MSc Digital Transformation for the Health and Care Professions BMDS7005

Developing a data analysis methodology for incident reporting data to better understand patient safety incidents

Dissertation submitted in partial fulfilment of the award of
Master of Science in Digital Transformation for the Health and Care Professions

Matt McCarthy
2112755
11th May 2024

Acknowledgements

Firstly, I would like to acknowledge the support provided by my supervisor, Felicity Peacock. Completion of this dissertation would not have been possible without her expert guidance. I also want to thank my Health Board colleagues, especially the Datix team for their assistance with data extraction. Finally, special thanks to my wife/proof-reader Soph for her support throughout the Masters course. This dissertation is dedicated to my three children, Mabel, Ruby and Otis.

Declaration

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

Signed

Date…11th May 2024…

Table of Contents

Chapter 1 - Introduction

1.1 Rationale for this study

Healthcare carries inherent risks, evidenced by the estimation that 1 in 10 patients experience harm while receiving care in hospital and up to 50% of this harm being preventable (Donaldson *et al.*, 2021).

The landmark report 'To Err is Human' (Institute of Medicine, 2000), underscored the critical role of incident reporting within healthcare, drawing inspiration from the safety processes of other safety-critical industries, such as aviation and nuclear power. The fundamental rationale behind this shift towards incident reporting lies in the understanding that the lack of detailed information regarding the circumstances under which patients suffer harm, significantly hampers efforts to implement effective preventative measures.

Incident reporting is a process by which healthcare staff can log adverse or unexpected events occurring during episodes of patient care. This includes incidents where patients have come to harm, and potential incidents where harm has been prevented – also known as 'near miss' incidents (Stavropoulou, Doherty & Tosey, 2015). The National Patient Safety Agency (NPSA) defines an incident as "any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare" (National Patient Safety Agency, 2005, p12).

Although intuitively, incident reporting is expected to improve patient safety, evidence of these improvements remains sparse (Mitchell *et al.*, 2016; Carson-Stevens, Donaldson & Sheikh, 2018). This paradox is the foundation of the research project's core challenge – to establish how a deeper comprehension of potential contributory and causative factors can be achieved through analysis of incident reports.

The field of incident reporting in healthcare has been a subject of considerable academic inquiry since its inception. A comprehensive review conducted by Archer *et al.* (2017) showed the breadth of research in this area, identifying over 3000 articles related to incident reporting systems. Key areas of research include the

examination of attitudes and behaviours towards incident reporting, as explored in studies by Evans *et al.* (2006), Jansma *et al.* (2010) and Kingston *et al.* (2004). Efforts have been made to understand reporting rates and incident detection as shown in the work of Cristiaans-Dingelhoff *et al.* (2011). A significant body of research has been directed to analysis of incidents relating to specific patient groups, healthcare services, and incident types, exemplified by Gibson *et al.* (2020), who studied incidents involving patients receiving opioid replacement therapy, Kasalak *et al.* (2021) who reviewed incidents occurring within radiology, and the study of medication-related incidents by Cousins, Gerrett and Warner, (2012). Each of these studies contributes to the understanding of the complexities and effectiveness of incident reporting systems and processes within healthcare.

Within the context of incident reporting in healthcare, an area of substantial concern is inpatient falls. Falls in hospital occur frequently and some falls cause physical harm or death (Weil, 2015). The Royal College of Physicians (2023) reports that during 2022, approximately 12,500 inpatient falls occurred within Wales. Inpatient falls are associated with significant morbidity and mortality, with up to 40% of these falls causing some degree of harm to the patient. Falls also impact on the wider healthcare system by increasing cost of treatment and length of stay, as well as injury and psychological damage to the patients involved, as documented by Simpson *et al.* (2013). The causes for falls are often multifactorial and can include environmental factors - such as an uneven floor, and physiological factors, which can be unexpected – in the case of a sudden collapse, or predictable, as with known walking difficulties (Terranova *et al.,* 2012). This combination of often interrelated causal factors, combined with a trade off between falls prevention and avoidance of physical deconditioning while in hospital, contextualises the challenge in achieving successful and sustained reduction in avoidable inpatient falls within a healthcare system.

1.2 Local context

This study takes place within a large National Health Service (NHS) Health Board in South Wales. The Health Board serves a population of approximately 500,000 and

includes tertiary and community hospital sites (Cardiff and Vale University Health Board, 2023a).

Within the United Kingdom (UK), health is a devolved matter in Scotland, Northern Ireland and Wales. Responsibility for healthcare falls to the Scottish Parliament, Northern Ireland Assembly and Welsh Senedd respectively (Institute for Government, 2020). NHS Wales delivers services through 7 local health boards and 3 trusts. The local health boards are responsible for providing primary, secondary, and mental health care within their areas (Welsh Government, 2023a). The quality and safety of healthcare services within NHS Wales is overseen by the NHS Wales Executive, which was formed in 2023 as a combination of several national organisations. Regulatory monitoring of services is the responsibility of Healthcare Inspectorate Wales, performing a similar role to the Care Quality Commission in England (Healthcare Inspectorate Wales, 2024).

1.3 Study background

The overarching aim of this study is twofold - to contribute to the falls prevention efforts within the Health Board, with an ultimate goal of reducing the harm caused to patients from avoidable falls while in hospital, and using falls as a test case for the development of an approach to analysis of patient safety incidents in order to better understand causative and contributory incident factors. The development of this study is informed by a comprehensive review of published literature, which is explored in chapter 2.

Chapter 2 – Literature review

2.1 Literature review aims

The three primary objectives of this literature review are to:

1. Assess the extent to which data analysis techniques have been applied to enhance understanding of incident reporting data within healthcare.
2. Explore potential analysis methods that could be employed with an inpatient falls dataset.
3. Situate this research within the broader landscape of patient safety, evaluating its alignment with current trends and future directions in the field.

2.2 Search strategy

The primary literature search was completed using the ProQuest Central database. This database was selected as it is the largest single repository of articles and includes relevant databases covering healthcare, medicine and nursing (ProQuest, 2022).

Search criteria were developed iteratively, with the final criteria shown in Table 2.1.

Table 2.1 – Search criteria

Criteria	Value
Search terms	“patient safety incident” analysis
Time period	2018 - 2023
Type	Peer reviewed

Searching using the defined criteria returned 260 results, the title, publication and abstract of which were retrieved for review. Initial review was undertaken using the title and abstract of each result to determine its potential relevance to the research question and aims. The results were checked for duplicates.

Following review, 22 results were excluded as duplicates and 180 results were excluded as not relevant to the research question. These excluded results primarily related to the following broad topic areas, with examples referenced:

- Development of classifications and taxonomies of patient safety incidents (World Health Organization, 2018)
- Perceptions and barriers to incident reporting (Hasanpoor, Haghgoshayie & Abdekhoda, 2022)
- Patient safety incidents relating to a specific clinical procedure (Favot *et al.*, 2019)
- Healthcare workers experiences following involvement in patient safety incidents and psychological safety (Lee *et al.*, 2019)

The full texts of the remaining 58 results were obtained and formed the primary literature review. The quality of the selected articles was considered and recorded using the Credibility, Reasonableness, Accuracy and Support (CARS) checklist (University of Strathclyde, 2023). One study was excluded as not relevant on review of the full text.

Where relevant additional articles were referenced within the 57 results initially identified, these were obtained to expand the review. A schematic of the literature review process is included as Figure 2.1. The obtained literature is synthesised below in chapter 2.3 to inform the study design and consider the value of the research.

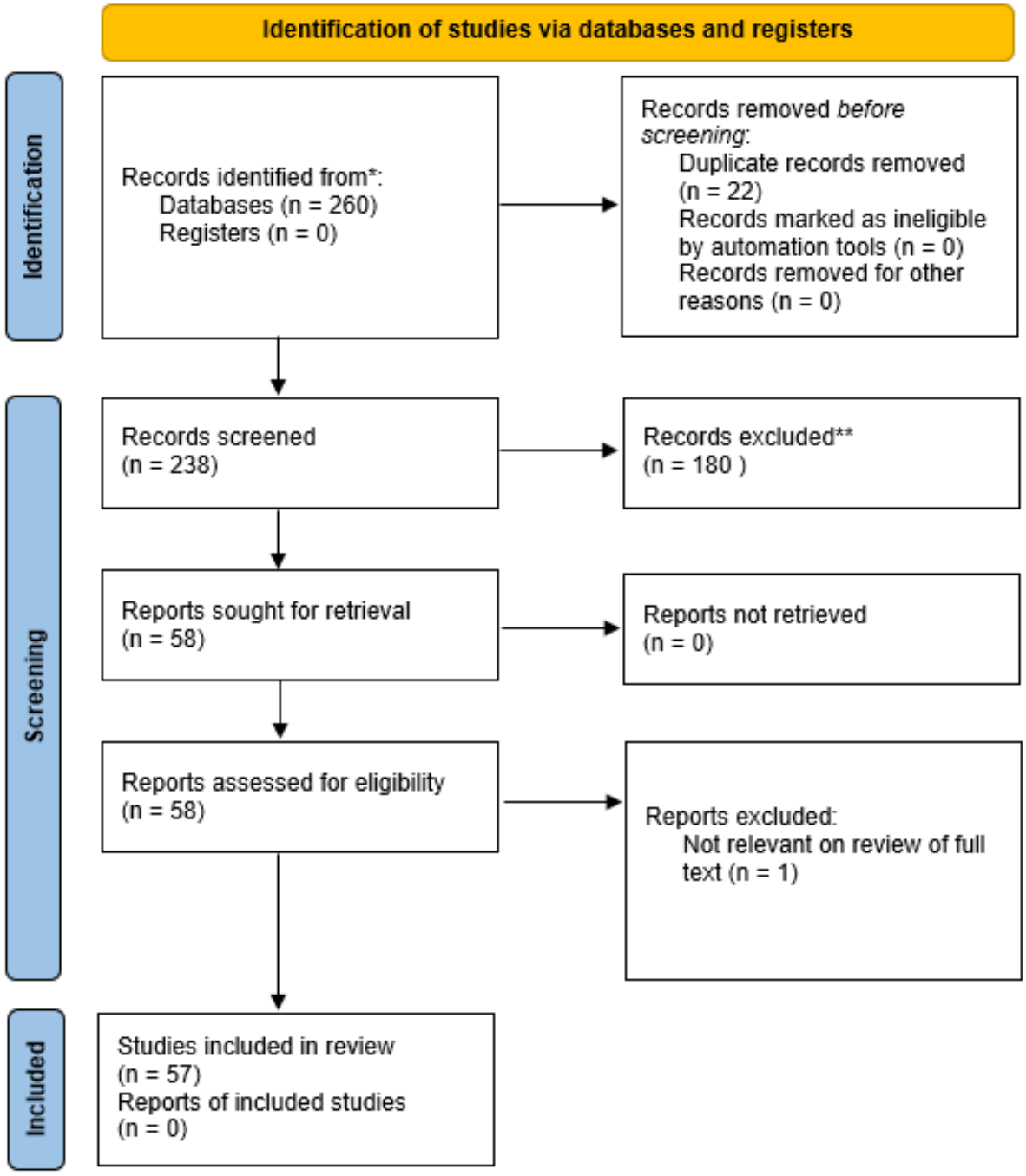

Figure 2.1 – PRISMA Diagram

2.3 Literature synthesis

2.3.1 Incident reporting

A number of authors have written about the lack of evidence that incident reporting leads to improvements in patient safety (Mitchell *et al.*, 2016; Carson-Stevens, Donaldson and Sheikh, 2018). Despite considerable efforts to promote incident reporting and to identify barriers to reporting in healthcare, it remains challenging to definitively ascertain whether these systems fail to improve safety, or if the link between reporting and safety improvements is inherently difficult to measure and demonstrate.

While incident reporting is a cornerstone of patient safety within healthcare, Pham, Girard and Pronocost (2013) warn that it is not a panacea. As Vincent (2004) explains, incident reports by themselves give very little information about the causes for incidents, or regarding interventions to improve prevention. The existence of an incident reporting system into which adverse events can be logged does not in itself improve safety. It is the investigation and analysis of these incident reports that can lead to improvements (Sun *et al.*, 2019).

The balance between the need to collect sufficient information about an incident to allow investigation and learning, considered against the time taken for clinicians to complete the report presents a significant trade-off. Recently, it has become apparent that incident reporting systems might not be contributing to the resultant safety improvements originally envisioned by those who advocated the introduction of incident reporting systems within healthcare (Donaldson, 2004). The lack of processes for analysis and learning from incidents is proposed as one of the causes for the absence of safety improvements that are seen in other safety-critical industries. Focus has historically been on the quantity of incident reports as a measure of ‘safety culture’, rather than outcomes from investigation and improvement. The issue is summarised succinctly by Macrae (2016, p74), who states “we collect too much and do too little” with patient safety incident data.

Incident reporting systems contain information on patient safety incidents with a range of outcome severities. The most severe incidents are subject to individual

investigation to identify the root causes and develop interventions to prevent recurrence (Vincent *et al.*, 2017). A number of different incident investigation methodologies exist and are used within healthcare, but all require a significant amount of time to complete, with even a very simple investigation taking at least a few hours. While this is appropriate and proportionate for incidents where patients have died or come to significant harm, applying this level of investigation to all incidents would be impossible when the volume of incidents is considered – between 17,000 and 27,000 annually in a typical large NHS Wales Health Board (Welsh Government, 2021a).

Fortunately, incidents causing death or severe harm are much rarer than those causing no harm (referred to as 'near misses') or causing low/moderate levels of harm (Welsh Government, 2021a). Analysis of these less-severe incidents can identify issues that, once addressed, may significantly reduce the risk of more severe incidents occurring in future. Considering the impracticality of individually investigating each incident, there is a significant need for alternative approaches in order to achieve the desired safety improvements. The healthcare sector could benefit from adopting analytical strategies used successfully in other safety-critical industries, where such approaches have been shown to enhance safety – an achievement yet to be mirrored in healthcare (Carson-Stevens, Donaldson & Sheikh, 2018). Methodical thematic analysis of incident data could surface critical insights into the causes of incidents, which might otherwise remain unidentified, thus hindering advancements in the safety of healthcare services.

The literature supports the value of incident data analysis in developing improvement strategies and this has been demonstrated across a range of topics such as medication errors, surgical incidents and primary care incidents (Khalid *et al.*, 2018; Mushtaq *et al.*, 2018; Chaneliere *et al.,* 2018).

While the need for greater analysis and learning from reported incidents is acknowledged in the literature, there has been very little written about how to put this into practice within a healthcare setting, illustrating the need for research in this area to support healthcare organisations in achieving the desired data-informed safety improvements.

2.3.2 Approaches to analysis

The studies identified from the literature review can broadly be grouped by the aspects of incidents which are subject to analysis. These aspects are set out below.

Incident identification

Further to the discussion on the importance of systematic incident data analysis, it is crucial to acknowledge and consider the challenges posed by the limitations which are inherent within the current reporting framework. As Macrae (2016) highlights, the efficacy of analysis is constrained by the voluntary nature of reporting and the variable rates of incident reporting between and within healthcare organisations. It is known that data from incident reporting systems likely under-represents patient safety incidents (Sari *et al.*, 2006). Some studies have sought to address this through the use of case note review to retrospectively identify patient safety incidents occurring during a period of care (Avery, 2020). This approach, while more robust, is significantly more time-consuming and may lose some of the additional information regarding an incident that is normally captured via the incident reporting system. Conversely, there are some incident types and circumstances that could not be identified solely from reviewing case notes. These incidents are primarily those which have the potential to cause harm but do not relate to specific patients, such as medication being stored incorrectly in a ward; a situation which has the potential to cause harm if the medication were to be administered but would not be recorded in patient notes if the error was rectified before any incorrectly stored medication was given.

The simplest measure from an incident reporting system is a count of the number of reported incidents. While it is acknowledged that this is likely an under-representation of the true number of incident occurrences, counting voluntarily reported incidents allow an estimation of the numbers of patient safety incidents which have occurred within a specified time period. The analytical value of this information can be enhanced by using an appropriate denominator to allow

consideration of incident rates.

