Medication Errors and Their Reporting: An Insight into the Acute Hospital Setting

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Summary

Medication errors represent a significant global public health concern, contributing substantially to preventable morbidity and mortality. Medication errors have far-reaching consequences, affecting patients, family members, healthcare professionals, and the wider healthcare organisations. Despite increasing efforts to put medication safety to the forefront, progress in this area has been limited. This dissertation, therefore, sought to explore the causes of medication errors and their reporting practices in the acute care setting in Malta.

The study utilised an explanatory-sequential mixed methods design. The initial quantitative phase involved a retrospective analysis of Individual Case Safety Reports (ICSRs) from the EudraVigilance database between 2022 and 2025. These findings then informed the qualitative phase, which sought to augment and interpret the quantitative results. Semi-structured interviews were conducted with front-line healthcare professionals, including a mix of doctors, nurses and pharmacists, working within two local acute hospital settings, as well as with select key players within the field of medication and patient safety. The qualitative analysis was informed by Reason's Accident Causation Model to classify the causes and contributory factors of medication errors, and by the Theoretical Domains Framework to explore the barriers and facilitators to reporting.

The most notable finding from the quantitative phase was the absence of medication error reports originating from Malta during the study period. Using the international ICSRs from this database, the most common stages associated with medication errors were prescribing (27.2%) and administration (24.4%), with anti-

infectives (23.1%) and nervous system agents (22.8%) being the most frequently implicated medication classes. Statistically significant associations ($p < 0.01$) were identified between error seriousness and both patient age group and reporter type.

The qualitative phase identified key causes and contributory factors to medication errors. While active failures such as selecting the wrong medication, incorrect dose calculations or deviations from hospital protocols emerged, error-provoking conditions, including heavy workload, time pressures, staff shortages, fatigue, the effect of look-alike and sound-alike medications and communication issues, were identified as the predominant factors leading to medication errors. Latent failures, linked to inadequate training and supervision, issues with staff allocation and roles, and problems with the quality of procured medications were also commonly cited. The main barriers to error reporting included hospital culture, fear of professional repercussions, insufficient awareness of reporting systems, and the time-consuming nature of reporting.

The qualitative insights from healthcare professionals' interviews gave insight into the lack of reporting shown by the EudraVigilance data. The findings aligned with international literature on both the underlying causes and the barriers to medication error reporting. These findings highlighted how medication errors often stem from complex, multi-factorial causes, where gaps in defences align to allow for an error to occur. The barriers to reporting identified by front-line healthcare professionals provided crucial insight into potential reasons behind the significant underreporting locally and underscored the need for urgent action. Various recommendations from the study findings emerged and were categorised into micro (individual), meso

(organisational) and macro (regulatory) level interventions. These included improving training and education on medication safety, fostering and sustaining an open patient safety hospital culture, implementing digital tools for medication use and addressing key issues such as procurement practices and staff shortages

In conclusion, medication errors are an important public health concern in Malta, necessitating urgent measures to address their widespread causes and the evident barriers leading to their current under-reporting.

