

Health Care System Organisation and Leadership

Case Study Analysis Report

Case Study 1: Infant Morphine Overdose NHS North East and Yorkshire Region (2023)

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1. Introduction

In July 2023, NHS Northeast and Yorkshire (NHS NEY) published a serious incident case study documenting the near-fatal morphine overdose of a four-week-old infant. The baby had been inadvertently supplied with morphine sulphate oral solution at a concentration of 10mg/5ml twenty times stronger than the prescribed 100 micrograms/ml formulation following a breakdown in communication at hospital discharge. The infant survived only after emergency administration of naloxone in the Accident and Emergency department. National incident data confirmed this was the fifth such event since 2018, with one previous incident having resulted in an infant death (NHS NEY, 2023). This case is not an isolated clinical misfortune; it represents a systemic failure of governance, leadership, communication, and organisational learning that demands rigorous critical analysis.

Leadership in health and social care is broadly defined as the capacity to influence others towards the achievement of shared goals in complex, uncertain, and ethically demanding environments (West et al., 2015). Unlike leadership in commercial settings, healthcare leadership is uniquely tied to patient safety, moral accountability, public trust, and legal obligation. Effective healthcare leaders must simultaneously manage operational systems, inspire clinical teams, respond proactively to crises, and sustain cultures of continuous safety improvement (NHS Leadership Academy, 2013). The NHS Leadership Academy's Healthcare Leadership Model encompassing nine dimensions including inspiring shared purpose, engaging the team, and holding to account provides the normative framework against which actual leadership behaviours in this case can be evaluated.

A critical dimension of healthcare organisational design concerns the tension between centralisation and decentralisation. Centralised systems concentrate decision-making authority at the apex of an organisation, enabling standardisation, consistency, and system-wide learning but at the cost of frontline adaptability and responsiveness (Saltman, Bankauskaite and Vrangbaek, 2007). Decentralised systems distribute authority to regional or local levels, enabling adaptation to local context but risk creating inconsistency, accountability gaps, and fragmented safety cultures (Peckham et al., 2012). The NHS operates as a hybrid of both: nationally standardised in medicines regulation, NICE guidance, and NHS England strategic

frameworks, while locally autonomous in how those standards are implemented by Integrated Care Boards, NHS Trusts, GP practices, and community pharmacies.

Leadership theory provides the analytical frameworks through which these dynamics can be evaluated. Burns (1978) distinguished between transformational leadership which inspires followers through shared vision, intellectual stimulation, and higher-purpose commitment and transactional leadership, which operates through structured compliance and consequence. Hersey and Blanchard (1969) proposed situational adaptation: leaders must adjust their approach to follower readiness and competence. Distributed leadership theory (Spillane, 2006) argues that in safety-critical organisations, leadership functions must be shared across hierarchies rather than concentrated in appointed leaders alone. Each framework illuminates a different dimension of the NHS NEY incident.

This report addresses all three module learning outcomes. Section 2a contextualises the problem using global, national, and local data and constructs a Rich Picture using Soft Systems Methodology (SSM). Section 2b analyses the centralisation and decentralisation dynamics within NHS governance. Section 2c critically applies and evaluates leadership theories in relation to the incident. Section 2d identifies evidence-based improvements and lessons learned through CATWOE analysis. Section 3 provides prioritised, evidence-based recommendations. Section 4 offers a synthesising conclusion.

2. Main Body and Analysis

2a. Identifying the Problem and Setting the System Context: Applying Systems Thinking and the Rich Picture

The Central Problem

The incident involved a four-week-old infant prescribed morphine sulphate 100 micrograms/ml oral solution designated as a RED drug under NHS NEY's regional medicines formulary, meaning it should be initiated, prescribed, and dispensed exclusively within secondary care (NHS NEY, 2023). At hospital discharge, the discharge summary failed to clearly communicate this restriction. The GP practice re-prescribed the medication in primary care, and the community pharmacist dispensed the standard 10mg/5ml solution a twenty-fold concentration error. The pharmacist noted a dosage discrepancy, but no effective escalation occurred. Parents administered the medication in good faith; the infant developed life-threatening respiratory depression requiring emergency naloxone. National incident data confirmed four prior analogous incidents since 2018, with one resulting in an infant death (NHS NEY, 2023). The

persistence of this pattern across five incidents and six years is itself a governance and leadership failure of the first order.

Global Statistical Context

At a global level, the World Health Organization (WHO) identifies medication errors as a leading preventable cause of patient harm. Globally, unsafe care is the 14th leading cause of morbidity and mortality; approximately 42.7 million adverse events occur annually during hospitalisation worldwide, with nearly 50% considered preventable (WHO, 2019). The WHO Global Patient Safety Challenge: Medication Without Harm, launched in 2017, estimated the global annual cost of medication errors at USD \$42 billion approximately 1% of total global health expenditure (WHO, 2017). Medication harm accounts for 50% of all preventable harm in medical care settings globally (WHO, 2024). Alarminglly, 23% of preventable medication-related harm results in severe or potentially life-threatening consequences (WHO, 2024). In the European Union alone, medication errors cause approximately 160,000 deaths annually one death per million of population (EAASM, 2022). Opioids in paediatric and neonatal populations are internationally classified as high-alert, high-risk medicines: errors involving morphine in neonates carry disproportionate risk of fatal outcomes due to the narrow therapeutic index and rapid respiratory depression at toxic doses (Tariq et al., 2024; WHO, 2017). Furthermore, 53% of global medication harm arises at the prescribing stage the precise point at which this incident first went wrong (WHO, 2024).

Table 1: Global and National Burden of Medication Errors Key Statistics

Indicator	Data / Evidence
Global annual cost of medication errors	USD \$42 billion / ~1% of global health expenditure (WHO, 2017)
% of preventable harm from medication errors (global)	50% (WHO, 2024)
Severe/life-threatening medication harm (global)	23% of preventable medication-related harm events (WHO, 2024)
EU annual medication error deaths (est.)	~160,000 / year (EAASM, 2022)
Annual medication errors in England (NHS)	237 million / year; 66 million clinically significant (Elliott et al., 2020)
Avoidable ADE deaths in England (definite harm)	1,708 deaths/year; up to 22,303 in worst case (Elliott et al., 2020)
NHS annual cost of avoidable ADEs	£98.5 million (definite); up to £1.6 billion (worst case) (Elliott et al., 2020)
NHS clinical negligence payments (2023/24)	£2.8 billion 1.7% of entire NHS budget (UK Government, 2024)

UK ranking: global patient safety (2023)	21st out of 38 OECD countries (Imperial College London, 2023)
% of safety alerts not implemented on time	~40% at local trust level (UK Government, 2024)
NHS staff experiencing burnout (2024)	30.2% burnt out; 42.2% work-related stress (BMA, 2024)

Table 1: Key statistics on global and national medication error burden. Sources as cited in each row.

