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1.INTRODUCTION

This case study analysis reports examines the death of Len, 89 year old man who suffered an unintentional overdose of morphine sulfate oral solution as a consequence of systemic failures in medication labelling, dispensing, and communication with the national health services (NHS) in England (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). This incident, investigated by the healthcare safety investigation branch (HSIB), exposes critical vulnerabilities at the intersection of health leadership, governance, and system design that collectively failed to protect a vulnerable elderly patient (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022).

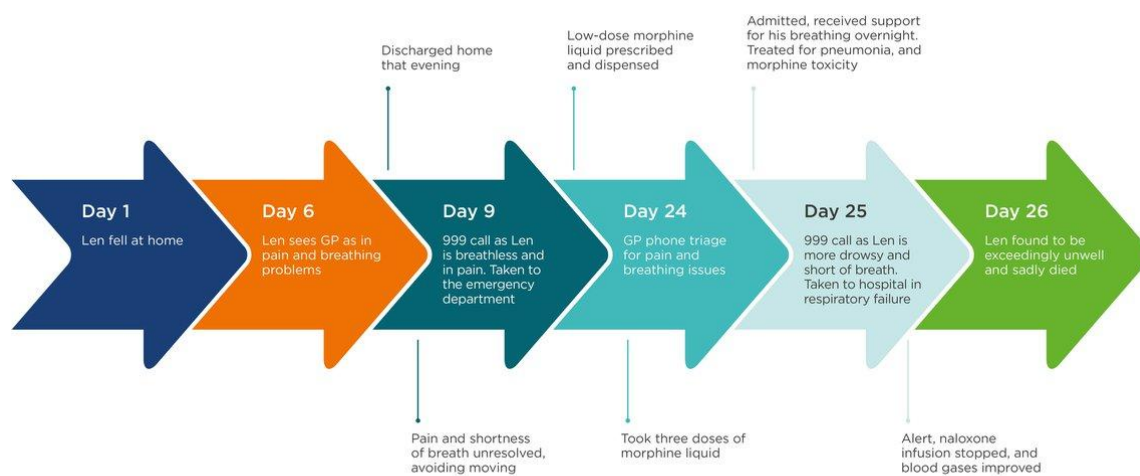


Fig 1 illustrates the summary timeline of Len's care in 2021.

Leadership in healthcare and social care refers to the capacity to influence and motivate others toward achieving shared goals that improve patient outcomes and organisational performance (Moss & Garside, 2001).. Effective leadership is not merely an administrative function; it shapes the safety culture, determines resource allocation, and governs how systems respond to risk (McFadden et al., 2009).

Within this framework, centralisation concentrates decision-making authority at the top of organisational hierarchies, whereas decentralisation distributes authority closer to the point of care, each offering distinct advantages and risks in crisis management.

Key leadership theories relevant to this analysis include transformational leadership, which inspires followers through vision and empowerment; transactional leadership, which relies on contingent rewards and monitoring; and situational leadership, which adapts style to context (Lo et al., 2018)(Walls, 2019). The selection of appropriate leadership style matters profoundly

because it determines how organisations anticipate, detect, and respond to safety threats, particularly during crises or periods of system strain (Wong & Cummings, 2007) .

This report addresses four principal areas: the identification and systems-context analysis of the problem using a rich picture approach; the examination of centralisation and decentralisation dynamics within the NHS as they relate to Len's case; the critical application of leadership theories to the incident; and the evaluation of improvement strategies and lessons learned.

Collectively, these sections demonstrate how systemic, governance, and leadership failures converged to produce a preventable death and what change to prevent recurrence.

2. IDENTIFYING THE PROBLEM AND SETTING THE SYSTEM CONTEXT: APPLYING SYSTEMS THINKING AND THE TICH PICTURE

The central problem in this case study is the unintentional overdose of morphine sulfate oral solution that contributed to the death of Len, and 89 year old man with Charcot-Marie Tooth (CMT) disease, following a fall at home in December 2020 (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). Len was prescribed morphine sulfate 10mg in 5ml oral solution at a dose of 1.25ml to 2.5ml (2.5mg to 5mg) to be taken up to every four hours when required (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). However, Len and his wife misread the manufacturer's label on the bottle, which states 10mg/5ml in large bold font, and interpreted this as the required dose (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). This dispensing label bearing the correct dose was placed on the outer cardboard box, which they did not notice. Len consequently took three doses of 5ml (10mg), which was two to four times his prescribed dose, before being found unresponsive the following morning.

Placing this incident within a broader context, the World Health Organisation (WHO) launched its third global patient safety challenge, medication without harm, in 2017, aiming to reduce severe avoidable medication- related harm by 50% within five years (Sheikh et al., 2017). The WHO estimates that medication errors cost approximately US\$42 billion annually worldwide, and that one in 20patients in high-income countries is affected by preventable medication-related harm (Panagioti et al., 2023)(Sheikh et al., 2017). Globally, approximately 10 million people become permanently disabled or die each year due to medical errors (Sakalli & Canbolat, 2023). The highest prevalence of preventable medication ham occurs in geriatric care settings at 17%, and opioids are consistently identified among the medications most

frequently associated with post-discharge safety incidents (Panagioti et al., 2023) (Alqenae et al., 2021).

