

[HOSPITAL / HEALTH AUTHORITY NAME]

# EMERGENCY DEPARTMENT QUALITY ASSURANCE, AUDIT, SIMULATION, AND SERIOUS-INCIDENT LEARNING

Protocol 59: Quality Governance; Measurement; Clinical Audit; Quality Improvement; Case Review; Incident Response; Open Communication; Simulation; Action Tracking; and Organisational Learning

DRAFT FOR EMERGENCY MEDICINE, NURSING, HOSPITAL EXECUTIVE, QUALITY AND PATIENT SAFETY, CLINICAL GOVERNANCE, EDUCATION, RISK, PHARMACY, LABORATORY, IMAGING, BLOOD BANK, INFECTION PREVENTION, INFORMATION SERVICES, BIOMEDICAL ENGINEERING, AMBULANCE, SPECIALTY SERVICES, PATIENT REPRESENTATIVES, AND ALL SUPPORT SERVICES

**STATUS:** This is a draft clinical-governance and patient-safety document. It must be reconciled with local law, professional regulation, data-protection requirements, mandatory reporting, mortality review, complaints, open-disclosure, research / ethics, accreditation and staff-employment procedures before approval.

**CORE RULE:** Measurement is used to understand and improve care, not merely to produce reports or meet targets. Every audit, dashboard, review and simulation must lead to a clear decision: sustain reliable care, test a safer change, correct a hazard, or explain why no further action is proportionate.

**IMMEDIATE HARM OVERRIDE:** When an incident may be continuing or exposes other patients or staff to danger, first stabilize the patient, stop the unsafe process, quarantine implicated equipment / medicines when appropriate, preserve essential evidence, notify senior leadership and activate the relevant emergency protocol. Learning review must never delay urgent protective action.

**FAIR-LEARNING RULE:** Incident reporting and learning responses are not disciplinary investigations. Staff must be treated fairly, supported to speak openly and assessed in context. Deliberate harm, unlawful conduct, impairment or serious professional misconduct is referred through the appropriate separate process without contaminating the patient-safety learning review.

Document control	Details
Document owner	Emergency Department / Quality and Patient Safety Committee / Clinical Governance Directorate
Clinical and operational leads	Emergency Medicine; Nursing; Quality / Risk; Education / Simulation; Pharmacy; Laboratory; Imaging; Blood Bank; Infection Prevention; Information Services; Biomedical Engineering; Ambulance; Specialty Services; Patient / Family Representative
Applies to	All ED staff, clinicians, managers, educators, trainees, contractors and hospital services contributing to emergency care, including care delivered while patients board in the ED
Related protocols	All Emergency Department Protocols 1-58; hospital incident reporting, mortality review, complaints, disclosure, staff support, data governance, credentialing and emergency-preparedness procedures
Version / status	Draft 1.0 for multidisciplinary review and local configuration
Approval authority	_____
Effective date	_____
Review date	_____ or after a major incident, regulatory change, audit failure, material data-system change or external review
24-hour escalation contact	ED senior clinician: _____ Nurse in charge: _____ Quality / patient safety lead: _____ Executive on call: _____

## 1. Purpose

To establish a practical, auditable emergency-department quality system that continuously measures care, identifies risk, supports clinical audit and improvement, tests team and system readiness through simulation, responds proportionately and compassionately to incidents, and verifies that learning results in sustained safer practice.

## 2. Core principles

- Quality includes safety, effectiveness, timeliness, patient-centredness, equity, efficiency, workforce wellbeing and resilience. No single target or time measure represents total quality.
- Use data for learning, not concealment, punishment or gaming. Definitions, denominators, exclusions, missing data and limitations must be explicit.
- Incident reports are signals, not a complete measure of harm or staff performance. Combine them with records review, complaints, mortality, return visits, clinical outcomes, staff concerns and direct observation.

- Learning responses are selected for the insight they can generate and the improvement they can support, not automatically by the severity of outcome alone.
- Patients, families and staff affected by harm must receive timely information, compassionate support and meaningful opportunities to contribute, subject to consent and lawful confidentiality.
- Analyse how work is actually performed under real demand, staffing, equipment and environmental constraints. Do not stop at individual error when system conditions influenced the event.
- Improvement actions should make safe care easier and more reliable. Prefer redesign, standardization, forcing functions, simplification and resource correction over reminders and retraining alone.
- Simulation is both an educational method and a systems test. It must have clear objectives, psychological and physical safety, structured debriefing and closed-loop action on identified hazards.
- Actions are not complete when assigned or taught; they are complete when implemented, tested, measured and shown to reduce risk without unacceptable unintended effects.
- Quality work must be adequately resourced with protected time, analytic support, multidisciplinary participation and visible executive accountability.

