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Title: Systemic Failure and Leadership Gaps in NHS Medication Safety: A Case Study Analysis of the 2023 Infant Morphine Overdose Incident

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Executive Summary

The report is a critical assessment of a serious incident in the North East and Yorkshire division of the NHS in 2023 in which a four-week-old baby was administered twenty times more morphine sulphate than was ordered due to a cascade of communication and governance failures in a hospital and GP/community pharmacy practice. It was the fifth nationwide since 2018, and one of the previous cases had led to the infant death, which proves that the pattern of systematic, not isolated, failure exists.

The report applied systems thinking and a Rich Picture and identified the major root causes to be communication breakdown, fragmented accountability, and lack of enforcement infrastructure. The review of the NHS hybrid model of governance demonstrates that the centralised system of RED drug classification was structurally incongruent with decentralised delivery model since there was no linking enforcement or warning mechanism across the care setting. A critical application of three leadership theories, transactional, distributed, and transformational, shows that compliance with rules, lacking any monitoring, lack of frontline empowerment, and reactive leadership instead of proactive leadership at the ICB level all contributed to the fact that repeated recurrence was made possible.

It is recommended that mandatory electronic discharges systems, shared formulary platform, clinician-to-clinician escalation protocols, teach back patient counselling, and transformational leadership development at the ICB level be in place. The proposals are factual, practically feasible, and crucial in avoiding further damage.

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Introduction

In July 2023, NHS England North East and Yorkshire issued a serious incident case study of a four-week-old infant who was given an oral dose of morphine sulphate twenty times higher than intended. The 10mg/5ml solution was provided to the parents rather than the specialist 100 micrograms/ml solution and hence instead of getting 190 micrograms per dose, the infant was given 3.8mg per dose. The baby survived after receiving naloxone but national incident records indicated that this was the fifth such mistake since 2018 and one of the past incidences had led to the death of an infant (NHS England NEY, 2023). This pattern is repeated and makes the case both locally and internationally important to health system governance and leadership failure discussions.

Health and social care leadership can be defined as the method of influencing people and systems to achieve the common goals related to safety, quality, and equitable outcomes (Edmonstone, 2020). Good health leadership is not just about personal clinical competence, but also about governance, accountability, and cultural transformation (Elliott et al., 2020). The role of leadership in influencing systems and responses to failure is thus key to the preventing recurrence of grave events.

This is because the NHS is a hybrid model of governance, with a centralised policy and regulatory governance at NHS England, NICE, national formularies, but a decentralised model of service delivery through Trusts, Integrated Care Boards (ICBs), GP practises, and community pharmacies. Ramsay et al. (2025) validate that the level of centralisation has a substantial impact on patient safety outcomes, especially when it comes to the process of handling specialised or high-risk drugs. This report involves the use of three leadership theories, namely, transactional leadership, where accountability is instilled through rules and monitoring; distributed leadership, where accountability is shared among teams and organisations; and transformational leadership, where accountability is a trend of cultural change and systemic redesign (Ahmed and Simha, 2023). According to Dalcher (2020), particulars of a crisis situation require proactive, goal-oriented leadership, but not reactive and compliance-oriented methods that are core to the analysis of this case.

This report discusses the system failures in the hospital, GP and community pharmacy environment that resulted in this near-fatal incident, evaluates the leadership gaps and

governance structures and provides realistic evidence based recommendations to curb recurrence.

Section A: Identifying the Problem and Applying Systems Thinking

The Incident

The 2023 incident was more of a cascade of failures in four separate care settings, which all had the potential to detect and remedy the error but failed to do so. The point that Table 1 tells us is not that particular negligence was occurring, but rather that this was a structural phenomenon: at all of the transition points, no common information was available, and nobody was accountable enough to question the mistake.

Table 1: Summary of the Multi-Provider Failure Chain

Provider	Key Failure	Missed Opportunity
Hospital	Written discharge summary; abbreviation "mcg" was used; brand name is "Oramorph" was mentioned, RED drug status was not reported to the GP.	Post-discharge RED drug was not interrupted by hospital pharmacist.
GP	Unaware that the 100mcg/ml specials product was available; brand name prescribing of 10mg/5ml; the dose is not raised in volume.	No pharmacist-to-pharmacist communication; no interaction with hospital pharmacist.
Community Pharmacy	Referred to technician and receptionist; poor pharmacist handover; neither pharmacist informed of specials product; no syringe was given.	No direct clinician-to-clinician escalation; no systematic counselling.
Parents	Further administering 1.9ml and not 0.1ml without any instruction.	None of the dosage or teach-back demonstrations were taken at any point.

