

MSc Public Health and Social Care in Practice

**Module: Quality Assurance and Service Improvements
(LCHS7006)**

**Title: Service Improvement Report: Quality Assurance
and Patient Safety Failures in the Lucy Letby Case**

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Introduction

Quality in health and social care concerns the provision of safe, effective, timely, equitable and person-centred care that achieves appropriate outcomes. The National Quality Board (NQB, 2021) identifies quality as a shared responsibility across health and care systems, while the World Health Organization (WHO, 2021) emphasises that patient safety is fundamental to high-quality healthcare and requires systematic action to reduce avoidable harm. More recently, WHO (2024) highlighted the importance of safety policies, reporting and learning systems, patient engagement and organisational improvement. In England, the Care Quality Commission (CQC, 2024) similarly emphasises safe systems, effective leadership and organisational cultures that support learning and improvement. Its subsequent State of Care report identifies continuing pressures on quality, workforce capacity and organisational performance across health and social care (CQC, 2025).

Quality assurance (QA) involves monitoring and evaluating care against established standards, whereas quality improvement (QI) focuses on changing services and systems to improve outcomes and performance. The Health Foundation (2021) argues that QI requires a systematic approach involving problem identification, process analysis, staff and patient engagement, measurement and evaluation. Although distinct, QA and QI are complementary: assurance identifies whether standards are being achieved, while improvement examines why weaknesses occur and how they can be addressed. NHS England's current quality strategy similarly emphasises leadership, accountability, data, transparency, staff engagement and continuous improvement (NHS England, 2026).

This report examines the case of Lucy Letby, a neonatal nurse employed at the Countess of Chester Hospital NHS Foundation Trust from June 2015 to June 2016. She was convicted of the murder of seven babies and the attempted murder of seven others, resulting in fifteen whole-life sentences (Lawrence and Conn, 2024). While criminal responsibility rests with the individual, evidence from the public inquiry and wider investigations has also raised significant questions about organisational governance, leadership, staffing, communication and responses to concerns raised by clinicians. Contemporary reporting identified weaknesses in the neonatal unit, including staffing

pressures, limited expertise and concerns about management responses to emerging problems (Lawrence and Conn, 2024). Evidence presented to the Thirlwall Inquiry has also examined the Trust's handling of concerns and interactions with senior clinicians (Lawrence and Conn, 2024).

The central quality concern is therefore the failure of organisational systems to recognise, escalate and respond effectively to repeated patient safety signals despite concerns raised by clinical staff. The case demonstrates that policies and governance structures cannot guarantee safe care if they are not effectively implemented. HSSIB (2023) similarly argues that safety management must be integrated into everyday organisational activities rather than treated as a separate compliance function.

The aim of this report is to critically analyse the root causes and policy issues associated with this quality failure and evaluate their effects on patient safety and service provision. The Fishbone Diagram and 5 Whys will examine underlying causes, the Donabedian Model will analyse structures, processes and outcomes, and SWOT analysis will assess factors affecting improvement. Contemporary research and policy guidance will inform evidence-based recommendations. Finally, PDSA will provide the implementation framework for sustainable improvements in governance, incident reporting, leadership, organisational culture and patient safety, building on the systems-based analysis developed in Component 1.

Main Body

2.1 Overview of Continuous Quality Improvement

Preventable harm remains a major concern across health and social care, demonstrating that quality improvement must be treated as a continuous organisational responsibility rather than a response to individual failures. WHO (2021) identifies patient safety as a fundamental component of healthcare quality and emphasises that avoidable harm

requires system-level action. The Health Foundation (2021) similarly argues that healthcare quality depends on how effectively processes function and whether organisations can identify problems and test improvements systematically. This is particularly relevant to the Lucy Letby case because the central concern was not simply individual actions, but the apparent failure of organisational systems to recognise, escalate and respond to repeated warning signs. NHS England (2022; 2026) similarly places patient safety incident response within wider quality improvement and governance systems, requiring organisations to translate learning into measurable improvement.