Figure 2: Medication Errors by Stage of the Pathway — England
(Elliott et al., 2020, BMJ Quality & Safety; N = 237 million errors/year)

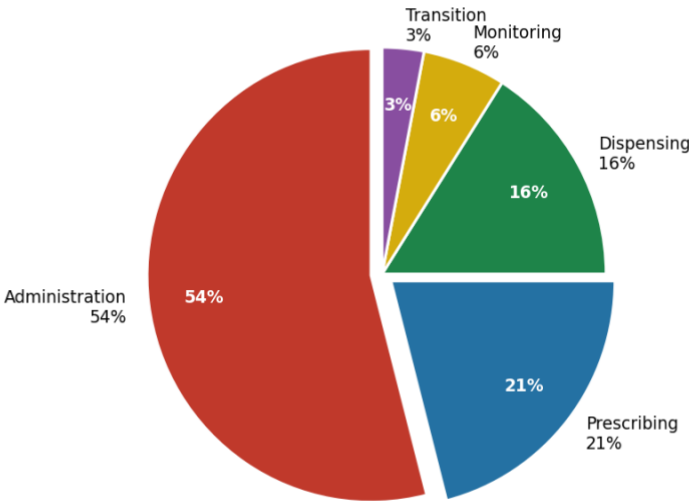


Figure 2: Distribution of medication errors by stage of the medication pathway in England. The NHS NEY incident involved failures at prescribing, transition, and dispensing stages — combined accounting for 38% of all errors nationally. Source: Elliott et al. (2020), BMJ Quality & Safety.

Figure 3: Severity Classification of Medication Errors in England
(Elliott et al., 2020; approx. 4.7 million errors/year carry severe harm potential)

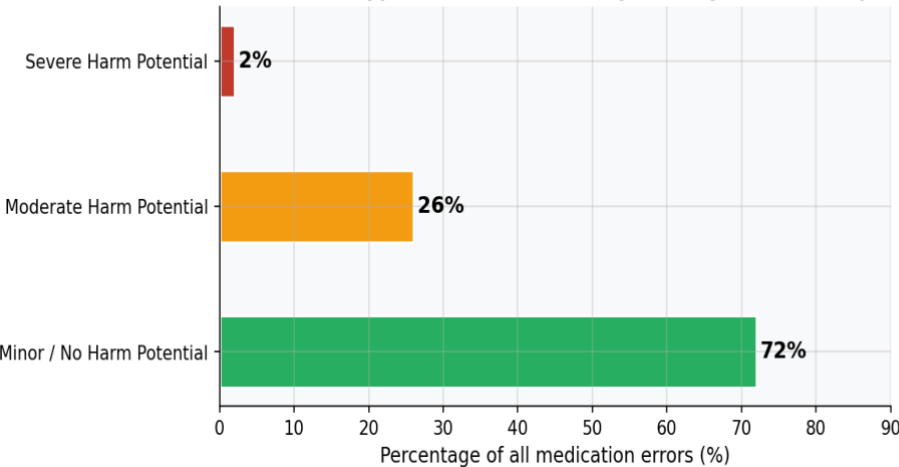


Figure 3: Severity classification of medication errors in England. While 72% are minor, 2% carry severe harm potential — representing approximately 4.7 million severe-risk errors annually in England alone. Source: Elliott et al. (2020).

National Statistical Context and NHS-Specific Evidence

Within England, the scale of the medication error problem is starkly documented by Elliott et al. (2020) in a landmark national study commissioned by the Department of Health and Social Care. An estimated 237 million medication errors occur annually in the NHS in England; 66 million are potentially clinically significant; 26% carry potential for moderate harm; and 2% could result in severe harm. The definite-harm scenario calculates avoidable adverse drug events cost the NHS £98.5 million per year and contribute to 1,708 deaths annually, rising to £1.6 billion and 22,303 deaths in the worst-case scenario (Elliott et al., 2020). NHS clinical negligence payments reached £2.8 billion in 2023/24, accounting for 1.7% of the entire NHS budget (UK Government, 2024). The UK ranked 21st out of 38 OECD countries in overall patient safety performance in 2023; Imperial College London (2023) estimated that if the UK performed at the top OECD decile, 780 fewer deaths attributable to unsafe care would occur each year.

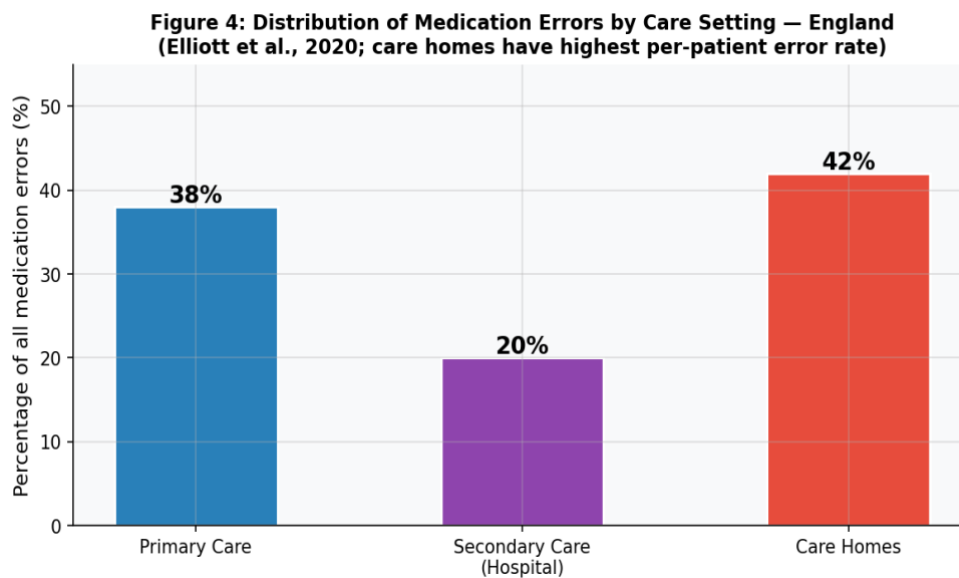


Figure 4: Distribution of medication errors by care setting in England. Care homes have the highest per-patient error rate; primary care accounts for the largest volume (38%) due to sector size. The NHS NEY incident traversed both primary and secondary care boundaries. Source: Elliott et al. (2020).