(Source: NHS England NEY, 2023)

The outcome was that the infant was given 3.8mg of morphine rather than 190 micrograms prior to being taken to the emergency department. It was not the first incident of this kind type of error, and NHS England NEY (2023) confirmed that it was the fifth case of this particular type of error since 2018, and one of them led to the death of a baby. Even this force of repetition is a strong argument in itself of systemic and not individual failure. More importantly, there was no actor that completely followed the medication process through - the hospital was not following-up, GP was not checking, and even the pharmacist was unable to escalate. The failure can be characterized by this disintegration, but not the fault of one clinician.

Global and National Statistical Context

Unsafe medication practices are a foremost cause of harm that can be prevented worldwide. WHO (2017) estimates the cost of medication errors at $42 billion approximately (£31.7 billion) annually and specifically has drawn transitions of care, high-risk medications, and polypharmacy as the three areas of action in its Medication Without Harm challenge that seeks to reduce severe avoidable medication-related harm by 50%. This situation fits directly into two of these areas: high-risk medications and transitions of care, both areas that were not managed adequately at each step.

On a national level, BMJ group (2020) indicates that more than 237 million medication errors take place each year in England at a cost of over 98 million pounds and over 1,700 lives a year to the NHS. Importantly, the greatest number of errors are made at the point of administration (54%) and during prescribing (21%) the two most involved stages in this case. According to NHS Resolution (2023), in April 2015 to March 2020 alone, 1,420 cases of medication-related negligence cases were received, of which 487 of those cases were settled with damages amounting to 35 million and opioids were found to be among the most frequently involved drug groups along with anticoagulants and antimicrobials.

It was shown through analysis of NRLS incident data that opioid drugs were the cause of 42.11% of high-risk medication incidents in three major drug categories (Alrowily et al., 2025). Of the opioid incidences in particular, 48.4% of the errors involved the administration process where incorrect drug administration (26.73%) and communication problems (8.40%) were found to be the most common contributory factors. These results are a direct reflection of the failures in this case and the fact that the circumstances that allowed this error are not unusual but structural features of NHS medication systems.

Systemic Weaknesses and Governance

Systemic vulnerabilities in local and regional communication, accountability, and governance are reflected in the case. A centralised safety control, the RED drug classification, was present in the formulary of this ICB but there were no enforcement mechanisms in primary care. The GP prescribing system did not have any alert, shared formulary platform across settings, and there was no protocol that involved clinician-to-clinician communication in high-risk medications. According to Amissah et al. (2020), systems thinking is characterised as the knowledge of the interaction between the components of a system to create collective behaviour, through this perspective the error was not made by one person but by the combination of a group of weak points within a system with no mutual feedback.

Rich Picture

The Rich Picture shows that there are four interrelated actors in this case, namely, the hospital team, the GP practice, the community pharmacy, and the parents, all being placed around the baby patient at the centre. The arrows are solid coloured pointing towards the baby, each actor has a red cross mark indicating to indicate the exact points where the communication failure occurred in each of the four care transitions. The broken grey lines along the outer perimeter represent the successive chain of care - hospital to GP to pharmacy to parents - the error was not prevented at each step but multiplied. The most significant systemic failure, which is the lack of the national incident learning loop, is depicted by the outer dashed red border. Although there had been four previous incidences of the same mistake since 2018, there was no system to disseminate that learning to frontline hospital teams, GP practises and community pharmacies. The external forces, such as staffing of pharmacies on weekends, the complexity of the NHS formulary, lack of a shared patient record and handwritten discharge records are mentioned at the bottom of the diagram as reflecting the structural circumstances that led to the situation where individual errors could go unchecked.