Incident rates

Where a suitable denominator can be identified, this can be used to calculate an incident rate, as demonstrated by Vossoughi *et al.* (2019) who analysed incidents related to blood and blood component transfusion. The authors used the number of transfusions administered as the denominator to calculate incident rates per 100,000 transfusions. This allowed comparison between adult and paediatric incidents which would not have been possible using the numbers of reported incidents alone due to the differences in the numbers of transfusions performed, with 128,560 paediatric and 377,563 adult transfusions during the 7-year study period.

Incident rates are used in other industries as part of their safety monitoring. In the UK, aviation aircraft proximity incident data are published by the UK Government. Reporting incident rates over time allows emerging areas of risk to be identified, such as the increasing numbers of incidents involving drones (UK Government, 2023). Incidents related to the emerging risk are reviewed and safety recommendations made (Air Accidents Investigation Brach, 2021).

While this approach was demonstrated to be effective in aviation, little evidence of the analysis of incident rates over time in healthcare was found within the literature review. Where incident numbers or rates were analysed over time, there was limited discussion of potential causes for changes in rates (Shin & Won, 2021; Danielis *et al.*, 2020). A study by Danielis *et al.* (2020) demonstrated increasing numbers of incidents over a 5-year period within an Italian intensive care unit, but this was not analysed against activity data, such as bed occupancy or patient acuity and therefore the reason for the increase was not established. The authors did explain that reporting rates can be affected by the safety culture in a particular healthcare setting, which highlights the need for careful analysis to ascertain whether a change in incident rates is due to fluctuations in safety culture and therefore a willingness for staff to report incidents, or a true change in the rates of patient safety incidents, with other causes.

Before conclusions are drawn from an increase or decrease in the numbers of patient safety incidents, it is crucial to consider whether there has been a change in the number of opportunities for the incidents to occur, such as the number of operations performed, the number of inpatient bed days or the number of times a medication is administered. It is for this reason that incident rates are a more valuable measure than pure incident numbers, but calculation of these rates will often involve obtaining information from outside the incident reporting system, such as with patient admission and discharge data to calculate incidents per 1000 bed days (Sahota *et al.*, 2014). Calculation of incident rates is complicated by the lack of a suitable single denominator across healthcare. While bed days is an appropriate measure of activity on an inpatient ward (Jones, 2022), this would not be suitable for an assessment and triage area such as the emergency unit, where the number of attendances could be considered a denominator which would be more reflective of the unit's activity at a point in time (Iacobucci, 2013). Further insight is gained through examination of incident rates for specific incident categories and classifications.

Incident categorisation and classification

Where the literature demonstrated groups of incident reports being subject to analysis, this most often involved individuals reviewing each incident to categorise it and identify themes or contributory factors (Gibson *et al.*, 2020; Yardley *et al.*, 2018). Illustrating the workload involved in manual analysis, McFadzean *et al.* (2023) conducted an investigation into healthcare-related incidents within prison settings, using data from the National Reporting and Learning System (NRLS). This comprehensive study required to clinicians to undertake detailed review of over 4000 incident reports. Although the article does not specify the duration of this review, a conservative estimate of 2 minutes per report would equate to more than 130 hours of clinician time. While such extensive review is achievable within a research project, in this case supported by funding from the National Institute for Health and Care Research (NIHCR), replicating this process within a healthcare organisation, with competing operational and clinical priorities, might not be feasible.

One paper explores the possibility of using natural language processing and machine learning to classify reported patient safety incidents (Evans *et al.*, 2020). The authors concluded that these techniques were not yet sufficiently accurate to replace manual review, proposing that this approach could provide a safety net to identify miscategorised incidents which have caused severe harm or death. Use of these techniques is in its infancy, with a systematic literature review of artificial intelligence (AI) in healthcare safety by Choudhury and Asan (2020) showing that the majority of papers relating to artificial intelligence within patient safety incident identification have been published within the last 5 years, with a focus on extracting risk factors from clinical notes. The authors highlight that risk analysis of clinical notes is advocated by the United States (US) Department of Health and Human Services, which may be the national driver for the significant number of US based studies within those reviewed. Choudhury and Asan (2020) comment on the difficulty in establishing the effectiveness of AI analysis techniques due to the heterogeneity in AI reporting, finding studies using differing evaluation metrics with the same AI model. Despite these challenges, AI may be a tool with future utility in reviewing and correcting the categorisation of submitted incident reports, reducing the workload on clinicians demonstrated in McFadzean *et al.* (2023).

The literature review highlighted some examples of statistical analysis being used within the field of patient safety, but direct analysis of incident reports was not common. Buwono, Suhardi and Pujiyanto (2019) describe the use of partial least square analysis to identify the most influential variables affecting patient safety, based on questionnaire responses from 70 hospital staff members. The credibility of the authors' assertion that working conditions significantly influence outcomes warrants scrutiny, given the paper's lack of detail on participant selection and bias mitigation strategies. However, the approach of employing statistical analyses to explore various potential influencing factors has potential application to incident report data. Whereas a questionnaire can be designed specifically with analysis in mind, the challenge in analysing data from incident reporting systems is the constraint of using predefined fields, many of which have been designed to provide system functionality rather than purely as a data collection tool. This necessitates a critical examination of how to adapt incident report data to enable analysis, ensuring

the chosen data fields are not only relevant, but also capable of yielding meaningful insights.

While considering common incident classifications and categories across a healthcare organisation provides a limited insight into the types of incidents which are prevalent, the specialised and varied nature of wards and departments mean that the incident landscape within one area may be very different to another. In order to better understand this variation, considering the location in which incident occur is essential.

Incident location

Gillespie *et al.* (2021) undertook analysis of 4358 patient safety incidents reported within an Australian tertiary hospital. The authors conducted statistical analysis to compare the numbers of reported incidents of different types between medical and surgical divisions within the hospital, which demonstrated falls being reported significantly more often in the medical division. While this analysis does not in itself identify potential causative factors for the falls occurring within the medical wards, it is likely to prompt further investigation into the differences between medicine and surgery, as well as consideration of the characteristics of the typical patient populations accessing medical or surgical services.

When evaluating the impact of the physical location on patient safety incidents, it is important to understand the interrelation between environmental and organisational factors. Some variation in incident types and rates can be due to the impact of the physical environment in which care is provided. Singh, Okeke and Edwards (2015) undertook an observational study of inpatient falls, comparing rates between a hospital site with 100% single-bedded patient rooms and sites with multi-bedded wards. With no changes in the demographics, size or characteristics of the studied population, a statistically significant difference in the fall rate was identified. A rate of 15.8 falls per 1000 bed days was shown in the single-bedded site and a rate of 5.4 falls per 1000 bed days in the multi-bedded site. The authors used the opportunity of a move to a new single-bedded hospital site to study the impact of the changed ward layout without differences in patient population. While the clear difference in fall rates

suggests that multi-bedded wards would be safer for patients, there are likely to be other countering safety considerations, such as the infection prevention and control advantages from single occupancy patient rooms, although these are disputed (van de Glind, de Roode & Goossensen, 2007).

Caution must be taken when evaluating differences in incident rate between locations to consider potential differences in patient populations. Even within a single healthcare organisation, hospital sites are typically configured with differing services provided at each site to prevent duplication and to centralise skills and resources. This has the effect of altering the patient groups who form the inpatient population for each hospital. As patient age has been shown to correlate with inpatient falls (Chang, Lin & Chiang, 2015), wards or hospitals with a greater proportion of older patients would be expected to have a higher number of falls, therefore comparing incident location in this context is more significantly affected by the differing patient population, as opposed to the differing physical location and associated environmental factors. Outside of a tightly controlled study, differing incident rates between locations is likely to be contributed to by both environmental and patient factors in varying proportions.

Careful consideration and an understanding of the locations being analysed is required to come to appropriate conclusions in relation to the impact of location on incident rates. Regardless of the location, incidents reported within healthcare settings can cause harm to patients, with the level of harm quantified within the incident reporting system.

Incident harm

The level of harm caused to a patient as a result of a safety incident can range from no harm (a near miss) up to severe and permanent injury or death. Thankfully, the typical profile of patient safety incidents is heavily skewed towards no harm and low harm incidents. It is not unusual for a typical healthcare service to have very small numbers of incidents where high levels of harm are caused (Anzai *et al.*, 2020; Gillespie *et al.*, 2021).

The severity of harm caused by patient safety incidents is commonly divided into levels, which are selectable within the incident reporting system. Globally, there is variation between the number of levels and the associated definitions of these levels. Australian healthcare services use Safety Assessment Code (SAC), comprising of three levels, whereas NHS Wales uses a five-level Putting Things Right (PTR) harm grading (Gillespie *et al.*, 2021; Welsh Government 2023b).

The significant challenge faced when analysing the harm caused by patient safety incidents is the inherent subjectivity in assigning a level of harm to an incident, especially in the mid-range, where a patient has sustained a moderate injury or illness.

Additional incident factors

The design of incident reporting systems allows, or sometimes requires, additional information to be recorded in specific incident types, such as recording a medication name for medicines-related incidents. This information allows greater analysis as numbers of incidents and the level of patient harm arising from those incidents can be split by the type of medication involved. Cousins, Gerrett and Warner (2011) demonstrated this using medication incident data from the National Reporting and Learning System (NRLS) over a 6-year period, showing that opioids were involved in greater than 10% of medication incidents with fatal or severe harm outcomes.

Echoing the sentiment on incident rate, the significance of raw data becomes limited without the appropriate background and context. Without this important context, it cannot be concluded whether opioids carry an inherently greater risk of severe or fatal incidents, or whether these medications are prescribed and administered more frequently than other types and therefore the numbers of incidents could be expected to be higher. A greater understanding could be gained if incident numbers for individual medications were provided along with a denominator for the number of prescriptions or administrations of the medications during the time period. This would achieve a retrospective equivalent to the prospective observational method used by Ghaleb *et al.* (2010) to establish medication error rates in a paediatric inpatient

setting. This again reinforces the message that data alone without analysis and context is of limited value.

2.4 Conclusion

The literature review demonstrates the potential to gain much greater insight and knowledge from existing data through the use of analytical techniques. Where others have previously used analysis techniques to understand incident reporting data, this has primarily been focused on an individual aspect of the incident report or for a specific clinical service. The outcomes from these studies support the utility of these techniques.

The most detailed incident analysis has been developed from academic perspective. Within the literature review a small number of examples were found where incidents were analysed to identify themes. These studies primarily used manual review of individual incidents, often by more than one clinician, to recategorise incidents into a coding framework which was separate from the incident classification selected by the reporter. While this ensures that the coding and therefore the identification of themes and trends is robust, the process is time consuming and relies on individuals who are trained in the use of the classification framework. These constraints make this approach impractical for most healthcare organisations in all but the smallest groups of incidents.

Focusing on coding alone risks missing other important factors, such as changes in numbers of incidents over time or locations in which incidents occur. While this classification approach has value in describing the types of incidents which occur within a particular specialty or setting, translating this information into actionable improvements requires further analysis and understanding.

From a healthcare perspective, very few studies show analysis of patient safety incidents. Where analysis has been performed, this is mainly concerned with an individual aspect of the incidents, such as incident rates (Vossoughi *et al.*, 2019), location (Gillespie *et al.*, 2021), or medication involved (Cousins, Gerrett & Warner, 2011). No literature was found that took a holistic approach to data analysis techniques across the range of factors recorded within an incident report.

The literature review surfaced key areas of opportunity and for future research with the patient safety field. Adoption of multivariate data analysis techniques would enable a multidimensional examination of incidents, enhancing understanding of underlying patterns and correlations. Advances in computational analytics, such as machine learning and natural language processing, could be used to automate extraction and analysis of incident data, mitigating the limitations of manual review.

To aid advanced analytics such as machine learning, incident reporting systems could be refined to improve the granularity and structure of captured data, while balancing the time burden on incident reporters.

In order to support research and development in this field, enhanced collaboration is required across data science, healthcare informatics and patient safety to develop analytical methodologies to aid understanding of patient safety incidents and strategies to improve healthcare safety.

2.5 Importance of the study

The academic studies' use of manual incident report review has provided an important foundation for this research, lending weight to the hypothesis that there is valuable knowledge to be gained from analysis of patient safety incidents, however there is a lack of literature proving the practicality and use of analysis in this form within a healthcare setting.

The literature review identifies the need for a usable generic data analysis approach, which can be applied to groups of incident reports. It is this lack of a structured approach that is the focus of the research project, setting the stage for a transformative step in patient safety research, enhancing clinical knowledge with straightforward analytical techniques which are practical and can be easily implemented within the resource and skills constraints of a typical healthcare organisation.

Chapter 3 – Research design and methodology

3.1 Research design and context

This research aims to ultimately improve the safety of patients who are receiving healthcare, through a greater insight and understanding of patient safety incident report data. The development of an analysis methodology will be achieved through the examination of an inpatient falls dataset in order to trial the use of a range of analysis techniques. The application, value and ease of use for each technique will be assessed to inform its inclusion in the proposed initial analysis methodology.

The use of data analysis techniques with falls data forms micro experimental sections of the research and provides insight into the falls data. This study is not designed to produce generalisable findings about inpatient falls, as the data is specific to the Health Board in which the study is performed and is not selected to be representative of the wider population.

This project takes place within a large NHS Wales Health Board, serving a population of over 500,000. The Health Board has a central patient safety and quality department, within which the author is employed. The Health Board uses an instance of Datix Cymru, which is the all-Wales incident reporting system and is also known as the Once for Wales Concerns Management System (NHS Wales Shared Services Partnership, no date). Design of the electronic incident reporting form is standardised across NHS Wales Health Boards and Trusts.

Incident reporting sits within a wider local and national policy context. Within the Health Board, the incident, hazard and near miss reporting policy requires all employees to report incidents using the electronic incident reporting system, which is currently Datix Cymru (Cardiff and Vale University Health Board, 2023b).

Prior to commencing the study, advice was obtained from the Health Board's Joint Research Office and confirmation received that the study did not meet the NHS criteria to be considered research. Therefore, Health Board ethical approval was not required. An ethical approval application was submitted to the University of Wales

Trinity Saint David and confirmation of approval received from the Programme Director. The completed ethics application is included as Appendix A.

3.2 Obtaining data

The project seeks to answer two key research questions:

- Which data analysis techniques can be used to identify potential causative or contributory factors in groups of patient safety incidents within a healthcare organisation?
- Can structured analysis of patient safety incident data be used to identify potential causative or contributory factors that are not identified by review of individual incidents?

Within healthcare, incident reporting systems typically capture a large volume of incidents, spread across a broad range of incident types. This is demonstrated by the list of incidents which must be reported to the NHS Wales Executive, which includes types such as avoidable pressure damage, maternal deaths, population screening errors and avoidable falls causing significant harm (NHS Executive, 2023).

Different incident types will have differing causative or contributory factors, although some factors will be common across incident types. In order to trial analysis techniques, an individual incident type is required which has the relevant data recorded to allow analysis.

Incident reporting within the Health Board is a manual process, which relies on staff who identify patient safety incidents recording the relevant details using the Datix Cymru system. It is known that incident reporting does not capture all patient safety incidents and reporting rates are impacted by a number of factors, such as workload, access to computers, and staff member's attitudes to reporting. Rates of incidents reported cannot be taken as a direct measure of the rate of incidents occurring, however incident reporting does provide important information on areas of risk. (Pham, Girard & Pronovost, 2013). The difficulty is that incident reporting is often the major data source for safety incidents. Despite the caveats with a voluntary incident reporting system, its data can be seen as a proxy for the numbers of actual safety

incidents which occur within an organisation.

3.2.1 Incident type selection

Following discussions within the patient safety and quality department, inpatient falls were selected as the incident type used to trial data analysis techniques as these incidents are frequently reported, with a rate of 3.44 falls per 1000 patient-days given by Staggs, Mion and Shorr (2014) and a range of 3 to 5 falls per 1000 bed-days reported by the World Health Organization (2023). Falls often cause harm to patients, with an estimated 30 to 51 percent of inpatient falls resulting in an injury (Costantinou & Spencer, 2021). Therefore, falls are a priority area for intervention within healthcare as a common source of patient harm, with UK Government recommending that senior healthcare leaders make falls a priority within their organisations (Office for Health Improvement and Disparities, 2022).