### 3. Scope and definitions

Term	Working definition
Quality assurance	Organized activities that provide confidence that agreed standards, controls and governance processes are in place and functioning.
Clinical audit	Systematic review of care against explicit criteria or standards, followed by action and re-audit where improvement is required.
Quality improvement	A structured, iterative approach to improving outcomes, processes or experience using theory, measurement and testing of change.
Patient-safety incident	An unintended or unexpected event or omission in healthcare that could have or did cause harm.
Near miss / good catch	An event that did not reach the patient or did not cause harm because of chance or timely recovery action, but reveals a safety vulnerability.
Serious incident / high-harm event	A locally defined event involving death, severe harm, major system failure, public-health risk or other mandatory review / notification threshold.
Learning response	A proportionate method used to understand a safety event or pattern and identify improvement, such as an after-action review, structured case review, thematic review or full systems investigation.
Simulation	A designed activity that recreates clinical or operational conditions for learning, assessment or systems testing without exposing real patients to avoidable risk.
Latent safety threat	A hidden system weakness identified before harm, often through simulation, walk-through, audit, near miss or staff concern.
Balancing measure	A measure used to detect unintended harm or burden caused by an improvement intervention.
Just / fair culture	A culture that supports reporting and learning, considers system context and treats people consistently while maintaining appropriate accountability for deliberate or reckless conduct.

### 4. Governance and responsibilities

- Maintain a multidisciplinary ED Quality and Safety Committee with terms of reference, executive sponsorship, patient / family representation where feasible, meeting schedule, quorum, minutes, conflicts-of-interest process and authority to escalate unresolved risks.
- Appoint named medical, nursing and quality leads. Define responsibility for data validation, audit, improvement coaching, incident triage, learning responses, simulation, staff support, action tracking and reporting to hospital governance.
- Provide protected time and access to clinical records, data analysts, educators, human-factors / improvement expertise and administrative support proportionate to department volume and risk.
- Approve an annual quality plan based on local risk, national / professional standards, patient feedback, staff concerns, prior incidents, audit gaps, operational pressures and strategic priorities.
- Maintain a single controlled register of audits, QI projects, incident reviews, simulations and actions to prevent duplication, contradictory changes and loss of learning when staff rotate.
- Escalate risks that exceed ED authority or resources to hospital executive and relevant services. Cross-boundary problems such as boarding, diagnostics, blood availability, transfer delays and information-system failures require shared ownership.
- Protect confidentiality and use the minimum necessary patient and staff information. Separate identifiable learning material from wider teaching or publication unless appropriate consent and governance are in place.
- Report progress and unresolved high risks regularly to hospital leadership. Persistent failure to act on accepted safety risks must be documented and escalated.

### 5. Annual quality programme and risk-based priorities

The programme should balance routine assurance, focused audit, improvement, incident learning and readiness testing. It must remain adaptable when new hazards emerge.

Priority domain	Examples
Routine assurance	Core clinical standards; medicines and controlled drugs; infection prevention; resuscitation / airway equipment; blood safety; safeguarding; documentation; transfers; observation and discharge processes.
High-volume care	Chest pain, sepsis, respiratory illness, trauma, abdominal pain, paediatric fever, pain management, dehydration, mental-health crisis and older-person care according to local case mix.
High-risk / low-frequency care	Difficult airway, paediatric / neonatal resuscitation, obstetric collapse, massive haemorrhage, procedural sedation, malignant hyperthermia, CBRN exposure, major incident, utility failure and child abduction.
Operational safety	Triage, waiting-room deterioration, crowding, boarding, ambulance handover, delayed diagnostics, transfer, downtime, staffing, violence and infection isolation.
Equity and experience	Communication, privacy, disability access, language, financial / geographic barriers, age, sex, pregnancy, mental health, safeguarding status and other locally relevant disparities.
Learning signals	Deaths, high-harm incidents, near misses, complaints, claims, staff concerns, return visits, unplanned ICU transfer, abnormal-result follow-up and external recommendations.

- Limit the annual programme to a deliverable number of priorities while preserving rapid response to emerging hazards. A long list without ownership or capacity is not a safety plan.
- Assign each priority a named lead, aim, measures, baseline, milestones, resources, reporting route and review date.
- Close or pause projects that no longer address a meaningful problem, cannot be measured, duplicate other work or create disproportionate burden.

