Supplementary File

Empirical studies of incident investigation: a brief narrative review

Background

To inform the development of the present paper and the development of the new London Protocol 2024 (Supplementary File 1), we conducted a narrative review of studies of the methods and process of incident analysis. Our search aimed to identify papers which either (i) described experience of incident analysis and subsequent learning and (ii) provided some comment, assessment or evaluation of the incident analysis method used.

Method

We conducted a focussed search of the literature to assess and summarise the research on incident investigation. We followed the following steps in line with Arksey and O'Malley and Levac et al. [1-2]: (1) identifying the research question; (2) identifying the relevant literature; (3) study selection; (4) charting the data; (5) collating, summarising and reporting the results.

We aimed to understanding the following:

(1) What are people's experiences using the London Protocol or other similar incident investigation methods?
(2) What learning has been reported from the use of the London Protocol or other similar incident investigation methods?
(3) What have we learned about the validity of the London Protocol or other similar incident investigation methods through their use?

Identifying relevant studies

We conducted a search of online databases using MEDLINE, Embase, CINHAL and PsychInfo. We combined keyword terms and phrases related to incident investigations, which were based on a search string of keywords and phrases for incidents, most commonly used investigation methods and healthcare settings. The search terms were developed and refined in discussion amongst the London Protocol 2024 development group and adapted slightly depending on the database being searched. The search was complemented by a hand search of relevant papers. The search terms were as follows:

((incident OR "adverse event" OR error or harm)

AND ("London Protocol" OR "root cause analysis" OR "protocol for the investigation and analysis of clinical incidents" OR "Alarm protocol" OR "learning review" OR "concise incident analysis tool" OR "critical incident technique" OR "AcciMap" OR "Yorkshire Contributory Factors Framework" OR "Health record review" OR "Patient safety incident response framework")

AND ("healthcare" OR "health care" OR "care home" OR "mental health" OR "primary care" OR "hospital"))

Study selection

The following inclusion and exclusion criteria were applied to identify studies for inclusion in the review.

Inclusion criteria

Research articles were empirical studies which had been set in any healthcare or community health setting. Their core focus was clearly relevant to the process of incident analysis and contributed to one or more of the research questions. Their study design used an incident analysis method to investigate an incident or group of similar incidents shortly after they had occurred (rather than identify system problems years after the event). Incidents were investigated individually even if findings were aggregated later. The incident analysis had access to patient records and interviews/focus groups/statements from staff or patients and families. The full text was accessible and available in the English language.

Exclusion criteria

Protocols, reports or abstracts only, commentaries, opinion pieces, letters to editors, conference proceedings reviews or editorials were excluded from the analysis. Articles where the core focus was to identify the occurrence of certain types of incidents, rather than incident analysis, were excluded. Prospective or retrospective study designs that used large data taken from incident report databases over long timeframes were excluded, as were reviews of incident analyses rather than the incident analysis itself, which did not make comment on the method used.

Review procedure

We included papers published anytime from 1990 to 11th January 2024 (the search date). Reference details (including abstracts) were downloaded into the reference software Endnote (v.21) and duplicates were removed. The references were then exported to Rayyan for title and abstract screening. In the first screening stage, the references were screened and assigned to 'included, excluded or uncertain'. In the second stage of screening, the full-text articles were retrieved, and screened against the study inclusion criteria. Any articles classed as 'uncertain' by the first screener (DI) were resolved through discussion with a second reviewer (CV). We have documented the reasons for the inclusion and exclusion of studies in a PRISMA flow diagram (see below). The last stage consisted of examining the reference lists of relevant papers for check for any final papers to include.

Data synthesis

We extracted the following data items for each study as a minimum: title, authors, year of publication, country of study, study aims, type of health setting (e.g. emergency medicine, care home), incident type, and incident investigation method used. We then reviewed each study in greater depth and extracted information relevant to the research questions (i.e. experience, learnings, and critiques using the incident investigation method), presented in the tables below.