Within the healthcare organisation providing the incident data for analysis, an established multi-agency group provides strategic direction in falls reduction and management. This group includes representation from primary and community care, local authorities, the ambulance service, the fire service, as well as falls specialists. Insights gained through analysis of falls incident data will be provided to the group to inform the development of falls prevention interventions.

3.2.2 Incident data

Within the Datix Cymru system, incident reports are collected using an electronic form which is available for all Health Board staff to access. Where a staff member has an NHS Wales email address, a logged-in form can be used which auto-populates the reporter's details and allows for patient details to be retrieved using the NHS Number. For those staff members without an email address, an alternative open access form is available, without auto-population or the ability to search patient details for information governance reasons (NHS Wales Shared Services Partnership, 2023).

The incident form comprises of a range of coded, date/time and free text fields used to capture information about the incident being reported. A number of the fields are mandatory and the incident form cannot be submitted without these being completed. Some additional fields are disclosed during the completion of the form, triggered from certain incident characteristics. For example, if medication is selected as the incident type, additional fields disclosed to capture the details of the medication involved, such as name, dose and form. An overview of the key data collected via the incident reporting form is given in Table 3.1.

Table 3.1 – Key incident report data fields

Field description	Mandatory	Field type	Example content (fictional)
Incident date	Y	Date – dd/mm/yyyy	
Incident time	N	Time – hh:mm	
Reported date	System generated	Date – dd/mm/yyyy	
Responsible service	Y	Single-pick coded	Critical care
Incident location	Y	Single-pick coded	Prince David Hospital / Ward 7 / Bathroom
Incident description	Y	Free text	
Immediate actions taken	Y	Free text	
Incident classification	Y	Single-pick coded	Accident, injury
Incident category	Y	Single-pick coded	Slip, trip or fall
Incident sub category	Y	Single-pick coded	Fall from commode
Reporter's view on level of harm	Y	Single-pick coded	Severe
Communication – who has been informed of the incident	N	Multi-pick coded	Consultant; Estates; Next of kin

Person affected	N	Free text fields for forename and surname	Jon Doe
NHS Number	N	Numerical	4857773456
Date of birth	N	Date – dd/mm/yyyy	01/01/1900

Upon submission, the incident form is made available to the relevant manager who will review and complete additional information on the management and actions taken in response to the incident report.

3.2.3 Developing a query

Details of submitted incidents can be extracted from the Datix Cymru system using a query. The individual aspects of the query used to extract the falls dataset and rationale for inclusion or exclusion are set out below.

Incident date

Including the incident date within the extracted data allows analysis of the volume of incidents over time and seasonality across months. The incident date can also be used to calculate the day of the week on which incidents have occurred to allow analysis of differences between weekdays and weekends, as well as differences on individual days.

In order to maximise the numbers of incidents available for analysis, an incident date range of 01/03/2022 to 31/12/2023 was selected. Prior to 01/03/2022, incident reports were held in a previous version of the incident reporting system, known as Datix Web. While falls incidents were captured in Datix Web, the data structure, fields and incident coding were different. This makes analysis of incidents across the changeover date challenging.

Incident time

When reporting an incident, a non-mandatory field is available to record the time of the incident in hours and minutes. Initial checks of incident data demonstrate that 17.5% of patient fall incidents do not have a time recorded. This proportion reduces to 15.2% when unwitnessed falls are excluded.

Including incident time within the extracted data allows analysis of incidents by time, which may demonstrate correlation with other factors such as patient wake/sleep, mealtimes or other ward activities.

Responsible service

The ‘responsible service’ field captures the speciality with responsibility to investigate the incident. For falls incidents, this is the speciality of the area in which the fall occurs. Including this data allows for analysis of differences in falls between different clinical specialities, as demonstrated by Gillespie *et al.* (2021). The responsible service can also give an indication of the types of medical conditions that patients are likely to be suffering from and in some circumstances, patient demographics. It is reasonable to expect that patients on an orthopaedic specialty ward have some form of musculoskeletal problem. Similarly, it could be reasonably surmised that patients in an induction of labour ward are of child-bearing age, or patients on a care of the elderly ward are over 60 years of age.

Incident location

Including the incident location within the extracted data allows analysis by location. For example, the number of falls in a community hospital can be compared to an acute hospital. Where patient areas have different layouts or other physical characteristics, incident location may be used to analyse any difference between the numbers of falls. For example, whether traditional nightingale style wards have more or fewer falls than other ward layouts.

Incident description and immediate action taken

The free-text ‘incident description’ and ‘immediate actions taken’ fields include important information about the circumstances of patient falls that may not be captured within other fields. In a falls context, this description may contain additional information about the type of fall and potential contributory factors, such as ill-fitting footwear. The effectiveness of using free-text for thematic analysis is supported by Jabin *et al.* (2019), who demonstrate its value in identifying underlying themes across incident reports. Adopting this approach to use incident description information, leads to a more holistic understanding of incidents and facilitates targeted interventions.

Incident classification, category and subcategory

Incident classification is a pivotal tool for selecting and analysing specific types of incidents. Despite the subjectivity of incident classification – with decisions initially made by the incident reporter, at a time when the full details of an incident may not be known - it is considered robust enough to use for selection of incidents for further analysis. The validity of using incident classification as a foundation for analytical selection is demonstrated in the work of Hussain *et al.* (2019), who utilised it in their study of diagnostic errors within emergency departments across England and Wales. This underscores the potential of incident classification to facilitate targeted investigations.

Reporters view of the level of harm

The level of harm recorded by the reporter ranges from no harm, such as a fall without injury, to catastrophic, in which an incident has led to the death of a patient. Quantifying the level of harm is essential to support the targeting of safety improvements to the areas of greatest impact and to explore whether specific incident sub categories are more harmful. While the level of harm is often included

within published incident data (Welsh Government, 2021a; Welsh Government, 2021b), the literature review showed that use of harm levels within incident analysis was limited.

3.2.4 SQL Query

The inbuilt search functionality within the Datix Cymru system was used to develop the query used to extract incident data. The rationale for each field and value included within the query is outlined in Table 3.2 and the resultant SQL code is shown in Figure 3.1.

Table 3.2 – SQL Query

Field	Explanation	Rationale
Incident date	The date of the fall incident as recorded by the incident reporter. Limited to incidents reported on or after 1st March 2022 and on or before 31st December 2023	Limit returned records to those submitted since the introduction of Datix Cymru to ensure data consistency, while maximising the range of data available.
Incident affecting	Incidents coded as affecting a patient	Staff accidents and falls are also reported using the Datix Cymru system, therefore selecting 'patient' as the person affected by the incident excludes these records.
Incident location	Incidents recorded with the inpatient hospital sites as the location	To exclude community falls.
Incident classification, category	Incidents coded as 'Accident/Injury' > 'Slip, trip or fall'	To include patient falls and exclude other types of injury.
DWEB reference number	Only incident reports where the field is blank are included.	To exclude incidents submitted via the previous Datix Web system which were transferred to Datix Cymru.
Validation status	Only incident reports that are not rejected are included.	Rejection is used to ensure data quality by identifying those incidents that may be duplicates or have been submitted in error.

```
incidents_main.recordid IN (

    SELECT

        incidents_main.recordid

    FROM

        incidents_main

        LEFT JOIN udf_values AS udf_1 ON (((incidents_main.recordid = udf_1.cas_id

            AND udf_1.mod_id = '3'

            AND udf_1.field_id = '1'

            AND udf_1.group_id = '0')))

    WHERE

        ((((udf_1.udv_string IS NULL) OR (udf_1.udv_string = '')))

        AND ((CAST( FLOOR( CAST( incidents_main.inc_dincident AS FLOAT ) ) AS DATETIME) BETWEEN '2022-03-01
00:00:00.000' AND '2023-12-31 00:00:00.000'))

        AND ((incidents_main.inc_affecting_tier_zero IN ('PT123')))

        AND ((incidents_main.inc_type_tier_one IN ('TR2')))

        AND ((incidents_main.inc_type_tier_two IN ('T140')))

        AND ((incidents_main.location_id IN (

            SELECT DISTINCT id FROM location WHERE [left] BETWEEN (

                SELECT [left] from location where id ='1258')

                AND (SELECT [right] from location where id ='1258') OR [left] BETWEEN (SELECT [left] from
location where id ='897')

                AND (SELECT [right] from location where id ='897') OR [left] BETWEEN (SELECT [left] from location
where id ='793')

                AND (SELECT [right] from location where id ='793') OR [left] BETWEEN (SELECT [left] from location
where id ='846')

                AND (SELECT [right] from location where id ='846'))))

                AND (((incidents_main.rep_approved != 'REJECT' OR incidents_main.rep_approved IS NULL))))

    GROUP BY incidents_main.recordid)
```

Figure 3.1 – SQL Query code

3.2.5 Data extraction

Once the query was run, the resulting list of incident reports was extracted as a .csv file using a mapping known as a ‘listing report’. The listing report template identifies the fields to be included and the order in which they are displayed in the resulting .csv file.

In order to extract the required fields for analysis, a custom listing report was created to ensure that only the necessary fields were included and any irrelevant or patient identifiable fields were excluded. This listing report template was saved so that the data could be re-extracted if necessary.

3.2.6 Information governance

When dealing with information relating to individuals, there are legal and ethical requirements to be considered. This is especially important when dealing with information relating to individuals’ physical and mental health. Within UK law, the General Data Protection Regulations set out the key principles under which organisations must operate when dealing with personal information (Information Commissioner's Office, no date).

Prior to the commencement of the research project, advice was obtained from the Health Board’s information governance department. A Data Protection Impact Assessment for the project was prepared and signed off.

The use of pseudonymisation and secure storage are the primary ways in which the confidentiality of the incident report subjects is ensured.

The data within the Datix Cymru system are secured using user profiles which ensure that individuals are only able to access those incident records that are relevant to their area of work or role within the Health Board. Logins to the system are managed via Microsoft Entra ID and contain multiple layers of protection from unauthorised access (Microsoft, 2024).

While the SQL query generates a list within the Datix Cymru system which contains the details of the affected patient as part of the incident record, the fields containing these details are deliberately excluded from the listing report used to generate the .csv file. This pseudonymises the incident reports, to reduce the risk of individual patients being identifiable without additional information from other sources.

Guidance and training for incident reporters state that personal identifiable information should not be included within the incident description or immediate actions taken. This reduces, but does not completely remove the risk of patient details being included within the pseudonymised file. Incident managers are trained to remove patient details erroneously recorded within these fields, which provides a secondary layer of protection.

After extraction from the Datix Cymru system, the .csv file was searched for potential patient identifiable information, to allow redaction as necessary. Patterns of alphanumeric characters were used to identify hospital or NHS numbers. The search did not return any patient identifiable information.

The extracted .csv file was stored securely within the NHS Wales Microsoft 365 tenant and access restricted. The file was subject to access control as standard within Microsoft 365, with two-factor authentication being required when appropriate, such as in the event of access from a remote working device.

3.2.7 Extracted data preparation

The .csv file was opened using Microsoft Excel. On visual inspection of the file, one error was identified as an incident description started with an equals character ‘=’, causing Excel to treat the field contents as a function. This was manually corrected by removing the erroneous character.

The file was searched for duplicate records using the ID field, which is automatically assigned by the Datix Cymru system on submission of the incident. The 121 duplicate records were removed, leaving 5767 unique incident reports for analysis.

To enable analysis of incident severity, additional columns were added and VLOOKUP used to generate a numerical severity for the fields [severity of incident

post investigation] and [reporters view on level of harm]. Records without a recorded severity were assigned a null value. The mapping from categorical to numerical values is show in Table 3.3.

Table 3.3 – Incident severity

Severity	Value
None	0
Low	1
Moderate	2
Severe	3
Catastrophic	4

Incident date was split into day, month and year columns using '/' as the delimiter to aid analysis. A formula was used to record the name of the day on which the incident occurred.

Blank time bands were filled with 'Not recorded' to allow for these to be easily shown when presenting data graphically.

3.3 Data analysis

3.3.1 Introduction

Employing descriptive statistics as a foundational analytical tool for incident report analysis offers provides a preliminary yet insightful examination of the data. This approach enables researchers to succinctly summarise key characteristics of the dataset, including trends, distributions, and central tendencies, thereby laying the groundwork for more complex analyses. Mishina *et al.* (2023) exemplify this technique through their analysis of incident reports in an inpatient psychiatric ward in Finland, illustrating how descriptive statistics can illuminate the data landscape and uncover patterns within variables. According to Ali and Bhaskar (2016), descriptive statistics play a crucial role in delineating the nature and interrelationships among variables, facilitating a structured understanding of the data at hand. By applying this approach, researchers can efficiently navigate vast datasets, identify salient

features, and formulate hypotheses for subsequent, more nuanced investigations. This rationale underscores the value of descriptive statistics not only as a preliminary step in data analysis but also as a strategic choice for enhancing the clarity and interpretability of incident report data.

3.3.2 Software and tools

A wide range of statistics and data analysis software applications are available, ranging from general programmes such as SPSS (IBM, 2024) and NVIVo (Lumivero, 2023), to highly specialised tools designed for specific data analysis scenarios. Many of these applications involve a cost to purchase the programme or a license cost for ongoing access.

The primary research question considers the use of analytical techniques within a healthcare setting. Therefore, in order for this study to reflect the available tools and resources available within a typical Welsh Health Board, only software which was available without cost or as part of an existing all-Wales contract were used. The primary software applications used were:

- Microsoft Excel
- Microsoft Power BI
- Anaconda
- Python
- NLTK

3.3.3 Levels of harm

Within Datix Cymru, incidents are assigned a level of harm, known in the system as ‘severity’. The assessment of harm is initially completed by the person reporting the incident. Prior to the incident being closed, the incident manager records their assessment of the level of harm caused to the patient following any further review or investigation of the incident. The harm field is coded and one of five levels of harm

can be chosen. The levels are set out in Table 3.3. An incident where no harm occurred to the patient is also known as a ‘near miss’. At the other end of the harm scale are catastrophic incidents, which have led to death or severe and permanent harm. Guidance on the application of harm levels with NHS Wales is set out by Welsh Government (2023b, p142).

3.3.4 Incident date

Each reported incident has an incident date as this is a mandatory field for the reporter to complete. Counting the numbers of incidents submitted on a date can give a measure of incident reporting over time. Numbers of reported falls were plotted monthly between the dataset period of 1st March 2022 – 31st December 2023. In addition, the numbers of reported falls in a ward where a training programme had been implemented were plotted over the same period.

3.3.5 Incident time

It has been demonstrated that there is variation in fall rates between daytime and nighttime hours (Magota *et al.,* 2017), and understanding patterns in incidents across a 24 hour cycle may uncover common times of falls risk.

The reporter has the facility to include the time of an incident within the incident reporting form. The time is recorded in HH:MM 24h format. The Datix Cymru system can group these into time bands for the purpose of data export. Incident time is a non-mandatory field as not all reportable patient safety incidents occur at a specific time.

Within Microsoft Excel, the COUNTIF function was used to count the number of incidents reported within each time band, and those where no time was recorded.

Numbers of reported falls were plotted against hourly time bands over the 24-hour period.

3.3.6 Incident description

Text from the incident description field of each incident was extracted from the .csv file into a .txt file to allow analysis. The resulting text file contained approximately 1.5 million characters.

Python was used to perform basic natural language processing using the Natural Language Toolkit (NLTK) (NLTK Project, 2023). The .txt file was loaded into JupyterLab.

The text within the file was tokenised, to separate paragraphs and sentences into individual words. Stop words – commonly used words such as ‘and’, ‘the’ and ‘a’ were removed. Frequently occurring patterns of two words and three words (bigrams and trigrams respectively) were examined and the most frequently used words plotted.

Concordance analysis was performed using the phrase “head on” to identify object and structures on which patients commonly strike their head during a fall. These results were categorised to quantify the numbers of incidents relating to each object or structure.

3.3.7 Incident type

A pivot table was used to total the number of incidents for each level of harm against the incident sub category. Incident types with fewer than 350 records were excluded. Harm was grouped into ‘Moderate or greater’ (moderate, severe, catastrophic/death) and ‘Low or no harm’ (low, no harm).