Nationally, the scale of medication errors in England is substantial. Elliott (2020) estimated that 237 million medication errors occur at some point in the medication process in England annually, with 34.8% occurring in primary care (Elliott et al., 2020). Although 72% of these errors have little or no potential for harm, approximately 66 million are potentially clinically significant, with prescribing in primary care accounting for 34% of all such errors (Elliott et al., 2020). Definitely avoidable adverse drug events are estimated to cost the NHS £98.5 million per year, consume 181,626 bed-days, and cause or contribute to 1,708 deaths (Elliott et al., 2020). The department of health and social care reported that medication errors lead to an estimated 712 deaths per year in England, with medication errors potentially contributing to between 1700 and 23,303 deaths annually (Wise, 2018). Within these figures, elderly patients are disproportionately affected: the highest rates of preventable medication harm are found in elderly care settings at 11%, and 55% of post- hospital discharge medication incidents involve patients aged over 65 (Hodkinson et al., 2020)(Alqenae et al., 2021). These statistics position Len's case as both locally devastating and globally relevant, reflecting systemic weaknesses that extend far beyond a single community pharmacy or general practice.

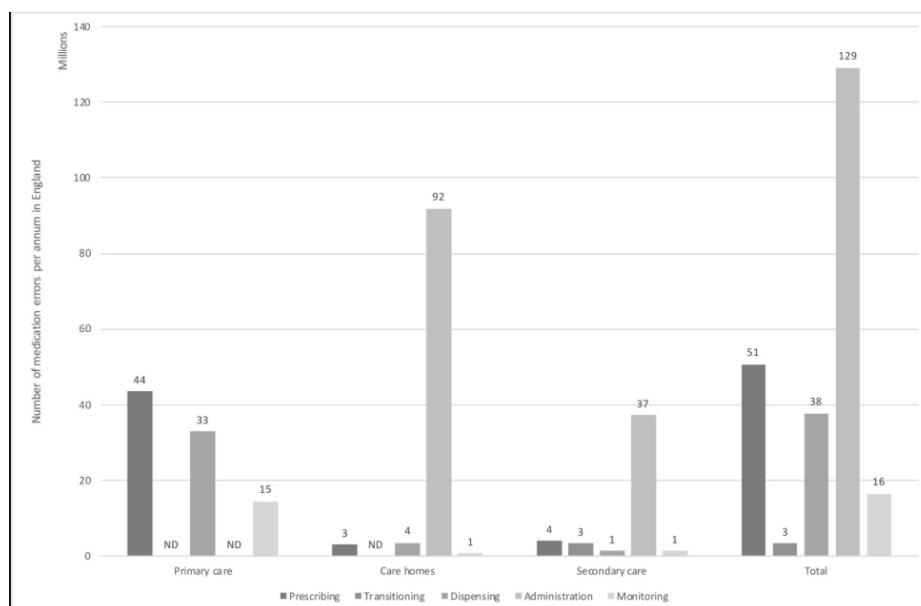


Fig 2 illustrates the medication errors in England in primary care, care home, secondary care and in total on X-axis .Y-axis indicates number of medication errors per annum in millions (Elliott et al., 2020).

Applying systems thinking through the systems engineering initiative for patient safety (SEIPS) framework, as HSIB themselves adopted in their investigation, reveals the interconnected work system factors that produced this outcome (Holden et al., 2013). The SEIPS model

describes how components of the work system, including people, tasks, equipment, the internal environment, organisation, and the external environment, interact to produce processes that lead to outcomes. In Len's case, multiple feedback loops and communication gaps are evident.

The rich picture visualises how people factors, including Len's age, his wife's hearing and memory problems, and their limited manual dexterity due to CMT, interacted with equipment factors, specifically the manufacturer's label design and the 5ml oral syringe that could not accurately measure a 1.25ml dose (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). The organisational dimension reveals that the COVID-19 pandemic forced the GP practice to adopt telephone triage, reducing the GP's ability to assess Len face to face and potentially limiting the quality of safety-netting advice (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). The external environment factor is equally critical: morphine sulfate oral solution 10mg in 5ml is classified as a schedule 5 controlled drug under the misuse of drugs regulations 2001, subject to fewer regulatory controls than schedule 2 morphine formulations, which may have reduced pharmacist scrutiny at the point of dispensing. Crucially, the community pharmacy declined to participate in the HSIB investigation, creating a significant gap in understanding of what dispensing advice was given (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). This non-engagement represents loop essential for systemic learning, as without the pharmacy's perspective, the full chain of failures cannot be understood or remedied. The governance level influencing this problem spans from locals, where the pharmacy and GP decisions were made, to national where the legislative framework for medication labelling and controlled drug scheduling is determined (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022).

Underlying challenges include staff shortages exacerbated by the COVID-19 pandemic, which prevented both the GP and community pharmacy from engaging with the investigation, and the failure to submit a yellow card report, which the Trust acknowledged should have been filed but was not due to workforce pressures (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022) (New HSIB Report Highlights Liquid Morphine Patient Safety Concerns, 2022).

3. CENTRALISATION or DECENTRALISATION WITHIN THE CASE STUDY

The NHS in England operates within a persistent tension between centralisation and decentralisation, where policy oscillates between centrally imposed targets and locally determined service delivery (Goddard & Mannion, 20026). Greener et al.(2009) argue that the term decentralisation is often so poorly defined that reforms made in its name cannot be properly assessed, and that despite claims of decentralisation, NHS governance has seen steadily increasing claims of authority by the centre (Greer 2023, Greener et al., 2009). This

centralising tendency manifests through national targets, performance monitoring, and standardised patient safety directives, while local organisations retain varying degrees of autonomy over operational delivery (Exworthy & Greener, 2008).