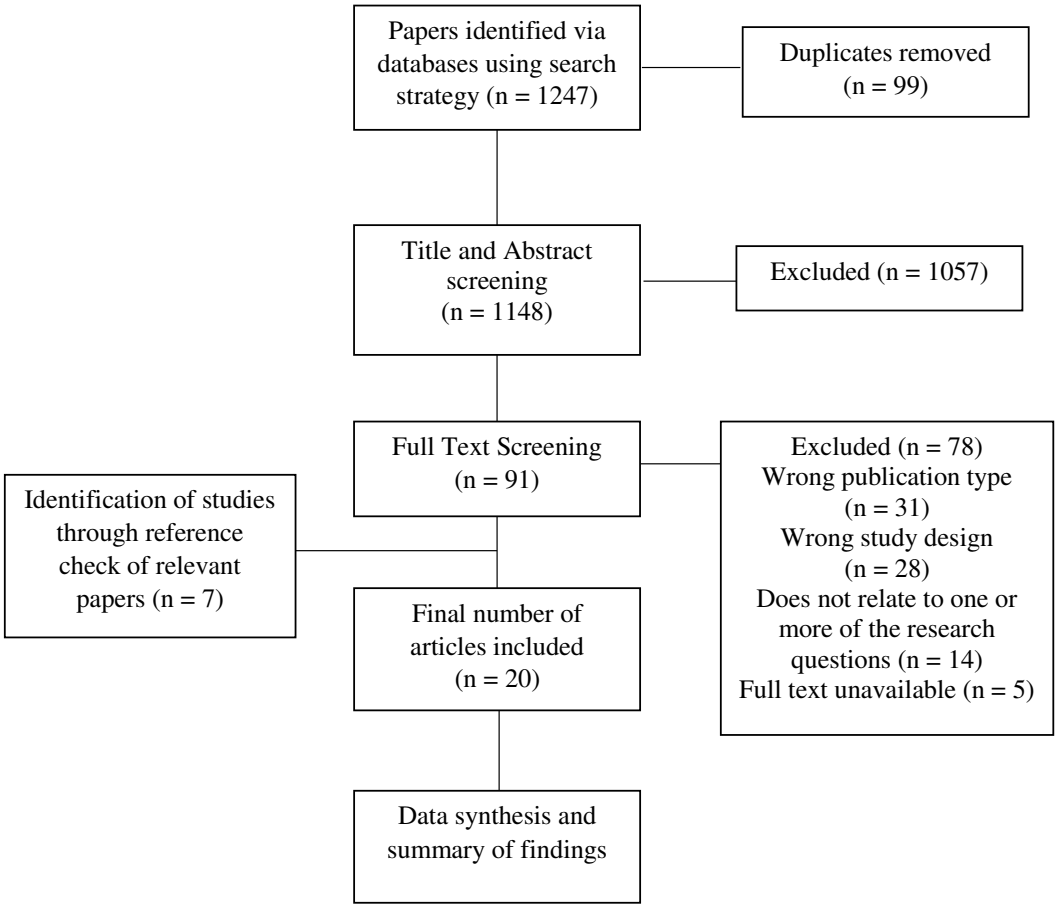

Figure 1. PRISMA flow diagram

Findings

The search identified 20 studies which met our inclusion criteria (Table 1). Studies were carried in the United Kingdom (n = 6), United States (*n* = 5), Brazil (n = 2) and single studies from Australia, India, Iran, Malta, Saudia Arabia, Switzerland and Uganda. Some studies described using more than one incident investigation method. The most commonly used method for incident investigation was 'root cause analysis' (n = 12), followed by the London Protocol (n = 5), then equal use of the Critical Incident Technique, AcciMap and Human Factors Analysis and Classification System (HFACS) (n = 2 each), one study included Work Domain Analysis and another incorporated Systems Theoretic Accident Modelling and Processes (STAMP) analysis. The term 'root cause analysis' appeared to be employed very widely as a catch-all term, with some studies examining a wide variety of contributory factors with no apparent search for root causes. The studies fell into two broad groups: (i) those reporting the investigation of an incident, which generally gave little attention to the method itself (Table 2); and (ii) studies which sought to develop, validate or compare methods for incident investigation through the analysis of an incident (Table 3).

Studies that describe and investigate an incident

The majority of studies focused on describing an incident analysis following an incident (*n* = 15; Table 2) [4-6, 8-13, 15-18, 20-21]. Across methods and tools, most of these incident investigations involved a multidisciplinary investigation team which had a range of experience in patient safety and/or clinical care who would meet to discuss the incident. The majority of studies included here were concerned with drug-related incidents (*n* = 10) and conducted in hospital settings (*n* = 14). Data sources were often unclear, but most commonly used were patient records and interviews with staff. Nearly all mapped the chronology of the incident in some way, but fishbone diagrams and flow-charts were also often used. Only two studies interviewed patients as part of the investigation process and only three studies mentioned disclosure or apology to the patient and family concerning the incident.

Across studies, there were many recommendations for change but almost no prioritisation or weighting of importance for these recommendations, and the collaboration with clinical teams in developing recommendations was variable. Most often, results from investigations were shared internally within organisations and about half of the studies reported results from implementation of actions based on recommendations and subsequent monitoring or follow-up.

Studies which assess or compare methods

We identified five studies of the process of analysis itself [3,7,14,19,22] (Table 3). These studies applied one or more methods to the analysis of an incident to examine the usability, strengths and limitations of the approaches considered. Four studies employed one or more methods, with one (Berlin et al. [3]) using only the critical incident technique. No studies used an experimental format or made direct comparisons between methods. Comparisons were drawn between approaches from the experience of participants in the process and the reflections of the authors of the studies. Root cause approaches were considered to be simple and accessible but often not clearly defined and lacking an appreciation of wider system influences. The critical incident technique did not specify a formal approach to analysis but was appreciated as a useful team reflection exercise suitable for rapid review of incidents. STAMP, AcciMap and HFACS and the London Protocol gave much more weight to system influences and the interactions between factors, but required significant expertise and understanding of human factors for effective application [14, 19-20, 22]. Lim et al. [7] compared the London Protocol with Work Domain Analysis, finding that the London Protocol was easier to use and that it could be widely applied because of the generic framework of contributory factors. They commented however that other contributory factors might also be relevant.