The expected values for each combination of harm and type were calculated using the formula [column total*(row total/table total)]. The X^2 value and the resultant ρ value were calculated.

Chapter 4 – Results

4.1 Levels of harm

The falls dataset was split by level of harm. The numbers of incidents recorded with each initial harm level is shown in Table 4.1 below.

Table 4.1 - Initial harm

Level of harm	Count	Percentage of total
None	2051	35.56%
Low	2884	50.01%
Moderate	764	13.25%
Severe	67	1.16%
Catastrophic	1	0.02%
Total	5767	

While the distribution of incidents within the harm categories is broadly similar to published data, the percentage of incidents categorised as no harm is lower than found in an extensive review of NRLS data by Healey *et al.* (2008).

The recording of levels of harm is hampered by the subjectivity of the levels themselves and a lack of supporting information. Confusion can also occur as the level of harm is intended to measure the harm caused by the Health Board to the patient. Where a patient has fallen and sustained a fracture, the level of harm recorded is the harm caused by actions or inactions of those working for the Health Board. When recording an incident where the patient has sustained an injury, reporting staff can be reluctant to record the incident as ‘no harm’, even if the care provided by the Health Board was appropriate and all necessary steps taken to prevent the fall.

The distribution of incidents across the levels of harm within the falls dataset is broadly similar to that demonstrated for all patient safety incidents reported within NHS Wales, where the most recently available data shows 88.2% of incidents (n=83,265) having low harm or no harm, which is comparable to 85.57% (n=4935) of

the falls data set. The percentage of incidents considered catastrophic is also comparable, with 0.04% (n=37) of all NHS Wales patient safety incidents and 0.02% (n=1) of the falls data set, although this is potentially affected by the small numbers of incidents involved (Welsh Government, 2021b).

4.2 Incident date

Incident reports were plotted against the month and year in which they occurred. Numbers of falls incidents per month ranged from 231 (February 2023) to 314 (December 2022). The mean incidents per month was 269.8.

The risk factors for falls are multi-factorial and vary between patients (Eldridge, 2007). Therefore, it would not be unexpected for the numbers of falls each month to be subject to variation. A month where the cohort of admitted patients has a greater number of risk factors for falls would likely see a greater number of falls. In the absence of other interventions or changes, this would be considered ‘common cause’ variation – that which is expected. ‘Special cause’ variation is that which is unusual and may indicate external influences on a system, such as the sudden drop in patients attending hospital during the Covid-19 pandemic (Thornton, 2020).

Using a Statistical Process Control (SPC) chart, common cause and special cause variation can be identified. An SPC chart highlights where a measure is deteriorating or improving (NHS Improvement, 2019a; NHS Improvement, 2019b).

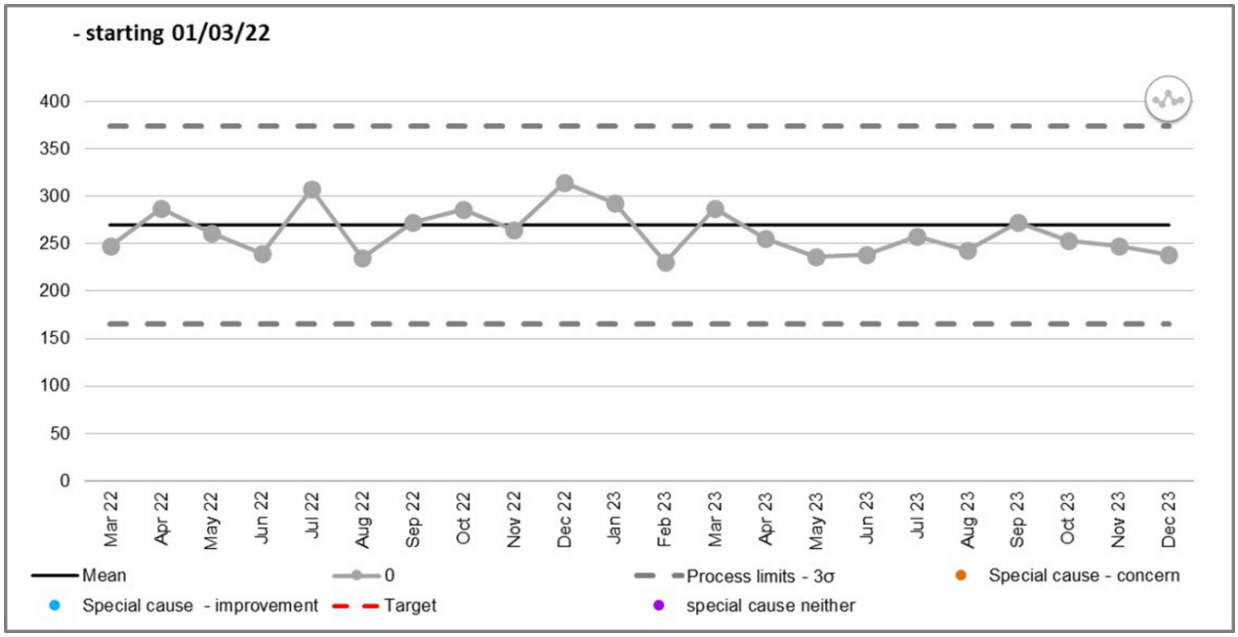

Figure 4.1 – Number of falls incidents per month by incident date

The SPC chart was generated using the NHS England Statistical Process Control Tool version 4.6 (NHS England, 2023).

The chart demonstrates common cause variation, with points within the process limits, set at 3 Sigma. There are no indications of special cause variation – it should be noted that the September 2023 data point is 273, so breaks the run of consecutive data points below the mean (269.8).

While no special cause variation was identified at Health Board level, the volume of incidents can obscure changes within individual areas. This is demonstrated by plotting falls by month from an individual Mental Health Services for Older People (MHSOP) ward.

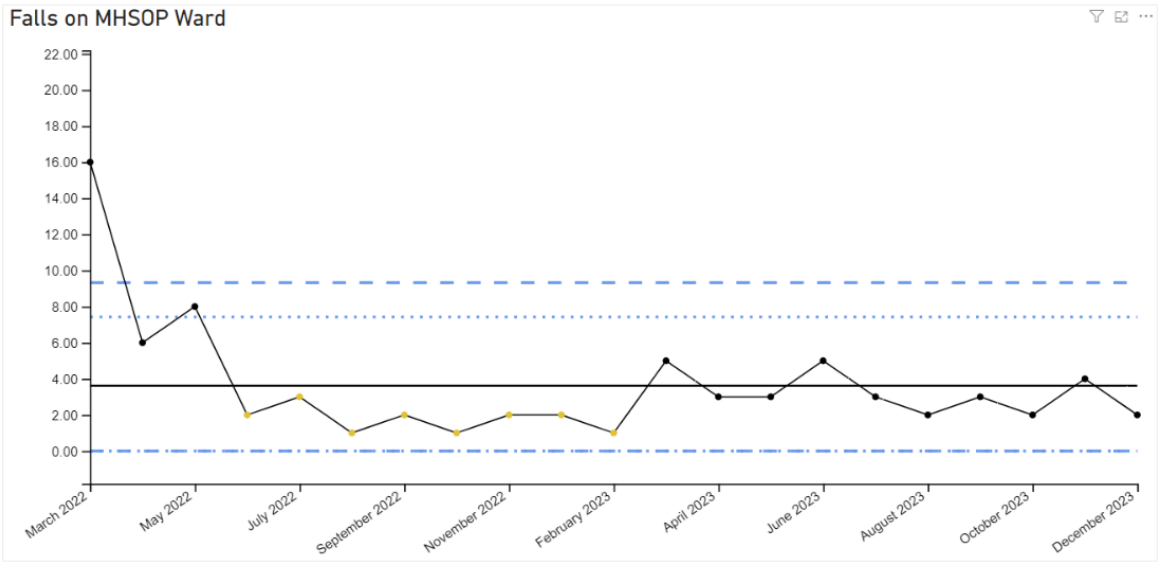

Figure 4.2 – Number of falls incidents per month on an MHSOP ward

The graph identifies special cause variation (highlighted in yellow), following the introduction of a falls prevention and management training programme on the ward. The run of 8 points below the mean indicates a shift in process (NHS Improvement, 2019a).

4.3 Incident time

Following the data preparation outlined in section 3.2.7, falls per time band were plotted. The records without a recorded time band (n=1018) were excluded. The resulting graph is shown in Figure 4.3.

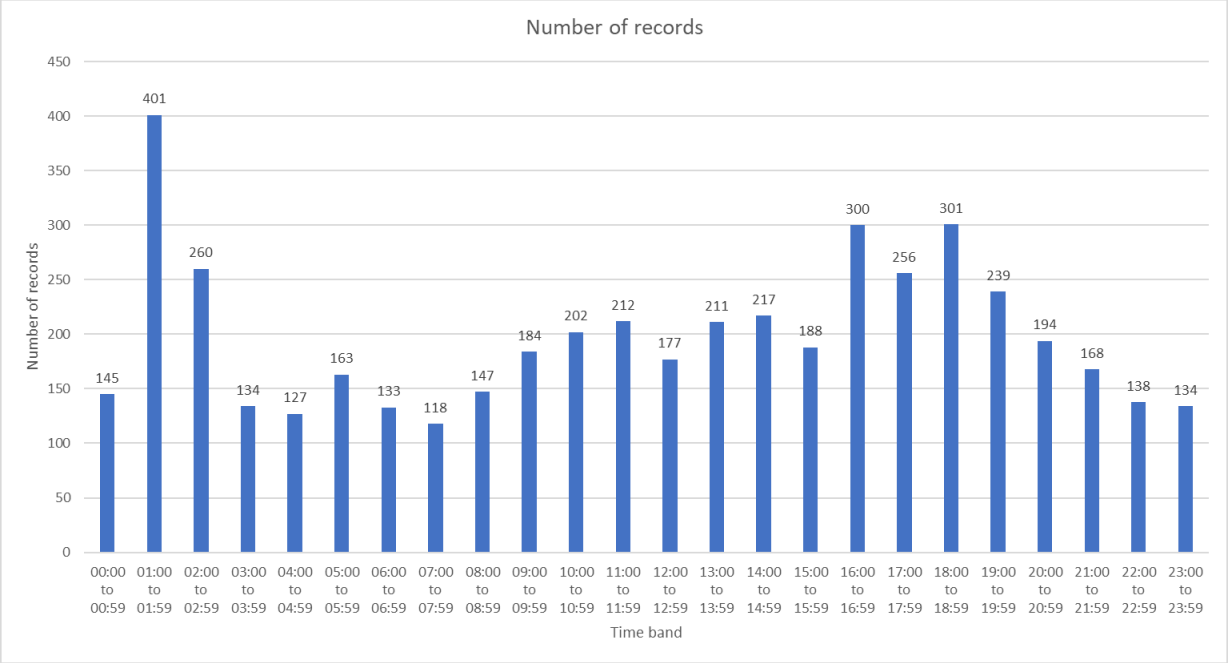

Figure 4.3 – Number of falls incidents per time band

The analysis of incidents against time bands shows variation across the 24 hours of a day, with the lowest rates early in the morning and the highest rates between 01:00-01:59 and a smaller peak late afternoon between 16:00 and 19:00. Two sharp increases in falls are seen from 00:00-00:59 to 01:00-01:59 and from 15:00-15:59 to 16:00-16:59. This variation is not unexpected as different patient activities undertaken over a 24-hour period will carry differing risks of falls. It is logical that the risk of falls is lower when the majority of patients are asleep and higher when they are mobilising within the ward environment.

It is important to caveat that there are a significant number of incidents where the time of the fall is not recorded (17%, n=1018). For some incidents, this may be appropriate – when a patient is found on the floor the time of the fall may not be known. In other cases, the time of the fall is missing as this is not a mandatory field when reporting. It is therefore unknown how these incidents would be distributed if the time had been recorded. While it could be considered reasonable to assume that these would be distributed evenly across the time bands, it is possible that other factors affect the completion of the time field. Falls occurring at night may be more likely to be unwitnessed, so the exact time of the fall is unknown. Alternatively, it may

be that incident forms completed at night are more thoroughly filled out as staff have more time.

While data quality could be improved through better completion of the time field, the insight provided by analysing incidents in this way is clear. The analysis, in itself, does not explain the reasons for the variation in falls across the 24-hour period. However, it does highlight areas for further exploration.

The temporal analysis of falls data shows some correlation with studies included as part of a mini systematic review by Manfredini *et al.* (2012). Pellfolk *et al.* (2009) described a peak in falls between 5pm and 6pm, similar to the falls dataset. However, the peak between 1am – 2am is not shared with any of the studies reported.

The 1am – 2am peak was unexpected and significantly higher than the next highest hours (6pm – 7pm and 4pm – 5pm). Due to the lack of published studies sharing this peak, further analysis was conducted. As the peak occurred during a time period where patients would typically be sleeping (Lee, Low and Twinn, 2007), the possibility of a data quality issue was explored.

Further investigation found errors with the system generated time bands, with some records having an incident time which did not match with the time band. In order to address this issue, a new time band for each record was generated in Excel using the incident time (where recorded). The updated distribution is shown in figure 4.4.

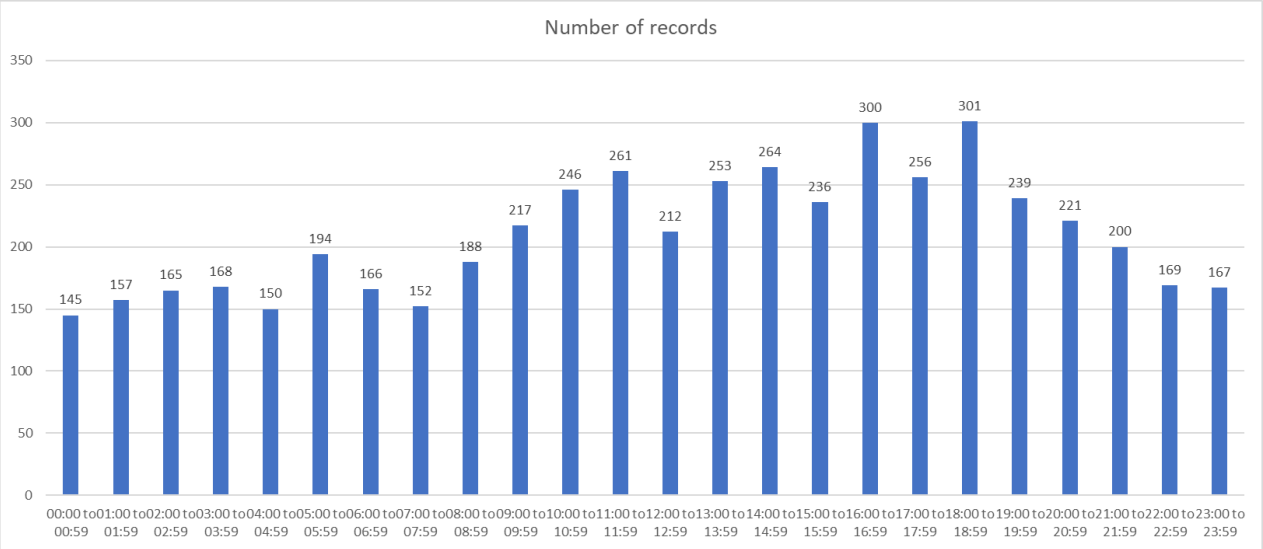

Figure 4.4 - Corrected number of falls per incident time band

Following correction of the system-generated time bands, the peak previously shown between 1am – 3am is no longer evident. The distribution pattern across the rest of the 24 hour period remains.

This exploration may involve drawing in data and information from other sources. When considering the peak at 16:00 for example, reviewing ward information shows that this is the end of visiting time on most inpatient wards (Cardiff and Vale University Health Board, 2024). It could be hypothesised that patients are likely to have been stationary either in bed or in a chair during the visiting period. After visitors leave, the patients may then try to stand to visit the toilet or to move between bed and chair, resulting in a fall.

During the Covid-19 pandemic, hospital visiting was restricted (Welsh Government, 2021c), only being allowed in exceptional circumstances, such as at the end of life. The inpatient population and other factors affecting falls differed between pandemic and non-pandemic time frames, therefore raw fall numbers are not necessarily directly comparable. However, there is value in considering any differences between 24 hour distributions during restricted and non-restricted visiting.