Table of Contents

Table of Contents ..... **vii**

List of Tables ..... **xi**

List of Figures ..... **xii**

List of Abbreviations ..... **xiii**

Chapter 1: Introduction **1**

1.1 Background 1

1.2 Culture in Healthcare 4

1.3 Delivery of Acute Healthcare in Malta 6

1.4 The Public Health Importance of Medication Errors 7

1.5 Addressing the Knowledge Gap and the Rationale for the Study 10

1.6 Study Aim and Objectives 11

1.6.1 Aim 11

1.6.2 Objectives 11

1.7 Chapter Summary 12

Chapter 2: Literature Review **13**

2.1 Introduction 13

2.2 Definition of Key Terminology 14

2.3 Medication Errors: The Scale of the Problem 19

2.4 Prevalence of Medication Errors by Stage of the Medication Use Process 21

2.5 Theoretical Frameworks Relevant to this Research 22

2.5.1 Introduction 22

2.5.2 Reason's Accident Causation Model 23

2.5.3 Theoretical Domains Framework 24

2.6 Causes and Contributory Factors of Medication Errors 25

2.6.1 Search Strategy – Search 1 26

2.6.2 Prescribing 29

2.6.3 Transcribing 35

2.6.4 Dispensing 39

2.6.5 Administration 44

2.6.6 Monitoring 49

2.6.7 Summary of the Main Literature Findings 50

2.7 Contributory Factors of Patient-Committed Medication Errors 53
2.8 The Consequences of Medication Errors 54
2.8.1 Impact of Medication Errors on Patients and Caregivers 55
2.8.2 Impact of Medication Errors on Healthcare Professionals 56
2.8.3 Impact of Medication Errors on Healthcare Organisations 56
2.9 The Costs of Medication Errors 57
2.10 Methods of Detecting Medication Errors 59
2.11 Reporting of Medication Errors 61
2.11.1 Legislative Background in Relation to Reporting of Medication Errors .. 62
2.11.2 Benefits of Medication Error Reporting 63
2.11.3 Underreporting of Medication Errors 65
2.12 Barriers and Facilitators of Medication Error Reporting 66
2.12.1 Search Strategy – Search 2 66
2.12.2 Mapping Barriers and Facilitators to the Theoretical Domains Framework 69
2.13 Interventions to Improve Medication Error Reporting 82
2.14 The Malta Context 84
2.15 Chapter Conclusion 89
Chapter 3: Methodology 90
3.1 Introduction 90
3.2 Overall Study Design 90
3.3 Phase 1: Quantitative Method 91
3.4 Phase 2: Qualitative Approach 94
3.4.1 Setting 94
3.4.2 Design 94
3.4.3 Participants and Data Collection 95
3.4.4 Data Analysis 98
3.4.5 Measures taken to enhance Quality and Trustworthiness 98
3.5 Ethical Considerations 99
3.6 Chapter Summary 100
Chapter 4: Results 101
4.1 Chapter Overview 101
4.2 EudraVigilance Results – Quantitative Structured Fields Analysis 101
4.2.1 Overview of the dataset from EudraVigilance 101

4.2.2 Temporal Distribution of Individual Case Safety Reports 102
4.2.3 Country of Report Origin 104
4.2.4 Patient Demographics 106
4.2.5 Reporter Type 109
4.2.6 Seriousness of Errors 110
4.2.7 Breakdown of Individual Case Safety Reports by Outcome 113
4.2.8 Characteristics of Reported Medications 114
4.3 EudraVigilance Results – Analysis of Unstructured Free-Text Narratives 117
4.3.1 Medication Errors by Stage of the Medication Use Process 117
4.4 Qualitative Results 123
4.4.1 Overview of Background Characteristics of Participants 123
4.4.2 Causes and Contributory Factors for Medication Errors 126
4.4.3 Facilitators and Barriers to Medication Error Reporting 145
4.4.4 Discussions with Selected Key Stakeholders 161
4.5 Chapter Summary 163
Chapter 5: Discussion 164
5.1 Introduction 164
5.2 Objective 2: Analysis of the EudraVigilance Database 165
5.2.1 Absence of Individual Case Safety Reports originating from Malta 165
5.2.2 Other Findings from Analysis of the EudraVigilance Database 166
5.3 Objective 3: Local Perspectives on the Causes and Contributory Factors of Medication Errors and the Barriers to Reporting 169
5.3.1 Causes and Contributory Factors to Medication Errors 169
5.3.2 Barriers and Facilitators to Medication Error Reporting 179
5.4 Strengths, Limitations and Biases of the study 189
5.4.1 Strengths 189
5.4.2 Limitations and Biases 191
5.5 Suggestions for Future Research 196
5.6 Chapter Summary 197
Chapter 6: Conclusions and Recommendations 199
6.1 Conclusions 199
6.2 Recommendations 200
6.2.1 Cultivate and Consolidate a Patient Safety Culture 201

6.2.2 Enhance and Strengthen Compliance with the Regulatory Framework for Medication Error Reporting 202
6.2.3 Address Staff Shortages and Workload Issues 203
6.2.4 Enhance Training on Medication Safety and Error Reporting Systems 204
6.2.5 Optimise Procurement Processes 206
6.2.6 Address Look-alike and Sound-alike Products 207
6.2.7 Implement Interventions to Target Risks for Errors During the Medication Use Process 208
6.2.8 Evaluate the Use of Digital Tools to Support the Medication Use Process and Reporting of Adverse Events 209
6.2.9 Promote Patient Health Literacy and Engagement 210
6.2.10 Summary of Recommendations 211
References 212
Appendices 236
Appendix A – Summary of Studies Used in the Structured Literature Search on the Causes and Contributory Factors to Medication Errors 236
Appendix B - Summary of Studies Used in the Structured Literature Search on the Barriers and Facilitators to Medication Error Reporting 259
Appendix C – Copy of the Combined Information Letter and Informed Consent Sheet for Participation in the Study 261
Appendix D – Copy of the Semi-Structured Interview Guide used for the Qualitative Interviews 263
Appendix E – Ethical Approval from the University of Malta's Faculty Research Ethics Committee 265

List of Tables

Table 1 - Medication Errors by Stage of the Medication Use Process 18
Table 2 - Overview of the Main Causes and Contributory Factors to Medication Errors by Stage of the Medication Use Process 51
Table 3 - Methods for Detecting Medication Errors (Adapted from Mulac and Granås, 2022) 60
Table 4 - Summary of the Main Barriers and Facilitators to Reporting Identified in the Literature 81
Table 5 - Count of Individual Case Safety Reports by Calendar Year 102
Table 6 - Top 10 Countries by Reporting Rate per 100,000 Population 106
Table 7 – Gender Gap in Individual Case Safety Reports Stratified by Age Group 109
Table 8 - Distribution of Seriousness of Outcomes Among Serious and All Individual Case Safety Reports 114
Table 9 - Top 10 Anatomical Therapeutic Chemical (ATC) Level 2 Codes Among Single-Agent Individual Case Safety Reports 116
Table 10 - Types of Medication Errors by Stage of the Medication Use Process 120
Table 11 - Breakdown of Participants by Professional Group and Grade 124
Table 12 - Summary of the Main Causes and Contributory Factors 145
Table 13 - Summary of the Main Barriers and Facilitators to Medication Error Reporting 160
Table 14 - Summary of the Key Recommendations Emerging from the Study 211