Table 1. Included study characteristics

Title	Authors	Year	Country	Study Aims/Research Questions	Setting	Incident/ Adverse Event	Incident analysis method/tool
Audit of deaths in general practice: pilot study of the critical incident technique [3]	Anita Berlin, John A Spencer, Raj S Bhopal, Timothy D van Zwanenberg	1992	UK	Evaluate the applicability and acceptability of auditing the care of patients who had recently died using the critical incident technique. Identify episodes in the patient's care that had been "critical"- that is, either beneficial or detrimental to the patient or carers with a view to improving and maintaining the quality of care. Assess the feasibility of creating a classification of the factors influencing patient care from the data collected.	Primary Care (General Practice)	Premature death	Critical Incident Technique
Developing a systematic method of analysing serious incidents in mental health [4]	Charles Vincent, Nicola Stanhope, Sally Taylor-Adams	2000	UK	To describe a structured and systematic method of investigating adverse incidents on an acute psychiatric ward.	Acute psychiatric ward	Self-harm	Early ALARM/CRU Protocol
Using system analysis to build a safety culture: improving the reliability of epidural analgesia [5]	P. Garnerin, A Huchet-Belouard, M Diby and F Clergue	2006	Switzerland	To describe the investigation of a potentially dangerous situation revealed by the report of an apparently minor incident.	Tertiary hospital	Drug-related adverse events	London Protocol
New Technology, New Errors: How to Prime an Upgrade of	Ann Rule, Andjela Drincic & Kimberly Galt	2007	US	To describe an incident when switching an ambulatory care clinic patient from an older	Ambulatory care clinic	Drug-related adverse event	Root cause analysis

Title	Authors	Year	Country	Study Aims/Research Questions	Setting	Incident/ Adverse Event	Incident analysis method/tool
an Insulin Infusion Pump [6]				model to a newer model of an ambulatory continuous sub cutaneous insulin infusion pump, and subsequent root cause analysis.			
Analysing Care Home Medication Errors: A Comparison of The London Protocol and Work Domain Analysis [7]	Rosemary Lim, Janet Anderson & Peter Buckle	2008	UK	To compare the relative strengths and weaknesses of two methods used to analyse medication errors: The London Protocol and Work Domain Analysis. These were used to analyse a sample of medication errors identified in UK care homes. The contributions of each method were examined and comparisons were made.	Care Home	Drug-related adverse event	London Protocol and Work Domain Analysis
Root cause analysis of transfusion error: identifying causes to implement changes [8]	Priti Elhence, S. Veema, Raj Kuma Sharma & RK Chaudhary	2010	India	To report an event of transfusion error and subsequent root cause analysis.	Hospital	Transfusion error	Root cause analysis
Shaping Systems for Better Behavioral Choices: Lessons Learned from a Fatal Medication Error [9]	Judy Smetzer, Frank Byrne, Michael Cohen	2010	US	To present a summary of the root cause analysis and the president of the hospital's comments on the lessons learned from an adverse event.	Community teaching hospital	Drug-related adverse event	Root cause analysis
Root-Cause Analysis of a Potentially Sentinel Transfusion Event: Lessons for Improvement of	Hossein Adibi, Nader Khalesi, Hamid Ravaghi, Mahdi Jafari, and Ali Reza Jeddian	2012	Iran	To specify system vulnerabilities and illustrate the potential of such an approach, the root cause analysis of a case of	hospital	Wrong patient – blood transfusion error	London Protocol

Title	Authors	Year	Country	Study Aims/Research Questions	Setting	Incident/ Adverse Event	Incident analysis method/tool
Patient Safety [10]				transfusion error in an emergency ward that could have been fatal is described.			
Automated electronic reminders to prevent miscommunication among primary medical, surgical and anaesthesia providers: a root cause analysis [11]	Robert E Freundlich, Louise Grondin, Kevin K Tremper, Kelly A Saran, Sachin Kheterpal	2012	US	To report an adverse event and describe the hospital's root case analysis and proposed solutions.	Hospital	Anaesthesia-related adverse event	Root cause analysis
Root cause analysis of falling accidents and medication errors in hospital [12]	Thalyta Cardoso Alux Teixeira, Silvia Helena de Bortoli Cassiani	2014	Brazil	To identify fall incidents and medication errors reported in a general private hospital and to introduce the causal factors categories of these incidents.	Hospital	Patient fall and drug-related adverse event	Adjustment of London Protocol (termed a root cause analysis methodology)
Recommendations and Low-Technology Safety Solutions Following Neuromuscular Blocking Agent Incidents [13]	Linda Graudins, Glenn Downey & Michael Dooley	2016	Australia	To describe the root cause analysis of the initial event, with case findings and corrective actions, along with the raft of strategies initiated to ensure safer selection and administration of neuromuscular blocking agents.	Tertiary multisite hospital	Drug-related adverse event	Root cause analysis
Integrating systemic accident analysis into patient safety incident investigation practices [14]	Canham A, Jun GT, Waterson P, Khalid S.	2018	UK	To investigate the application of an Human Factors and Ergonomics-led systems approach to healthcare incident analysis.	Hospital and community health services	Drug-related adverse event	Root Cause Analysis and Systems Theoretic Accident Modelling and Processes analysis
Complementing Root Cause Analysis With	Justin Slade, Carolyn E	2020	US	To present a root cause analysis of a hospital-acquired	Hospital	Drug-related adverse event	The Joint Commission RCA