Figure: Rich Picture — Infant Morphine Overdose, (Developed by Author; Information Source: NHS England NEY, 2023)

Section B: Centralisation and Decentralisation

Overview

The NHS is a hybrid system of governance, as NHS England, NICE and MHRA centrally establish policy and safety standards, and Trusts, ICBs, GP practices and local pharmacies devolve service delivery. Greer et al. (2021) state that the trade-off between centralisation and decentralisation is essential in the context of a crisis - the former creates the opportunity to respond with uniform policies within a short period, whereas the latter provides the opportunity

to adapt in response to a crisis on a local scale, but may create a disintegration of responsibility. This tension is evident in this case and needs to be interrogated critically. To structurally locate this, NHS of England has its activities in 42 ICBs, 6,311 GP practices, and more than 10,500 community pharmacies, which are legally independent organisations (NHS Digital, 2024; House of Commons Library, 2024). Any centristically controlled safety regulation like the RED drug classification has to work through thousands of independent providers with no common enforcement in place.

Centralised Elements

The centralised mechanism of safety is the RED/AMBER/GREEN formulary classification system. The fact that morphine sulphate 100mcg/ml oral solution was named a RED drug, meaning that only specialists should initiate the usage, and the drug maintenance within the secondary care facility was specifically tailored to avoid the mistake that transpired. Ramssey et al. (2025) affirm the fact that the centralisation of specialised healthcare services can positively influence the safety outcomes as long as the governance structures are robust enough and enforcement infrastructure is present. The benefit of this centralised classification is that it is nationally standardised and it has standard expert control on high risk medications.

Nevertheless, the inherent drawback that this situation reveals is that the centralised rule lacked a mechanism of enforcement on the aspect of prescribing in the primary care setting. The GP did not know that there was a product with 100mcg/ml. The GP prescribing system did not carry any warning. The community pharmacists were as well ignorant of the specials product. The lack of a centralised safety classification with no one major care alert system and knowledge sharing system provided no viable protection at any of the failure points.

Decentralised Elements

The hospital Trust, the GP practise and the community pharmacy were legally and operationally separate organisations with no shared electronic patient record, no shared access to formulary and no single responsible clinician in charge of the overall medication process after discharge. The harmfulness of such fragmentation is not a secret: a study published in BMJ Quality and Safety estimates that every year about 1.8 million medication errors at the time of hospital transitions are observed in England alone, and about 380,000 patient episodes suffer, as well as at least 31,500 patients are harmed unexpectedly (Sheehan et al., 2024). More

importantly, 44% of such transition errors happen at the moment of hospital discharge, when this case started, therefore, the lack of shared digital prescribing records among the care settings is not a mere organisational inconvenience but a structural patient safety threat. This is listed by Pires (2022) as one of the structural risks in the UK model of community pharmacies and, according to him, the pharmacists in the proposed model have limited access to the complete medical history of a patient, and thus, their ability to perform a thorough medicines reconciliation is heavily limited in this case, which, in turn, can be directly applied to this case, with the dispensing pharmacist having no way of checking whether the prescription was intended to be made by a hospital, or not.

Cunha Leal et al. (2025) note that the role of community pharmacy in England is changing such that pharmacists are expected to be important participants in medicines management yet the increased professional role is not accompanied by access to clinical information systems or formalised escalation routes. The suspected issue in this instance was the dose volume but the community pharmacist did not have a direct channel to communicate with the prescribing GP, but was instead directed to non-clinical staff, which is a consequence of structural decentralisation without communication governance.

The issue of centralised policy/decentralised delivery is best revealed when the various facets of governance are overlaid against the points of failure in this instance. As shown in Table 2, there was a centralised safety mechanism at each level, but none of them had a route of enforcing safety measures into the decentralised environment in which the error was made.

Table 2: Centralisation vs Decentralisation — Impact on the Case

Dimension	Centralised Feature	Decentralised Feature	Critical Impact
Drug classification	RED drug designation (NHS England)	No GP system alert enforcing the rule	Classification existed but was not enforced in primary care
Prescribing	BNF guidance centrally available	GP operated independently, unaware of specials product	Error passed through the prescribing stage unchallenged

Communication	National discharge summary standards exist	Each organisation communicated independently	No shared patient record; safety query was diluted
Accountability	ICB governance framework	No single responsible clinician post-discharge	Accountability fragmented across four independent actors
Learning	National NRLS/LFPSE incident reporting system	Local organisations responsible for own learning responses	Five national incidents without systemic prevention

(Sources: NHS England, 2025; Ramsay et al., 2025; Pires, 2022)

Table 2 shows a similar pattern across the five dimensions: there were central rules but these did not extend past the boundary of the organisation that produced them. It is not a policy design failure but an integration failure - the NHS had the right classifications but no way of making them transit.