To undertake this analysis, the period of initial hospital visiting prohibition (26th March 2020 – 25th August 2020) was plotted against the equivalent period with no visiting restrictions (26th March 2023 – 25th August 2023). The comparison non-restricted time period was selected to ensure that variation due to seasonality was avoided as it has been demonstrated that fall rates vary over a yearly cycle (Kakara *et al.,* 2021).

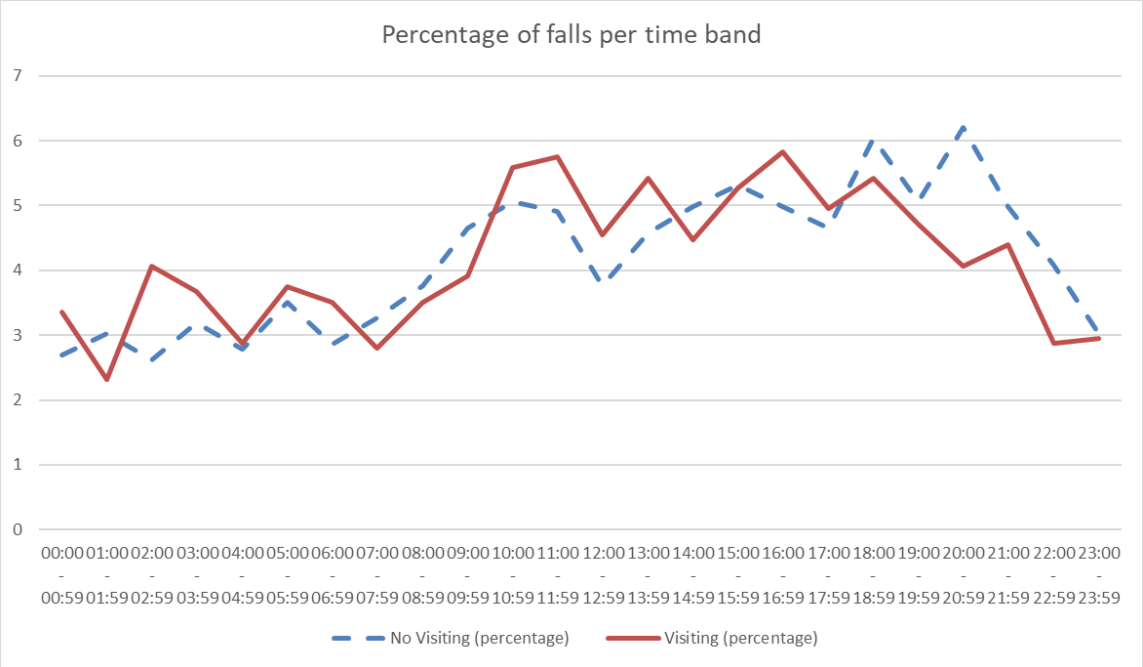

Figure 4.5 – Percentage of falls per time band

Plotting across a 24h period has been used in other industries to analyse events, such as photo and social media post counts (Juhasz and Hochmair, 2019), and some use in healthcare has been documented (Mandfredini *et al.,* 2012).

4.4 Incident description

The quantity of text recorded within the incident description fields was extensive, with an average of 260 characters per incident report.

The most frequently included bigrams and trigrams are listed in Table 4.1 and Table 4.2.

Table 4.1 - Bigrams

Bigrams	
compos	mentis
heart	rate
en	suite
â€	“
speciality	hub
support	worker
health	care
cognitive	impairment
manual	handling
service	user

Table 4.2 – Trigrams

Trigrams		
care	support	worker
uhl	falls	protocol
health	care	support
per	uhl	falls
night	site	pract
did	n't	hit
with	zimmer	frame
neuro	obs	done
no	visible	injuries
complaint	of	pain

Bigrams and trigrams are sequences of two and three words respectively. NLTK can be used to identify the most frequently occurring within a section of text.

Within tables 4.1 and 4.2, some sequences relate to job roles, such as ‘health care support [worker]’. ‘Service user’ is often used to refer to patients in mental health

settings. The ‘â€ “’ bigram is likely to be the result of a right single quotation mark character being incorrectly encoded (Kuhn, 2007). This could be corrected by removing these characters from the text file prior to analysis.

NLTK was used to count the number of times a word or phrase is used within a section of text. Within the incident description field of the falls dataset, “slippers” was used 74 times and “bin” was used 76 times.

The 25 most frequently occurring words were plotted using matplotlib, with the resultant chart included as Figure 4.4 below.

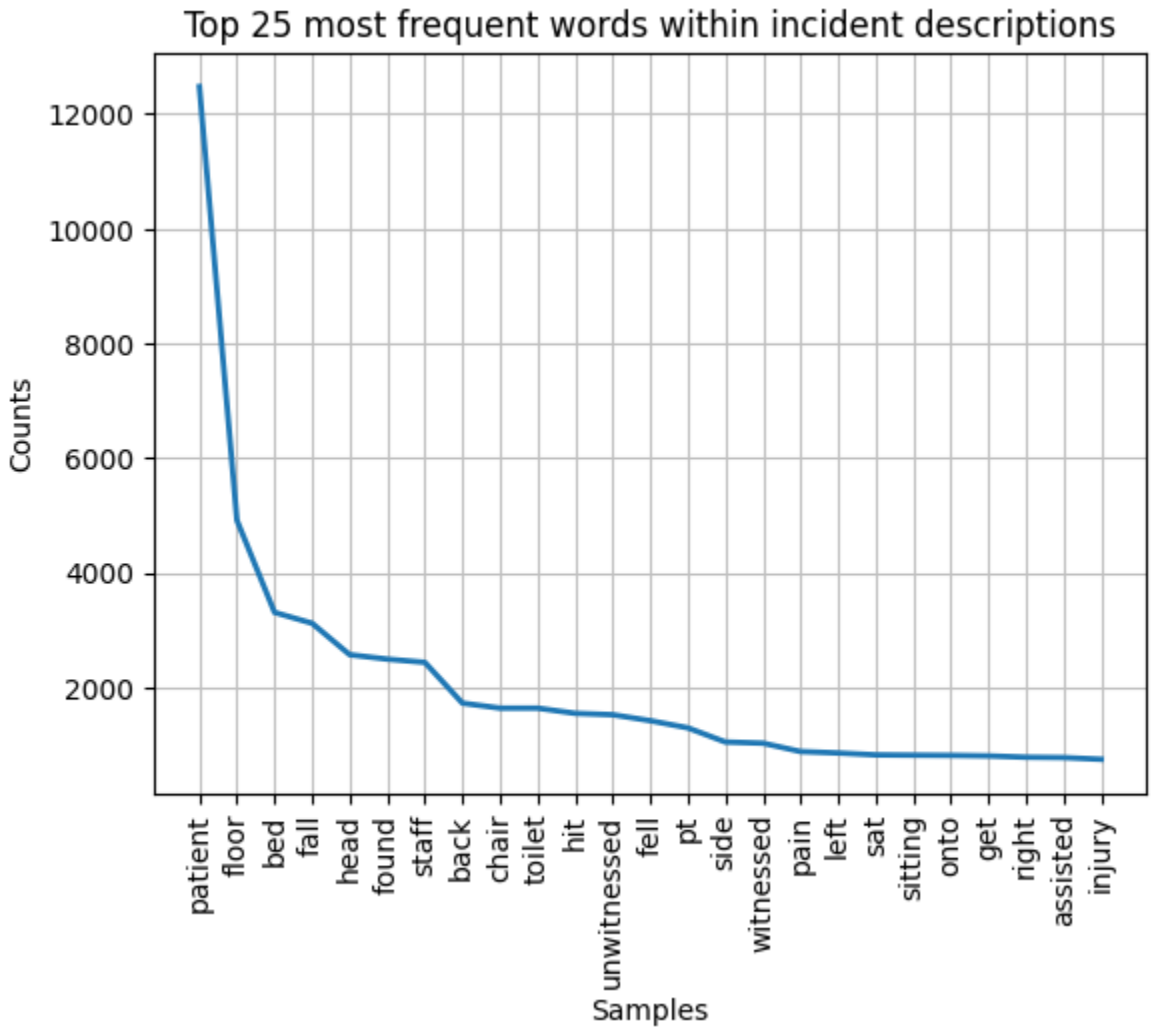

Figure 4.4 – Frequently occurring words

The figure demonstrates that ‘bed’ is mentioned more frequently than ‘chair’ and ‘unwitnessed’ is mentioned more frequently than ‘witnessed’.

Concordance analysis was performed for the phrase ‘head on’ to examine the objects and surfaces from which patients are sustaining head injuries during falls. A sample of the output from the analysis is included in Figure 4.5.

```
Displaying 25 of 395 matches:
 unwittnessed fall . No pain in the head on palpation . Superficial wound on r.
ds onto the floor . Patient hit his head on the floor . '' Alerted that patient
f the room and had a fall , hit his head on side table . I went to answer call
mmer frame and had a fall , hit his head on the side table . patient fell unwit
. He stated that he did no bang his head on anything . Pt had an unwitnessed fa
or unwitnessed . It appears she hit head on chair Patient had an unwitnessed fa
chair and hit her right side of the head on the wall.Bruise to right knee and s
cerns . witnessed fall , banged his head on the board The NA specialling the pa
 side and then fell forward and hit head on the wall on the way down Patient tr
his side , hitting his shoulder and head on the wall of the cubicle . No loss o
d , patient states she fell and hit head on the edge of the bed when mobilising
down on the floor , did not hit her head on anything . Denied any pain . Patien
 floor . Patient states she hit her head on the bed rail on the way down but th
is sitting on the floor resting his head on the shower seat.advised patient to
 floor on his left side and hit his head on the bed end of 33 . Patient was fou
hair tipped back . Ioan scraped his head on the chair behind as it fell . He cr
d fell on to floor . She banged her head on the bedside table and there is a lu
formed . Patient reports he hit his head on radiator . Reviewed by on call , no
l backwards to the floor and bumped head on bottom of bed . Found on the floor
r buttocks and elbow and tapped her head on the floor . She immediately sat up
alling to his left side and hit his head on the floor as he landed . Patient sh
uld not remember if she had hit her head on the plastic part of the bedrail , s
m . She said she might have hit her head on floor as well . She sustained a ver
Zimmer frame . Lost balance and hit head on weighing scales . Small laceration
rds , hitting his left shoulder and head on the foot of Bed One and landing on
```

Figure 4.5 – Concordance analysis

The output of the concordance analysis was exported to Microsoft Excel. Each row was categorised to identify the object on which the patient hit their head during the fall. Incidents where the object could not be established from the incident description were categorised as ‘unknown’ and incidents where the description indicated that the patient did not hit their head during the fall were categorised as ‘none’.

The categorisation of incident records allows quantification of the objects which are most frequently the cause of a head injury during an inpatient fall. The results of this analysis are set out in Table 4.3.

Table 4.3 – Object categorisation

Object	Number of incidents
Floor	100
None	51
Wall	41
Bed	40
Unknown	28
Door	26
Table	21
Chair	17
Bin	13
Sink	8
Trolley	6
Handrail	6
Luggage	4
Cupboard	4
Radiator	3
Toilet	3
Cabinet	3
Windowsill	3
Shower chair	2
Zimmer frame	2
Board	1
Scales	1
Furniture	1
Locker	1
Drip stand	1
Wheelchair	1
Bench	1
Fall	1
Hoist	1
Obs machine	1
Magazine stand	1
Shower seat	1
Bath	1
Commode	1

4.5 Incident type

Incidents are categorised by the reporter prior to submission, using a pre-defined list of classifications, categories and sub categories. Patient falls are coded as 'Accident, Injury' > 'Slip, trip or fall', and then further divided into a number of sub categories, including 'found on floor' and 'fall from chair'.

The extracted dataset included the classification, category and sub category for each incident. As the fields are mandatory at incident submission, there were no uncoded incidents within the dataset.

Following the methods outlined in section 3.3.4, the numbers of incidents with each of the most common sub categories were counted against the level of harm. The resulting data are shown in Table 4.4.

Table 4.4 – Incidents by sub category and harm

	Fall from bed/trolley	Fall from chair	Fall using bathroom/ toilet	Fall/slip from chair, bed or trolley	Found on the floor	TOTAL
Moderate or greater harm	614	615	369	429	1053	3080
Low or no harm	726	686	448	467	1254	3581
TOTAL	1340	1301	817	896	2307	**6661**

The null hypothesis (H_0) was set as incident (fall) sub category and the level of harm being independent.

This was examined using a Chi-Square X^2 test, which is used to assess whether particular combinations of categories, in this case harm and sub category, occur more frequently than would be expected to by chance (Swinscow, 1997).

It is not unreasonable to hypothesise that some fall types may be more harmful than others. A fall from a bed or trolley generally involves a greater height than a fall from

a chair. Applying a simple data analysis technique allows for this to be explored statistically.

The X^2 value was 2.33 and the ρ value was 0.68, therefore there was insufficient evidence to conclude that there is an association between the incident sub category and level of harm.

While the pseudonymised falls dataset did not include patient demographics, a similar approach could be taken to explore levels of harm, sub-divided by characteristics such as gender or age.

Chapter 5 – Discussion

5.1 Falls data analysis

Using the falls dataset allowed a range of basic data analysis techniques to be explored and demonstrated the additional insight gained from this approach that would not have been possible when looking at individual patient safety incidents.

Individual review of incidents has an important place in an organisation's approach to patient safety, but this is best aligned with the most serious incidents which have caused high levels of patient harm. However, this should be supplemented with wider analysis of themes and trends within incident reporting data.

Analysis of the falls dataset produced valuable insights which have application within a healthcare setting. Analysis of incidents by type in section 4.5 demonstrated that falls from chairs were not statistically more harmful than falls from beds or trollies. This knowledge can be used as part of falls awareness training and to support patients being assisted to 'sit out' rather than remain in bed, something which has been shown to prevent deconditioning and consequently to reduce the risk of falls (Maher, 2021). This demonstration of one incident analysis aspect shows the insight that could not have been obtained through individual incident analysis alone. Detailed discussion of each aspect of analysis is set out in this chapter.

5.2 Levels of harm

The analysis of falls incidents by level of harm showed a harm profile broadly in line with national reporting across all patient safety incident types. Reporting high numbers of incidents has traditionally been considered an indicator of a good 'safety culture' within an organisation, where staff feel open to report incidents and near misses, without fear of blame (Flott *et al.,* 2018), although the insight and resultant improvements provided by these high frequency, low harm incidents is limited (Mayer *et al.,* 2016).

The level of harm sustained by a patient during a fall is partially dependent on their age, physical condition, ongoing treatments and co-morbidities (AlSumadi *et al.,* 2023). Insight is gained through comparison of the harm profile for an area and incident type with similar areas either within a healthcare organisation, or from an equivalent peer organisation. Care must be taken to select a peer with a similar level of services and patient population as comparing to organisations which are neighbouring or within the same region may be unreliable due to varying structures. With other aspects of healthcare data, comparators are selected based on the characteristics of the organisation, such as whether it provides tertiary services. This approach is taken with mortality data by CHKS (CHKS, no date) to provide context and benchmarking between organisations which may undertake care or procedures for patients with varying complexity and underlying risk of mortality.

Considering the harm profile of a group of incidents gives an understanding of the potential impact on patients and the organisation, forming an assessment of risk from ongoing incidents.

5.3 Incident date

Reviewing numbers of incidents reported over a period of days, weeks or months can give an important insight into changes over time. It is important to consider that incident reporting is not a direct measure of patient safety incidents as the process is voluntary and there are barriers to reporting, including time and access to the system. In the absence of significant interventions or external pressures on the incident reporting rate, the numbers of reported incidents can be taken as a suitable proxy for the numbers of actual incidents.