Title	Authors	Year	Country	Study Aims/Research Questions	Setting	Incident/ Adverse Event	Incident analysis method/tool
Improvement Strategies to Optimize Venous Thromboembolism Prophylaxis in Patients With Epidural Catheters [15]	Wrzesniewski, Oluwatobi O. Hunter, Nazima Allaudeen			venus thromboembolism.			Framework
Root cause analysis to identify contributing factors for the development of hospital acquired pressure injuries [16]	Genevieve Abela	2021	Malta	To determine the cause of pressure injuries and identify ways to reduce reoccurrences. A root cause analysis approach was chosen as the methodology for the study with the intention of improving patient safety within the hospital.	Geriatric rehabilitation hospital	Pressure injuries	Root cause analysis according to the National Patient Safety Agency
Why women die after reaching the hospital: a qualitative critical incident analysis of the 'third delay' in postconflict northern Uganda [17]	Gasthony Alobo, Emmanuel Ochola, Pontius Bayo, Alex Muhereza,Violah Nahurira, Josaphat Byamugisha	2021	Uganda	To critically explore and describe the pathways that women who require emergency obstetrics and newborn care go through and to understand the delays in accessing this care after reaching a health facility in a conflict-affected setting.	Primary care and hospital	Maternal death and near-misses due to delayed care	Critical Incident technique
Root cause analysis of Na131I contamination [18]	Dhingra J, Santana C, Harvey J, Miller A, Benton A, Childs M, Halkar R.	2021	US	To describe an adverse event in which a hot lab and radioisotope dosing room were contaminated, the events leading to the incident, the immediate remedial steps taken, the subsequent root	Hospital lab	Radioisotope contamination	Root cause analysis

Title	Authors	Year	Country	Study Aims/Research Questions	Setting	Incident/ Adverse Event	Incident analysis method/tool
				cause analysis, corrective actions and their effectiveness.			
To err is system; a comparison of methodologies for the investigation of adverse outcomes in healthcare [19]	Peter Isherwood & Patrick Waterson	2021	UK	To apply three different adverse outcome methodologies in the investigation of a healthcare incident.	Hospital	Delay in performing MRI scan	Root cause analysis, AcciMap & Human factors analysis classification system
Implementation of Improvements Based on the Analysis of Severe Adverse Events in Pediatric Patients [20]	Cecilia T. Bigio, Marcia R. Rodrigues, Carolina de Melo, Catherine S. Isoppo, and Louíse V. Hoffmeister.	2022	Brazil	To describe a severe drug-related adverse event and present the root cause analysis and implemented improvements.	Paediatric hospital	Drug-related adverse event	London Protocol
Can't find the antidote: A root cause analysis [21]	Laila Carolina Abu Esba, Ghada Mardawi, Mohammad Al Deep	2022	Saudi Arabia	Share a learning experience of an adverse event and describe the root cause analysis of the incident and measures taken to ensure patient safety and prevent a recurrence.	Tertiary care hospital	Drug-related adverse event	Root cause analysis
Investigations by acute-hospital staff: AcciMaps or HFACS? [22]	Nick Woodier Karen Whiting & Owen Bennett	2022	UK	To identify an appropriate and usable patient safety investigation method for use by healthcare staff.	Hospital	Drug-related adverse event	AcciMap Human factors analysis classification system

Table 2. Studies which investigate an incident using an incident analysis method

Study	Brief incident synopsis	Methodology for incident analysis	Sources of information	Aftermath
Vincent et al. 2000 [4]	A female patient was admitted to an acute psychiatric ward with a recorded recent overdose but no other attempts at self-harm. Father telephoned with concerns. Patient was judged to be depressed and there were concerns from nurses about self-harm. An alarm sounded (by the patient) and patient was found with wrist and neck lacerated, a broken bottle on the bed. Blood pressure and pulse were taken. Fluids were unavailable having been used for another patient and an ambulance was called. Patient taken to A&E and later reported blood tests, blood pressure and pulse recovered to normal.	• ALARM/CRU Framework. • Checklist of contributory factors was developed for the interviewed based on the ALARM/CRU framework. • 12 members of a mental health multidisciplinary team conducted the interviews. • Review of relevant literature. • Pilot interviews and other conversations with staff following incidents in the psychiatric unit suggested additional to include, which informed interview questions. • Semi-structured interviewed conducted with 8 staff members present at the time of the incident, or shortly before/after.	• Interviews • Case notes	