Critical Analysis

According to Pechenskaya-Polishchuk (2021), centralisation and decentralisation are not opposites but rather the two dimensions of governance that need to be aligned consciously. The effects of this misalignment are quantifiable: out of the 237 million medication errors each year in England, 71% of all potentially clinically relevant errors, in the given case where the RED drug classification was not visible at all, occur in primary care (Elliott et al., 2021). Although by November 2023, 90% of NHS Trusts had implemented Electronic Patient Records, cross-organisational data sharing (shared safety information) between organisations was not yet possible, as these systems had not been interoperable with GP and pharmacy systems (NHS England, 2023). The cost of misalignment in this case is that the central classification system acted in isolation of the decentralised model of delivery and there was no linking mechanism between them, no joint alert system, no compulsory escalation protocol, no systemised medication record. Yousef (2022) also notes that the successful adoption of NHS-wide medication safety standards needs integration infrastructure, not policy requirements. The implication that comes up is not to either decentralise or centralise but to create the connective

tissue of shared systems, shared knowledge, and shared accountability that enables the two dimensions to work together in a successful way.

Section C: Leadership Theories and Application

Theory 1: Transactional Leadership

Transactional leadership is typified by application of explicit rules, formal organisations, performance monitoring and corrective systems to control behaviour (Jaqua and Jaqua, 2021). According to Dong (2023), transactional leadership is essentially contingency-based - it functions based on established expectations and reactions to adherence or non-adherence. This is in the form of clinical guidelines, systems of drug classification, required reporting processes and audit mechanisms in the field of healthcare. Transactional control structures include the RED drug classification, the BNF prescribing standards and MHRA pharmacovigilance systems.

Berkovich and Eyal (2021), however, warn that the efficiency of transactional leadership is all determined by the presence of a strong monitoring and enforcement system, as rules without oversight are ineffective. The transactional framework, in this case, was completely dysfunctional: the GP was not observed to adhere to the rules of drug prescribing in the RED; the review of the discharge summary by the hospital pharmacist did not have any formal procedure attached to it; the safety concern described by the pharmacist did not initiate any form of formal escalation. Alrowily et al. (2025) add this concern by stating that 67.28% of the reports of incidents related to opioid were of poor quality to learn in the NRLS, which means that even the transactional mechanisms of reviewing the incidents and correcting the system were not functioning. The fifth time this particular error was made is the most damaging fact: under an operating transactional system, audits after occurrences one through four should all have resulted in system-wide modifications that were enough to ensure that the same would not happen again.

Theory 2: Distributed Leadership

Distributed leadership views leadership as a group activity scattered among people and groups instead of being held by a higher authority (Youngs, 2020). According to Johnson et al. (2022), distributed leadership establishes cultures of cooperation, which is necessary to operate a multi-

actor system of complex systems, and organisations are more adaptive to unforeseen risks. This case demanded exactly such a culture: the error chain might have been interrupted anywhere between four points had any of the actors been empowered and held himself accountable to do as a safety leader.

The RED drug discharge could have been intercepted by hospital pharmacist. Face-to-face medicines reconciliation could have been performed by the GP. The community pharmacist would have gone directly up to the prescriber. None did. The distribution of a clinical issue by a pharmacist to a pharmacy technician and a GP receptionist is symptomatic of a system lacking distributed leadership - that is, frontline professionals do not perceive themselves to be sufficient in ownership and psychological safety to take independent actions. In their cross-sectional study of healthcare leaders who were identified to have distributed and participative leadership styles, Al-Thawabiya et al. (2023) determined that they are largely linked to better patient safety behaviours and reporting culture, which supports the thesis that the empowered frontline professionals, and not just the senior managers, are an imperative safety infrastructure.