In Len's case, the medication dispensing and prescribing system exhibited characteristics of a centralised structure at the regulatory level but a decentralised structure at the operational level. At the centralised level, the Human Medicines Regulations 2012 and MHRA guidance set national standards for medication labelling and packaging that apply uniformly across all pharmacies and manufacturers. NICE clinical knowledge summaries provide standardised, stepwise guidance for pain management that the GP was required to follow. The national patient safety agency (NPSA) published guidance in 2007 recommending that dispensing labels be placed on the medication itself rather than the outer packaging, recognising that if the outer container is discarded, label information is lost. However, HSIB noted that these recommendations are difficult to find online and are no longer hosted on any NHS website, indicating has not been effectively disseminated or enforced.



Fig 3 demonstrates the step wise guidance for pain management (National institute for Health & care Excellence, 2020).

At the operational level, the system was heavily decentralised. The GP made an independent clinical decision to prescribe morphine by telephone consultation without face-to-face assessment, exercising professional autonomy within the constraints of the COVID-19 pandemic practice (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). The community pharmacy, operating as an independent decided the placement of the dispensing

label, whether to offer substitution of a non-child-resistant lid, and what verbal advice to provide at the point of dispensing practice (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). The hospital trust independently managed Len's emergency care, deciding treatment pathways including the administration and cessation of naloxone practice (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). Each of these decisions was made autonomously, without a coordinating mechanism to ensure that information about the correct dose flowed consistently from prescriber to dispenser to patient.

The advantages of this decentralised operational structure are that it allows healthcare professionals to exercise clinical judgement and adapt to individual patient needs, which the GP did by prescribing a reduced dose appropriate for Len's age and kidney function practice (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). However, the disadvantages proved fatal in this case. The absence of a central coordinating mechanism meant there was no system to verify that Len and his wife understood the prescribed dose before self-administration began. The dispensing label placement was left to the pharmacy's discretion, guided only by legislation that permits labelling the outer box rather than the bottle practice (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). No central authority mandated that pharmacists provide standardised verbal counselling for high-risk opioid patients in the community. Had the system been more centralised in its approach to high-risk medication dispensing, mandatory counselling protocols and enforced label placement standards could have prevented the fatal misinterpretation (Grissinger & Gaunt, 2011).

Numerical evidence further illustrates how system structure hindered crisis management. The Elliott et al., (2020) study found that prescribing in primary care accounts for 33.9% of all potentially clinically significant errors in England, suggesting that the decentralised primary care prescribing model carries inherent risks that centralised safety mechanisms have not adequately addressed (Elliott et al., 2020). HSIB found that oral morphine sulfate liquid has been directly linked to the cause of death in 13 prevention of future death reports issued by coroners since 2013, the majority relating to chronic use, but demonstrating that the risks associated with this medication are well documented and yet insufficiently addressed by either central regulation or local practice (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). The failure of the community pharmacy to participate in the investigation, and the GP practice's inability to engage due to COVID-19 pressures, underscores how a decentralised system can impede accountability: when individual organisations can opt out of participating in safety investigations, systemic learning is blocked (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022).

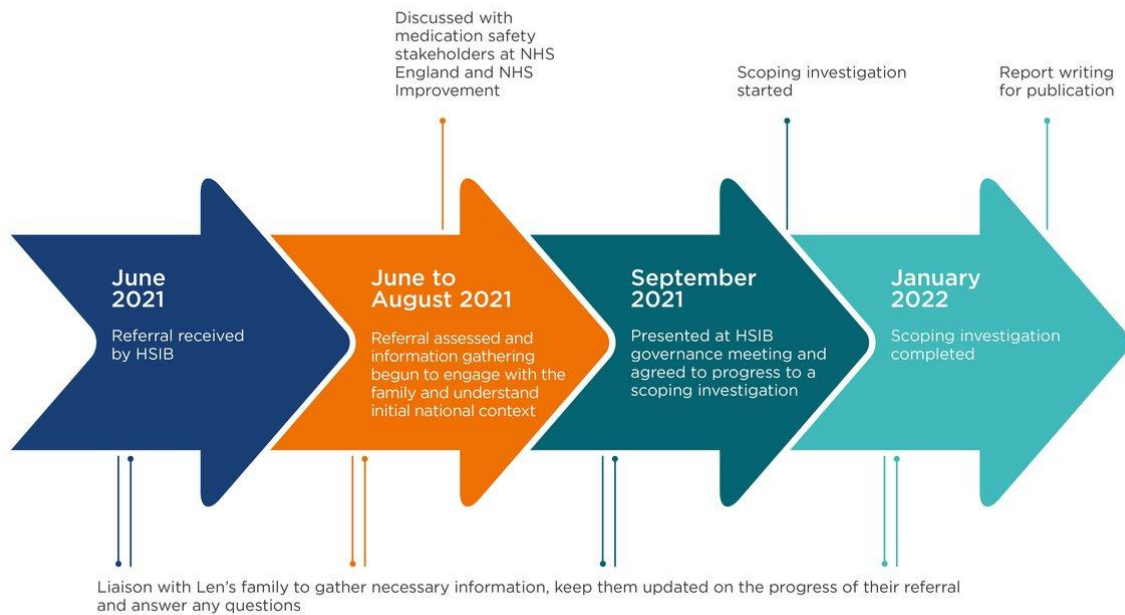


Fig 4 depicts the HSIB processed Len's referral.