Study	Brief incident synopsis	Methodology for incident analysis	Sources of information	Aftermath
		• Analysis involved identifying clinical management problems and contributory factors according to the framework.		
Garnerin et al. 2006 [5]	A patient entered ICU after abdominal surgery. A continuous IV analgesia administered through epidural catheter using an S-pump. The next day patient was transferred to urology to free the bed. The nurse did not replace S-pump with PCEA pump because none was available. Patient transferred to ward with nurse not trained on PCEA. Treatment was interrupted because syringe was empty and nurse unfamiliar with it continued by other means (a V-pump). Night nurse noticed this did not comply with recommendations of acute pain team and after two hours successfully got hold of a PCEA pump. No adverse consequences for patient.	• London Protocol. • A joint team formed with two investigators one from anaesthesiology and one from surgical ICU who were experienced in quality and safety issues. • Established chronology, care-delivery problems, listed and categorised factors that facilitated these problems. • Devised corrective actions using prevention and absorption.	• Interviews	• Meeting was organised to decide on corrective action by senior and frontline medical and nursing manager of departments involved. • Development of new protocols and training of nurses in pain-management. • Posters displaying recommendations made available to all wards.
Rule et al. 2007 [6]	The nurse practitioner reviewed the new insulin pump's mechanics with the patient, who had a 26-year history of Type 1 diabetes mellitus, and supervised the patient's programming of the pump. At bedtime, a blood sugar of > 250 mg/dL prompted the patient to give herself insulin via the pump. The next morning, she was treated at the emergency department for diabetic ketoacidosis. The pump had been improperly primed meaning no insulin had	• Root cause analysis. • Team of physician, pharmacist and medication error specialist was formed to perform analysis. • This was informed by a systems view analysis using the Systems Engineering Initiative for Patient Safety (SEIPS)	• Patient chart	• A number of changes were made regarding usability and instruction of the device, follow-up support to patients, training in its use and checklist for induction, revision of policies and procedure to ensure patient has adequate time.

Study	Brief incident synopsis	Methodology for incident analysis	Sources of information	Aftermath
	been delivered.	framework, which took into account characteristics of the work system. • Timelines of events created and fishbone diagram.		
Elhence et al. 2010 [8]	A blood request for a patient 1 with accompanying blood sample was made and prepared. However, when it came to transfusion, the nurse found it had already been collected. On inspection, it was found that the blood had been given to a different patient on a different ward with the same first name. Blood type happened to be the same so no harm came to patient 2. The remaining blood was transfused to patient 1 as intended until the family informed medical staff that she was a different blood type. Another compatibility test confirmed this was the case and the right blood was then ordered and transfused.	• Root cause analysis. • Chronology and causal tree constructed.	• Medical records	• Implementations such as continuing medical education for existing and newly joining staff about bedside procedures and patient wristband identification. • Standards of procedures revised and displayed as charts on wards for reference.
Smetzer et al. 2010 [9]	A 16-year-old patient came to the hospital to deliver her baby. During the process of her care, an infusion intended exclusively for the epidural route was connected to the patient's peripheral intravenous line and infused by pump. The patient experienced cardiovascular collapse. A caesarean section resulted in the delivery of a healthy infant, but the medical team was unable to resuscitate the mother. A partially infused epidural solution bag and an unused	• Root cause analysis. • External multidisciplinary team (Institute for Safe Medication Practice) invited to conduct on-site review.	• Interviews with staff involved, related staff and hospital leadership • Patient record • Written hospital policies and procedures • Published literature • National regulation	• Apology to family and acknowledgement of error. • A number of recommendations were made relating to training, protocols, work practice and procedures. • Findings and learnings shared with internal stakeholders and wider network of hospitals in the

Study	Brief incident synopsis	Methodology for incident analysis	Sources of information	Aftermath
	penicillin bag were discovered, and it was determined that the patient had received an IV infusion of fentanyl and bupivacaine instead of penicillin.		and standards • Demonstration of processes (bar-coding system) • Tour of relevant units • Discussion with other hospitals that use the same processes	health system. • Actions taken based on recommendations • Organisational learning on safety management implemented: Twice a month senior leadership staff member conducts a walkaround to learn about safety concerns of staff.
Freundlich et al. 2012 [11]	Male patient with history of cancer admitted with mental changes and left side weakness. Patient was scheduled for brain biopsy under general anaesthesia for treatment planning purposes, which was performed without intraoperative complications. Several hours later patient was found unresponsive and CT scan revealed massive haemorrhage with herniation. He later died. The patient partial thromboplastin time was markedly elevated before surgery when previously normal but neurosurgery and anaesthesiology were unaware of this at time of the operation.	• Sentinel event review process including root cause analysis undertaken by involved departments, plus office of clinical affairs, office of risk management and department of quality improvement.	• Medical records	• Inventions implemented based on recommendations from the root cause analysis, including improved processes as mandated use of the electronic medical record system across departments, expanded preoperative checklists and improved communication between staff. • Measurements of intervention included audits.
Teixeira & Cassiani [12]	5 falls and 14 medication errors reported on internal report system by nurses were individually investigated	• Root cause analysis team (n = 6) formed to analyse falls composed of treatment nurses, coordinating nurses, nurse from hospital infection control service and pharmacist. • Root cause analysis team	• Incident notification forms • Medical records	• Teams made recommendations based on the causal factors highlighted during the RCA to avoid future occurrences within the institution

Study	Brief incident synopsis	Methodology for incident analysis	Sources of information	Aftermath
		(n = 7) formed to analyse medication errors made up of attending nurses, coordinating nurses, nurse from hospital infection control service, auditor nurse and pharmacist. • 10 meetings were held.		
Graudins & Dooley [13]	Three incidents of mis-selection of cisatracurium. Incident 1: a drug swap involving cisatracurium instead of intended midazolam. The patient developed anaphylaxis but required urgent surgery which went ahead. On waking, she described paralysis and distressing awareness of induction of anaesthesia, for which she required ongoing treatment for PTSD. Two additional medication errors involving the same drugs occurred within 12 months of the first.	• Root cause analysis conducted by the hospitals' clinical governance unit.	• Interviews and submissions from all involved staff	• Working party was formed by department heads and senior nursing, medical and pharmacy staff to address specific recommendations • Responsibility for each recommendation was allocated to a senior clinician with an expected completion date. • A risk manager is responsible for tracking progress of recommendations. • Outcomes of the root cause analysis was presented at relevant staff meetings. • Recommendations where possible were linked to a risk register. • Improvements were made relating to packaging review and in-house labelling, guidelines development and implementation, storage,