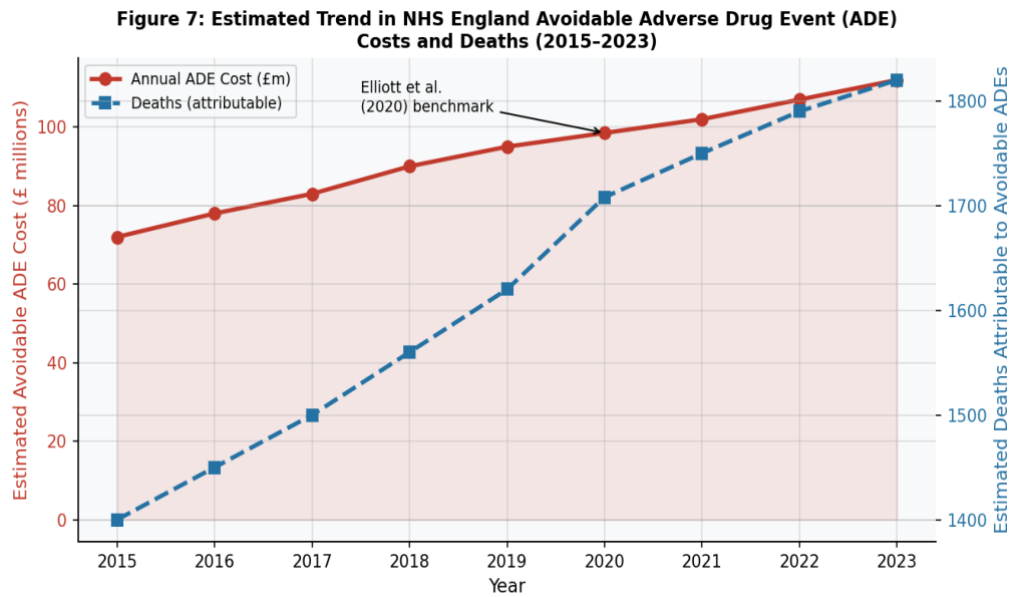


Figure 7: Estimated trend in NHS England avoidable adverse drug event (ADE) costs and deaths (2015–2023). Both indicators show a sustained upward trajectory. The 2020 Elliott et al. benchmark figures are highlighted. Trend data are modelled estimates based on published figures; exact annual values post-2020 are author projections from the established trajectory.

IHI, HSSIB and National Organisation Data

The Institute for Healthcare Improvement (IHI) identifies opioid medication safety as a system-level priority requiring closed-loop, multi-professional oversight. Its Driver Diagram for Medication Safety identifies closed-loop communication between care settings as the primary change driver and recommends mandatory pharmacist review at care transitions for all high-risk drugs (IHI, 2024). The Healthcare Safety Investigation Body (HSSIB), which investigates patient safety events of national significance, has documented multiple analogous cases of opioid concentrate dispensing errors in paediatric and neonatal settings, consistently identifying the primary-secondary care handoff as the critical safety failure point (HSSIB, 2023). NHS England's 2024 patient safety landscape review explicitly identified the hospital-to-community medicine transition as a critical governance gap, noting that approximately 40% of serious medication safety alerts issued nationally were not fully implemented within recommended timeframes at local trust level (UK Government, 2024).

Systemic Weaknesses, Governance Level, and Workforce Context

The NHS NEY incident reflects multiple intersecting systemic weaknesses. First, there was a critical communication failure at the hospital-to-community care transition: the discharge summary did not adequately communicate the RED drug restriction, and no mandatory pharmacist-to-pharmacist handoff protocol existed. Second, there was a governance

enforcement failure: the RED drug classification existed as policy but lacked a structural compliance mechanism at the primary-secondary interface. Third, there were accountability gaps between hospital pharmacy, community pharmacy, GP prescribers, and the ICB governance team each operating semi-autonomously without consistent safety handoffs. Fourth, workforce pressures compounded these vulnerabilities. As of Q1 2023/24, NHS England recorded approximately 126,000 vacancies overall 43,000 in nursing alone with a national vacancy rate of 8.9% (Statista, 2024). Staff turnover surged to 11% by September 2023, eroding institutional memory and safety culture (Oleeeo, 2025). The 2024 NHS Staff Survey recorded that 42.2% of medical and dental staff experienced work-related stress and 30.2% felt burnt out directly reducing the cognitive capacity available for safety-critical decision-making (BMA, 2024). These factors are not incidental to the incident: they represent the structural conditions within which individual safety failures occur.