The presentation of incident data is important as this can affect the conclusions drawn from the data and the decisions that are informed by these data. It is not uncommon to see incident numbers presented as a raw figure for each time period (Oxford University Hospitals NHS Foundation Trust, 2021). Presenting data in this way can lead to decision-makers overreacting to changes that are part of normal, expected variation. This can be demonstrated by considering the incident numbers shown in Figure 4.2. If this monthly data were presented in a table format, the

increase in falls between June 2023 and July 2023 might lead to a conclusion that the training programme had failed and was not reducing falls. This narrow view and comparison of two data points obscures the overall trend of a sustained shift in falls.

SPC charts encourage an appreciation that point-to-point increases can be part of common cause variation, or even part of an overall downward trend or shift. While SPC charts are not suitable where there are insufficient data points, where data are available, they provide decision makers with a much greater insight into common cause and special cause variation.

More widely within healthcare there is a gradual move towards the use of SPC charts, supported by initiatives such as the 'Making Data Count' programme from NHS Improvement, this should be considered as the primary way of presenting data on incidents over time. While it can be argued that interpreting SPC charts requires more knowledge than simple RAG ratings, the risk of inappropriate actions taken in response to individual data points is such that it is worthwhile investing time in education regarding SPC. More recently, a number of electronic SPC tools have been developed and, in some cases incorporated into existing software, supporting the interpretation of SPC charts (NHS Improvement, 2019b).

The most significant caveat when considering numbers of incidents over time is that within healthcare, demand is not consistent. The number of patients attending accident and emergency departments varies hour to hour and day to day, although usually in a predictable pattern (McAllan *et al.,* 2019), which feeds into the number of ward admissions.

Without the context of a denominator, it can be impossible to determine whether variation in the numbers of patient safety incidents is due to variation in activity within a healthcare setting. There is not one universal denominator that is suitable for all areas. Within an accident and emergency department, the denominator may be attendances, as a proxy for the how busy the unit is. In a ward setting, the number of bed days is more appropriate as this relates to the numbers of patients within the ward at any one time.

The most commonly used denominator for inpatient falls is 1000 bed days, which is also utilised at a national level as part of the National Audit of Inpatient Falls (NAIF) (Royal College of Physicians, 2015). Calculating falls per 1000 bed days requires

additional data from patient management systems which is not contained within the Datix Cymru incident reporting system. Using this measure gives a much truer reflection of positive or negative changes in the rate of falls as it corrects for changes in activity. However, it should be taken into consideration when analysing changes in incident rates that using 1000 bed days as the denominator does not provide any correction for changes in the inpatient population. While the number of occupied beds may remain stable over time, the demographics of the patients in hospital can vary, even being affected by external influences such as the weather (Oudin Astrom, Bertil & Joacim, 2011).

Although this study focuses on the use of incident data alone, greater insight is likely to be gained through the combination of data from multiple sources. In addition to the discussed advantages of a denominator to calculate incident rates, more complex data linkage at a patient level could provide even greater insight and enable understanding of patterns of falls during a patient's hospital stay, potentially answering questions such as whether multiple ward moves increases a patient's likelihood of suffering a fall while in hospital.

5.4 Incident time

Analysing incidents by the time of day at which they occur can provide specific areas of focus for further investigation. Many factors that affect falls through the day are related to patient activities and characteristics, such as periods of mobilisation and rest, toileting and other events within the ward.

For other incident types, different factors may contribute, including staff factors such as fatigue and dehydration (Brennan, Hardie & Oeppen, 2023).

Analysis of incident times can assist in considering how the incident is affected by other systems and processes within the provision of healthcare. Using incident time allows comparison of incidents occurring during daytime and night time hours.

The unexpected peak in falls between 1am-2am that was initially shown by the data analysis demonstrates the importance of considering the wider context of findings

from data and remaining inquisitive to potential causes for these findings. The potential error with system-generated time bands has been raised to the local Datix team for further investigation and escalation. This issue also serves to highlight the need for clinical engagement when considering data analysis findings as it is this clinical knowledge that aids interpretation of data and generation of safety interventions.

While not all incident types are suited to analysis by incident time, the valuable insight and prompt for further investigation shown through the analysis of the falls dataset demonstrates the utility of this analytical technique. Accuracy of the conclusions which can be drawn from this analysis is dependent on the completion of the incident time by the reporter. The strength of this aspect of analysis could be further enhanced through improved data quality. Capturing whether an incident occurred during daytime or nighttime hours could add valuable information in cases when the exact time of an incident is not known. Simple changes to the incident reporting form such as this could strengthen this analytical technique.

5.5 Incident description

The initial natural language processing performed on the falls data incident description demonstrates the potential insights that can be gained. While this is dependent on the level of detail given by the incident reporter, this study has demonstrated that freely available tools can be used to extract this additional information.

Caution must be applied when undertaking analysis of free-text fields as the recorded information is subject to variation in language and phrasing. Simplistic counting of words or phrases is unlikely to yield accurate insights. Searching falls incidents for the phrase ‘neuro obs’ would return records where the reporter states ‘neuro obs were completed’ as well as those where they state ‘neuro obs missed’.

An area where this approach may have a benefit would be in analysis of medication or equipment-related issues as the description could be searched for an individual

medication - ‘sodium valproate’ or a piece of equipment - ‘bladder scanner’. This form of analysis requires input from those with an understanding of the subject matter to ensure that appropriate synonyms, alternative names or common misspellings are included. In this example, sodium valproate may also be known by brand names including ‘Epilim Chrono®’ or ‘Epival®’ (NICE, 2024).

The plotting of word frequencies was of limited value in relation to falls incidents. Without the context for inclusion of a word, analysis of word frequencies is prone to error. While results from the test dataset showed that ‘bed’ was mentioned more frequently than ‘chair’ within the incident description, this may have been due to phrases such as ‘the patient was lifted into bed’ so it cannot be deduced that the fall was from or involving a bed, based on incident description alone.

The primary issues with individual word frequency analysis were mitigated through the use of the concordance function within NLTK to search for words and phrases, displaying these with the surrounding text to aid understanding of the context. A greater understanding of the nature of head injuries sustained during falls is gained through concordance analysis of the phrase ‘head on’. Concordance allows the object or surface on which the patient has hit their head to be rapidly identified:

“...frame and had a fall, hit his head on the side table. Pt had an....”
“...then fell forward and hit his head on the wall on the way down..”

It also allows exclusion of those incidents where ‘head on’ is included in the incident description, but context changes the meaning:

“...unwitnessed fall. No pain in the head on palpation. Superficial wound...”

This form of analysis was not noted in any of the studies forming part of the literature review, however its potential value is clearly demonstrated. Further insight was gained from grouping the output of the concordance analysis by the words following the search phrase so that the numbers of incidents where patients hit their head on specific objects or structures could be quantified. This insight was valuable as while some structures cannot be changed, some objects are removable, such as trolleys, bins and luggage. This presents an opportunity to improve safety by removing or considering the design of items that cause injury during a fall. While a robust metal bin may be appropriate from fire safety perspective (NHS Scotland, 2004), sharply

angled corners present a risk of significant head injury in the event of a fall. Safety may be improved by altering the bin design or relocating bins away from the immediate patient area.

As demonstrated by the utility of concordance analysis, it is important not to exclude the useful knowledge that can be gained by manual review of information. Concordance analysis presents information from the incident description in a way that can be rapidly assessed and includes important context. The aim of analysis should be to provide insight in a way which is useful and supports those using the data to draw appropriate and well-informed conclusions, or to highlight areas for further investigation.

5.6 Incident type

When reporting an incident, the reporter is required to select an appropriate coding, comprised of classification, category and sub category. While this can be subjective – at what angle does a ‘fall on level surface’ become a ‘fall on sloping surface’ – this is the primary method for dividing tens of thousands of incidents reported annually within a typical Health Board.

5.7 Patient demographics

While this study used a pseudonymised dataset as the basis for analysis, further opportunities for insight would be gained through inclusion of patient details, allowing analysis of incidents against patient demographics. Using patient identifiers, data could be linked to other sources, such as clinical coding and patient administration data to enable further opportunities for analysis and to establish new knowledge, such as calculating when during a patient’s hospital admission are they most at risk of falls.

5.8 Limitations

The most significant limitation of the study was presented through the use of an pseudonymised dataset. Within a non-research healthcare setting, analysis of incident data is likely to include access to patient demographics. This allows analysis of incident severity by subset of patient characteristics, such as gender and age. Taking this a stage further, data linkage between clinical coding and incident data would allow incidents to be analysed by patient conditions, procedures or outcomes. This has particular value when considering the equitability of healthcare services in line with the legal duty of quality (Welsh Government, 2023c).

While potentially valuable insight has been gained through analysis of the inpatient falls incident dataset, it is beyond the scope of the study to establish whether this insight translates into real-world improvements in prevention and management of inpatient falls.

The insights gained through the analysis of the reported incident data should be considered with the caveats of the voluntary nature and potential data quality issues inherent in an incident reporting framework. Where possible, the conclusions drawn from the data have been compared with other studies – this comparison highlighted the technical issues with the initial analysis of falls by time band – however, direct comparison with an alternative data source, such as clinical audits, would support or refute the validity of the analysis findings, although alternative data sources have their own limitations which must also be considered.

The analysis techniques used as part of this study have been shown to be appropriate for the specific incident type of inpatient falls. While it can be reasonably suggested that these techniques would be transferrable to other incident types, further research is required to demonstrate this and to consider whether any modification of the techniques is required to gain insight into other incidents.

Conclusions drawn from the incident data cannot be generalised to be representative of the wider healthcare system due to potential differences in population characteristics and other environmental and organisational factors. Further research using data from multiple healthcare organisations could identify those factors which are common across health boards and those which are specific to individual settings.

If this study were to be repeated, obtaining information governance approval to securely use patient demographic data would significantly supplement the value of the insight gained and more accurately reflect the information available for analysis within a healthcare organisation.

5.9 Analysis methodology

This study has demonstrated the use of analytical techniques to gain a greater understanding of inpatient falls within an NHS Wales Health Board. Each of the techniques has shown to be practical to undertake within the resources and capabilities of a healthcare organisation. While more complex analytical techniques have been used, primarily in academic settings, and demonstrated in the literature, there is an operational need for simple and valuable initial analysis of patient safety incident data.

The analytical techniques trialled as part of this study can be summarised in the following methodology.

When

Plot incidents over time, using a denominator to produce a rate where possible.

Where relevant for the incident type being analysed, plot incidents by time and identify any peaks and variation between daytime and night time.

What

Assess the distribution of harm among the incidents.

Use incident classification in conjunction with other factors to provide insight.

How

Analyse the free-text fields, which hold valuable information not captured elsewhere within the incident report. Natural Language Processing (NLP) can be used to extract common words and phrases to aid this insight.

This simple approach forms a starting point for incident analysis, and not an end point. The initial analysis is designed to highlight areas for further investigation, as demonstrated by the peaks in falls at 4pm, which requires additional analysis and discussion to identify potential interventions in order to reduce the risk of falls at this time. The analysis does not lead to safety improvements by itself, rather it surfaces insights into causative and contributory factors that may be amenable to intervention.

5.10 Data to improvement

One of the fundamental challenges described in the literature review was the lack of safety improvements as a result of incident reporting (Mitchell *et al.*, 2016; Carson-Stevens, Donaldson & Sheikh, 2018). Even with careful analysis, incident data does not lead directly to safety improvements. These improvements require changes in systems, practice and behaviours, which are not automatic.

The insights provided through analysis of incident data are themselves subject to interpretation and the positionality of the individual considering the data. Discussions with clinical colleagues regarding the peak in falls at 4pm demonstrated this, with occupational therapists suggesting that the peak could be due to the reduction of therapy staff on the ward after 4pm, whereas nurses proposed a link with the end of visiting time. The author's clinical background as a radiographer provides a neutral position as radiographic work is commonly performed away from a ward environment, therefore having less direct experience of the daily patterns of ward activities and schedules. It is likely that the true cause of the peak may include multiple factors and the suggestions of both occupational therapists and nurses could be valid.

Apart from in some very specific incident types, such as a particular coding error in a healthcare software application, the contributory factors are likely to be somewhat subjective and will be coloured by the experience, profession and background of the individual undertaking the analysis. Because of this factor, it is good practice to involve multi-disciplinary teams in discussion of incident analysis as each profession's viewpoint demonstrates potential causative and contributory factors through a different lens.

This approach has been taken with aspects of the data analysis from this study, with the temporal analysis of falls being the focus of the first meeting of the Health Board's falls learning group, involving staff from nursing, occupational therapy, physiotherapy, geriatric medicine, patient safety and education. The greater insight from the analysis performed as part of this study enables a more focused discussion due to the specific nature of the highlighted issue – the group will consider why there is a peak in falls at 4pm across the inpatient wards, and what steps could be taken to reduce these falls. These specific questions support small tests of change and ongoing quality improvement more strongly than presenting a high-level overview of falls numbers within the Health Board.

5.11 Future research

While analysis of incident data has shown to be valuable and provided important insights into potential causative and contributory factors affecting patient falls, this analysis sits on the foundation of a voluntary and manual incident reporting system. As many aspects of healthcare undergo digital transformation, the opportunity for a step change in patient safety arises.

Digitisation of traditionally paper-based processes provides a rich data source from which to learn. Although this study focused on one dataset, significant opportunities for insight are gained when incident data are combined with other sources, both within a healthcare organisation and potentially with other organisations involved a responsibility towards the individual, such as social care providers and other third sector bodies.

While manual incident reporting is unlikely to become redundant, advances in digital clinical systems provide an opportunity to improve incident identification and reduce the administrative burden of incident reporting on busy clinicians. It is not beyond the capabilities of existing technology for a wearable sensor to detect a patient fall, for this to be logged and for an electronic patient record system to identify that the patient has not had a lying and standing blood pressure recorded since their admission. Similarly, the electronic prescribing and medicines administration (ePMA) system could identify the patient is taking a combination of medications which

increase the risk of falling. This information could be used to generate an incident form with much richer information than would be recorded in a manual incident report, including the identification of two potential contributory factors – the blood pressure monitoring and the polypharmacy.

The logical progression from this concept is the identification of risk factors before an incident occurs. An electronic patient record system prompting healthcare staff when a lying and standing blood pressure is required, based on patient demographics and risk factors, coupled with an ePMA system which provides clinical decision support to suggest medication changes to reduce the risk of falls may prevent the patient fall from occurring.

This study has shown the impact of data quality and the design of software systems, particularly choices regarding input forms, on the ease and validity of analysis based on the collected data. It is prudent to consider data analysis and linkage with other sources at the original design stage of a healthcare software system, especially with large national systems such as Datix Cymru.

Making sense of the vast amounts of data from clinical and administrative systems is a challenge that has a potential solution in the use of artificial intelligence (AI), which has been identified as a tool to improve the safety of healthcare services. While primarily at the scoping stage, AI is likely to be pivotal in addressing some of the lack of progress in safety improvements over the last three decades (Bates *et al.,* 2021).

While emerging technology such as AI has significant potential, there remains an underlying need for healthcare organisations to maximise the insight and knowledge obtained from existing data and systems. This study has demonstrated the use of basic data analysis techniques, which could be replicated in other organisations and with alternative incident reporting systems. Further research is needed to develop methodologies tailored to specific incident types and to improve the design of the incident reporting systems to enable and support these analysis efforts.

Chapter 6 – Conclusion

The gap between incident reporting and safety improvements has been frequently discussed in the literature. Healthcare organisations have a duty, both moral and legal, to ensure that safety risks highlighted through incident reporting are acted on and future care made safer for patients (Welsh Government, 2023c). There is also a duty to the healthcare staff who take the time to report incidents that the maximum value is gained from each report. While established processes for the most serious incidents are in place, the literature review clearly demonstrated a lack of value from the low and no harm incidents, that could inform safety improvements to prevent future harm.

Using inpatient falls as a test case for the development of a simple and effective data analysis approach has shown its value, with clear insights that were not previously known and many of which would not have been identified from review of individual incidents.

An important aspect of this study was to consider analysis techniques that were simple and practically achievable within the resource and skills limitations of a typical Health Board. Even greater value is likely to be gained through more advanced analysis and drawing in other data sources to provide further context. The rapid progress in the use of AI in the field of patient safety is expected in future to provide additional tools to support analysis, however this study clearly demonstrates the value of basic analysis using tools and technology which is currently available to healthcare organisations.