Study	Brief incident synopsis	Methodology for incident analysis	Sources of information	Aftermath
				product review and red-barrel syringes.
Slade et al. 2020 [15]	A male patient with hypertension and smoking history received surgery to remove mass on oesophagus, without notable intraoperative complications. He received heparin and once pain control improved catheter was removed. He developed fever and scan revealed pulmonary emboli. After intervention and treatment he was discharged and monitored from home. Pharmacologic VTW prophylaxis had not been appropriately resumed following removal of an epidural catheter.	• Multidisciplinary stakeholder team assembled made up of relevant clinical staff from the departments involved (including staff directly involved) and patient safety officers with expertise in systems thinking. • Team leader assigned (physician champion with Lean training and root cause analysis experience). • Process map created focussing on key steps. • Case review of previous 3 months. • Identify causal factors (aims to consider potential contributing factors rather than single root cause).	• Frontline providers accounts • Electronic medical records	• Countermeasures were prioritised using Institute for Safe Medication Practices framework to identify measures with greatest power or leverage to combat contributing factors. • Recommendations were disseminated to through huddles. • Subsequent 6 months of patients reviewed after interventions.
Abela 2021 [16]	Investigations over the course of six months concerned patients over the age of 60 who developed a stage 3 or 4 pressure injury unstable or deep tissue injury post-admission.	The National Pressure Ulcer Advisory Panel Root Cause Analysis Toolkit	• Medical and nursing notes • Audit forms • Referrals to other specialties • Interviews of healthcare workers	• Outcome of each root cause analysis was discussed with the Charge Nurse of the ward involved, another Tissue Viability Nurse and the Senior Practice Nurse. • Suggestions for quality improvement from this

Study	Brief incident synopsis	Methodology for incident analysis	Sources of information	Aftermath
			and patients	meeting were then discussed with the ward nurses and the Multi-Disciplinary Team to explore how the suggested recommendations could be implemented. • Subsequent monitoring of audits after recommendations had been implemented showed a decrease in number and severity pressure injuries.
Alobo et al. 2021 [17]	Eight maternal deaths and 15 maternal near misses related to delayed care were investigated over the study period. These concerned eclampsia and pre-eclampsia, antepartum and post-partum haemorrhage, delayed referral and operation and failures to deliver.	• Critical incident technique • Key informant interview • Research team-led (all clinical background)	• Semi-structured interviews with key informants within 2 weeks of the incidents, which included doctors, midwives, ambulance drivers, patients and family/carers • Part of this interview involved sketching a diagrammatic pathway for each case	• Interviews included asking for recommendations to improve the services with a focus on reducing the delay. • Results were shared with the district and national stakeholders.
Dhingra et al. 2021 [18]	Physician found patient was unable to swallow $Na^{131}I$ capsule for radioiodine therapy, contacted the radiopharmacy and told that the liquid form would not be available for 3 days as it was a weekend.	• Root cause analysis. • Unbiased team consisting of a nuclear medicine physician, a technologist supervisor and	• Interviews • Patient notes	• Staff comprehensively reviewed the incident and underwent retraining within a week afterwards. • Corrective actions suggested

Study	Brief incident synopsis	Methodology for incident analysis	Sources of information	Aftermath
	Patient not willing to return, the physician decided to open capsule and dissolve in water. Due to the difficulty opening the capsule, the dosing room and hot lab became contaminated with radioactive substance. The patient and relevant staff were monitored for contamination and radioactivity. Patient sent home without treatment and rescheduled.	technologist led the root cause analysis. • Why questions asked until the answers guided the team towards corrective actions.		in the root cause analysis were added to the policy and checklist for radioiodine therapy. • Addition made to the consultation form that the capsule should never be tampered with. • Protective flooring installed in the renovated hot lab, dosing room and bathrooms. • Corrective actions were monitored and followed-up over one year.
Adibi et al. 2022 [10]	Two patients with partially similar names were admitted from the emergency department, one requiring a transfusion and the other an appendectomy. Blood was mistakenly administered to the wrong patient. This was noticed a few minutes later and immediately discontinued and interventions initiated. The patient had their intended procedure, was then transferred to ICU and discharged without any serious consequence.	• London Protocol. • Reviewed by a committee of experts plus a panel of six internal heads/managers of clinical governance, hospital, ward and the blood lab. • Analysis involved producing a timeline, brain storming and fishbone diagram discussing care/service delivery problems, safeguards and preventative measures.	• Record of event on reporting system • Interviews with responsible personnel	• Conclusions reported to senior managers of related departments of the hospital and the Medcare Management Deputy of the University. • A number of preventative measures were suggested relating to acceptable nurse ration, reestablishment of shift supervisor role, nurse training and development of practical guidelines.
Bigio et al. 2022 [20]	Three-month-old patient transferred to another hospital for therapeutic cardiac catheterization. On transport back to original hospital, compressive dressing had	• London protocol. • Internal patient safety centre multidisciplinary	• Interviews • Reports	• Results were analysed by the hospitals' quality, safety and risk management teams. Interventions contributory