Critically, the comparison reveals that neither pure centralisation nor pure decentralisation is adequate. Centralised regulation produced labelling standards that, while intended to differentiate between morphine concentrations through large bold font, inadvertently created an error trap that confused rather than informed patients (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). Decentralised operational decision-making, without standardised safety protocols at the point of dispensing, left a vulnerable elderly couple without guidance they needed. What was required was a hybrid model: centralised mandates for safety-critical processes, such as mandatory dispensing label placement on the medication bottle and standardised pharmacist counselling for opioid prescriptions, combined with decentralised clinical autonomy for treatment decisions.

4. LEADERSHIP THEORIES AND APPLICATION TO THE CASE STUDY

Three leadership theories offer analytical lenses through which to evaluate the leadership failures exposed by Len's case: transformational leadership, transactional leadership, and situational leadership. Each theory illuminated different aspects of the healthcare system either contributed to or failed to prevent this tragedy.

4.1 Transformational leadership

First conceptualised by Burns and later refined by Bass, involves four dimensions: idealised influence, inspirational motivation, intellectual stimulation, and individualised consideration (Collins et al., 2019). Transformational leaders inspire followers to transcend self-interest for the collective good, foster a culture of continuous improvement, and encourage critical thinking about established practices (McFadden et al., 2009). Within the NHS, transformational leadership has been consistently associated with improved patient safety outcomes, including reduced medication errors and stronger safety cultures (Wong & Cummings, 2007) (Lievens & Vlerick, 2014). McFadden et al (2009) demonstrated through structural equation modelling that transformational leadership among hospital chief executives predicts safety culture, which in turn predicts improved patient safety outcomes (McFadden et al., 2009). In Len's case, a transformational approach was conspicuously absent at multiple levels. National leaders at NHS England and the MHRA failed to exercise intellectual stimulation by critically examining whether existing labelling regulations for morphine oral solution were fit for purpose, despite accumulating coroner's reports linking the medication to preventable deaths since 2013 (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). At the local level, there is no evidence that pharmacy or GP practice leaders challenged the status quo of dispensing and prescribing practices that placed inadequate safeguards around high-risk opioid medications in community settings. Had transformational leadership been present, leaders would have proactively identified the labelling and measurement aid deficiencies as systemic risks and championed redesign before another patient was harmed (Nursing Transformational Leadership for Patient Safety, 2019).

4.2 Transactional leadership

By contrast, operates through contingent rewards and corrective actions, establishing clear expectations and monitoring compliance (Walls, 2019). While often criticised as insufficient for cultural change, transactional mechanisms serve important functions in ensuring that established safety protocols are followed (Alabdullatif et al., 2025). In Len's case the failure of transactional leadership is evident in the breakdown of monitoring and accountability mechanisms. The NSPA recommendations on dispensing label placement, published in 2007, represented a transactional expectation that pharmacies should preferentially label the medication itself rather than the outer packaging (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). However, there was no central monitoring system to ensure compliance with this guidance, and the recommendations became effectively inaccessible over time (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). The yellow card reporting system represents another transactional mechanism: the Trust acknowledged that a yellow card report should have been submitted but was not, because staff under great pressure did not consistently file reports (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022).

Research consistently demonstrates that fear of blame and inadequate reporting systems undermine transactional accountability in healthcare, with one integrative review identifying organisational barriers including inadequate reporting systems, management behaviour, and unclear definitions of medication error as key impediments to error reporting (Afaya et al., 2021). The absence of enforceable accountability for the community pharmacy's refusal to participate in the HSIB investigation further illustrates the weakness of transactional leadership: there existed no mechanism to compel cooperation with a safety investigation, meaning that critical information about dispensing practice was lost (New HSIB Report Highlights Liquid Morphine Patient Safety Concerns, 2022).

4.3 Situational leadership

As described by Hersey and Blanchard, proposes that e

Situational leadership, as described by Harsey and Balnchard, proposes that effective leaders adapt their style to the readiness and needs of their followers and the demands of the situation (Walls, 2019).

The COVID-29 pandemic created an unprecedented situation requiring adaptive leadership responses. In Len's case, the GP demonstrated elements of situational awareness by prescribing a reduced morphine dose appropriate for an older adult with kidney dysfunction and by conducting a telephone consultation a telephone consultation when face to face assessment was constrained by pandemic restrictions (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). However, the GP failed to adapt sufficiently to Len's specific vulnerabilities: an 89 year old man with CMT, a wife with hearing and memory problem, and no previous opioid experience merited a more directive and supportive approach, including clear verbal instructions, a follow up a call to verify understanding, and consideration of whether telephone prescribing of a high-risk medication was appropriate (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). At the pharmacy level, there is no evidence of situational adaptation: standard dispensing procedure were followed without recognition that an elderly couple collecting a first-time morphine prescription required additional counselling and that the manufacturer's label design posed a specific risk of dose misinterpretation. The hospital Trust's management of Len's care demonstrated reactive rather than proactive leadership: while the emergency treatment followed appropriate clinical protocols, the failure to file a yellow card report and the lack of a systemic debrief after the incident reflect a reactive posture that complied with immediate clinical requirements but failed to address systemic learning needs (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022).