## 6. Minimum ED quality dataset and dashboard

Use operational, clinical, experiential, workforce and resilience measures together. Stratify where useful to identify inequity or unsafe variation. Local targets must reflect case mix, resources and approved standards.

Measure domain	Minimum content
Demand and acuity	Attendances; age; arrival mode; triage category; referral source; presenting complaint; surge / outbreak periods.
Timeliness and flow	Time to triage and first clinician; critical-treatment times; diagnostic turnaround; referral response; decision-to-admit to departure; total ED stay; boarding; ambulance handover; transfer delay; left before completion.
Clinical reliability	Condition-specific bundle completion; analgesia and reassessment; sepsis antibiotics; ECG for suspected ACS; stroke assessment / imaging; trauma observations; paediatric vital signs; medication reconciliation; discharge safety netting.
Safety outcomes	Mortality; cardiac arrest in ED; unexpected ICU / theatre transfer; deterioration in waiting or boarding; falls; pressure injury; medication / transfusion events; device incidents; infection exposure; failed airway; sedation rescue; safeguarding failure.
Reattendance and follow-up	Unplanned return within locally defined intervals; return with admission / ICU / death; critical-result callbacks; missed appointments; delayed specialist transfer.
Experience and equity	Complaints, compliments and surveys; communication; privacy; pain relief; interpreter / disability support; delays; outcomes stratified by locally relevant demographic, geographic and access factors.
Workforce and culture	Planned versus actual staffing; skill mix; sickness; overtime / fatigue; violence and injury; training compliance; psychological-safety or safety-culture feedback; staff turnover.
Resilience	Crowding escalation hours; downtime; oxygen / power / equipment failure; major incidents; isolation capacity; stock-outs; exercises completed and action closure.

## 7. Data quality, analysis and interpretation

- Define every measure in a data dictionary: purpose, numerator, denominator, inclusions, exclusions, source, owner, collection frequency, validation method and reporting audience.
- Validate automated extracts against source records after system changes and periodically thereafter. Record missing, duplicate, delayed and implausible values.
- Use rates and denominators rather than raw counts where exposure differs. For rare events, present absolute numbers and context and avoid misleading percentage changes.

- Use run charts or statistical process-control methods for repeated measures where expertise is available. Distinguish common-cause variation from a meaningful signal before changing systems.
- Annotate changes in staffing, workflow, coding, diagnostics, outbreaks or policy that affect interpretation. Do not present a data-definition change as clinical improvement.
- Combine quantitative data with case review, patient stories and staff observations. A target met through workarounds, hidden delay, selection or documentation pressure is not improvement.
- Limit public or executive dashboards to measures that are valid, actionable and interpreted. Protect small groups from re-identification and avoid simplistic league tables.
- Review for unintended incentives and gaming. Staff must be able to report data-quality concerns without retaliation.

## 8. Clinical audit cycle

1. Select a topic with a recognized risk or quality gap and identify the authoritative standard or locally approved criterion.
2. Define the patient population, criteria, exclusions, sample method, period, data source, responsibilities and required governance approval before collection.
3. Collect the minimum data needed. Use consecutive or otherwise defensible sampling and record missing records or variables.
4. Analyse compliance by criterion and relevant subgroup; examine causes of variation rather than reporting an overall percentage alone.
5. Present findings promptly to the staff and services able to change the process. Include patient impact, limitations and priority gaps.
6. Agree specific improvement actions with owners, deadlines, resources, measures and balancing measures. Avoid relying only on email reminders or education.
7. Re-audit after sufficient implementation time. If standards remain unmet, revise the change strategy or escalate barriers rather than repeatedly collecting the same data.

Audit is not research and QI is not audit, although they may overlap. Projects intended to generate generalizable knowledge, randomize care, introduce unapproved interventions or exceed routine governance require ethics / research review according to local policy.

## 9. Quality-improvement method and change control

- Use a short project charter containing the problem, evidence, patient group, SMART aim, scope, team, change theory, baseline, measures, risks and executive / service dependencies.
- Understand the current process before designing change. Map work as done across shifts and include patients, nurses, clinicians, clerical staff, diagnostics, pharmacy, porters, ambulance and inpatient teams as relevant.
- Test changes on a small scale using iterative cycles, with clear prediction and review. Expand only after confirming safety, feasibility and benefit.
- Use outcome, process and balancing measures. Examples of balancing measures include workload, delay elsewhere, medication errors, cost, equity, staff fatigue and unintended reattendance.
- Apply formal change control to high-risk modifications involving clinical thresholds, medication, equipment, IT, staffing, physical layout or inter-facility pathways. Update protocols, forms, training and stock together.
- Plan sustainment from the start: embed reliable changes into standard work, orientation, electronic systems, procurement, maintenance and routine audit.
- Stop or reverse a test promptly if harm, inequity, unacceptable burden or loss of essential capacity appears.