Continuous Quality Improvement (CQI) is therefore relevant because it emphasises ongoing learning, measurement and service modification. The Countess of Chester Hospital had formal governance and reporting arrangements, but their existence does not necessarily demonstrate effective quality assurance. Contemporary CQC evidence shows that organisational quality depends on leadership, workforce capacity, governance and effective responses to identified risks (CQC, 2024; CQC, 2025). HSSIB (2023) further argues that effective safety management requires proactive risk identification, clear accountability and integration of safety activities into routine organisational management. The case therefore illustrates the distinction between having quality systems and using them effectively.

2.2 The Swiss Cheese Model

Reason's Swiss Cheese Model remains useful for understanding how multiple weaknesses can align to permit serious harm, although its original formulation predates contemporary systems-based approaches. The model conceptualises safety as organisational barriers, with weaknesses allowing hazards to pass through when gaps align (HSSIB, 2023). In healthcare, these barriers may include clinical monitoring, incident reporting, supervision, governance, staffing and external regulation. PSIRF supports this systems perspective by emphasising contributory factors and system interactions rather than individual blame (NHS England, 2022).

Applied to the Letby case, several layers of defence can be considered. Clinical monitoring should have identified repeated unexpected neonatal deterioration and deaths. Incident reporting and escalation should have triggered timely review and protective action. Leadership and governance should also have enabled emerging patterns to be recognised and challenged, alongside appropriate external scrutiny. PSIRF reinforces the need to connect patient safety, quality improvement and clinical governance rather than treating incidents separately (NHS England, 2026).

The model's main strength is shifting analysis from individual blame towards interacting system weaknesses. However, it can oversimplify complex healthcare events if barriers are viewed as independent or failures as linear. HSSIB (2023) highlights the need for coordination across organisational levels, while Crompton et al. (2025) emphasise system-wide learning. Therefore, the model is best used as an initial systems perspective rather than a complete explanation.

2.3 Identifying Contributing Factors: The Fishbone Diagram

Root cause analysis (RCA) provides a structured approach to examining why adverse events occur and identifying factors that can be modified to reduce recurrence. Martin-Delgado et al. (2020) found that RCA is widely used in patient safety, although its effectiveness depends on investigation quality and whether learning leads to meaningful improvement. The Fishbone or Ishikawa diagram is useful because it organises multiple contributing factors rather than assuming a complex event has one cause. Boi (2021) demonstrates its practical value in healthcare for structuring potential causes and supporting RCA.

This makes the Fishbone approach appropriate for the Letby case, where organisational, cultural, leadership and communication factors interacted. Six major branches can be identified: clinical governance, including weaknesses in oversight and risk identification; incident reporting, including inadequate escalation; leadership, including delayed decision-making and insufficient challenge; policies and procedures, including

implementation weaknesses; staffing and organisational culture, including hierarchy and psychological safety; and communication, including failures to share concerns.

Contemporary evidence supports the importance of speaking up and psychological safety (Kane et al., 2023; LaPlante, Ponte and Magny-Normilus, 2025). The Fishbone diagram therefore demonstrates that the quality concern cannot be reduced to one failure. However, it identifies contributing factors without establishing their relative causal importance, making it appropriate to combine with the 5 Whys and Donabedian Model.

2.4 Augmenting the Fishbone with the 5 Whys

The 5 Whys technique provides greater causal depth by repeatedly asking why a problem occurred. RCA literature suggests that causal investigation should avoid simplistic assumptions about one root cause and instead consider multiple interacting factors (Martin-Delgado et al., 2020). This is consistent with PSIRF, which encourages system-based investigation rather than a narrow search for individual blame (NHS England, 2022).

In this analysis, it is applied primarily to the leadership and culture branches of the Fishbone diagram:

Why did concerns about neonatal harm fail to result in sufficiently rapid protective action?