Data from across the healthcare system reveals the consequences of these leadership failures. Wong and Cummings (2007) found in their systemic review that transformational leadership was significantly associated with reduced medication errors, with relational leadership styles consistently predicting lower adverse events (Wong & Cummings, 2007). Lievens and Vlerick (2014) demonstrated that transformational leadership exerted a significant positive impact on nurses safety compliance and safety participation, mediated by knowledge-related job characteristics (Lievens Vlerick, 2014). Conversely, the laissez-faire leadership evident in the gaps between national guidance and local implementation, and in the absence of enforcement mechanisms for safety recommendations, has been consistently associated with poorer safety outcomes (Al-Raimi 2026). What could have been done differently includes the adoption of distributed leadership, where accountability for medication safety is shared across the prescribing-dispensing-administration chain, and emotionally intelligent leadership that recognised the specific vulnerabilities of elderly patients and their carers when dispensing high-risk medications (Gautam et al., 2026).

5. IMPROVEMENT AND LESSONS LEARNED

Critically evaluating how leadership and governance interacted to produce the outcomes in Len's case requires examining the missed opportunities at each stage of the medication pathway. The HSIB investigation identified that the GP's prescribing decision followed national guidance, yet the chain from prescription to self-administration contained multiple points where interventions could have prevented harm (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022).

5.1 PROBLEM: Confusing manufacturer labelling and inadequate dispensing label placement

The manufacturer's label displayed 10mg/5ml in large bold font to differentiate between the two concentrations of morphine oral solution (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). While this design serves the regulatory purpose of preventing ten-fold medication errors between concentrations, it created an errors trap for patients who interpreted the strength information as the prescribed dose (New HSIB Report Highlights Liquid Morphine Patient Safety Concerns, 2022). The dispensing label, placed on the outer box rather than the bottle, compounded this risk.

Data: Elliott et al (2020) estimated that wrong dose or strength errors account for a significant proportion of medication incidents in primary care (Elliott et al., 2020). The NPSA's 2007 guidance explicitly warned that labelling outer container was discarded, yet this guidance was

neither effectively disseminated nor enforced (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022).

Improvement: Mandate through MHRA regulation that dispensing labels for high-risk liquid medications must be placed on the immediate medication container, not solely on the outer packaging, Implement standardised cautionary labels using pictograms and colour-coded dose indicators specifically designed for elderly designed for elderly patients, addressing the WHO priority of universally applicable pictograms to avoid medication-related harm (Sheikh et al., 2019).

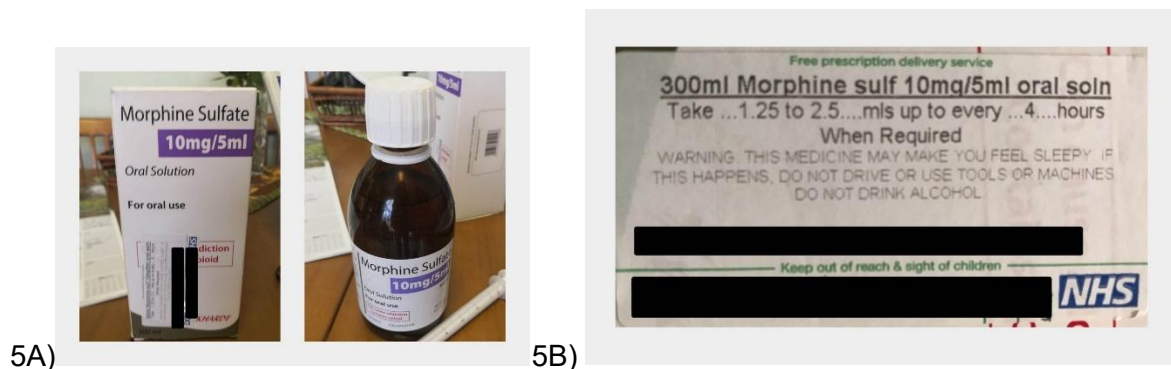


Fig 5 depicts A) Morphine packaging bottle & B) Dispensing label on outer box

5.2 Problem: Inadequate measurement aids for sub-standard doses.

The 5ml oral syringe supplied with the morphine could not accurately for Len (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). The syringe markings indicated 1.2ml and 1.3ml, making accurate measurement of 1.25ml impossible.

Data: HSIB's safety observation O/ 2022/165 specifically noted the need for dose measurement aids capable of measuring the full range of possible doses (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). Patient safety learning argued that this observation alone is insufficient without a formal framework to ensure manufacturers act on it (New HSIB Report Highlights Liquid Morphine Patient Safety Concerns, 2022).

Improvement: Require manufacturers supplying dose measurement aids with morphine oral solution to include graduated syringes capable of measuring all clinically relevant doses, including 0.5ml increments. Pharmacists should be mandated to supply appropriate where the manufacturer's aid is insufficient for the prescribed dose.

5.3 Problem: Absence of standardised pharmacist counselling for high-risk opioid prescriptions.

The investigation could not determine what verbal advice Len's wife received at the pharmacy due to the pharmacy's refusal to participate (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). Len's wife's hearing and memory problems further reduced the likelihood that any advice given was accurately received and retained (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022).