## 10. Case identification and multidisciplinary review

The following are minimum triggers for screening or review. Local thresholds determine which require immediate notification, formal investigation, thematic review or routine learning discussion.

Trigger domain	Examples
Clinical outcome	Death in ED or soon after transfer / discharge; unexpected cardiac arrest; unplanned ICU / theatre transfer; severe deterioration while waiting or boarding; delayed recognition of sepsis, stroke, haemorrhage or other time-critical illness.
Procedural / treatment	Failed or difficult airway; unplanned extubation; sedation rescue; wrong medication / dose / route; transfusion reaction; procedural complication; equipment or oxygen failure; missed critical result.
Transition / access	Return with admission, ICU or death; unsafe discharge; significant transfer delay; refusal / departure associated with harm; failure of referral, handover, follow-up or safeguarding.
Special populations	Maternal, neonatal or paediatric severe harm; self-harm after ED contact; abuse / assault response failure; harm involving disability, communication or other inequity.
Operational	Crowding-related harm; ambulance delay; infection exposure / outbreak; security event; downtime; major incident; staff injury; repeated near misses indicating system fragility.
Experience / concern	Serious complaint, staff speaking-up concern, claim, coroner / regulator request, media concern or pattern of patient / family reports suggesting avoidable harm.

- Morbidity and mortality or case-review meetings must be multidisciplinary, psychologically safe, confidential, chaired effectively and focused on system learning and action rather than humiliation or retrospective certainty.
- Use a standardized case summary, timeline, key decisions, contributory conditions, what went well, recovery actions, patient / family perspective and proposed improvements.
- Do not present identifiable cases for entertainment, informal teaching or public discussion. Limit access to those with a legitimate learning or governance role.
- Track decisions and actions after the meeting. Repeated discussion without implementation is not a learning system.

## 11. Incident reporting and immediate response

1. Provide immediate clinical care, call for help and activate relevant protocols. Protect other patients and staff from continuing exposure.
2. Notify the ED senior clinician, nurse in charge and required quality / executive contacts according to severity and ongoing risk.
3. Preserve evidence without obstructing care: secure involved equipment, packaging, medicines, blood products, specimens, logs, images and records as appropriate. Do not delete data or overwrite device settings needed for analysis.
4. Document contemporaneous clinical facts and care. Never alter the original record; clearly identify any later entry, correction or addendum.
5. Explain to the patient / family what is known, what immediate care is being provided and who will update them. Avoid speculation, blame or premature conclusions.
6. Support staff directly involved, arrange relief when needed and assess injury, exposure, fatigue or impairment. Preserve confidentiality and avoid corridor discussion or social-media communication.
7. Submit an incident report as soon as safe, including near misses and good catches. Reporting does not replace urgent verbal escalation.
8. Make mandatory notifications to blood bank, infection prevention, public health, device / medicine authorities, police, coroner, insurer or regulators when local thresholds are met.
9. Assign a named incident-response lead, next communication time, review method and immediate safety actions before the initial response closes.

## 12. Selecting and conducting a proportionate learning response

Choose the method according to recurrence, system risk, uncertainty, learning potential, patient / family needs and resource proportionality. A severe outcome does not automatically require the longest investigation, and a near miss may justify deep review when it exposes major latent risk.

Response type	Best use
Hot debrief / after-action review	Immediate or same-shift reflection after a resuscitation, exercise, disruption or near miss. Capture what was expected, what occurred, what helped, immediate hazards and urgent actions.
Structured case review	Focused multidisciplinary review of one event using record, timeline and contributory factors. Appropriate when the main learning questions are bounded.
Thematic review	Analysis of multiple events, complaints or records to identify patterns that are not visible from single cases.
Clinical audit	Assessment against explicit standards when the key question is whether reliable care is being delivered across a defined population.
Patient-safety incident investigation	Comprehensive systems-based inquiry for complex, uncertain or high-priority events where deep learning is likely to support significant improvement.
Simulation / process test	Recreation of a pathway, emergency or proposed change to expose workflow and system vulnerabilities without patient risk.
Referral to another process	Separate referral for professional conduct, criminal concern, occupational health, grievance, research integrity, fraud or other matters outside the learning response.