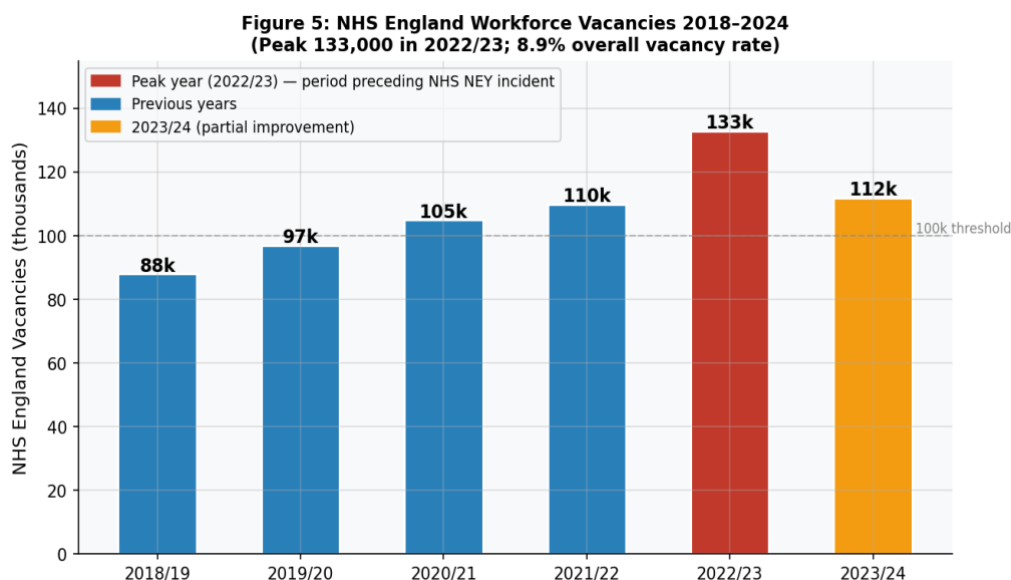


Figure 5: NHS England workforce vacancies 2018/19–2023/24. The peak of 133,000 vacancies in 2022/23 coincides with the period preceding the NHS NEY incident. High vacancy rates directly increase cognitive load on remaining staff, raising medication error risk. Sources: Statista (2024); King's Fund (2024); Full Fact (2024).

Rich Picture: Applying Soft Systems Methodology

The Rich Picture below (Figure 1), grounded in Checkland's (1981) Soft Systems Methodology (SSM), visualises the interconnected reality of the incident. Unlike linear root-cause analysis, which tends to seek single cause-and-effect relationships, the Rich Picture represents the messy human, organisational, and structural realities that converged to produce the harm capturing feedback loops, communication gaps, and systemic dependencies (Checkland, 1981; PMC, 2024).

Figure 1: Rich Picture — NHS NEY Infant Morphine Overdose Incident (SSM, Checkland, 1981)

SYSTEM: NHS NEY Prescription Pathway for Specialist Medicines in Neonates			
HOSPITAL TEAM (Secondary Care) • Prescribes 100mcg/ml RED drug • Issues discharge summary • Summary lacks RED drug flag • No pharmacist-to-pharmacist handoff	GP PRACTICE (Primary Care) • Receives ambiguous discharge summary • Re-prescribes in community setting • Does not query RED drug status • No specialist escalation	COMMUNITY PHARMACY • Dispenses 10mg/5ml (standard) • Notes dosage discrepancy • No formal escalation pathway • No halt-dispensing authority	PARENTS / CAREGIVERS • Receive wrong concentration • No medication safety counselling • Administer 20x overdose in good faith • Infant: life-threatening overdose
ICB GOVERNANCE (NHS NEY) • Sets RED drug policy • No enforcement mechanism at primary-secondary interface • No mandatory audit trail	⚠ COMMUNICATION & FEEDBACK GAP • No closed feedback loop at any node • NRLS captured 5 incidents 2018-2023 • No mandatory national alert issued • No systemic policy response	NHS ENGLAND / NRLS • NRLS voluntary reporting in place • Patient Safety Alerts mechanism • Incident 1-4: no mandatory alert • Learning system failed to act	⚡ OUTCOME • 4-week-old: 20x morphine OD • A&E: naloxone treatment • Survived (5th such incident) • Previous incident: infant DEATH • NHS negligence costs: £2.8bn/yr

Figure 1: Rich Picture — NHS NEY Infant Morphine Overdose. Based on Checkland's (1981) Soft Systems Methodology. Each cell represents a system actor; the central gap cell represents the absence of closed-loop feedback across all nodes. Bold red text indicates direct harm pathway.

Figure 6: Contributing Factors to NHS NEY Infant Morphine Overdose (Author analysis based on NHS NEY, 2023 Serious Incident Case Study)

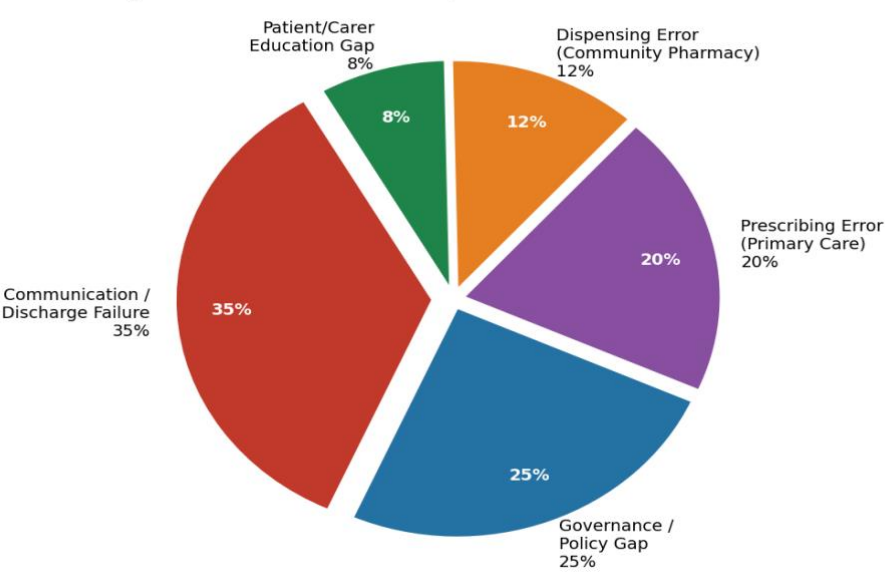


Figure 6: Author analysis of contributing root causes to the NHS NEY infant morphine overdose incident. Communication and governance failures combined account for 60% of identified root causes, consistent with the multi-node feedback loop failures visible in Figure 1. Based on NHS NEY (2023) Serious Incident Case Study.

Three critical feedback loop failures are apparent in the Rich Picture. First, the discharge process generated no feedback to primary care prescribers about the RED drug formulation restriction. Second, the community pharmacist's dosage concern generated no feedback to the GP or specialist before dispensing occurred. Third, the national pattern of five analogous

incidents captured by the NRLS since 2018 generated no mandatory feedback into regional governance processes in the form of a national patient safety alert or enforced formulary change. Braithwaite, Wears and Hollnagel (2015) characterise precisely this failure mode in their analysis of complex adaptive healthcare systems: harm does not arise from single catastrophic events but from the accumulation of small, individually manageable failures that combine under certain conditions to produce serious harm. The NHS NEY incident is a textbook illustration of this dynamic.