Data: a UK study found that errors associated with opioids rank among the top medication subgroups involved in post-hospital discharge incident (Alqenae et al., 2021). The WHO identifies patient engagement as one of four key domains for medication safety, yet patient understanding of medication risks remains consistently poor (Cox et al., 2020).

Improvement: Introduce mandatory pharmacist counselling protocols for all schedules 5 opioid prescriptions dispensed to patients aged 65 and over or those with first-time opioid prescriptions. This counselling must include verbal explanation of the correct dose, demonstration of the measuring device, and written supplementary instructions in large print. Pharmacists must document that counselling was provided and received.

5.4 Problem: Failure of the system yellow card reporting and incident learning system.

The trust acknowledged that a yellow card should have been submitted but was not, reflecting a pattern where reporting is deprioritised during periods of high workload (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). The independent medicines and medical devices safety review (2020) documents significant shortcomings in the yellow card scheme's effectiveness, and patient safety learning identified underreporting as a systemic issue (New HSIB Report Highlights Liquid Morphine Patient Safety Concerns, 2022).

Data: Cousins et al. (2012) found that 526,186 medication incidents were reported to the national reporting and learning system over six years, with only 0.9% resulting in death or severe harm, yet many more incidents likely went unreported (Cousins et al., 2012).

Improvement: implement digital, automated yellow card prompts within electronic patient record systems that trigger when naloxone is administered or when opioid toxicity is documented. Designate incident reporting as a protected, non-punitive activity, and incorporate reporting compliance into organisational performance metrics.

5.5 Problem: Non-engagement of the community pharmacy with the safety investigation.

The community pharmacy that dispensed Len's morphine declined to participate despite repeated attempts by HSIB to engage. This refusal meant critical questions about dispensing advice, label placement rationale, and awareness of the patient's vulnerabilities could not be answered (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022).

Data: Patient safety learning described this as demonstrating a shocking degree of disregard toward that affected family and called for stronger regulatory powers to compel cooperation (New HSIB Report Highlights Liquid Morphine Patient Safety Concerns, 2022).

Improvement: Support the implementation of statutory powers for the health service safety investigations body (HSSIB) to compel witness evidence and organisational cooperation. Professional bodies including the General pharmaceutical council and royal pharmaceutical society should issue explicit guidance that non-cooperation with patient safety investigations constitutes professional misconduct (New HSIB Report Highlights Liquid Morphine Patient Safety Concerns, 2022).

Linking these findings together reveals that the interaction between system structure, leadership style, and feedback mechanisms produced the outcome, the decentralised operational structure, lacking centralised safety mandates for high-risk medication dispensing, meant that each professional acted within their own silo without a coordinating mechanism. The predominantly transactional and laissez-faire leadership at system level failed to enforce existing guidance or champion new safeguards despite accumulating evidence of harm. The absence of effective feedback loops, exemplified by the yellow card failure and the pharmacy's non-engagement, prevented the system from learning and adapting. Other health organisations can learn that high-risk medications in community settings require a systems approach that standardises critical safety processes while preserving clinical autonomy elsewhere (Guntschnig et al., 2025). Evidence and data must be used not only to identify problems retrospectively but to design proactive safeguards, as the WHO's third global patient safety challenge advocates: deploying technology, developing guidelines for high-risk situations, and increasing patient medication literacy (Sheikh et al., 2019)

6. RECOMMENDATIONS

Based on the analysis presented, the following evidence-based recommendations are proposed for the NHS and relevant regulatory bodies to prevent recurrence of incidents like Len's case. These recommendations address leadership style, governance strengthening, systems integration, and continuous improvement.

First, MHRA should mandate that dispensing labels for all opioid medications must be placed on the immediate medication container, not solely on the outer packaging. This addresses the root cause of Len's misinterpretation and aligns with the NPSA's 2007 guidance has been insufficiently enforce (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). Manufacturers should be required to include graduated syringes capable relevant doses,

including sub-5ml doses for elderly patients, reflecting HSIB's safety observation O/2022/165 (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022).

Second, NHS England should introduce mandatory pharmacist counselling protocols for all first-time opioid prescriptions and all opioid prescriptions for patients aged 65 and over. This counselling must include verbal explanation of the correct dose, physical demonstration of dose measurement, and written supplementary instructions in large-print format. Pharmacists must document that counselling was delivered and that the patient or carer demonstrated understanding. This recommendation addresses the communication gap at the dispensing stage and reflects the WHO domain of engaging patients and the public in medication safety (Sheikh et al., 2017).

Third, the most effective leadership style for sustaining improvement in medication safety is a combination of transformational and situational leadership. Transformational leadership is needed at the national level to champion medication safety culture, challenge outdated labelling regulations, and inspire systemic redesign around high-risk medications (McFadden et al., 2009). Situational leadership is required at the local level, where clinicians and pharmacists must adapt their communication and counselling strategies to the specific vulnerabilities of individual patients, particularly elderly patients with sensory or cognitive impairments (Walls, 2019). NHS leadership development programmes should incorporate training in both styles, with specific modules on medication safety and high-risk prescribing.

Fourth, governance structures should be strengthened through the implementation of statutory investigation powers for HSSIB, enabling the body to compel organisational cooperation and witness evidence (New HSIB Report Highlights Liquid Morphine Patient Safety Concerns, 2022). The general pharmaceutical council and royal pharmaceutical society should incorporate professional obligations to participate in safety investigations into their standards of conduct. At the national level, the MHRA should review the scheduling of morphine sulfate oral solution 10mg in 5ml under the misuse of drugs regulations, considering whether schedule 2 controls are warranted given the medications' association with preventable deaths (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022).