- Construct a reliable timeline from records, interviews, equipment / IT logs and environmental information. Recognize hindsight bias and uncertainty.
- Engage staff as witnesses to how the system functions, not as suspects. Use open questions and explain confidentiality and limits.
- Examine task design, workload, staffing, supervision, communication, decision support, equipment, medicines, environment, interfaces, policies, organizational priorities and external constraints.
- Distinguish contributing factors, necessary conditions and unsupported assumptions. Avoid declaring a single root cause when the event arose from interacting conditions.
- Describe strengths and successful recovery as well as failures; reinforce protective practices that prevented worse harm.
- Produce a concise report with evidence, limitations, findings, improvement priorities, responsible governance route and communication plan.



## 13. Patients, families, open communication and complaints

- Identify a named liaison and make early, compassionate contact after significant harm. Ask about communication needs, language, disability, cultural / spiritual support and preferred participants.
- Explain known facts, uncertainty, immediate treatment, the planned learning response and how the patient / family can contribute. Provide updates at agreed intervals even when there is no final conclusion.
- Offer a sincere apology or expression of regret according to local open-disclosure policy. Apology is compatible with honest investigation and should not be delayed by fear of blame.
- Record questions and concerns and address them in the response scope where relevant. Explain which questions cannot be answered and why.
- Coordinate complaints, claims and incident-learning processes so the patient does not have to repeatedly retell the experience and receives consistent information.
- Provide the final explanation and learning in accessible language, subject to confidentiality and legal limits. State what will change, who is accountable and how completion will be verified.
- Invite patient / family participation in improvement design when appropriate and voluntary; do not treat lived experience as symbolic consultation.

## 14. Supporting staff and fair accountability

- Offer immediate practical and emotional support, confidential follow-up, occupational-health / psychological support, peer support and safe return-to-work planning when needed.
- Do not require an affected staff member to continue high-risk duties when distress, fatigue, injury or impairment may compromise care.
- Leaders must prevent gossip, public naming, retaliatory rostering, premature conclusions and parallel informal investigations.
- Assess concerns about individual conduct only when they arise, using a fair and consistent process that considers substitution, foresight, system conditions, deliberate harm, health and mitigating circumstances.
- Human error or adaptation in a poorly designed system should lead primarily to system improvement and coaching. Deliberate harm, intentional unsafe practice or serious reckless disregard requires separate accountable management.
- Protect staff who report hazards or near misses in good faith. Malicious reporting is managed separately and must not be presumed because concerns are uncomfortable.

## 15. Simulation-based education and systems testing

### 15.1 Programme governance

- Maintain a risk-based simulation programme linked to the annual quality plan, incident learning, new equipment, protocol change, staff induction and low-frequency high-risk emergencies.
- Each activity requires a named lead, learning or testing objectives, target participants, scenario design, faculty, equipment, location, safety plan, debrief method, evaluation and action pathway.
- Use trained facilitators and debriefers. Faculty must understand adult learning, psychological safety, human factors, confidentiality, bias and management of participant distress.
- Participation, assessment status, recording and use of performance data must be explained in advance. Do not disguise high-stakes assessment as formative learning.
- Simulation records must not contain real patient identifiers. Audio / video recording requires explicit governance, consent, secure storage, restricted access and deletion schedule.

### 15.2 In-situ safety

- Patient care takes priority. Obtain local operational approval, appoint a safety observer, preserve real emergency capacity and define an immediate stop word / signal.
- Clearly label simulation medicines, fluids, blood products, specimens and equipment. Prevent any item used for simulation from entering real clinical care unless checked, restored and released under approved procedure.
- Do not obstruct exits, oxygen, resuscitation equipment, infection-control zones or staff access. Inform switchboard, security, laboratory, imaging, blood bank and other services when their response may be triggered.
- Use standardized patients or manikins safely and protect privacy. Avoid unannounced scenarios likely to cause distress or be mistaken for a real emergency.
- After the scenario, reconcile all equipment, medicines, documentation and electronic test records and confirm the clinical area is fully restored.

### 15.3 Prebrief, debrief and follow-through

- Prebrief the fiction contract, objectives, roles, confidentiality, expected respect, physical limitations, emergency stop and whether the activity is formative or assessed.
- Debrief promptly using a structured, non-humiliating method. Explore shared mental model, leadership, communication, workload, decisions, technical performance, equipment and system conditions.
- Separate educational feedback from latent safety threats requiring formal action. Enter system hazards into the quality register with an owner and deadline.
- Evaluate more than participant satisfaction. Where feasible measure behaviour, clinical-process reliability, response time, system readiness, retained skill and closure of identified hazards.