Because concerns were not consistently converted into effective escalation and organisational intervention.

Why was escalation ineffective?

Because leadership responses did not consistently prioritise precautionary patient safety when uncertainty remained.

Why was uncertainty allowed to delay stronger action?

Because organisational decision-making was influenced by competing managerial, employment and reputational considerations.

Why could these considerations outweigh challenge from clinicians?

Because hierarchical relationships and weaknesses in psychological safety could discourage persistent challenge and escalation.

Why did this culture persist?

Because governance arrangements were not sufficiently effective in ensuring that concerns, risks and staff challenges were independently reviewed and translated into action.

This analysis identifies interacting organisational root causes, rather than claiming that one factor caused the criminal harm. The National Guardian's Office (2025) provides contemporary evidence that inappropriate attitudes and behaviours remain a major theme within Freedom to Speak Up concerns. However, the 5 Whys can oversimplify complex healthcare events because its linear structure may encourage investigators to search for one dominant explanation. PSIRF therefore provides a more contemporary approach by encouraging system-based examination of contributory factors (NHS England, 2022).

2.5 Donabedian Model

The Donabedian Structure-Process-Outcome (SPO) model provides a complementary framework for evaluating whether weaknesses were embedded within organisational resources and arrangements, care processes or outcomes. Tossaint-Schoenmakers et al. (2021) demonstrate that structure, process and outcome indicators remain useful for examining organisational quality, while recognising that their relationships can be complex.

In the Letby case, structure relates to staffing arrangements, leadership capacity, governance structures, reporting systems and independent scrutiny. Process relates to how concerns were reported, escalated, investigated and communicated. Outcome relates to repeated episodes of serious neonatal harm and the delayed organisational

response. This demonstrates that poor outcomes cannot be separated from the structures and processes through which care and governance were organised.

The model also exposes the difference between formal organisational capacity and actual operational performance. A Trust may possess reporting systems, governance committees and policies, but these contribute to quality only when processes operate effectively. NHS England's Quality Strategy (2026) similarly links leadership, data, accountability and organisational culture to quality improvement. However, the traditional Donabedian model may underestimate the complexity of healthcare systems when interpreted too rigidly. It is therefore used alongside the Swiss Cheese and Fishbone approaches.

2.6 SWOT Analysis

A SWOT analysis helps translate the preceding diagnostic analysis into a strategic assessment of organisational capacity for improvement.

Strengths	Weaknesses
Existing clinical governance and reporting structures	Weak escalation and challenge
Access to multidisciplinary expertise	Leadership and accountability weaknesses
Current NHS patient safety frameworks	Potentially low psychological safety
Established regulatory oversight	Risk of policies existing without effective implementation

Opportunities	Threats
Implementation of PSIRF and systems-based learning	Defensive or blame-oriented culture
Stronger Freedom to Speak Up arrangements	Staff fear of repercussions

Independent review of serious safety signals	Reputational and legal pressures
Board-level quality and safety oversight	Workforce and resource pressures

The SWOT analysis demonstrates that the organisation does not necessarily require more policies alone. Its major opportunity is to improve the implementation, integration and assurance of existing safety mechanisms. HSSIB (2023) argues that effective safety management requires clear accountability and integration into everyday organisational practice. PSIRF is particularly relevant because it connects incident response with quality improvement and clinical governance (NHS England, 2026).

2.7 Critical Synthesis of Findings

Taken together, the analytical approaches identify a consistent pattern. The Swiss Cheese Model demonstrates how several safety barriers can fail simultaneously; the Fishbone diagram identifies governance, leadership, culture, communication, staffing and reporting as interconnected contributory factors; the 5 Whys explores the depth of leadership and cultural weaknesses; and the Donabedian Model demonstrates how structural and process weaknesses can influence outcomes. SWOT then identifies opportunities to convert these findings into organisational improvement.