Fifth, technical and allocative efficiency can be enhanced through the deployment of electronic prescribing systems with clinical decision support that flag high-risk prescribing situations, such as the prescriptions of opioids to elderly patients with kidney dysfunction, and that automatically generate structured counselling requirements for pharmacist. Automated yellow card prompts within electronic patient records should be implemented to ensure that adverse drug reactions and medication errors are consistently reported, closing the feedback loop that

is essential for continuous improvement (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022).

Sixth, continuous learning should be embedded through annual medication safety audits at every GP practice and community pharmacy, with results reported to NHS England as part of the national medication safety improvement programme. Stakeholder engagement and co-production should be prioritised by involving patients and families in the design of medication labelling and counselling materials, ensuring that information is presented in formats accessible to elderly patients and those with sensory impairments. The WHO's 5 moments for medication safety patient engagement tool provides a practical framework for this co-production approach (Cox et al., 2020).

7. CONCLUSION

This case study analysis has examined the unintentional morphine overdose that contributed to the death of Len, demonstrating how systemic failures in medication labelling, dispensing practice, communication, and governance converged to produce a preventable tragedy. The application of systems thinking through the SEIPS framework and rich picture analysis revealed that the incident was not the result of a single individual's error but the product of interacting work system factors, including confusing manufacturer labelling, inappropriate dispensing label placement, inadequate measurement aids, and the absence of standardised pharmacist counselling for high-risk medications (Unintentional Overdose of Morphine Sulfate Oral Solution, 2022). The analysis of centralisation and decentralisation demonstrated that a decentralised operational structure, lacking centralised safety mandates for critical processes, left a vulnerable patient without the coordinated protection he needed, while centralised regulation inadvertently created the labelling error trap that Len and his wife fell into (Goddard & Mannion, 2006).. The critical application of leadership theories established that the absence of transformational leadership at the national level, the weakness of transactional accountability mechanisms, and the failure of situational adaptation at the local level collectively produced the conditions for harm (McFadden et al., 2009; Lievens & Vlerick, 2014).. The recommendations proposed, including mandatory label placement on medication containers, pharmacist counselling protocols, strengthened investigation powers, and electronic prescribing safeguards, address the systemic root causes identified in this analysis. Above all, Len's case underscores the fundamental importance of leadership, governance, and systems thinking in driving change: when anyone of these elements fails, patients are placed at risk, and when all three fail simultaneously, the consequences can be fatal. The lessons from this case must be translated into systemic action, not additional reports that sits

unenforced, if the NHS is to fulfil its fundamental commitment to patient safety and ensure that no other family experiences the same preventable loss (Webster, 2022).

8. REFERENCES

- Afaya, A., Konlan, K.D. and Kim Do, H. (2021) 'Improving patient safety through identifying barriers to reporting medication administration errors among nurses: an integrative review', *BMC Health Services Research*, 21, 1156. Available at: <https://doi.org/10.1186/s12913-021-07187-5>
- Alqenae, F.A., Steinke, D., Carson-Stevens, A. and Keers, R.N. (2021) 'Medication safety challenges following hospital discharge: an exploratory analysis of incidents reported in England and Wales over a 5-year period', *Pharmacoepidemiology and Drug Safety*, 30(Suppl. 2), pp. 14–15. Available at: <https://doi.org/10.1002/pds.5315>
- Alqenae, F.A., Steinke, D. and Keers, R.N. (2020) 'Prevalence and nature of medication errors and medication-related harm following discharge from hospital to community settings: a systematic review', *Drug Safety*, 43(6), pp. 517–537. Available at: <https://doi.org/10.1007/s40264-020-00918-3>
- Cousins, D.H., Gerrett, S.P. and Warner, B. (2012) 'A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years (2005–2010)', *British Journal of Clinical Pharmacology*, 74(4), pp. 597–604. Available at: <https://doi.org/10.1111/j.1365-2125.2011.04166.x>
- Collins, E., Owen, P., Digan, J. and Dunn, F. (2020) 'Applying transformational leadership in nursing practice', *Nursing Standard*, 35(5), pp. 59–66. Available at: <https://doi.org/10.7748/ns.2019.e11408>
- Cox, A.R., Wilkins, S.J. and Routledge, P.A. (2020) 'How do pharmacists contribute to global medication safety?', *International Journal of Pharmacy Practice*, 28(6), pp. 549–551. Available at: <https://doi.org/10.1111/ijpp.12676>
- Donaldson, L.J., Kelley, E.T., Dhingra-Kumar, N., Kieny, M.-P. and Sheikh, A. (2017) 'Medication without harm: WHO's third global patient safety challenge', *The Lancet*, 389(10080), pp. 1680–1681. Available at: [https://doi.org/10.1016/S0140-6736\(17\)31047-4](https://doi.org/10.1016/S0140-6736(17)31047-4)
- Elliott, R.A., Camacho, E., Jankovic, D., Sculpher, M.J. and Faria, R. (2021) 'Economic analysis of the prevalence and clinical and economic burden of medication error in England',

BMJ Quality & Safety, 30(2), pp. 96–105. Available at: <https://doi.org/10.1136/bmjqs-2019-010206>

Exworthy, M. and Greener, I. (2008) 'Decentralisation as a means to re-organise health-care in England: from theory to practice', in McKee, L., Ferlie, E. and Hyde, P. (eds.) *Organising and re-organising: power and change in health-care organisations*. Basingstoke: Palgrave Macmillan, pp. 46–58.