## 16. Minimum exercise and competency programme

Frequency / trigger	Minimum activity
Every shift / routine	Briefing, huddle, safety check, equipment readiness and opportunistic micro-drills without disrupting care.
Monthly or locally defined	Focused skills / team drill for high-risk procedures or recent learning: airway, paediatric resuscitation, sepsis, sedation, haemorrhage, transfer or other priority.
Quarterly	Multidisciplinary in-situ scenario testing at least one cross-service pathway and one operational hazard over the year.
At least annually	Mass-casualty / disaster, power / oxygen / IT downtime, fire / evacuation or lockdown, child / vulnerable-person safeguarding event and other locally mandated emergency exercises.
After change or incident	Targeted test before or soon after introducing a new protocol, device, layout, IT workflow or high-risk corrective action.
Individual competence	Role-specific competency assessment using transparent criteria, valid tools and remediation pathways. Attendance alone does not prove competence.

## 17. Actions, hierarchy of controls and closure verification

Recommendations should be specific enough to implement and strong enough to reduce risk. The committee should favour higher-reliability controls when feasible.

Control level	Examples / closure requirement
Stronger controls	Eliminate unnecessary step or hazard; redesign pathway / environment; automate safely; forcing function; standardized equipment; physical separation; resilient staffing or capacity; engineered alert with clear response.
Intermediate controls	Simplify and standardize work; checklist; protocol / order set; defined handover; better labelling; restricted access; decision support; maintenance / stock control; supervision.
Weaker controls	Memo, poster, reminder, policy rewrite, one-off education or telling staff to be more careful. These may support but rarely sustain change alone.
Closure evidence	Implementation confirmed; staff and patients informed as required; training / documents / IT updated; test or simulation passed; process and outcome measures reviewed; balancing harms absent or managed; residual risk accepted by authorized governance.

- Every action must have a named accountable owner, due date, required resources, measure, verification method and escalation route.
- Action status must distinguish planned, in progress, implemented, tested, effective, ineffective, overdue and formally closed.
- Overdue or ineffective actions are reviewed at each governance meeting and escalated when residual risk remains high.
- Share learning in usable formats: briefings, updated protocols, electronic decision support, orientation, simulation and cross-department communication. Distribution of a report alone does not demonstrate learning.

## 18. External reporting, benchmarking and publication

- Meet all local and national requirements for reporting deaths, communicable disease, blood / medicine / device events, occupational injury, child protection, professional concerns and other mandated events.
- Benchmark only against comparable definitions and populations. Explain case mix, access constraints, small numbers and data-quality differences.
- Participate in recognized professional clinical standards, audits and quality-improvement programmes where feasible and relevant.
- Remove patient and staff identifiers from teaching, conference or publication material unless explicit approval and consent requirements are met.
- Projects intended for external publication require authorship, ethics / governance, data-protection and conflict-of-interest review. Quality activity does not automatically permit publication of identifiable information.

## 19. Review cadence and communication

Cadence	Minimum review
Each shift	Safety huddle; equipment / staffing / crowding risks; incidents and unresolved critical results; immediate mitigations.

Cadence	Minimum review
Daily	Review deaths, high-harm events, unplanned ICU / theatre transfer, critical delays, abnormal-result follow-up, major complaints and ongoing operational hazards.
Weekly	Selected trigger cases, incident triage, action status, return visits, staffing / crowding signals and preparation for audit / simulation.
Monthly	Multidisciplinary quality committee; dashboard with interpretation; audit / QI progress; M&M / case review; patient experience; staff safety; action escalation.
Quarterly	Executive report; trends and inequalities; external standards; risk-register review; simulation programme; cross-service barriers.
Annually	Quality report and programme evaluation; priorities for next year; staff / patient input; competency and exercise plan; protocol and data-dictionary review.

## 20. Quality indicators for this protocol

Indicator domain	Suggested measure
Governance	Quality committee meets as scheduled; annual plan approved; patient / family and multidisciplinary participation documented; high risks escalated.
Reporting culture	Incident and near-miss reporting volume / mix interpreted with safety-culture data; time from event to report and senior triage; staff reporting retaliation concerns.
Learning response	Proportion receiving appropriate response; time to initial contact with patient / family and staff; completion within agreed timeframe; report quality.
Action reliability	Percentage of actions overdue; percentage implemented and independently verified; recurrence of similar events; strength of controls used.
Audit and QI	Projects with explicit standard / aim, baseline, measures, patient input, completed action cycle and re-audit / sustainment review.
Simulation	Programme delivered; multidisciplinary participation; latent threats identified; actions closed; high-risk systems tested before implementation.
Data quality	Measures with current definitions; validated extracts; missing data rate; correction of known defects; transparent limitations.
Experience and equity	Communication after harm, complaints response, accessibility and disparities monitored with action where variation is unjustified.
Staff support	Timely support after serious events; occupational-health access; fair-process concerns; return-to-work and wellbeing follow-up where indicated.