Theory 3: Transformational Leadership

Transformational leadership deals with cultural change inspiration, shared vision, and root cause, and systemic improvement over and above compliance (Ahmed and Simha, 2023). In their study of high-risk settings, Dartey-Baah et al. (2021) have discovered that transformational leadership was also a significant predictor of safety citizenship behaviours, whereas transactional leadership alone failed to maintain safety culture. Kotamena et al. (2020) warn that transformational leadership should not be adopted at surface level as this seemingly adopted leadership style may create an appearance of cultural change and lack its substance. O'Reilly and Chatman (2020) introduce an additional important aspect of the problem because inadequately executed transformational leadership in hierarchical organisations may become performative, i.e. it will produce statements of intent to replace structural change.

The NHS England North East and Yorkshire response, which issued a case study alert following the fifth incident, in this case, is a transactional response, which attempts to pass as system learning. The second or third incident would have been followed by a truly transformational leadership reaction, which would have been mandatory electronic discharge systems, shared formulary platforms, and clinician-clinician escalation protocols.

Collectively, the three theories reveal a transactional structured, non-distributive, and rhetorical transformational leadership system. Table 3 cross tabulates each theory and the case to indicate where each type of leadership actually failed.

Table 3: Leadership Theories Applied to the Infant Morphine Overdose

Theory	Core Principle	Application to Case	Critical Evaluation
Transactional	Rule-based compliance; monitoring and enforcement	RED drug rules existed but were unenforced; no audit of discharge process	Rules without enforcement are ineffective; five incidents indicate systemic audit failure
Distributed	Shared accountability; every clinician is a safety leader	No actor in the chain intercepted the error; pharmacist's concern not escalated directly	Absent psychological safety and escalation culture; accountability diffused and lost
Transformational	Cultural change; systemic redesign; proactive improvement	Response was reactive post-fifth incident; no redesign after prior events	Leadership was command-driven, not purpose-driven; case study alert insufficient for systemic change

(Sources: Ahmed and Simha, 2023; Youngs, 2020; Dartey-Baah et al., 2021; Dalcher, 2020)

The main result of this comparison is not that one leadership model was absent, but that all three of them became unsuccessful concurrently and through interconnected causes: the absence of rules monitoring and empowerment of frontline clinicians as well as lack of ownership of one of the leaders at the ICB level onto a recurrent national pattern. Compliance-oriented governance will keep on producing short-term responses to avoidable damage until they can be dealt with simultaneously.

Section D: Improvement and Lessons Learned

Problem 1: Handwritten Discharge Summary with Incomplete Dosing Information

The initial mistake was made at the discharge point of hospital. The handwritten summary abbreviated the name of the brand, Oramorph, and indicated the dose (in micrograms) that was used without indicating the volume that corresponded to the dose. This is where the initial failure occurred and the source of the whole downstream error cascade. According to BMJ Group (2020), 21% of all medication errors in England are prescribing errors, and discharge and transitions of care has a disproportionate representation among serious harms. The transition of care is specifically identified by WHO (2017) as one of the priority areas of action in their Medication Without Harm challenge, saying that communication failure during discharge is one of the most prevalent causes of preventable harm in the world.

The desired improvement is the implementation of mandatory electronic discharge summaries, with structured and validated fields of full drug name, formulation, strength, and dual-format dosing, i.e. quantity (mg/micrograms) and volume (ml) implemented in all Trusts, with all RED drug discharges reviewed by hospital pharmacists before issue. Kennedy et al. (2022) proved that adopting a designated, titled safe discharge care pathway in paediatrics greatly minimised post-discharge adverse events - the evidence that has been accessible and can be applied prior to this fifth incident. The critical analysis should remember that after this incident, though being positive, is a reactive and not a proactive governance.

Problem 2: Knowledge Gap at the Primary-Secondary Care Interface

The GP was not aware that there is a specials product of morphine sulphate 100mcg/ml oral solution. Although this is an indication of a lack of individual clinical knowledge, it cannot be divorced of the system circumstances that lead to it: there was no common formulary platform to warn GPs about specials products, no compulsory handover with the discharging hospital pharmacist, no primary care training route that included high-risk neonatal drugs. The gap in knowledge of the GP was thus an individual as well as a structural failure - the clinician failed to know something because the system was not constructed to make them know. Youssef (2022) also reports that the implementation models of NHS on specialist medications often lack the inclusion of primary care training and awareness plans, and frontline GPs lack the information they need to handle high-risk prescriptions safely. As confirmed by NHS Resolution (2023), opioids are a leading type of drug in claims of medication-related negligence, implying that the systemic risk in question is not a novel issue - but the gap in knowledge that facilitated the case in question was still unaddressed on five such occasions.