List of Figures

Figure 1 - Structure of the Literature Review 14
Figure 2 - Stages of the Medication Use Process (Adapted from Vest et al., 2024) 17
Figure 3 - Flowchart Illustrating Reason's Accident Causation Model (Adapted from Reason, 2000) 24
Figure 4 - PRISMA Flowchart Showing the Selection Process for the Literature on the Causes and Contributory Factors of Medication Errors 28
Figure 5 - PRISMA Flowchart Showing the Study Selection Process for the Literature on the Barriers and Facilitators to Medication Error Reporting 68
Figure 6 - Flowchart Summarising the Main Steps of the Explanatory-Sequential Mixed-Methods Approach (Adapted from Cresswell et al., 2009) and its Application in this Study 91
Figure 7 - Flowchart Illustrating the Data Cleaning and Selection of Individual Case Safety Reports for Analysis 93
Figure 8 - Number of Individual Case Safety Reports by Quarter and Calendar Year .. 103
Figure 9 - Number of Individual Case Safety Reports Received Over Three 12-Month Periods (March 2022 - March 2025) 104
Figure 10 - Number of Individual Case Safety Reports by Country 105
Figure 11 - Distribution of Individual Case Safety Reports by Gender 106
Figure 12 - Distribution of Individual Case Safety Reports by 10-Year Age Groups..... 107
Figure 13 - Gender Differences in Individual Case Safety Reports Stratified by 10-Year Age Groups..... 108
Figure 14 - Distribution of Individual Case Safety Reports by Reporter Type 110
Figure 15 - Proportion of Serious and Non-Serious Individual Case Safety Reports 111
Figure 16 - Heatmap Showing Standardised Residuals for Seriousness by 10-Year Age Groups..... 112
Figure 17 - Distribution of Single Agent Individual Case Safety Reports by Anatomical Therapeutic Chemical Level 1 Code 115
Figure 18 - Distribution of Individual Case Safety Reports with a Known Route of Administration 117
Figure 19 - Distribution of Individual Case Safety Reports by Stage (n = 349) 118
Figure 20 - Distribution of the Participants at the interview by Gender 123
Figure 21 - Distribution of Participants by Speciality..... 125
Figure 22 - Distribution of Participants by Years of Experience (in 5-Year Groups)..... 126

List of Abbreviations

ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
ATC	Anatomical Therapeutic Chemical
BNF	British National Formulary
CEO	Chief Executive Officer
CME	Continuous Medical Education
C I	Confidence Interval
EAHP	European Association of Hospital Pharmacists
ECG	Electrocardiogram
EEA	European Economic Area
EMA	European Medicines Agency
ERNST	European Researchers' Network Working on Second Victims
EU	European Union
EV	EudraVigilance
EVDAS	EudraVigilance Data Analysis System
FREC	Faculty Research Ethics Committee
GDPR	General Data Protection Regulation
GVP	Good Pharmacovigilance Practices
HR	Human Resources
ICSR	Individual Case Safety Report
IM	Intramuscular
IOM	Institute of Medicine

IQR	Interquartile Range
ISO	International Organisation for Standardisation
ITU	Intensive Treatment Unit
IV	Intravenous
MeSH	Medical Subject Headings
MSc	Master of Science
NCCMERP	National Coordinating Council for Medication Error Reporting and Prevention
NHS	National Health Service
NHSS	National Health Systems Strategy
NPICU	Neonatal Paediatric Intensive Care Unit
OECD	Organisation for Economic Co-operation and Development
OR	Odds Ratio
PSA	Prescribing Safety Assessment
RR	Risk Ratio
SD	Standard Deviation
SMS	Safety Management System
SOP	Standard Operating Procedures
TDF	Theoretical Domains Framework
UK	United Kingdom
US	United States
WHO	World Health Organisation

Chapter 1: Introduction

1.1 Background

"*Primum non nocere*", first do no harm, is a guiding ethical principle for healthcare professionals, underscoring the importance of safeguarding patient safety above all. While healthcare interventions are intended to benefit the patient, they may inadvertently cause harm. Each year, unsafe care results in a sizeable number of patients suffering from preventable morbidity or mortality, culminating in a considerable public health burden globally (World Health Organisation [WHO], 2021). Recently, patient harm resulting from unsafe care was estimated to be the 14th highest contributor to the worldwide overall disease burden (Slawomirski and Klazinga, 2022).