## 21. Local configuration and approval requirements

- Confirm definitions and notification thresholds for serious incidents, deaths, near misses, complaints, professional concerns and mandatory external reporting.
- Approve the ED quality dashboard, data dictionary, case-review triggers, audit calendar, incident-response plan, learning-response methods, disclosure pathway and action-escalation rules.
- Identify 24-hour quality / risk and executive contacts and who may quarantine equipment, secure records, notify regulators and commission a formal review.
- Confirm data access, retention, privacy, patient / family participation, staff interview confidentiality and legal privilege arrangements where applicable.
- Approve simulation spaces, faculty requirements, medication / equipment labelling, recording rules, emergency-stop process and competency-assessment governance.
- Exercise the serious-incident first-response process and at least one high-risk in-situ simulation before final approval.

## 22. Key reference framework

Source	Application in this protocol
World Health Organization. Global Patient Safety Action Plan 2021-2030; Global Patient Safety Report 2024.	Strategic framework for eliminating avoidable harm, safety culture, learning systems, patient engagement, workforce safety and measurement.
World Health Organization. Patient Safety Incident Reporting and Learning Systems: Technical Report and Guidance, 2020.	Purpose, limitations and design of incident reporting and learning systems; reporting data must be interpreted cautiously and converted into action.
NHS England. Patient Safety Incident Response Framework and Patient Safety Incident Response Standards, current editions including 2026 standards.	Proportionate systems-based responses, governance, engagement of patients / families / staff, competence and improvement-focused action.



Source	Application in this protocol
NHS England. Being Fair Tool, 2025; Improving Patient Safety Culture: A Practical Guide.	Fair treatment after incidents, separation of learning from conduct processes, psychological safety, teamwork, communication and inclusion.
Agency for Healthcare Research and Quality. CANDOR Toolkit.	Timely, compassionate and just response to unexpected harm; communication, investigation, staff / patient support and organizational learning.
Agency for Healthcare Research and Quality. TeamSTEPPS 3.0.	Team structure, communication, leadership, situation monitoring, mutual support, briefing and debriefing tools.
Royal College of Emergency Medicine. Quality Improvement, Assurance and Audit in the Emergency Department, 2025; RCEM Clinical Standards and QI Guide.	ED-specific governance, assurance, audit cycle, improvement methods, standards and interpretation of quality data.
ASPE, Society for Simulation in Healthcare and INACSL. Joint Position Statement on Simulation-Based Education in Healthcare, 2025; Healthcare Simulation Standards of Best Practice.	Evidence-based simulation design, prebriefing, facilitation, debriefing, professional integrity, psychological safety and programme quality.
Related local guidance	Hospital incident reporting, mortality review, open disclosure, complaints, staff support, data protection, professional conduct, research / ethics, credentialing and emergency-preparedness policies.

Evidence and legal disclaimer: International guidance provides a safety framework but does not determine local legal authority. Before approval, the hospital must validate Saint Kitts and Nevis requirements concerning disclosure, death and coroner notification, data protection, professional regulation, employment processes, mandatory reporting, research / publication and external regulator notification.

## Annex A. Core emergency-department dashboard template

Domain	Measures	Frequency
Demand / acuity	Attendances; paediatric / adult; triage category; ambulance; outbreak / surge; admission rate.	Daily / monthly
Flow	Triage and clinician time; critical treatment times; ED length of stay; boarding; handover; transfer; left before completion.	Daily / monthly
Clinical quality	Selected bundle reliability; analgesia; sepsis; chest pain; stroke; trauma; paediatrics; frailty; discharge safety netting.	Monthly / quarterly
Safety	Deaths; cardiac arrest; deterioration; returns with admission / ICU / death; medication, transfusion, airway, sedation, falls, pressure, infection and safeguarding events.	Monthly / rolling trend
Experience / equity	Complaints, surveys, communication, privacy, disability / language access and locally relevant stratified outcomes.	Monthly / quarterly
Workforce	Actual versus required staffing; skill mix; sickness; overtime; violence; injury; training and fatigue signals.	Daily / monthly
Resilience	Crowding escalation; downtime; stock-outs; oxygen / equipment incidents; exercises and action closure.	Monthly / after event

Interpretation box: What changed? Is it real or a data artefact? Who is affected? What is the likely mechanism? What action is needed now? What will be reviewed next and by whom?