Goddard, M. and Mannion, R. (2006) 'Decentralising the NHS: rhetoric, reality and paradox', *Journal of Health Organization and Management*, 20(1), pp. 67–73. Available at: <https://doi.org/10.1108/14777260610656561>

Greener, I., Exworthy, M., Peckham, S. and Powell, M. (2009) 'Has Labour decentralised the NHS? Terminological obfuscation and analytical confusion', *Policy Studies*, 30(4), pp. 439–454.

Guntschnig, S., Barbosa, R., Jenzer, H., Greening, M., Hayde, J., Heery, H., Iglesias Serrano, M.C., Lajtmanová, K., Rossin, E., Tentova-Peceva, S., Kohl, S. and Mulac, A. (2025) 'Tackling medication errors: how a systems approach improves patient safety', *European Journal of Hospital Pharmacy*, pp. 1–7. Available at: <https://doi.org/10.1136/ejpharm-2025-004533>

Healthcare Safety Investigation Branch (2022) *Unintentional overdose of morphine sulfate oral solution*. Available at: <https://www.hssib.org.uk/patient-safety-investigations/unintentional-overdose-of-morphine-sulfate-oral-solution/investigation-report/>

Hodkinson, A., Tyler, N., Ashcroft, D.M., Keers, R.N., Khan, K., Phipps, D., Abuzour, A., Bower, P., Avery, A., Campbell, S. and Panagioti, M. (2020) 'Preventable medication harm across health care settings: a systematic review and meta-analysis', *BMC Medicine*, 18, 313. Available at: <https://doi.org/10.1186/s12916-020-01774-9>

Holden, R.J., Carayon, P., Gurses, A.P., Hoonakker, P., Hundt, A.S., Ozok, A.A. and Rivera-Rodriguez, A.J. (2013) 'SEIPS 2.0: a human factors framework for studying and improving the work of healthcare professionals and patients', *Ergonomics*, 56(11), pp. 1669–1686. Available at: <https://doi.org/10.1080/00140139.2013.838643>

Lievens, I. and Vlerick, P. (2014) 'Transformational leadership and safety performance among nurses: the mediating role of knowledge-related job characteristics', *Journal of Advanced Nursing*, 70(3), pp. 651–661. Available at: <https://doi.org/10.1111/jan.12229>

McFadden, K.L., Henagan, S.C. and Gowen, C.R. III (2009) 'The patient safety chain: transformational leadership's effect on patient safety culture, initiatives, and outcomes',

Journal of Operations Management, 27(5), pp. 390–404. Available at:
<https://doi.org/10.1016/j.jom.2009.01.001>

Moss, F. and Garside, P. (2001) 'Leadership and learning: building the environment for better, safer health care', *Quality in Health Care*, 10(Suppl. 2), pp. ii1–ii2. Available at:
<https://doi.org/10.1136/qhc.0100001>

Panagioti, M., Hodkinson, A., Planner, C., Dhingra, N. and Gupta, N. (2023) *Global burden of preventable medication-related harm in health care: a systematic review*. Geneva: World Health Organization. Available at: <https://iris.who.int/handle/10665/376203>

Patient Safety Learning (2022) 'New HSIB report highlights liquid morphine patient safety concerns', 28 April. Available at: <https://www.patientsafetylearning.org/blog/new-hsib-report-highlights-liquid-morphine-patient-safety-concerns>

Sakallı, D. and Canbolat, Ö. (2023) 'A threat to patient safety: medication errors, reporting of medication errors and the concerns with regard to nurses', *Journal of Gazi University Health Sciences Institute*, 5(2), pp. 93–100. Available at: <https://doi.org/10.59124/guhs.1287029>

Sheikh, A., Rudan, I., Cresswell, K., Dhingra-Kumar, N., Tan, M.L., Häkkinen, M.L. and Donaldson, L. (2019) 'Agreeing on global research priorities for medication safety: an international prioritisation exercise', *Journal of Global Health*, 9(1), 010422. Available at:
<https://doi.org/10.7189/jogh.09.010422>

"Transformational leadership: Is this still relevant to clinical leaders?" David Lo, Judy Mckimm and Alex Till, published in *British Journal of Hospital Medicine*, 79(6), 344–347.

Walls, E. (2019) 'The value of situational leadership', *Community Practitioner*, 92(2), pp. 31–33.

Wong, C.A. and Cummings, G.G. (2007) 'The relationship between nursing leadership and patient outcomes: a systematic review', *Journal of Nursing Management*, 15(5), pp. 508–521. Available at: <https://doi.org/10.1111/j.1365-2834.2007.00723.x> (Accessed: 11 August 2026).

Webster, C.S. (2022) 'Existing knowledge of medication error must be better translated into improved patient safety', *Frontiers in Medicine*, 9, 870587. Available at:
<https://doi.org/10.3389/fmed.2022.870587>

Wise, J. (2018) 'Government takes steps to reduce annual burden of medication errors in England', *BMJ*, 360, k903. Available at: <https://doi.org/10.1136/bmj.k903>