One of the most pressing concerns in this context is medication errors, which contribute to a wide range of adverse health and non-health outcomes both within healthcare settings and within the community. Medication errors have been documented as a leading cause of preventable medical harm, with consequences to patients ranging from no or negligible harm in the majority of cases, to more severe outcomes such as hospitalisation, permanent disability or even death (Panagioti et al., 2017). The impact of medication errors and other forms of medical harm came to the forefront following the landmark report published by the United States (US) Institute of Medicine (IOM, 2000) at the end of the previous century, titled '*To err is human: building a safer health system*'. This report found that nearly 100,000 people pass away every year in the US alone due to preventable medical harm, of which medication errors play a leading role (IOM, 2000). Despite increased awareness following the IOM

report, more than two decades later, medication errors remain a persistent and significant global health challenge, with high rates of medication errors even in developed countries. According to the WHO, an estimated 1 in 30 patients are affected by medication errors (WHO, 2023).

Considering the harm from errors, over the following years, international health organisations have prioritised patient safety, including medication safety, to reduce preventable harm, improve health outcomes and strengthen healthcare systems. The WHO has been a leading driver in advocating for patient safety and over the past decades has published regularly on the topic. In 2017, WHO launched its third Global Patient Safety Challenge, titled "*Medication Without Harm"*. This report highlighted that many medication errors can be considered preventable when they result from an identifiable cause. WHO emphasised that by strengthening healthcare systems and improving practices across the entire medication use pathway, the frequency of many of the medication errors can be reduced or outright prevented (WHO, 2017). To this effect, in 2017, the WHO set an ambitious target of reducing medication errors by half over the subsequent 5 years in a bid to combat the harm caused by medication errors. This third WHO Global Patient Safety Challenge has been endorsed by two-thirds of signatories (WHO, 2024b).

Emanating from the third Global Patient Safety Challenge, three main priority areas were identified for reducing medication-related harm: transitions of care, polypharmacy, and care in high-risk situations, with WHO technical reports published on each topic (WHO, 2019a, 2019b, 2019c). The first priority area, concerning transitions of care, refers to those points in the treatment trajectory when a patient

either changes physical location or engages a healthcare provider to obtain treatment or services. These moments are at risk of medication errors to occur as they routinely involve starting, changing or discontinuing one or more medications (WHO, 2019c). A 2018 Cochrane Review found that just under 56% of patients were at risk of at least one medication discrepancy at transitions of care (Redmond et al., 2018). The second priority area focused on polypharmacy, which refers to the concurrent routine use of multiple, usually defined as at least five, medications (WHO, 2019b). The patients most impacted by polypharmacy are the elderly and those residing in long-term care institutions (WHO, 2019b). Polypharmacy, while at times necessary, is a significant challenge in medication safety as it increases the likelihood of an adverse event, particularly due to a higher risk of drug-to-drug interactions (Wolff et al., 2021), and augments the risk of medication error as the number of medications taken increases (Sears, Scobie and MacKinnon, 2012). The WHO technical report outlining the third priority area, Medication Safety in High-Risk Situations, describes the factors which more regularly result in medication errors and significant harm. These include medication-related factors, such as high-alert medications, as well as healthcare provider and patient factors, and system factors. The latter can either be related either to the setting or the situation, with the acute care hospital setting being a particularly high-risk area for medication errors (WHO, 2019a).

Further supporting global patient safety efforts, at the start of this decade WHO launched the "*Global Patient Safety Action Plan (2021-2030)*". Within this action plan, strategic objective 3, titled 'Safety of Clinical Processes', highlights medication errors as a priority area (WHO, 2021). According to WHO's 2024 Global Patient Safety Report,

41% of countries have launched patient safety improvement programmes, of which 78% have launched initiatives specifically targeting medication errors (WHO, 2024b).

1.2 Culture in Healthcare

The culture within healthcare organisations has a fundamental role in influencing patient outcomes and the safe delivery of care, as it influences how healthcare professionals view and approach patient safety, error reporting, and quality improvement. A positive safety culture, described as the shared understanding, attitudes and standards present within a healthcare institution regarding the expected behaviours and practices towards patient safety, is essential for improving patient safety and reducing medication errors within healthcare systems (Reis, Paiva and Sousa, 2018). According to WHO, an underdeveloped and undervalued culture of quality and safety, coupled with disengaged leadership, reduces the ability of healthcare systems to ensure safe care to patients (WHO, 2019c).

James Reason proposed that the most effective safety cultures are those that are informed by the best safety practices, are open to and able to report incidents, and have a clear commitment to learning from mistakes (Reason, 2016). This view, however, contrasts with the punitive or blame-oriented cultures which were common across many healthcare institutions in the past (Yusof and Razali, 2024). While such cultures have reduced, unfortunately, such beliefs are still encountered in some healthcare settings in the present day. Punitive or blame-oriented cultures hinder opportunities for learning and prevent safety improvements as healthcare staff

become less willing to report patient safety incidents openly and willingly (Cooper et al., 2017).