Study	Brief incident synopsis	Methodology for incident analysis	Sources of information	Aftermath
	been displaced resulting in significant blood loss. ECG showed surgical prosthesis did not get dislocated. Protamine was prescribed but none available in date and so promethazine was dispensed. Nurse administered promethazine with prescribed dose of protamine (20x higher than correct dose for patient weight). Patient went into cardiorespiratory arrest and resuscitated. Admitted to PICU and discharged after 3 months with permanent tracheostomy.	team analysed the incident. • Analysis involved identifying processes involved in patient's care, creating chronological report, identifying care delivery problems and contributory factors, from which a list of planned actions was proposed.		factors were inserted into hospitals action plan and presented to general management teams. • Parents met with the hospital's management director, cardiologist, patient safety coordinator and ICU psychologist for disclosure of the event and subsequent investigation.
Abu Esba et al. 2022 [21]	A patient presented to the ER with methanol toxicity and dialysis and IV fomepizole were ordered. No stock were available in the ER pharmacy but electronic inventory system showed there were stocks in the warehouse. Over the phone the pharmacist misheard fomepizole for omeprazole and said there was no stock. The patient was transferred to ICU where process started again. Patient received the drug 6 hours after initial order.	• Root cause analysis • An internal multidisciplinary team of 16 members was formed to conduct the root cause analysis and hold a meeting to discuss.	• Individual interviews with stakeholders • Inspection visits to the area	• Family was disclosed about the event. • Meeting with other stakeholders and parties involved, the root cause analysis team agreed a list of recommendation. • Improvements achieved based on recommendations made were listed which included those related to workflow, storage & workspace, pharmaceutical planning, education and technical root causes.

Table 3. Studies that review or compare methods

Study	Brief event synopsis	Methodology/ Methodologies	Usability and experience	Strengths	Limitations
Berlin et al. [3]	Eight cases investigated over four months, one of which was an 89 year old woman who died at home and was found by her son. She was housebound owing to osteoarthritis, episode of chest pain one year previously, presumed myocardial infarction (no ECG performed), and managed at home, for which she recovered.	• Critical incident technique. • Meetings by a facilitator (research GP) with help of practice manager with all personnel involved in the case. • Medical records circulated with brief written summaries.	• Teams were positive about the meetings – provided an opportunity to reflect on their role in patient care and increased awareness of the problems that may arise.	• Avoids problems of lag between event and feedback which results in smaller impact on practice – feedback is immediate. • Internal audit specific to each case. • Implicit, grounded in the data. • Longer-term maintaining of changes were not known. • Change resulted from setting standards during the case analysis.	• Some teams not comfortable with emotional content which accompanies the frank discussion around an adverse event. • Discussions were time consuming and may place demands on skills of inductive reasoning – facilitator crucial depending on skills of the team. • Adequate information about the event needs to be readily available.
Lim et al. [7]	Nine medication administration errors in seven care homes: three omissions, one extra dose, one wrong dose and four other errors resulting from not following administration instructions.	• Semi-structured interviews with care home staff involved in administering medication. • Review of medical records and clinical medication reviews. • Case summaries produced for each error. • Field observations of care home and medication rounds • Analysed using	• Less time taken to analyse errors using London Protocol and easier to use compared to Work Domain Analysis, which was more time consuming to create abstraction hierarchy.	Work Domain Analysis • The abstraction hierarchy of the Work Domain Analysis method allowed analysis to consider elements in each case beyond apparent information collected. • Recommendations were less prescriptive. • The structure links that link work categories at each level aids planning and	Work Doman Analysis • Abstraction hierarchy specific to care home medication system. London Protocol • By only analysing these contributory factors, others may have been missed. • Generic framework which could be applied in many work settings made it difficult to relate problem areas to care home system.

Study	Brief event synopsis	Methodology/ Methodologies	Usability and experience	Strengths	Limitations
		London Protocol and Work Domain Analysis		prioritising interventions. London Protocol • Context-free and can be applied to different work settings and identified factors that could be applied to a range of medication errors. • Suitable to generate short-term solutions with little time and financial resources.	• Analysis of relative importance of contributory factors difficult. • Event-dependent looking specifically at factors surrounding the error and not the wider deficient work system
Canham et al. [14]	Patient admitted to emergency department following a fall and transferred between wards. After finding high glucose levels, suggested that patient start insulin glargine 10 units once/day. The recommended dosage was misread and 100 units were prescribed and administered twice, once in two different wards.	• Root cause analysis • Systems Theoretic Accident Modelling and Processes (STAMP) analysis	• Lack of knowledge about STAMP meant healthcare investigators weren't able to use it alone without the human factors and ergonomics practitioner present.	• STAMP approach helped the team think more broadly about system controls and failure points, multifactorial causation and the interactions between groups/individuals involved. • RCA identified contributory factors to the incident.	• STAMP requires human factors and ergonomics expertise. The time needed to undertake and difficult to coordinate healthcare stakeholders in the same location at the same time for 2-3 hours a week needed for the workshops. • RCA lacked description or explanation of the relationships and interactions between humans and components across the system.
Isherwood &	Patient presented with a traumatic brain injury,	• Two-person investigation team:	Root cause analysis • The five whys	• Root cause analysis: good usability	• Root cause analysis: little evidence of benefit