If the safety improvements seen in other critical industries are to be replicated in healthcare, there is an urgent need to develop the use of data analytics within patient safety. As traditionally paper-based systems such as medication prescribing are becoming digitised, there is a wealth of data on the horizon which can be used to inform significant improvements in patient safety and a much greater understanding of the factors which contribute to safety incidents. The study has also considered how the design of incident reporting systems can be improved to support analysis and gain greater value from each incident report.

The types of incidents which occur within healthcare are widely varied and specific incident types will likely require an individual analysis approach. This study lays a platform for further research and the further development of patient safety analysis in a way that builds on the robust, but resource-intensive approaches used in some studies carried out in an academic setting, considering the real-world application within healthcare organisations, and taking into account limited funding, tools and capacity.

One of the strongest arguments for further research in this field is the analysis does not require additional data collection, rather it makes better use of data already held in incident reporting systems. This allows a significant return on investment of staff time to undertake analysis of incident data, especially when resultant safety improvements can be demonstrated.

It must not be forgotten that these incidents are not just numbers in a database, but affect real patients. Each one of the 5767 falls within the dataset used in this study had an impact on a patient. Even if no injury occurred, the fall is likely to have caused an increased fear of future falls, delayed recovery, or even affected whether a patient could return to their own home upon discharge. It is with these patients in mind that those working in the field of patient safety should focus efforts to better understand and prevent avoidable harm from healthcare.

Chapter 7 - Recommendations

Data quality affects the robustness of conclusions drawn from analysis of incident report data. Efforts should be made to improve the completeness of incident reports through the use of mandatory fields.

While mandating recording of incident time would not be practical for all incident types, as some incidents do not occur at a specific time, enabling mandating for certain incident types, such as falls, would lead to much improved data quality. This change would need to be accompanied by guidance for reporters about how the incident time for unwitnessed falls should be recorded to ensure consistency. Ideally this should be agreed on a national basis to allow comparison between organisations.

Simplification of the sub category codes used for patient falls would aid analysis. The current set of incident codes includes duplication with multiple codes for specific fall types – 'Fall/slip from chair, bed or trolley' and 'Fall from chair' could both be used to categorise a chair related fall. Data quality is also affected by a lack of agreed definitions, which contribute to the subjectivity of selecting a particular sub category.

The data analysis techniques within this study are simple and can be performed using software which is freely available and already used within NHS Wales. While some techniques, such as concordance analysis within Python require a reasonable level of technical ability, this barrier to access could be eliminated through integration of analysis tools within incident reporting systems. Developing an incident reporting system's free text search functionality to return the segment of text containing the key word would not be technically challenging but could add considerable value to the user as demonstrated in analysis of the falls data.

With many incident reporting software suppliers providing systems for multiple organisations both within the NHS and across the global healthcare market, improving the utility of collected data has the potential to improve for a vast number of patients.

Incorporating data analysis tools within the incident reporting system has the additional benefit of maintaining data security and alleviating some of the information

governance barriers that occur with extracting data outside the system for the purposes of analysis. As techniques such as machine learning are further developed, the inclusion of supporting tools within incident reporting systems could reduce the time taken to analyse data and improve the availability and quality of insights from data analysis.

This study has demonstrated the value of incident analysis techniques as applied to the understanding of inpatient falls. Insights have been gained that were not previously known and these should be used to focus further analysis and the development of changes to address the underlying risk of falls.

Healthcare organisations should consider how they are gaining an understanding of contributory and causative factors leading to patient safety incidents. The initial analysis approach described in this study provides a valuable starting point that can be replicated and adapted to suit specific incident types. It is also important to consider how outputs from analysis are shared with clinical teams and how moving from analysis to action is supported within the organisation.

Better understanding of reported patient safety incidents can lead to more effective interventions and a safer provision of healthcare for future patients.

Further research in this area, coupled with the ongoing development of digital and data analysis within healthcare provides a significant opportunity to obtain the safety improvements envisaged since the beginning of the patient safety movement, supporting the population to live longer, healthier lives and fulfilling the Hippocratic aim to ‘first, do no harm’.

References

Air Accidents Investigation Branch (2021) *Annual Safety Review 2021*. Available at: https://assets.publishing.service.gov.uk/media/62a1c1b1e90e070396c9f75d/Annual_Safety_Review_2021.pdf (Accessed: 28 December 2023)

Ali, Z. & Bhaskar, S. (2016) 'Basic statistical tools in research and data analysis', *Indian Journal of Anaesthesia,* 60(9), pp. 662-669. Available at: https://doi.org/10.4103/0019-5049.190623

AlSumadi, M., AlAdwan, M., AlSumadi, A., Sangani, C. & Toh, E. (2023) 'Inpatient falls and orthopaedic injuries in elderly patients: A retrospective cohort analysis from a falls register', *Cureus,* 15(10), p.e46976. Available at: https://doi.org/10.7759/cureus.46976

Anzai, H., Sudo, S., Obayashi, Y., Mori, S., Sasaki, M., Katsumata, Y., Yoshizumi, J., Tanaka, F., Yokoo, Y., Nagashima, K., Inoue, Y., Yonezu, H., Hashimoto, K., Hiraki, A. & Ikebe, T. (2020) 'An analysis of the dental patient safety incidents occurring in the oral and maxillofacial surgery department', *Journal of Oral and Maxillofacial Surgery, Medicine and Pathology,* 32(3), pp. 184-189. Available at: https://doi.org/10.1016/j.ajoms.2019.11.004

Archer, S., Hull, L., Soukup, T., Mayer, E., Athanasiou, T., Sevdalis, N. & Darzi, A. (2017) 'Development of a theoretical framework of factors affecting patient safety incident reporting: a theoretical review of the literature', *BMJ Open,* 7(12), p017155. Available at: https://doi.org/10.1136/bmjopen-2017-017155

Avery, A.J., Sheehan, C., Bell, B., Armstrong, S., Ashcroft, D.M., Boyd, M.J., Chuter, A., Cooper, A., Donnelly, A., Edwards, A., Evans, H.P., Hellard, S., Lymn, J., Mehta, R., Rodgers, S., Sheikh, A., Smith, P., Williams, H., Campbell, S.M. & Carson-Stevens, A. (2020) 'Incidence, nature and causes of avoidable significant harm in primary care in England: a retrospective case note review', *BMJ Quality and Safety,* 0, pp. 1-16. Available at: https://doi.org/10.1136/bmjqs-2020-011405

Bates, D.W., Levine, D., Syrowatka, A., Kuznetsova, M., Craig, K.J.T., Rui, A., Jackson, P.J. & Rhee, K. (2021) 'The potential of artificial intelligence to improve

patient safety: a scoping review', *NPJ Digital Medicine,* 4(1), p.54. Available at: https://doi.org/10.1038/s41746-021-00423-6

Brennan, P.A., Hardie, J. & Oeppen, R.S. (2023) 'Applying human factors to improve patient safety, morale and team working for oral pathology and medicine specialists', *Journal of Oral Pathology & Medicine,* 52(4), pp.283-287. Available at: https://doi.org/10.1111/jop.13404

Buwono, R.I., Suhardi, B. & Pujiyanto, E. (2019) 'An analysis of variables affecting the implementation of patient safety in Budi Sehat Hospital Purworejo using partial least square', *IOP Conference Series: Materials Science and Engineering,* 598, p. 012068. Available at: https://doi.org/10.1088/1757-899X/598/1/012068

Cardiff and Vale University Health Board (2023a) *Annual Report 2023-2023.* Available at: https://cavuhb.nhs.wales/files/board-and-committees/other-board-related-documents/2a-cav-annual-report-2022-2023-pdf/ (Accessed: 1 March 2024).

Cardiff and Vale University Health Board (2023b) *Incident, Hazard and Near Miss Reporting Policy.* Available at: https://cavuhb.nhs.wales/files/policies-procedures-and-guidelines/patient-safety-and-quality/i-j-patient-safety/incident-reporting-policy-ehia-v5-final-for-publish-doc/ (Accessed: 27 January 2024)

Cardiff and Vale University Health Board (2024) *University Hospital of Wales Visiting Times.* Available at: https://cavuhb.nhs.wales/hospitals-and-health-centres/our-hospitals/uhw/uhw-ward-visiting-times/ (Accessed: 19 February 2024)

Carson-Stevens, A., Donaldson, A. & Sheikh, A. (2018) 'The rise of patient safety-II: Should we give up hope on Safety-I and extracting value from patient safety incidents? Comment on "False dawns and new horizons in patient safety research and practice", *International Journal of Health Policy and Management,* 7(7), pp. 667-670. Available at: https://doi.org/10.15171/ijhpm.2018.23

Chaneliere, M., Koehler, D., Morlan, T., Berra, J., Colin, C., Dupie, I. & Michel, P. (2018) 'Factors contributing to patient safety incidents in primary care: a descriptive analysis of patient safety incidents in a French study using CADYA (categorization of errors in primary care)', *BMC Family Practice, 19(1),* p. 121. Available at: https://doi.org/10.1186/s12875-018-0803-9

Chang, C-M., Lin, H-F. & Chiang, H-H. (2015) 'A study on the relationship between age and inpatient falls in Taiwan', *International Journal of Nursing Practice,* 21(5), pp. 605-611. Available at: https://doi.org/10.1111/ijn.12342

CHKS (no date) *CHKS Mortality Profiling.* Available at: https://www.chks.co.uk/userfiles/files/Flyers/Mortality%20Profiling.pdf (Accessed: 17 April 2024).

Choudhury, A. & Asan, O. (2020) 'Role of artifical intelligence in patient safety outcomes: Systematic literature review', *JMIR Medical Informatics,* 8(7), p. e18599. Available at: https://doi.org/10.2196/18599

Christiaans-Dingelhoff, I., Smits, M., Zwaan, L., Lubberding, S., van der Wal, G. & Wagner, C. (2011) 'To what extent are adverse events found in patient records reported by patients and healthcare professionals via complaints, claims and incident reports?', *BMC Health Services Research,* 11(1), p. 49. Available at: https://doi.org/10.1186/1472-6963-11-49

Constantinou, E. & Spencer, J.A. (2021) 'Analysis of inpatient hospital falls with serious injury', *Clinical Nursing Research,* 30(4), pp. 482-493. Available at: https://doi.org/10.1177/1054773820973406

Cousins, D.H., Gerrett, D. & Warner, B. (2012) 'A review of medication incidents report to the National Reporting and Learning System in England and Wales over 6 years (2005-2010)', *British Journal of Clinical Pharmacology,* 74(4), pp. 597-604. Available at: https://doi.org/10.1111/j.1365-2125.2011.04166.x

Donaldson, L. (2004) 'When will healthcare pass the orange wire test?', *The Lancet,* 364, pp. 1567-4568. Available at: https://doi.org/10.1016/S0140-6736(04)17330-3

Donaldson, L., Ricciardi, W., Sheridan, S. & Tartaglia, R. (eds) (2021) *Textbook of Patient Safety and Clinical Risk Management.* Cham: Springer

Eldridge, C. (2007) *Evidence-based Falls Prevention: A Study Guide for Nurses.* Massachusetts: HCPro

Evans, S.M., Berry, J.G., Smith, B.J., Esterman, A., Selim, P., O'Shughnessy, J. & DeWit, M. (2006) 'Attitudes and barriers to incident reporting: a collaborative hospital

study', *Quality and Safety in Health Care,* 15(1), pp. 39-43. Available at: https://doi.org/10.1136/qshc.2004.012559

Favot, M., Gallien, J., Malik, A., Kasten, A., Wells, R. & Ehrman, R. (2019) 'Contrast extravasation as a complication of emergency nurse-performed ultrasound-guided peripheral intravenous catheter placement', *Journal of Emergency Nursing,* 45(5), pp. 512-516. Available at: https://doi.org/10.1016/j.jen.2019.05.016

Flott, K., Nelson, F., Moorcroft, T., Mayer, E.K., Gage, W., Redhead, J. & Darzi, A.W. (2018) 'Enhancing safety culture through improved incident reporting: A case study in translational research', *Health Affairs,* 37(11), pp. 1797-1804. Available at: https://doi.org/10.1377/hlthaff.2018.0706

Ghaleb, M.A., Barber, N., Franklin, B.D. & Wong, I.C.K. (2010) 'The incidence and nature of prescribing and medication administration errors in paediatric inpatients', *Archives of Disease in Childhood,* 95(2), pp. 113-118. Available at: https://doi.org/10.1136/adc.2009.158485

Gibson, R., MacLeod, N., Donaldson, L.J., Williams, H., Hibbert, P., Parry, G., Bhatt, J., Sheikh, A. & Carson-Stevens, A. (2020) 'A mixed-methods analysis of patient safety incidents involving opioid substitution treatment with methadone or buprenorphine in community-based care in England and Wales', *Addiction,* 115(11), pp. 2066-2076. Available at: https://doi.org/10.1111/add.15039

Gillespie, B.M., Chaboyer, W., Boorman, R.J., Sladdin, I., Withers, T. & de Wet, C. (2021) 'Characterising the nature of clinical incidents reported across a tertiary health service: a retrospective audit', *Australian Health Review,* 45(4), pp. 447-454. Available at: https://doi.org/10.1071/AH20271

Hasanpoor, E., Haghgoshayie, E. & Abdekhoda, M. (2022) 'What are the barriers to nurses reporting incidents?', *Evidence Based Nursing,* 25(3), p. 97. Available at: https://doi.org/10.1136/ebnurs-2021-103440

Healey, F., Scobie, S., Oliver, D., Pryce, A., Thomson, R. & Glampson, B. (2008) 'Falls in English and Welsh hospitals: a national observational study based on retrospective analysis of 12 months of patient safety incident reports', *Quality and Safety in Healthcare,* 17(6), pp. 424-430. Available at: https://doi.org/10.1136/qshc.2007.024695

Healthcare Inspectorate Wales (2024) *About us,* Available at: https://www.hiw.org.uk/about (Accessed: 17 April 2024).

Hussain, F., Cooper, A., Carson-Stevens, A., Donaldson, L., Hibbert, P., Hughes, T. & Edwards, A. (2019) 'Diagnostic error in the emergency department: learning from national patient safety incident report analysis', *BMC Emergency Medicine,* 19(77). Available at: https://doi.org/10.1186/s12873-019-0289-3

Iacobucci, G. (2013) 'Minor units take a growing share of emergency department attendances', *The British Medical Journal,* 347(4), p.7233. Available at: https://doi.org/10.1136/bmj.f7233

IBM (2024) *IBM SPSS Statistics.* Available at: https://www.ibm.com/products/spss-statistics (Accessed: 6 March 2024).

Information Commissioner's Office (no date) *A guide to the data protection principles.* Available at: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/data-protection-principles/a-guide-to-the-data-protection-principles/ (Accessed: 27 January 2024).

Institute for Government (2020) *Devolution and the NHS.* Available at: https://www.instituteforgovernment.org.uk/explainer/devolution-and-nhs (Accessed: 23 January 2024).

Institute of Medicine (2000) *To Err is Human: Building a Safer Health System.* Washington DC, The National Academies Press.