Recognising the limitations of a punitive culture, healthcare systems globally are moving away from blame-oriented cultures. Some organisations have adopted a no-blame approach; however, while this moves away from a punitive approach that discourages error reporting, it may inadvertently limit an individual's own accountability and minimise the sense of responsibility when a mistake happens (Parker and Davies, 2020). In contrast, a just culture is a systems thinking approach which balances organisational accountability for the systems in place with individual accountability for the choices and actions performed (Paradiso and Sweeney, 2019). A just culture, therefore, distinguishes between those mistakes that result from a system failure, and those errors stemming from otherwise reckless or substandard behaviour or practices that warrant individual accountability (Mira, 2023).

The transition to a just culture aligns with Domain 4 of the WHO Global Patient Safety Challenge, focused on the systems and practices of medications. This Domain emphasises the importance of resilient healthcare systems and practices that are properly designed to minimise risk and harm, supported by blame-free reporting mechanisms, institutional learning and evidence-based policies (WHO, 2024b). The relationship between culture and reporting practices becomes evident in medication safety reporting systems, which largely rely on voluntary reporting. One of the main barriers that limits reporting is the lack of a supportive environment, causing healthcare professionals to feel uncomfortable reporting errors or near misses (OECD, 2022).

This intricate relationship between organisational culture and reporting practices demonstrates that the establishment of a just culture, focused on organisational learning and promoting an open error reporting culture free from unjust blame, could enhance reporting behaviours. This underscores the need for cultural transformation within healthcare institutions to embrace a just culture, which is vital for organisational learning, continual improvement, and ultimately enhanced patient safety outcomes (Boysen, 2013; OECD, 2022).

1.3 Delivery of Acute Healthcare in Malta

Acute care is defined as the provision of often time critical healthcare services that address urgent medical or surgical conditions (Hirshon et al., 2013). This includes emergency medicine, potentially life or limb-threatening clinical scenarios, trauma cases, acute surgical interventions, intensive care and conditions which require inpatient medical stabilisation or treatment (Hirshon et al., 2013).

In Malta, healthcare is delivered through both the public and the private sectors. The public sector is the main healthcare provider, offering prevention, promotion, primary, secondary and tertiary level and long-term care in Malta. The private healthcare sector has an important complementary role in the local healthcare provision, offering both outpatient and inpatient services (OECD, 2023). In recent years, the public sector has outsourced several services to the private sector, including certain surgical procedures and some aspects of emergency care (Times of Malta, 2025). Given that acute hospital settings are identified as high-risk environments for medication errors and considering the increased service provision through the private sector

recently, this dissertation will explore medication errors in the context of Malta's acute hospital settings.

The National Health Systems Strategy (NHSS) for Malta 2023-2033 outlines several initiatives undertaken and proposed to improve patient safety within the Maltese healthcare system. A Patient Safety and Quality Improvement Team and a Clinical Risk Assessment Unit within Mater Dei Hospital have been set up, with the aim of reducing the occurrence of adverse events, strengthening error reporting practices, fostering greater organisational learning, and ultimately improving patient outcomes. The NHSS also highlights the importance of bringing patient safety issues to the forefront and strengthening the legal basis to support these initiatives (Ministry for Health, 2022). The National Patient Safety Strategy 2025-2035 was launched for public consultation on 4th September 2025 (Ministry for Health and Active Ageing, 2025).

1.4 The Public Health Importance of Medication Errors

Patient harm during healthcare delivery remains one of the leading causes of preventable morbidity and mortality worldwide, with medication errors a leading contributor to this burden. According to the WHO's "*Global burden of preventable medication-related harm in healthcare",* as many as 1 in 20 patients experience preventable medication-related harm, underscoring the scale of the problem (WHO, 2024a). The OECD reported that 1 in 10 hospitalisations are caused by medication-related harm, and 1 in 5 inpatients experience medication-related harm during their admission episode (OECD, 2022).

The consequences of medication errors extend beyond direct clinical consequences to the patient. Medication errors may cause potentially long-term physical harm to the patient, as well as psychological harm to both patients and their caregivers (Ottosen et al., 2021). Furthermore, patients who suffer a medication error may also be discouraged from engaging with healthcare services in the future (Ottosen et al., 2021). Medication errors also result in adverse consequences to healthcare professionals, who may experience emotional distress, guilt and a loss of professional confidence (Robertson and Long, 2018), while the healthcare organisations where the error occurs may endure reputational damage and a loss of trust (Mira et al., 2015).

Medication errors are also associated with substantial financial implications, such as prolonged hospital stays, increased readmissions and greater healthcare costs, culminating in an added strain to the healthcare system (Rasool et al., 2020). In Europe alone, the total costs of medication errors were estimated to range between €4.5 to €22 billion (WHO, 2022). The WHO has highlighted that comprehensively tackling and investing in patient safety initiatives, especially high-cost and harmful events like medication errors, can yield a significant return on investment and reduce avoidable harm (WHO, 2024b).