Some of the areas that need improvement include the use of a common formulary platform to automatically flag RED and specials products on GP prescribing systems; complex neonatal discharge should have mandatory face-to-face medicines reconciliation; and high-risk paediatric drugs and especially specials should be the focus of targeted GP education efforts.

Problem 3: Pharmacy Communication Routed Through Non-Clinical Staff

The community pharmacist realised that 0.1ml was a very challenging dose to measure and questioned the prescription, which was a clinically reasonable action. Nonetheless, the issue was relayed to the GP practise through a pharmacy technician and receptionist, but not among clinicians. The context has been lost; the issue has not been properly communicated; and no specific action was taken. The second dispenser did not have all the information about the ongoing safety query because poor handover notes were exchanged between the Friday and Saturday pharmacists. The parents were not given any syringe and no structured counselling was given.

As shown by both Worthington (2024) and James (2025), the teach-back counselling technique (when patients/carers repeat important information to the specialist to understand it) is an efficient approach, as it can enhance medication adherence and decrease medication errors in the community. Pires (2022) and Cunha Leal et al. (2025) state that communication infrastructure is one of the key weaknesses of the UK community pharmacy model that needs structural and cultural reformation. This can be improved by ensuring all high-risk drug requests are communicated to a pharmacist directly by the prescribers, counselling records are documented through the use of a teach-back methodology, and a 1ml oral syringe is provided each time a paediatric liquid medication is dispensed under a volume of 0.5ml.

Problem 4: Absence of Systemic Learning from Prior Incidents

The worst among the four problems is not a failure of any individual but lack of a learning system. By 2023, the same error had led to five instances of death among infants in the country, and one of them had already been documented, but no compulsory modifications were made in all the care settings that were involved. Alrowily et al. (2025) discovered that the reporting infrastructure was not working as a remedial mechanism since 67.28 percent of opioid incidences reported in the NRLS did not provide sufficient information on which meaningful learning could be conducted. All four problems and their evidence base together with suggested

improvements are brought together in Table 4 and demonstrate the fact that the failure points had solutions, which were never required.

Table 4: Problem, Evidence, and Improvement Summary

Problem	Supporting Evidence	Proposed Improvement
Handwritten discharge summary; incomplete dosing	BMJ Group (2020): 21% of medication errors at the prescribing phase; WHO (2017): transitions of care are one of the priorities in the world.	Mandatory electronic discharge summaries; dual-format dosing; pharmacist review of RED drug discharges
GP knowledge gap on specials product	NHS Resolution (2023): opioids are among the most frequent classes of drugs in claims; Alshaikhmubarak (2025): structural risk of primary-secondary interface.	Shared formulary platform with GP alerts; targeted paediatric medication education
Pharmacy query via non-clinical staff; no counselling	Alrowily et al. (2025): communication issues in 8.40% of opioid Cases.	Mandatory clinician-to-clinician escalation; teach-back counselling; 1ml syringe provision
No systemic learning after four prior incidents	Alrowily et al. (2025): 67.28% opioid incidents report had poor learning quality.	National recurring incident learning loop; mandatory implementation review; IHI PDSA cycles

(Sources: BMJ Group, 2020; WHO, 2017; NHS Resolution, 2023; Alrowily et al., 2025; IHI, 2024)

The most pressing of them is that a nationally recurring patient safety event, five incidents, one death, is a system-level failure as much as a clinical failure at the patient or individual level. Greer et al. (2021) claim that blame games tend to be the dominant forces in crisis governance whereby the individual mistakes of the error are given attention whereas the systemic factors that allow the mistakes to occur go unchecked. The reaction of NHS to the four incidents, which were not enough to stop a fifth one, is a classic example of this dynamics. The structural conditions under which this mistake could become perpetuated were the influence of a

centralised classification lacking enforcement, the decentralised delivery lacking shared accountability and the reactive governance through transactions lacking transformational redesign.