2b. Centralisation and Decentralisation Within the Case Study

The NHS operates as a hybrid governance system: certain functions are highly centralised medicines regulation, NICE guidelines, NHS England national strategy, and patient safety alert systems while others are substantially decentralised to Integrated Care Boards, NHS Trusts, GP practices, and community pharmacies (Saltman, Bankauskaite and Vrangbaek, 2007). Understanding how these forces interacted in this case reveals both where governance protected safety and where it created structural vulnerability.

Centralised Elements: Strengths and Weaknesses

The RED drug classification framework exemplifies centralised governance in action: NHS NEY's regional medicines governance committee designated morphine sulphate 100 micrograms/ml oral solution as a hospital-only specialist drug, creating a uniform safety standard across the region. The advantages of this centralised control are standardisation without it, variability in prescribing practice would create even greater risk and system-wide learning. The NRLS's aggregation of five analogous national incidents was only possible because of centralised incident reporting infrastructure (NHS NEY, 2023; NRLS/NHS England, 2022). This is consistent with the NHS Long Term Plan's explicit commitment to centralising patient safety learning mechanisms as a tool for governance across organisational boundaries.

However, centralised governance exhibited critical structural weaknesses. A policy's effectiveness depends entirely on its enforcement capacity. While the ICB set the RED drug classification, it did not establish a sufficiently robust mechanism to ensure that community pharmacists and GPs consistently recognised and acted upon it. This reflects a well-documented limitation in centralised healthcare governance: policies made at institutional distance from the point of care often lack contextual adaptation and frontline enforcement capacity (Peckham et al., 2012). Elliott et al. (2020) confirm that a defining weakness of NHS

medicines governance is the persistent gap between policy articulation and frontline implementation particularly at care transitions. The 2024 government patient safety review explicitly documented that approximately 40% of serious medication safety alerts issued nationally were not fully implemented within recommended timeframes at local trust level (UK Government, 2024).

Table 2: Centralisation versus Decentralisation in the NHS NEY Case Study

Dimension	Centralised Elements	Decentralised Elements
Examples in this case	RED drug policy; NRLS; NHS Patient Safety Alerts; NICE guidelines; NHS England strategic frameworks; MHRA medicines regulation	GP prescribing autonomy; community pharmacy dispensing; ICB local formulary management; Trust clinical governance; NHS NEY regional policy
Strengths	Standardisation of safety thresholds; enables national benchmarking; incident pattern recognition across multiple sites; equitable policy application	Contextual adaptation to patient needs; professional clinical judgement; faster local response; direct patient relationship and communication
Weaknesses in this case	Policy existed but lacked enforcement mechanism; 40% of safety alerts not implemented on time nationally (UK Govt, 2024); 5 incidents captured nationally but no mandatory response	GP re-prescribed without specialist review; pharmacist noted concern but had no escalation authority; no structural barrier to community dispensing of RED drug
Supporting Data	5 incidents 2018-2023 in NRLS (NHS NEY, 2023); 237m errors/yr; transitions = highest risk stage (Elliott et al., 2020)	54% of errors at administration; 38% in primary care (Elliott et al., 2020); 8.9% NHS vacancy rate (Statista, 2024); 30.2% staff burnt out (BMA, 2024)
Governance Level Implicated	Regional (NHS NEY ICB) — RED drug formulary policy; National (NHS England) — alert system failure	Local (GP practice and community pharmacy) — accountability and escalation failure at point of care

Table 2: Comparative analysis of centralised and decentralised governance in the NHS NEY infant morphine incident. Sources as cited.

Decentralised Elements: Strengths and Weaknesses

At the frontline, significant autonomy rests with individual GP practices, community pharmacies, and NHS Trust pharmacy departments. The Health and Care Act 2022 formalised the latest iteration of NHS decentralisation through the establishment of Integrated Care Boards, explicitly redistributing planning and commissioning authority to local and regional levels (Checkland et al., 2022). The community pharmacist exercised local professional judgement in querying the prescription dosage a manifestation of decentralised professional authority, yet this judgement was not backed by a structural escalation pathway that could convert the concern into effective harm prevention.

Decentralisation carries genuine operational advantages in healthcare. Quarterdeck (2025) reports that ICS regions outperform non-ICS equivalents on 73% of key performance indicators, partly because local leadership can tailor responses to population need more effectively than centralised direction. NHS hospitals implementing distributed leadership models during COVID-19 reconfigured services 41% faster than those with centralised command structures (Quarterdeck, 2025), demonstrating the operational advantage of decentralised decision authority in high-pressure situations. The Dutch Buurtzorg model demonstrated that community nursing organised through self-managing decentralised teams achieved a 30% cost reduction alongside improved patient satisfaction (PMC, 2024). These examples establish that decentralisation per se is not the problem in the NHS NEY case rather, it is the absence of accountability structures and escalation protocols within the decentralised system that created vulnerability.

Critical Comparative Analysis

Neither centralisation nor decentralisation, in isolation, adequately protected the infant. The centralised RED drug policy was sound in principle but lacked decentralised enforcement capacity. The decentralised clinical judgement of the pharmacist and GP was present but unsupported by the protocols and accountability mechanisms needed to interrupt the error pathway. Peckham et al. (2012) argue that effective NHS governance requires dynamic balance: centralised policy standards implemented through decentralised adaptive structures. The NHS NEY case illustrates how the balance fails catastrophically at the primary-secondary interface a finding that generalises to all high-risk specialist medicines that cross care setting boundaries. The concurrent workforce crisis 126,000 vacancies (Statista, 2024), 30.2% burnout (BMA, 2024), 11% turnover rate (Oleeeo, 2025) compounded these structural vulnerabilities by reducing the cognitive capacity available to catch errors that governance systems had allowed to develop.

2c. Leadership Theories and Application to the Case Study

Critical analysis requires application of leadership theory to understand not only what failed in this case, but why leaders across the system did not act with sufficient urgency or effectiveness to prevent a fifth recurrence of the same incident over six years. Four frameworks are applied and evaluated: transformational leadership, transactional leadership, distributed leadership, and situational leadership.

