and improve (Ockenden, 2022; Dobson, 2023). Successful PDSA cycles can be integrated into a permanent trust policy supported by Six Sigma statistical control – viewed as a cultural change rather than a set of tools – which can be applied in Chester and to any trust wishing to maintain its improvement over time (Rathi, Vakharia and Shadab, 2021). Ensuring local capacity matches national policy (closing the gap between anticipated tertiary transfers and supply of transport and co transport locally) is relevant to Chester and to any trust aiming for regional resilience (Lawrence and Conn, 2024). These five areas – structure, process, governance, sustainability and national alignment – are all based on the principle that PDSA based change should be 'tested and spiralled up' rather than 'spoon fed and hoped for', and apply to Chester and to any trust aiming for lasting improvement (The Health Foundation, 2021).

8. Conclusion

The failures at the Countess of Chester Hospital neonatal unit were not just the fault of one person; they were brought about through a combination of structural under-investment, poor escalation systems and a management culture that focused on institutional reputation rather than patient safety. The Fishbone diagram, the 5 Whys technique, and the Donabedian model revealed the layered nature of these causes, and the Donabedian model helped to clarify how the problems in structure and in process led to measurable and preventable harm in the outcomes. SWOT and PESTLE analysis placed these local failures in the broader context of the national picture, where significant workforce shortages, changes to regulations and increased scrutiny of governance and transparency of other NHS maternity and neonatal services were evident following similar failures in those other services.

The recommendations outlined in this report are an independent escalation pathway and restore staffing levels, mortality surveillance based on data and a staged PDSA implementation plan with a Lean Six Sigma discipline approach are intentionally designed to target root causes instead of symptoms. None of these actions is a standalone solution; a cultural change is needed in which reporting a safety concern is regarded as a professional duty rather than a risk to be managed. Wherever there have been similar failures across the country, the voices of the families involved, as well as the commitment of leaders, have always been the most important and most likely to create meaningful change, not the imposition of it from on high. Quality assurance in health and social care, therefore, must not be seen as a compliance process that takes place after the event, but rather it is a continuous proactive process that is part of the day-to-day work of care providers. Without staff, systems can't protect their patients.

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