In view of the above implications of medication errors, a comprehensive understanding of the underlying causes and contributory factors of medication errors is essential for developing effective, evidence-based prevention strategies to mitigate against errors. Naseralallah et al. (2022) identified that medication errors stem from an interplay of various contributory factors, ranging from active failures by front-line

professionals to latent issues such as inadequate staffing, management decisions and hospital culture (Naseralallah et al., 2022).

A positive reporting culture helps to better understand the root cause of errors, learn from past mistakes and implement targeted interventions (Wolf and Hughes, 2008). Despite the implementation of international regulatory frameworks, such as the EU Directive 2010/84/EU and the Commission Implementing Regulation (EU) No 520/2012, which mandate the reporting of suspected medication errors, gaps remain in the translation of these regulations into clinical practice. Evidence from the literature indicates that under-reporting of medication errors remains widespread (Vrbnjak et al., 2016), suggesting that current legislative measures have not yet sufficiently fostered the culture, behaviours and practices required for effective error reporting and surveillance. This disparity between legislation and practice directly hinders patient safety efforts, ultimately resulting in poorer patient outcomes (Alshammari et al., 2021). Various barriers to reporting, such as fear of reporting, time constraints, unclear reporting processes and many others, have been documented in the literature (Bonella et al., 2023). These barriers ultimately suppress surveillance efforts, resulting in the true burden of medication errors being underestimated and opportunities for system improvement being missed (Rutledge, Retrosi and Ostrowski, 2018).

Given their frequency, severity, economic and system-wide implications for healthcare systems, as well as the need to understand their causes and improve reporting practices, medication errors are therefore a topic of substantial Public Health importance (WHO, 2024a).

1.5 Addressing the Knowledge Gap and the Rationale for the Study

Despite the growing international body of literature on the prevalence, causes, contributory factors and reporting practices of medication errors, only a few peer-reviewed publications and university dissertations have been published over the past decade focusing on this topic within the Maltese healthcare context, most of which have adopted a predominantly quantitative approach.

This study seeks to bridge these gaps through an explanatory-sequential mixed-methods approach. The quantitative phase will utilise data from the EudraVigilance, the EU's centralised electronic reporting system, which enables the collection and monitoring of suspected adverse drug events through Individual Case Safety Reports (ICSRs). The EudraVigilance allows for the identification of any safety risks, informs medication safety practices, and supports the implementation of swift actions to safeguard patient safety (European Medicines Agency [EMA], no date).

Through a retrospective analysis of ICSRs from EudraVigilance, the quantitative phase of this dissertation will map medication error reporting patterns across the European Economic Area (EEA), including Malta, and the United Kingdom (UK), identify the main stages and types of errors across the medication-use process, and identify any pertinent patient factors and the medications frequently involved in errors.

Informed by the results of the quantitative analysis, the qualitative phase of this study then seeks to obtain a rich and deeper understanding of the issue in Malta through the perspectives of various healthcare professionals, including nurses, doctors and pharmacists. The qualitative phase explores their perspectives on the causes and

contributory factors of medication errors and their reporting practices. This qualitative approach is particularly valuable as it uncovers underlying attitudes and barriers that may not be captured through quantitative methods alone and helps to explain any notable patterns or gaps identified from the analysis of the EudraVigilance database. As far as the author is aware, this is also the first local study to gather insights from professionals working within different acute hospital settings in Malta. This may therefore reveal both differences and similarities in the causes of medication errors, barriers to reporting and highlight successful prevention and mitigation strategies across different healthcare settings locally.

The findings from this study, undertaken as partial fulfilment of the MSc in Public Health, will provide valuable insight into the issue, support the development of targeted prevention strategies, strengthen reporting systems and safety culture, and contribute to the growing body of evidence on medication errors and patient safety.

1.6 Study Aim and Objectives

1.6.1 Aim

The aim of this study is to explore medication errors and reporting practices in the acute care setting in Malta

1.6.2 Objectives

The objectives of this study are:

To carry out a thorough literature review to appraise, assimilate and present the current evidence on the prevalence and causes of medication errors, the barriers to their reporting, and the theories and models relevant to the study.

To carry out a retrospective, quantitative analysis of anonymised individual case study reports (ICSRs), from the countries in the European Economic Area (EEA) and the UK (including Malta), submitted to the EudraVigilance database over the latest available 3-year period.

To explore the perspectives of healthcare professionals on causes of medication errors, contributory factors and the barriers to reporting faced by healthcare professionals within an acute hospital setting using a qualitative approach.

To suggest potential strategies to reduce the occurrence of medication errors and to improve reporting in the acute hospital setting.

1.7 Chapter Summary

This chapter established medication errors as a significant global public health challenge and a leading cause of preventable morbidity and mortality, and outlined the impact on patients, family members, healthcare professionals and healthcare organisations. The chapter identified recent global patient safety initiatives and priority areas aimed at addressing this issue. The introduction also set the scene for this dissertation by outlining the research aim and objectives.