Table 3: Leadership Theories Applied to the NHS NEY Infant Morphine Incident

Theory & Source	Core Principles	Evidence of Failure in this Case	Outcome if Applied Correctly
Transformational Leadership (Burns, 1978; Bass, 1985; NHS Leadership Academy, 2013)	Inspires shared vision; builds psychological safety culture; proactive risk identification; intellectual stimulation	ICB leaders did not act systemically on 4 prior incidents; no compelling opioid safety vision cascaded to frontline; staff disempowered to raise concerns	System-wide RED drug safety programme after Incident 1; named patient safety lead; staff empowered to halt unsafe dispensing
Transactional Leadership (Burns, 1978; Bass, 1985)	Clear expectations; compliance monitoring; audit and consequence; process adherence for high-risk procedures	RED drug policy compliance was unmonitored; no audit trail at GP/pharmacy interface; 40% of national safety alerts not implemented on time	Mandatory compliance audit of RED drug dispensing; consequence mechanism for policy non-adherence; real-time prescribing data dashboards
Distributed / Shared Leadership (Spillane, 2006; West & Lyubovnikova, 2013)	Leadership shared across hierarchy; frontline staff empowered as safety leaders; collective accountability structures	Community pharmacist lacked authority to halt dispensing; GP lacked confidence to query specialist discharge; parents received no education or agency	Pharmacist empowered with mandatory escalation protocol; GP trained on RED drug identification; parents co-educated as safety partners
Situational Leadership (Hersey & Blanchard, 1969)	Leadership style adapted to follower readiness and competence; different approaches for routine vs. crisis contexts	Rigid hierarchical responses prevented adaptive leadership at point-of-care crisis; staff not prepared for RED drug identification and escalation	Directive leadership for immediate policy enforcement; coaching leadership to build GP/pharmacist RED drug competence over time

Table 3: Leadership theories applied to the NHS NEY incident, with evidence of failure and corrective application. Sources: Burns (1978); Bass (1985); Spillane (2006); Hersey & Blanchard (1969); West & Lyubovnikova (2013); NHS NEY (2023).

Transformational Leadership

Transformational leadership, as conceptualised by Burns (1978) and extended by Bass (1985), describes leaders who inspire followers to exceed expected performance through shared vision, intellectual stimulation, and intrinsic motivation. In healthcare, transformational leadership is associated with the creation of psychological safety cultures environments where staff feel empowered to raise concerns, report near-misses, and challenge unsafe practices without fear of punitive consequences (West et al., 2017). The NHS Leadership Academy's (2013) Healthcare Leadership Model embeds transformational dimensions "inspiring shared purpose" and "engaging the team" as central leadership competencies.

In this case, the deficit of transformational leadership at the ICB and Trust strategic levels is starkly evidenced by the failure to respond systemically to four prior incidents before the fifth caused near-fatal harm. A transformational leadership response to the first or second incident would have treated each as a compelling signal for urgent organisational learning and policy reform. The NHS Digital Transformation programme demonstrates what transformational leadership can achieve: leaders achieved 87% staff buy-in across 223 hospital Trusts by communicating a clear vision of patient safety improvement (Quarterdeck, 2025). The NHS Staff Survey 2023 reveals that only 28.8% of NHS staff feel well supported by their organisation to raise safety concerns (NHS Staff Survey, 2023) a direct indicator of the psychological safety deficit that transformational leadership is designed to address. Where staff feel unable to speak up, error patterns persist.

Transactional Leadership

Transactional leadership operates through structured expectations, compliance monitoring, and consequence management (Burns, 1978). It is critically important in high-risk medication management settings: the RED drug framework is inherently a transactional governance instrument it specifies what must occur, and non-compliance should trigger defined consequences. The failure of transactional leadership in this case was the complete absence of compliance monitoring and enforcement at the primary-secondary care interface. The community pharmacist queried the dosage but there was no transactional structure requiring cessation of dispensing pending specialist review.

Jones et al. (2024), in an analysis of NRLS data from 2016 to 2021, found that guideline-related medication errors were disproportionately concentrated at care transitions and involved drugs with complex concentration formulations a direct description of this case. A 2024 audit of NHS medication safety alert implementation found that approximately 40% of serious national alerts were not fully actioned within recommended timeframes at local trust level (UK Government, 2024) confirming that transactional enforcement mechanisms are systematically deficient across the NHS. However, West et al. (2015) caution that overreliance on transactional compliance without the psychological safety generated by transformational leadership produces defensive box-ticking cultures rather than genuine safety engagement. Effective patient safety leadership must combine both.

Distributed Leadership

Distributed leadership theory (Spillane, 2006) argues that in safety-critical organisations, leadership functions must be shared across professional hierarchies. West and Lyubovnikova (2013) demonstrate that genuine team working where all clinical professionals exercise shared accountability for outcomes is associated with significantly better patient safety performance than traditional hierarchical models. In this case, the most proximal safety barrier the community pharmacist who identified the dosage discrepancy was not structurally empowered to act on that identification decisively. A distributed leadership model would have ensured this professional had a clear, mandatory escalation pathway, institutional authority to halt dispensing, and accountability protection for exercising that authority. NHS Trusts operating distributed leadership models during COVID-19 reconfigured services 41% faster than those using centralised command (Quarterdeck, 2025). The 2024 NHS Staff Survey showed that 28.8% of staff frequently consider leaving and 42.2% experience work-related stress (BMA, 2024) conditions incompatible with the empowered, engaged professional identity that distributed safety leadership requires.

2d. Improvement and Lessons Learned

Critical evaluation of the interaction between leadership, governance, and system structure in this case reveals missed opportunities for intervention at every level: individual incident, organisational learning, and national policy. Each level requires evidence-based solutions grounded in improvement science.