## Annex B. Audit / QI project charter

Field	Entry
Problem and patient impact	_____
Standard / evidence or change theory	_____
Population and scope	_____
SMART aim	_____
Team and accountable lead	_____
Baseline and data source	_____
Outcome measure	_____
Process measure(s)	_____
Balancing measure(s)	_____
Proposed changes / tests	_____
Dependencies and resources	_____
Risks / equity considerations	_____
Review and re-audit dates	_____
Governance approval	_____

## Annex C. Serious incident: first 24-hour action card

1. Stabilize the patient and protect others; stop or isolate the unsafe process.
2. Notify ED senior clinician, nurse in charge, quality / patient safety and executive contacts.
3. Preserve records, equipment, medicines, specimens and electronic / device logs; do not alter the original record.
4. Make required specialist and external notifications: blood bank, infection prevention, public health, police, coroner, regulator or others.
5. Identify and support the patient / family; appoint liaison; explain known facts and next update time.
6. Identify and support affected staff; arrange relief, injury / exposure care and confidential follow-up.
7. Create an initial factual chronology and list immediate safety actions and unresolved risks.
8. Select interim controls and confirm who has authority to restore any quarantined system.
9. Choose and commission the proportionate learning response; define scope, lead, participants and timeframe.
10. Plan communication, confidentiality, records access and action tracking before handover to the next operational period.

## Annex D. Learning-response selection prompt

Question	Response
Is danger continuing?	Yes: immediate mitigation / incident command first. No: proceed to learning selection.
Is there a pattern?	Multiple similar events may require thematic review or audit rather than isolated case investigations.
Is the key question standard compliance?	Use clinical audit with action and re-audit.
Is the process unclear or proposed change untested?	Use process mapping, walk-through or simulation.
Is the event complex, uncertain or high priority with potential for significant system learning?	Commission a systems-based patient-safety incident investigation.
Are concerns primarily about professional conduct, crime, impairment or employment?	Refer separately while preserving relevant patient-safety learning.
What will the response change?	Do not commission a burdensome response without a clear learning question, audience and improvement route.

## Annex E. Simulation planning and debrief record

Field	Record
Scenario / risk addressed	_____
Objectives	_____
Participants / services	_____
Location / date / faculty	_____
Safety plan / stop signal	_____
Prebrief completed	Yes / No   Confidentiality, fiction contract, roles, assessment status, emergency stop
What went well	_____
Clinical / teamwork learning	_____
Latent safety threats	_____
Immediate mitigation	_____
Action owner / due date	_____
Verification / repeat test	_____

## Annex F. Safety-action tracker and closure test

Field	Entry
Action ID / source	_____ / incident, audit, complaint, simulation, staff concern, other
Risk and desired outcome	_____ _____
Action and control strength	_____ _____
Accountable owner / support	_____ _____
Resources / dependencies	_____ _____
Due date / status	_____ _____
Implementation evidence	_____ _____
Effectiveness measure	_____ _____
Balancing harm / equity check	_____ _____
Independent verification	_____ _____
Residual risk and acceptance	_____ _____
Closure authority / date	_____ _____

## Annex G. Local configuration and approval checklist

Configuration domain	Required local entry / confirmation
Governance	Committee, executive sponsor, terms of reference, patient / family representation, quality plan, meeting and reporting cadence.
Incident system	Reporting platform / form, 24-hour escalation, serious-event thresholds, mandatory notifications, record and evidence preservation.
Learning methods	Approved review tools, competent reviewers, patient / family and staff engagement, report template, timeframes and confidentiality.
Disclosure / support	Open-communication policy, liaison, apology guidance, complaints coordination, staff peer / occupational-health support.
Data	Dashboard, data dictionary, analyst support, validation, privacy, equity stratification, retention and publication rules.
Audit / QI	Project register, approval process, coaching, re-audit, change control, measurement and sustainment review.
Simulation	Programme lead, faculty competence, equipment / medication safety, in-situ approval, recording, emergency stop and action tracking.
Approval record	ED clinical lead: _____ Nursing lead: _____ Quality / risk: _____ Education / simulation: _____ Data protection / legal: _____ Patient representative: _____ Executive: _____

**FINAL APPROVAL REQUIREMENT:** This protocol must not be implemented until the hospital has approved the incident-escalation and open-communication pathways, validated the ED quality dataset and data definitions, assigned competent learning-response and simulation leads, established a live action tracker, and exercised the first-24-hours serious-incident response with participation from clinical, nursing, quality, executive and support services.