Chapter 2: Literature Review

2.1 Introduction

This chapter presents a comprehensive review of the literature on medication errors, including definitions, prevalence, impact, causes and contributory factors, consequences and reporting practices. It also explores the theoretical frameworks that informed and were utilised in the study. A narrative literature review was undertaken to provide a broad overview of the topic, which was supplemented with a focused and structured search of the literature for the sections on causes and contributory factors to medication errors and the barriers and facilitators to reporting. The structured search drew on studies published in the last 10 years and used defined search strategies and inclusion criteria. This ultimately provides a foundation for understanding key issues and for contextualising the research aims of this study. *Figure 1* provides a graphical illustration of the structure of the literature review, distinguishing between the sections with a narrative review and the two structured searches.

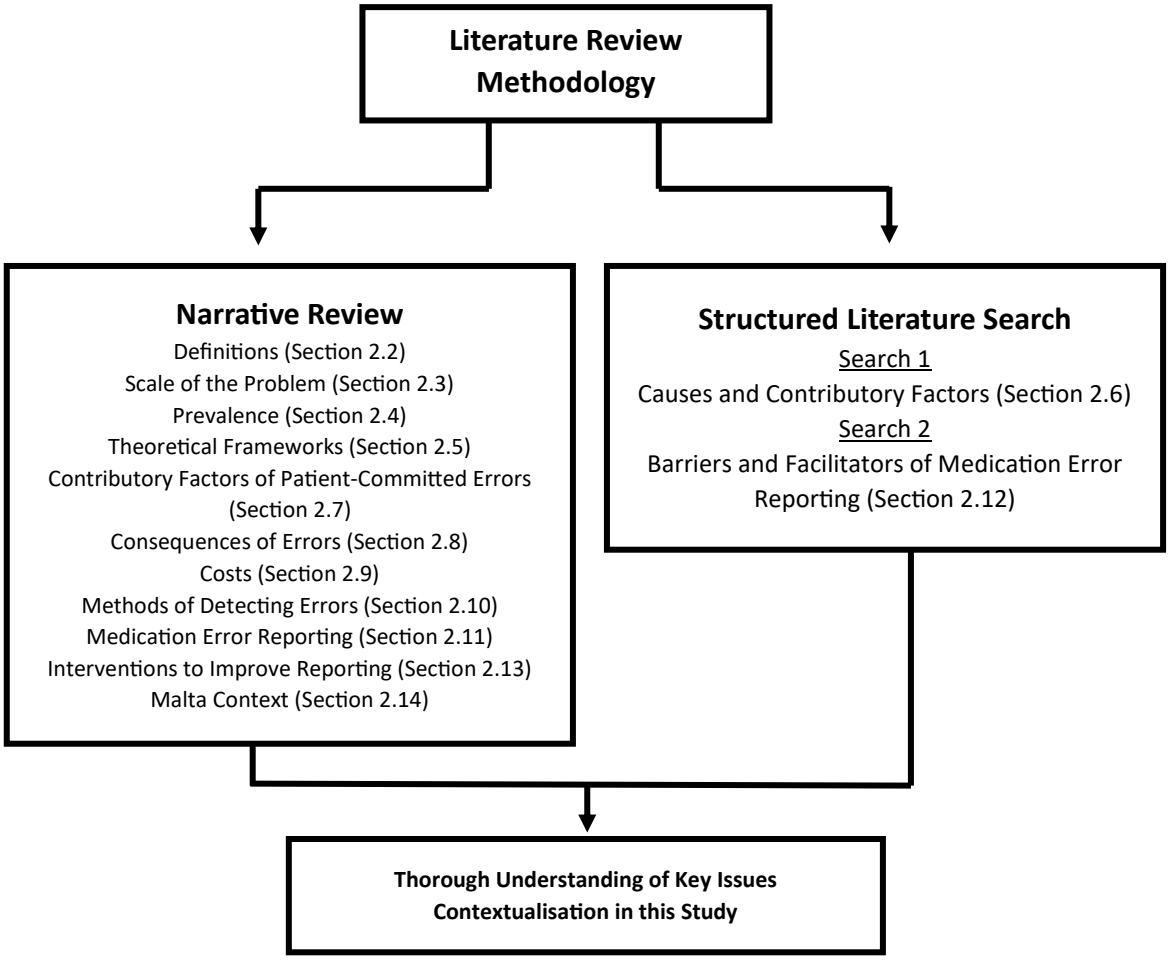

Figure 1 - Structure of the Literature Review

2.2 Definition of Key Terminology

The following are the definitions of the key terms used when describing Adverse Drug Events (ADEs), Adverse Drug Reactions (ADRs) and Medication Errors.

Adverse Drug Events (ADEs) have been defined as any "*injury resulting from the use of a drug…that encompass adverse drug reactions and harm resulting from medication errors*" (Nebeker, Barach and Samore, 2004). Similar to this definition, the Good Pharmacovigilance Practices (GVP) describe ADEs as any untoward or unintended sign, symptom or disease following the administration of a medication to a patient,

which may or may not be directly related to the drug itself (European Medicines Agency [EMA], 2024a).