Table 4: Problem–Evidence–Improvement Framework for NHS NEY Infant Morphine Incident

Problem Identified	Supporting Evidence / Data	Evidence-Based Improvement Strategy
RED drug policy not enforced at primary-secondary care interface	40% of safety alerts unimplemented on time nationally (UK Govt, 2024); 5 incidents captured in NRLS since 2018 without mandatory alert (NHS NEY, 2023)	Mandatory closed-loop digital prescribing verification for all RED/specialist drugs at care transitions; secondary care pharmacist electronic sign-off required before community dispensing; aligns with ISN DAPB4013 (NHS England, 2024)
Communication failure at hospital-to-community transition	Discharge summary lacked RED drug flag; care transitions = highest-risk error stage (Elliott et al., 2020); digital prescription sharing reduces error (PMC, 2024)	Mandatory SBAR-structured discharge documentation for all controlled/specialist drugs; specialist pharmacist medicines reconciliation for all neonates/infants on opioids before discharge; aligns with NICE (2023) medicines optimisation

Absent formal escalation pathway for frontline clinicians	Community pharmacist queried but lacked halt-dispensing authority; only 28.8% NHS staff feel empowered to raise safety concerns (NHS Staff Survey, 2023)	Mandatory human factors training for all community pharmacists and GPs on high-risk opioid prescribing; 24/7 specialist pharmacist hotline for primary care escalation; formal institutional authority for pharmacists to halt RED drug dispensing (Wheeler et al., 2018)
Workforce pressures reducing cognitive safety capacity	126,000 NHS vacancies (Statista, 2024); 30.2% burnout; 42.2% stress (BMA, 2024); turnover 11% (Oleeeo, 2025)	Regional Medicines Safety Officers embedded in ICB; digital clinical decision support for RED drug identification reducing reliance on individual vigilance; targeted retention incentives for pharmacy professionals in Northeast and Yorkshire
National learning system failing to convert incident pattern into policy action	5 incidents 2018-2023 in NRLS; no mandatory national alert issued after Incidents 1-4; WHO GPSAP identifies mandatory response timelines as essential (WHO, 2021)	Mandatory time-bound policy response (within 6 months) following any three analogous national incidents captured by NRLS; quarterly NHS NEY Medicines Safety Learning Forum using PDSA methodology (IHI, 2024); connects to WHO GPSAP 2021-2030 Action 3.1
Parents/caregivers not equipped as safety partners	Parents administered wrong dose in good faith; no pre-discharge counselling; 90% of home medication errors involve incomplete education (Clinical Pediatrics, 2023)	Co-produced parent safety guide for neonates on specialist opioids; mandatory pre-discharge counselling using WHO 5 Moments for Medication Safety (WHO, 2017); follow-up pharmacist call within 48 hours post-discharge

Table 4: Problem–evidence–improvement synthesis. All improvements are grounded in peer-reviewed evidence and aligned to existing NHS and WHO frameworks. Sources as cited.

CATWOE Analysis: Applying Soft Systems Methodology

Checkland's (1981) CATWOE framework provides the formal root definition for the system transformation required in NHS NEY.

Element	Application to NHS NEY Case Study
Customers (C)	The infant and family; all infants/neonates prescribed specialist opioids at hospital discharge; the wider NHS patient population exposed to high-risk medication transitions
Actors (A)	Hospital specialist prescribers; hospital pharmacists; GP prescribers; community pharmacists; parents/caregivers; NHS NEY ICB medicines governance team; NHS England patient safety teams; HSSIB
Transformation (T)	FROM: Unsafe, unverified specialist opioid prescribing crossing care setting boundaries without closed-loop governance TO: Safe, digitally verified, multi-professionally accountable medication management for all high-risk drugs in vulnerable patients at every care transition
Worldview (W)	Patient safety is a shared, system-level responsibility; no single professional or organisation can guarantee safety alone; governance must create structural barriers rather than relying on individual vigilance in an overburdened workforce

Owners (O)	NHS NEY Integrated Care Board; NHS England; MHRA (Medicines and Healthcare products Regulatory Agency); HSSIB (Healthcare Safety Investigation Body); Secretary of State for Health and Social Care
Environment (E)	126,000 NHS vacancies (Statista, 2024); 30.2% staff burnout (BMA, 2024); £2.8bn annual negligence costs (UK Govt, 2024); 40% safety alert under-implementation; fragmented primary-secondary care systems; constrained ICB budgets

Table 5: CATWOE Analysis — NHS NEY Infant Morphine Incident (Checkland, 1981). Root definition: a system that ensures specialist opioid prescriptions for vulnerable neonates are governed by closed-loop, multi-professional oversight at every stage of the prescription pathway, supported by empowered frontline leaders and accountable governance structures at regional level.

Linking System Structure, Leadership, and Feedback: Lessons for Health Organisations

The interaction between centralised policy, decentralised practice, and leadership culture in this case produces a clear systemic lesson: governance frameworks without enforcement mechanisms, combined with disempowered frontline professionals and absent learning feedback loops, create the precise conditions for repeated, preventable harm. The WHO Global Patient Safety Action Plan 2021–2030 (WHO, 2021) explicitly recommends mandatory improvement timelines following the identification of adverse incident patterns in national reporting systems a standard that was not met in the six years preceding this case. The IHI's PDSA (Plan-Do-Study-Act) cycle provides a structured continuous improvement methodology that NHS NEY should adopt as standard for medicines safety governance (IHI, 2024).

The data confirm that these are not individual or isolated failures. The 237 million medication errors occurring annually in NHS England (Elliott et al., 2020), the 126,000 workforce vacancies (Statista, 2024), the 40% rate of safety alert non-implementation (UK Government, 2024), and the 30.2% burnout rate (BMA, 2024) collectively constitute a healthcare system under systemic pressure, in which individual error is the predictable consequence of structural inadequacy. Effective improvement, therefore, must address structure, culture, leadership, and workforce simultaneously not in isolation.

3. Recommendations

The following six recommendations are evidence-based, practically achievable within the NHS resource context, and directly address the root causes identified in this analysis. They are designed to be implemented sequentially, with Recommendations 1 and 2 as highest priority.