The central quality issue is therefore best understood as a failure of organisational assurance and learning rather than simply a failure to possess policies. This conclusion is consistent with PSIRF principles, which emphasise systems thinking, proportionate learning responses, staff and family involvement, governance oversight and translation of learning into improvement (NHS England, 2022; NHS England, 2026). Crompton et al. (2025) further highlight the importance of system-wide learning from patient safety investigations.

The subsequent recommendations should therefore focus on strengthening escalation, psychological safety, governance and organisational learning, supported through a structured improvement methodology such as PDSA.

Recommendations

Addressing the organisational causes identified through the Swiss Cheese Model, Fishbone diagram, 5 Whys and Donabedian analysis requires coordinated action rather than additional policies alone. Priorities should include governance, organisational culture, incident learning, communication and independent scrutiny. These recommendations align with PSIRF, which promotes systems-based learning and integration between patient safety, quality improvement and clinical governance (NHS England, 2022; NHS England, 2026).

First, clinical governance and escalation should be strengthened. The Trust should monitor neonatal outcomes through dashboards identifying unusual patterns of mortality, deterioration and unexpected events. Multidisciplinary governance meetings should review these data using predefined escalation thresholds and independent clinical review, consistent with HSSIB's (2023) emphasis on proactive safety management and accountability. SBAR should support clear escalation, although standardisation alone does not guarantee improved outcomes (Lo, Rotteau and Shojania, 2021; Müller et al., 2018). It should therefore complement professional judgement.

Second, incident reporting should be integrated with organisational learning. The Trust should conduct regular thematic analysis of incidents, near misses, complaints and clinical outcomes to identify recurring patterns. Each action should have a named owner, measurable indicator and review date. This is essential because reporting has limited value when information remains fragmented rather than becoming organisational intelligence (Jazieh, 2020; HSSIB, 2024). PSIRF requires proportionate, system-based responses linked to quality improvement (NHS England, 2022; NHS England, 2025).

Third, psychological safety and Freedom to Speak Up should be strengthened. Staff should have confidential escalation routes, visible leadership support and regular board-level reporting. Psychologically unsafe cultures and hierarchical relationships can restrict effective escalation (NHS England, 2023), while inappropriate attitudes and behaviours remain concerns (National Guardian's Office, 2025). A Just Culture should distinguish

human error and system weaknesses from reckless or deliberate misconduct while maintaining individual accountability (Barkell and Snyder, 2021).

Fourth, communication and multidisciplinary collaboration should be improved. Regular safety meetings should involve neonatal clinicians, nurses, governance professionals and senior management. Concerns should be documented, assigned and followed to resolution, with families involved in communication and learning following serious incidents (NHS England, 2026). Communication approaches should be adapted to neonatal care rather than transferred uncritically from other safety-critical industries (HSSIB, 2023).

Fifth, independent scrutiny and accountability should be strengthened. External peer review should be undertaken for significant or unresolved safety concerns, with non-executive directors and board-level safety committees receiving reports on unresolved risks, Freedom to Speak Up themes and safety actions. PSIRF requires oversight roles to apply systems thinking and challenge safety actions (NHS England, 2026). The Ockenden Review demonstrates the importance of stronger investigation, governance, communication and safety culture following serious maternity and neonatal failures (Ockenden, 2022). Independent scrutiny can therefore provide an additional defence against organisational blind spots, while the Duty of Candour reinforces openness when things go wrong (CQC, 2025).

Sixth, workforce capability and quality improvement skills should be developed. Staff and managers should receive training in human factors, escalation, psychological safety, incident learning and systems thinking. PDSA should be used to test the revised escalation and reporting processes before wider implementation:

PDSA Stage	Application to the Trust
Plan	Establish baseline measures, identify gaps, assign leaders and design revised escalation and reporting processes.
Do	Pilot the changes within one neonatal service with frontline staff and, where appropriate, patients and families.