Study	Brief event synopsis	Methodology/ Methodologies	Usability and experience	Strengths	Limitations
Waterson 2021 [19]	aspiration pneumonia and a cervical spinal cord injury. They underwent emergency surgery to stabilise the cervical spine. Three days after the operation the patient was unable to move the only functioning limb post injury. Took 24 hours to have the needed scan to determine time-critical limb-saving surgery. Scan did not reveal reversible cause so classed as "near miss" incident.	A Consultant with an interest in adverse outcome investigation and an expert in system-based investigation methodologies. • Timeline of incident established. • Data gathered for analysis through medical notes and semi-structured interviews with staff involved. • Root cause analysis - 'five whys' approach. • AcciMap. • Human factors analysis classification system.	approach provides an understandable structure and a fishbone diagram can be produced with minimal training. Human factors analysis classification system • Requires understanding of human factors and systems. • Usable, reliable and valid but requires initial training. AcciMap • Requires considerable expertise to identify, place and link multiple factors at different levels. The output is time consuming to generate.	• Human factors analysis classification system: inherent structure to explore different system levels, reflecting its complexity. Theory driven with high validity in healthcare and high inter-rater reliability both established. • AcciMap demonstrates complexity of incidents in complex systems and provides inherent structure to explore multiple system levels, providing useful graphical illustration to support analysis and recommendations.	in healthcare systems and application is often flawed. Qualitative approach is open to interpretation by different investigators and lack of structure to explore different system levels. Absent or poor geographical output. • Human Factors Analysis Classification System requires understanding in human factors systems and the structure doesn't specifically guide investigator to regulatory levels of the system. • AcciMap requires significant expertise to execute and although theory-driven and advocated, it has not yet been widely applied in healthcare so validity isn't really known. The qualitative approach is open to interpretation by different investigators and a taxonomy would be useful.

Study	Brief event synopsis	Methodology/ Methodologies	Usability and experience	Strengths	Limitations
Woodier et al. 2022 [22]	A significant harm incident which involved the incorrected route of administration.	Multidisciplinary investigation team of healthcare staff who would normally undertake patient safety incident root cause analyses analysed incident using HFACS and AcciMaps.	• Confusing to create and interpret but some the team felt the visual approach was more appropriate and supported learning. • Needs facilitation to undertake and regular use to develop familiarity.	• The prescriptive nature of Human Factors Analysis Classification System considered all aspects of their systems and highlighted potential contributory factors and was given face & content validity. • Human Factors Analysis Classification System moves investigation away from individuals and a blame-focussed approach, showing the influence of organisations and external factors. • Codes developed using Human Factors Analysis Classification System for this setting were found to be appropriate and valid.	• The Human Factors Analysis Classification System requires some initial training and support to undertake investigations using this method. The language and linear/hierarchical nature may miss complexity in the system. • Moderate inter-rater reliability for the Human Factors Analysis Classification System. • Electronic version of Human Factors Analysis Classification System would be useful • Difficult to know when investigators should stop coding using Human Factors Analysis Classification System

Commentary

The most remarkable finding was the paucity of research with only 20 papers on incident analysis identified over two decades, a tiny amount compared with the very large number of commentaries and studies of incident reporting. Of these, only five provided any direct assessment of the methods themselves and none used any formal comparison or experimental approach. Healthcare has seemingly been obsessed by reporting incidents but paying minimal attention to understanding them.

Many of the studies reported that using an incident investigation method was useful in generating a shared understanding, helped to move teams away from a blame narrative and some suggested that reviews could enhance safety culture more generally. However, studies and commentaries suggest that many of the analyses that are conducted do not lead to effective actions or improvements. We also noted that many methods were not fully implemented. For example, one study claimed to have applied the London Protocol but did not produce any recommendations.

More comprehensive and theory-driven frameworks, such as the HFACS, developed by the US Navy, have high validity and allow the investigation to explore different system levels [19, 22]. However, these methods require some degree of training and expertise in human factors and patient safety. In contrast the various approaches described as 'root cause analysis' tended to be simpler, quicker but correspondingly more limited in their conclusions. The more comprehensive methods appeared to have a much greater capacity to develop a range of recommendations. This was available for all methods but used to varying degrees of completeness and quality in the studies identified.

We appreciate that the published research represents only a very small proportion of the incident investigations carried out and cannot be considered to be representative of practice more generally. Greater encouragement for the publication of full incident investigations using established methods is needed to build a body of knowledge and enable wider learning and sharing of successful intervention strategies which may be adapted and applied in subsequent investigations of incidents. There is a need to further validate these methods in different healthcare settings, particularly in settings like primary care where the majority of healthcare is delivered or mental health services [23]. To this end, more empirical research is also needed on the relative strength, impact and unforeseen consequences of recommendations resulting from incident analyses in practice [24].

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