Jabin M.S.R., Magrabi, F., Hibbert, P., Schultz, T. & Runciman, W. (2019) 'Identifying and characterizing system issues of health information technology in medical imaging as a basis for recommendations', *International Conference on Imaging Systems and Techniques*, pp.1–6. Abu Dhabi: IEEE Xplore. Available at: https://doi.org/10.1109/IST48021.2019.9010280

Jansma, D.J., Zwart, D.L.M., Leistikow, I.P., Kalkman, C.J., Wagner, C. & Bijnen, A.B. (2010) 'Do speciality registrars change their attitudes, intentions and behaviour towards reporting incidents following a patient safety course?', *BMC Health Services Research,* 10(1), p.100. Available at: https://doi.org/10.1186/1472-6963-10-100

Jones, R.P. (2022) ‘A model to compare international hospital bed numbers, including a case study on the role of indigenous people on acute ‘occupied’ bed demand in Australian states’, *International Journal of Environmental Research and Public Health,* 19(18), p.11239. Available at: https://doi.org/10.3390/ijerph191811239

Juhasz, L. & Hochmair, H. (2019) ‘Comparing the spatial and temporal activity patterns between Snapchat, Twitter and Flickr in Florida’, *Journal for Geographic Information Science,* 7(1), p.S134-147. Available at: https://doi.org/10.1553/giscience2019_01_s134

Kakara, R.S., Moreland, B.L., Haddad, Y.K., Shakya, I. & Bergen, G. (2021) ‘Seasonal variation in fall-related emergency department visits by location of fall – United States, 2015’, 79, pp.38-44. Available at: https://doi.org/10.1016/j.jsr.2021.08.002

Kasalak, O., Yakar, D., Dierckx, R.A.J.O. & Kwee, T.C. (2021) ‘Patient safety incidents in radiology: frequency and distribution of incident types’, *Acta Radiologica,* 62(5), pp. 653-666. Available at: https://doi.org/10.1177/0284185120937386

Khalid, W.M., Carson-Stevens, A., Avery, A.J. & Boyd, M.J. (2018) ‘What medication errors occur in community pharmacies and why do they occur? A national analysis of patient safety incidents’, *Research in Social and Administrative Pharmacy,* 14(8), p. 37. Available at: https://doi.org/10.1016/j.sapharm.2018.05.061

Kingston, M.J., Evans, S.M., Smith, B.J. & Berry, J.G. (2004) ‘Attitudes of doctors and nurses towards incident reporting: a qualitative analysis’, *Medical Journal of Australia,* 181(1), pp. 36-39. Available at: https://doi.org/10.5694/j.1326-5377.2004.tb06158.x

Kuhn, M. (2007) *ASCII and Unicode Quotation Marks.* Available at: https://www.cl.cam.ac.uk/~mgk25/ucs/quotes.html (Accessed: 23 February 2024).

Lee, C.Y., Low, L.P.L. & Twinn, S. (2007) ‘Older men’s experiences of sleep in the hospital’, *Journal of Clinical Nursing,* 16(2), pp.336-343. Available at: https://doi.org/10.1111/j.1365-2702.2005.01491.x

Lee, W., Pyo, J., Jang, S.G., Choi, J.E. & Ock, M. (2019) ‘Experiences and responses of second victims of patient safety incidents in Korea: a qualitative study’,

BMC Health Services Research, 19(1), pp. 100-112. Available at: https://doi.org/10.1186/s12913-019-3936-1

Lumivero (2023) *Leading Qualitative Data Analysis Software with AI Solution.* Available at: https://lumivero.com/products/nvivo/ (Accessed: 6 March 2024).

Macrae, C. (2016) 'The problem with incident reporting', *BMJ Quality and Safety,* 25(2), pp. 71-75. Available at: https://doi.org/10.1136/bmjqs-2015-004732

Maher, G. (2021) 'To identify whether the current seating available in an Irish emergency department meets the needs of the older population', *Age and Ageing,* 50(s3), p.9. Available at: https://doi.org/10.1093/ageing/afab219.110

Mahota, C. (2017) 'Seasonal ambient changes influence inpatient falls', *Age and Ageing,* 46(3), p. 513. Available at: https://doi.org/10.1093/ageing/afw254

Manfredini, R., Fabbian, F., Pala, M., De Giorgi, A., Menegatti, A.M., Boari, B., Salmi, R. & Gallerani, M. (2012) 'Time of occurrence of in-hospital falls: A systematic mini review', *Journal of the American Geriatrics Society,* 60(6), pp. 1183-1184. Available at: https://doi.org/10.1111/j.1532-5415.2012.03984.x

Mayer, E., Flott, K., Callahan, R. & Darzi, A. (2016) *NRLS Research and Development.* Available at: https://www.imperial.ac.uk/media/imperial-college/institute-of-global-health-innovation/IMPJ4219-NRLS-report_010316-INTS-WEB.pdf (Accessed: 1 April 2024).

McFadzean, I.J., Davies, K., Edwards, A., Hellard, S., Ashcroft, D.M., Avery, A.J., Flynn, S., Hewson, T., Jordan, M., Keers, R., Panagioti, M., Wainwright, V., Walter, F., Shaw, J. & Carson-Stevens, A. (2023) 'Patient safety in prisons: a multi-method analysis of reported incidents in England', *Journal of the Royal Society of Medicine,* 116(7), pp. 236-245. Available at: https://doi.org/10.1177/01410768231166138

Microsoft (2024) *Azure Active Directory is now Microsoft Entra ID,* Available at: https://www.microsoft.com/en-gb/security/business/identity-access/microsoft-entra-id (Accessed: 29 April 2024).

Mishina, K., Berg, J., Vainila, V., Korte, M. & Lahti, M. (2023) 'Safety incidents in psychiatric inpatient care: A qualitative content analysis of safety incident reports',

Perspectives in Psychiatric Care, pp. 1-11. Available at: https://doi.org/10.1155/2023/3159566

Mitchell, I., Schuster, A., Smith, K., Pronovost, P. & Wu, A. (2016) 'Patient safety incident reporting: a qualitative study of thoughts and perceptions of experts 15 years after 'To Err is Human'', *BMJ Quality and Safety,* 25(2), pp. 92-99. Available at: https://doi.org/10.1136/bmjqs-2015-004405

Mushtaq, F., O'Driscoll, C., Smith, F.C.T., Wilkins, D., Kapur, N. & Lawton, R. (2018) 'Contributory factors in surgical incidents as delineated by a confidential reporting system', *The Annals of the Royal College of Surgeons of England,* 100, pp. 401-405. Available at: https://doi.org/10.1308/rcsann.2018.0025

National Patient Safety Agency (2005) *Building a memory: preventing harm, reducing risks and improving patient safety.* Available at: https://webarchive.nationalarchives.gov.uk/ukgwa/20170906180536/http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/human-factors-patient-safety-culture/?entryid45=59797&cord=ASC (Accessed: 9 January 2024).

NHS England (2023) *Statistical Process Control Tool.* Available at: https://www.england.nhs.uk/statistical-process-control-tool/ (Accessed: 15 February 2024).

NHS Executive (2023) *Supporting section 3 – guidance on specific incident types.* Available at: du.nhs.wales/files/incidents/supporting-section-3-guidance-on-specific-incident-types-pdf/ (Accessed: 2 January 2024).

NHS Improvement (2019a) *Making data count: Getting started.* Available at: https://www.england.nhs.uk/wp-content/uploads/2019/12/making-data-count-getting-started-2019.pdf (Accessed: 15 February 2024).

NHS Improvement (2019b) *Making data count: Strengthening your decisions.* Available at: https://www.england.nhs.uk/wp-content/uploads/2019/12/making-data-count-strengthening-your-decisions.pdf (Accessed: 15 February 2024).

NHS Scotland (2004) *Scottish Health Technical Memorandum 83, Version 3.* Available at: https://www.nss.nhs.scot/media/1561/shtm-83-v30-apr-2004.pdf (Accessed: 10 April 2024).

NHS Wales Shared Services Partnership (2023) *Incidents Module Full Reporter / Investigator / Handler Guide.* Available at: https://nwssp.nhs.wales/a-wp/pcir/primary-care-wales-incident-reporting-documents/general-documents/datix-cymru-incident-reporting-use-guide-v3b/ (Accessed: 26 March 2024).

NHS Wales Shared Services Partnership (no date) *Once for Wales Concerns Management System.* Available at: https://nwssp.nhs.wales/a-wp/once-for-wales-concerns-management-system/ (Accessed: 2 January 2024).

NICE (2024) *Sodium Valproate.* Available at: https://bnf.nice.org.uk/drugs/sodium-valproate/ (Accessed: 23 February 2024).

NLTK Project (2023) *Natural Language Toolkit.* Available at: https://www.nltk.org/ (Accessed: 23 February 2024).

Office for Health Improvement and Disparities (2023) *Falls: Applying All Our Health.* Available at: https://www.gov.uk/government/publications/falls-applying-all-our-health/falls-applying-all-our-health (Accessed: 26 March 2024).

Oudin Astrom, D., Bertil, F. & Joacim, R. (2011) 'Heat wave impact on morbidity and mortality in the elderly population: A review of recent studies', *Maturitas,* 69(2), pp.99-105. Available at: https://doi.org/10.1016/j.maturitas.2011.03.008

Oxford University Hospitals NHS Foundation Trust (2021) *An annual review of the Serious Incidents requiring investigation (SIRI) and Never Events reported during financial year 2020/21.* Available at: https://www.ouh.nhs.uk/about/trust-board/2021/november/documents/TB2021.90-siris-never-events.pdf (Accessed: 17 April 2024).

Pellfolk, T., Gustafsson, T., Gustafson, Y. & Karlsson, S. (2009) 'Risk factors for falls among residents with dementia living in group dwellings', *International Psychogeriatrics,* 21(1), pp. 187-194. Available at: https://doi.org/10.1017/S1041610208007837

Pham, J.C., Girard, T. & Pronocost, P.J. (2013) 'What to do with healthcare incident reporting systems', *Journal of Public Health Research,* 2(3), p. e27. Available at: https://doi.org/10.4081/jphr.2013.e27

ProQuest (2022) *What's New in ProQuest Central?,* Available at: https://pq-static-content.proquest.com/collateral/media2/documents/whatsnew-proquestcentral.pdf (Accessed: 8 December 2023)

Royal College of Physicians (2015) *National audit of inpatient falls Commissioners' report 2015.* Available at: https://www.rcplondon.ac.uk/file/6156/download (Accessed: 17 April 2024).

Royal College of Physicians (2023) *State of the nation Wales report 2022.* Available at: https://www.rcplondon.ac.uk/projects/outputs/state-nation-wales-report-2022 (Accessed: 16 January 2024)

Sahota, O., Drummond, A., Kendrick, D., Grainge, M.J., Vass, C., Sach, T., Gladman, J. & Avis, M. (2014) 'REFINE (REducing Falls in InpatieNt Elderly) using bed and bedside chair pressure sensors linked to radio-pagers in acute hospital care: a randomised control trial', *Age and Ageing,* 24(2), pp. 274-253. Available at: https://doi.org/10.1093/ageing/aft155

Sari, A.B., Sheldon, T.A., Cracknell, A. & Turnbull, A. (2006) 'Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review', *British Medical Journal,* 334(7584), pp. 79-81. Available at: https://doi.org/10.1136/bmj.39031.507153.AE

Shin, S. & Won, M. (2020) 'Trend analysis of patient safety incidents and their associated factors in Korea using national patient safety report data (2017~2019)', *International Journal of Environmental Research and Public Health,* 18(16), p. 8482. Available at: https://doi.org/10.3390/ijerph18168482

Simpson, J.R., Rosenthal, L.D., Cumbler, E.U. & Likosky, D.J. (2013) 'Inpatient falls: Defining the problem and identifying possible solutions. Part II: Application of quality improvement principles to hospital falls', *Neurohospitalist,* 3(4), pp. 203-208. Available at: https://doi.org/10.1177/1941874412470666

Singh, I., Okeke, J. & Edwards, C. (2015) 'Outcome of in-patient falls in hospitals with 100% single rooms and multi-bedded wards', *Age and Ageing,* 44(6), pp. 1032-1035. Available at: https://doi.org/10.1093/ageing/afv124

Staggs, V.S., Mion, L.C. & Shorr, R.I. (2014) 'Assisted and unassisted falls: Different events, different outcomes, different implications for quality of hospital care', *The Joint Commission Journal on Quality and Patient Safety,* 40(8), pp. 358-364. Available at: https://doi.org/10.1016/S1553-7250(14)40047-3

Stavropoulou, C., Doherty, C. & Tosey, P. (2015) 'How effective are incident-reporting systems for improving patient safety? A systematic literature review', *The Milbank Quarterly,* 93(4), pp.826-866. Available at: https://doi.org/10.1111/1468-0009.12166

Sun, B., Zhao, T., Guta, A., Kamal, G., Zhang, T. & Mutic, S. (2019) 'Patient safety and process improvements in radiation therapy through 10 years of incident reporting and learning', *International Journal of Radiation Oncology, Biology, Physics,* 105(1). p. S24. Available at: https://doi.org/10.1016/j.ijrobp.2019.06.426

Swinscow, T.D.V. (1997) *Statistics at Square One,* Available at: https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/8-chi-squared-tests (Accessed: 29 April 2024).

Terranova, C., Cardin, F., Martella, B., Amato, B. & Militello, C. (2012) 'Death after an accidental fall of a 101 year old hospitalized patient. Medico-legal implication of falling in geriatrics', *BMC Surgery,* 12(S1), p.S34. Available at: https://doi.org/10.1186/1471-2482-12-S1-S34

Thornton, J. (2020) 'Covid-19: A&E visits in England fall by 25% in week after lockdown', *BMJ,* 369, p1401. Available at: https://doi.org/10.1136/bmj.m1401

UK Government (2023) 'Aviation statistics: data tables (AVI)'. Available at: https://www.gov.uk/government/statistical-data-sets/aviation-statistics-data-tables-avi#aviation-accidents-and-incidents-avi04-series (Accessed: 28 December 2023).

University of Strathclyde (2023) *Systematic Review: Quality assessment.* Available at: https://guides.lib.strath.ac.uk/systematic/quality (Accessed: 28 December 2023).

Van de Glind, I., de Roode, S. & Goossensen, A. (2007) 'Do patients in hospitals benefit from single rooms? A literature review', *Health Policy,* 84(2), pp.153-161. Available at: https://doi.org/10.1016/j.healthpol.2007.06.002

Vincent, C., Carthey, J., Macrae, C. & Amalberti, R. (2017) 'Safety analysis over time: seven major changes to adverse event investigation', *Implementation Science,* 12(1), p.151. Available at: https://doi.org/10.1186/s13012-017-0695-4

Vincent, C.A. (2004) 'Analysis of clinical incidents: a window on the system not a search for root causes', *BMJ Quality and Safety*, 13, pp. 242-243. Available at: https://doi.org/10.1136/qshc.2004.010454

Vossoughi, S., Perez, G., Whitaker, B.I., Fung, M.K., Rajbhandary, S., Crews, N. & Stotler, B. (2019) 'Safety incident reports associated with blood transfusions', *Transfusion,* 59, pp. 2827-2832. Available at: https://doi.org/10.1111/trf.15429

Weil, T.P. (2015) 'Patient falls in hospitals: An increasing problem', *Geriatric Nursing,* 36(5), pp. 342-347. Available at: https://doi.org/10.1016/j.gerinurse.2015.07.004

Welsh Government (2021a) *Patient safety (monthly incidents based on when it was reported).* Available at: https://www.gov.wales/patient-safety-monthly-incidents-based-when-it-was-reported-august-2021 (Accessed: 9 January 2024).

Welsh Government (2021b) *Patient safety (incidents based on when the incident occurred by local health board/trust).* Available at: https://www.gov.wales/patient-safety-incidents-based-when-incident-occurred-local-health-boardtrust-april-2020-march-2021 (Accessed: 26 March 2024).

Welsh Government (2021c) *Updated guidance for hospital visiting in Wales.* Available at: https://www.gov.wales/updated-guidance-hospital-visiting-wales (Accessed: 2 April 2024).

Welsh Government (2023a) *NHS Wales health boards and trusts.* Available at: https://www.gov.wales/nhs-wales-health-boards-and-trusts (Accessed: 23 January 2024).

Welsh Government (2023b) *Putting Things Right.* Available at: https://www.gov.wales/information-handling-concerns-staff-working-nhs-putting-things-right (Accessed: 3 February 2024).

Welsh Government (2023c) *Duty of quality in healthcare.* Available at: https://www.gov.wales/duty-quality-healthcare (Accessed: 20 March 2024).

World Health Organization (2018) ‘Classification of patient-safety incidents in primary care’, *Bulletin of the World Health Organization,* 96(7), pp. 498-505. Available at: https://doi.org/10.2471/BLT.17.199802

World Health Organization (2023) *Patient Safety.* Available at: https://www.who.int/news-room/fact-sheets/detail/patient-safety (Accessed: 2 January 2024).

Yardley, I., Yardley, S., Williams, H., Carson-Stevens, A. & Donaldson, L.J. (2018) ‘Patient safety in palliative care: A mixed-methods study of reports to a national database of serious incidents’, *Palliative Medicine,* 32(8), pp. 1353-1362. Available at: https://doi.org/10.1177/0269216318776846