Study	Compare escalation response time, completion of safety actions, staff confidence in speaking up and recurrence of similar incidents against the baseline measures.
Act	Refine successful interventions and determine whether they should be implemented across the Trust.

PDSA supports iterative learning, but its effectiveness depends on implementation quality, organisational support and interprofessional engagement (Rose et al., 2021; Sutton et al., 2021; Manandi et al., 2024). Lean can complement PDSA by reducing unnecessary delays and duplication, although sustainability varies between settings (Lima et al., 2020; Zepeda-Lugo et al., 2020). Six Sigma and DMAIC should be used selectively where quantitative data allow process variation to be analysed (Niñerola, Sánchez-Rebull and Hernández-Lara, 2020).

The recommendations should be prioritised according to patient safety risk and organisational feasibility rather than implemented simultaneously without evaluation. Immediate attention should therefore focus on escalation, psychological safety and governance oversight, followed by wider workforce development and process optimisation. This staged approach can reduce implementation burden while allowing early evidence of improvement to inform subsequent changes. Sustained improvement will also require continued leadership accountability, regular measurement and feedback from frontline staff and families (NHS England, 2026).

Implementation should progress in three stages: an initial stage establishing baseline measures and assigning responsible leaders; a second stage piloting the revised processes through PDSA with frontline staff and, where appropriate, patients and families; and a third stage evaluating outcomes and spreading successful interventions across the Trust. Key indicators should include escalation response time, completion of safety actions, recurrence of similar incidents, staff confidence in speaking up and evidence of measurable change (NHS England, 2026).

Overall, leadership commitment is critical. Policies and reporting systems will have limited value if leaders respond defensively to challenge. The objective should therefore be an

organisation where concerns are actively sought, independently examined and converted into measurable safety action.

Conclusion

This report has critically analysed the organisational quality and patient safety failures associated with the Lucy Letby case at the Countess of Chester Hospital NHS Foundation Trust. The Swiss Cheese Model demonstrated how weaknesses across multiple organisational safeguards can align, while the Fishbone diagram identified interconnected problems involving clinical governance, incident reporting, leadership, policy implementation, organisational culture, staffing and communication. The 5 Whys analysis provided greater causal depth by demonstrating how weaknesses in leadership, challenge and psychological safety could prevent concerns from being translated into timely protective action. The Donabedian Model further showed that the problem extended across organisational structures, care and governance processes, and ultimately patient outcomes.

The analysis indicates that the organisational problem cannot be explained by the absence of policies alone. Rather, it involved interacting weaknesses in governance, leadership, escalation, communication and organisational culture that reduced the effectiveness of existing safety barriers. This distinction is important because focusing solely on individual accountability or additional documentation would not address the wider system conditions that allowed concerns to remain insufficiently acted upon. Contemporary NHS safety policy supports this interpretation by emphasising systems-based learning, organisational accountability, psychological safety, staff involvement and measurable improvement (NHS England, 2022; NHS England, 2026).

The recommendations therefore focus on strengthening clinical escalation, integrating incident reporting with organisational learning, improving psychological safety and Freedom to Speak Up, strengthening multidisciplinary communication, increasing independent scrutiny and developing workforce capability. Their implementation through PDSA provides a practical mechanism for testing and refining interventions before wider

adoption, while Lean and Six Sigma can be applied selectively where they add value. Evidence from contemporary QI literature suggests that improvement is most effective when interventions are tested systematically, measured appropriately and adapted to organisational context rather than introduced as isolated initiatives (Jazieh, 2020; Manandi et al., 2024).

Ultimately, the case reinforces that quality assurance depends not simply on whether safety systems exist, but on whether they function effectively in everyday practice. A learning-oriented organisation must actively listen to staff and families, welcome constructive challenge, identify patterns in safety data and ensure that concerns lead to measurable action. The proposed approach therefore seeks to move service improvement from policy compliance towards a sustained culture of learning, accountability and safer care.

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