Recommendations

Governance and System Design

The most critical governance suggestion is compulsory adoption of electronic discharge summaries with formatted fields of high-risk drugs in every NHS Trust, and no discharge communication should be in handwriting in case of controlled or RED drugs. The the communication should include the complete drug name, drug formulation, strength, dose in both amount and volume as required by NHS England NEY (2023). There should be a common formulary platform that is available to both GP and community pharmacy prescribers at ICB level and that produce automatic alerts when either RED or specials products are ordered out of their prescribed care environment. The patient safety data of NHS England (2025) (stored in the LFPSE system) must be proactively analysed to reveal patterns of incidents and those reviews of cross-regional implementation should be obligatory in case the identical type of error is repeated more than twice on a national scale.

Leadership Development

The best leadership approach that would be suitable to maintain the change in this multi-organisational setting is a calculated mix of transformational leadership and distributed leadership. As Berkovich and Eyal (2021) show, transformational leadership, as opposed to transactional ones, has been shown to be more effective in creating a strong culture of patient safety, whereas Johnson et al. (2022) confirm that distributed leadership is a key to effective management of complex, multi-actor systems. ICBs must then invest in the leadership development programmes that are specifically aimed at the proactive development of the safety culture without relying on compliance-oriented frameworks but with the purpose-oriented systemic advancement (Dalcher, 2020). On the frontline, pharmacists and GPs must be officially established as safety leaders in the medication management pathway, with safeguarded time and structural pathways of direct clinician-to-clinician communication on the high-risk prescription. Al-Thawabiya et al. (2023) discovered that the direct relationship exists between participative and distributed leadership styles with enhanced safety reporting and

safety citizenship behaviours - which directly applies to community pharmacy and primary care practises.

Communication and Patient Engagement

Pharmacies with high-risk paediatric drugs must also be mandated to perform structured patient counselling via the teach-back procedure, requiring carers to repeat the dose, volume, and method of administration and then leave the pharmacy (Worthington, 2024; James, 2025). Any liquid medication dispensed in a volume below 0.5ml should be provided necessitating the provision of an oral syringe of an adequate size. In complex neonatal discharges, a named community pharmacist must be officially designated as the Discharge Medicines Service that has direct access to the discharge summary and has a standard protocol to communicate with the discharging hospital pharmacist in case of any query. As shown by Kennedy et al. (2022), structured discharge pathways and designated responsible clinicians reduced post-discharge adverse events significantly in comparison with traditional ones - data, which has to be implemented as a standard practise. Ward and practise-level improvement cycles based on IHI Plan-Do-Study-Act improvement cycles should be integrated throughout the cycle of continuous improvement (IHI, 2024), and the annual audit of RED drug discharge processes across all Trusts and the co-production of patient-facing materials designed with and not just to the affected families.

Evaluation and Risk Considerations

These recommendations should be followed up with annual ICB audit cycles of the RED drug discharge processes, and KPIs used to monitor electronic discharge completion rates and LFPSE incident recurrence. Nevertheless, there are two risks in implementation that should be considered. First, the risk of mandatory prescribing alerts is that they can cause alert fatigue, i.e. clinicians can disregard the warnings by overexposing themselves to them, which diminishes their effectiveness as protective measures. Second, the concurrent implementation of thousands of independent organisations imposes a huge implementation strain on community pharmacies that are already strained in terms of workforce and funding demands (House of Commons Library, 2024). The two risks would be alleviated through a staged process of implementation that incorporates staff education.

Conclusion

In this report, the 2023 NHS England North East and Yorkshire case involving infant morphine overdose, where a four-week-old infant was given a dosage twenty times greater than it should have been as a result of cascading failures throughout hospital, GP, and community pharmacy, has been critically analysed. It was the fifth nationally since 2018, and one of the earlier cases had resulted in infant death, a trend that makes this case a change of a clinical failure to a top-level governance and leadership failure.

As illustrated by the analysis, the NHS hybrid model of governance created a gap in the structure where the RED drug classification was present with no infrastructure of enforcement, and the lack of professional accountability that was spread among separate organisations with no common records, no common formulary access, and no common protocols of communication. The results of transactional leadership were rules that were not monitored; distributed leadership did not exist; and the lack of transformational leadership at the ICB and NHS England level were the factors allowing four past incidents to go unpunished and not be able to trigger the systemic redesign that could save lives.

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