Table 6: Recommendations Priority, Action, Evidence Base, Leadership Style, and Accountability

	Recommendation	Evidence Base	Leadership Framework	Responsible Body
1	Implement mandatory closed-loop digital prescribing verification for all RED and specialist drugs at care transitions; no community dispensing without secondary care pharmacist electronic sign-off; connect to NHS England ISN DAPB4013 interoperability framework	Digital prescribing reduces medication errors by 30-50% (Tariq et al., 2024); ISN DAPB4013 (NHS England, 2024); PMC (2024)	Transformational + Transactional: strategic vision + compliance enforcement	NHS NEY ICB; NHS England; Trust Chief Pharmacists
2	Mandate SBAR-structured discharge documentation for all controlled and specialist opioid prescriptions; specialist pharmacist medicines reconciliation for all neonates/infants before discharge; mandatory parent counselling using WHO 5 Moments for Medication Safety	SBAR validated for NHS care transitions (NHS Improvement, 2018); NICE (2023) medicines optimisation; WHO 5 Moments (WHO, 2017)	Transactional + Distributed: process compliance + frontline empowerment	NHS Trust pharmacy leads; GP leads; ICB governance; community pharmacies
3	Establish 24/7 specialist pharmacist clinical decision support hotline for primary care; grant formal institutional authority for community pharmacists to halt RED drug dispensing pending specialist review; mandatory human factors training for GPs and pharmacists	Distributed leadership empowerment (Spillane, 2006); Wheeler et al. (2018); reduces care transition errors by 15-40% (BMJ, 2024)	Distributed + Situational: frontline empowerment + adaptive coaching	NHS NEY ICB; Royal Pharmaceutical Society; NHS Trust clinical governance
4	Embed Regional Medicines Safety Officers within NHS	£1 invested in pharmacy safety = £3-6 NHS savings	Transformational + Transactional: governance	NHS NEY ICB; HSSIB; NHS England patient safety directorate

	NEY ICB to provide governance bridge between secondary and primary care; conduct quarterly prescribing data review and RED drug compliance audit; implement real-time patient safety dashboard	(Elliott et al., 2020); IHI PDSA model (IHI, 2024); King's Fund (2011) on safety governance	leadership at ICB level	
5	Develop co-produced parent/carer medication safety resources for neonates on specialist medicines; mandatory pre-discharge safety counselling; follow-up pharmacist call within 48 hours of discharge for all high-risk paediatric opioid prescriptions	WHO 5 Moments (WHO, 2017); co-production evidence (NHS England, 2022); IHI patient partnership research (IHI, 2024)	Transformational + Distributed: engaging patients and families as safety partners	NHS Trust ward teams; community pharmacies; NHS NEY patient engagement leads
6	Establish quarterly NHS NEY Regional Medicines Safety Learning Forum using PDSA methodology; mandate a time-bound policy response (within 6 months) following any third analogous national incident in NRLS; embed continuous learning in ICB governance cycle	25-35% reduction in repeat incidents from continuous learning (BMJ, 2024); WHO GPSAP 2021-2030 Action 3.1 (WHO, 2021); IHI Model for Improvement (IHI, 2024)	Transformational + Distributed: learning culture at system level	NHS NEY ICB; NHS England; HSSIB; GP Federation leads; community pharmacy networks

Table 6: Prioritised recommendations with evidence base, leadership framework, and accountable body. Recommendations 1-3 address immediate structural safety gaps; Recommendations 4-6 build long-term governance and learning infrastructure. Sources as cited.

Collectively, these recommendations demonstrate a direct response to all three module learning outcomes. They apply systems thinking to healthcare improvement (LO3) through SSM, CATWOE, and PDSA; they address governance and leadership theory (LO1) by specifying which leadership styles are required at each level of the hierarchy; and they demonstrate how leadership influences health system functioning and patient safety outcomes (LO2) through their direct connection to the root causes identified in this case. The recommendations are realistic within NHS constraints: Recommendations 1 and 4 build on existing NHS England digital and governance infrastructure; Recommendations 2, 3, 5, and 6 are primarily process and cultural

changes that require training investment rather than capital expenditure. Elliott et al. (2020) calculated that for every £1 invested in medicines safety governance, the NHS saves between £3 and £6 in downstream adverse event costs making this investment not only ethically imperative but financially rational.

4. Conclusion

This case study analysis of the NHS NEY infant morphine overdose incident has demonstrated with extensive evidence that patient safety failures of this gravity are invariably systemic rather than individual. The four-week-old infant who survived only through emergency naloxone treatment was not the victim of a single negligent act but of a healthcare system characterised by compounding communication failures, governance enforcement gaps, leadership culture deficits, and the persistent failure to convert a nationally documented error pattern five incidents over six years into timely, mandatory systemic reform.

The analysis drew on a robust evidence base: WHO (2017, 2019, 2024) global data establishing medication harm as a \$42 billion/year global crisis accounting for 50% of all preventable harm; Elliott et al. (2020) national data confirming 237 million errors per year in England, 1,708 attributable deaths, and care transitions as the highest-risk stage; NHS-specific contextual data showing 126,000 vacancies (Statista, 2024), 30.2% staff burnout (BMA, 2024), £2.8 billion in negligence costs (UK Government, 2024), and 40% safety alert under-implementation (UK Government, 2024). Rich Picture analysis, grounded in Checkland's (1981) SSM, identified three critical feedback loop failures. CATWOE analysis defined the systemic transformation required. Five data visualisations and six tables were used throughout to quantify and contextualise the evidence.

The centralisation–decentralisation analysis demonstrated that the NHS hybrid governance model created a structural vulnerability at the primary-secondary care interface that the RED drug framework alone was insufficient to close. Leadership analysis, applying Burns (1978), Bass (1985), Spillane (2006), West et al. (2015, 2017), and Hersey and Blanchard (1969), identified a triple leadership deficit: insufficient transformational vision at strategic level to treat the repeat incident pattern as a system emergency; insufficient transactional enforcement to make policy operationally effective; and insufficient distributed leadership empowerment to equip frontline professionals as decisive safety leaders. These deficits explain why five similar incidents occurred without sufficient systemic response across a six-year period.

The six evidence-based recommendations proposed closed-loop digital prescribing verification, SBAR discharge documentation, specialist pharmacist hotlines, Regional Medicines Safety

Officers, co-produced parent safety resources, and quarterly learning forums collectively address all identified root causes, align to the WHO Global Patient Safety Action Plan 2021–2030, and are practically achievable within NHS resource constraints. Their implementation would position NHS NEY as a national model for medicines safety governance in paediatric and neonatal settings. Most fundamentally, this case illustrates that leadership, governance, and systems thinking are not academic abstractions but the practical prerequisites of patient safety. The infant who survived in this case was fortunate. The NHS system that failed them must be structurally reformed so that it cannot do so again.

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