Adverse Drug Reactions (ADRs) refer specifically to the harmful responses caused by the intrinsic properties of a drug when it is used at its normal doses. These reactions often have the risk of reoccurring and may require specific action to be taken, such as changes in the dose or stopping the medication altogether (Edwards and Aronson, 2000). Similar to this definition, the GVP described ADRs as a harmful and unintended response to the medication, where an association between the drug and the reaction is possible (EMA, 2024a).

When describing medication errors, various definitions are used in the literature or by prominent international organisations. While the core concept of each remains largely similar, some slight differences do exist. EMA defines medication errors as "*an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient. Mistakes in the prescribing, dispensing, storing, preparation and administration of a medicine are the most common preventable cause of undesired adverse events in medication practice and present a major public health burden*" (EMA, no date). The 'failure' described above refers to process or human failures, and not simply a lack of therapeutic effect of the medication (EMA, 2024a). While the definition has various strengths, certain authors have critiqued it due to attributing medication errors as a 'failure', which may have negative connotations (Lisby et al., 2010).

Another one of the most commonly used definitions of medication error is that by the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP, no date), which defines medication errors as:

"*any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use*".

While similar to EMA's definition, the NCCMERP's definition is more comprehensive and highlights that medication errors can occur at various stages, referred to as the medication use process, and that medication errors can occur either by a healthcare or a non-healthcare worker. This definition also highlights the preventable aspect of medication errors, as opposed to ADRs. The definition by the NCCMERP was used to guide this dissertation.

The concept of a 'never event', defined as a serious yet largely preventable patient safety incident that should not occur in any scenario, is also applicable to medication errors (Agency for Healthcare Research and Quality [AHRQ], 2024). While traditionally referred to medical errors in surgical settings, such as operating on the wrong limb, the AHRQ explicitly classify severe medication errors as never events, namely those involving the wrong dose or drug which lead to a patient's death or serious harm (AHRQ, 2024).

In addition to medication errors that actually reach the patient, it is also important to define near-miss events. A near miss is defined as either an error that occurs and has the potential to harm the patient but then does not reach the patient, or a situation where an error could have occurred but ultimately did not happen, either due to timely intervention or else by luck (World Health Organisation [WHO], 2005; Claffey, 2018).

The medication use process provides the framework for safe medication use across all settings and encompasses the five (5) main stages of the pathway: prescribing, transcribing, dispensing, administering, and monitoring, as shown in *Figure 2* (Vest et al., 2024). Each stage of the medication use process can lead to medication errors, as each stage has its associated challenges and factors that can lead to an error in medication use (Yu et al., 2025).

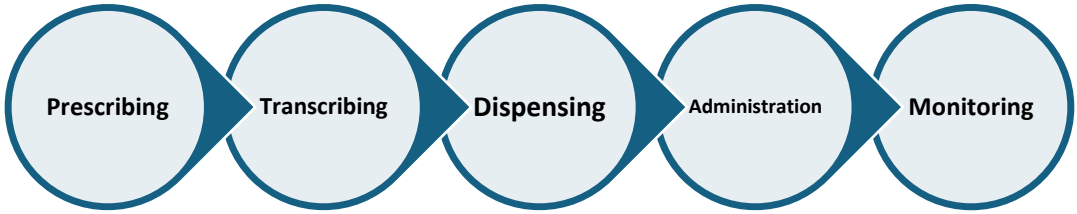

Figure 2 - Stages of the Medication Use Process (Adapted from Vest et al., 2024)

Table 1 provides the definitions of medication errors at each stage of the medication use process and highlights the healthcare professionals involved.

Table 1 - Medication Errors by Stage of the Medication Use Process

Stage of the Medication Use Process	Definition of Stage	Healthcare professionals involved
Prescribing Error	When a prescribing decision results in an unintentionally large decrease in the likelihood that treatment will be timely and effective, or result in a greater risk of harm, when compared to standard practice (Dean, 2000).	Primarily doctors. Nurse practitioners can prescribe in some countries.
Transcribing Error	Any discrepancy between the prescribed medication and any document related to the patient, including but not limited to the medical record, medication request sheet or discharge documents (Shawahna, Abbas and Ghanem, 2019).	Various healthcare professionals, primarily doctors (e.g. when (re-) writing treatment charts) and nurses (e.g. compiling medication request forms sent to pharmacy).
Dispensing Error	Any disparity between a prescription and the medications provided to the patient or supplied to the ward based on this prescription. Dispensing errors also include providing a medication that is of lower quality pharmaceutically or informationally (Um, Clough and Tan, 2024).	Pharmacists
Administration Error	Any deviation from the prescribed medication order as documented in the patient's medical record, administration guidelines provided by the drug manufacturer or any other relevant internal guideline (Shawahna et al., 2016)	Primarily nurses. Doctors may also administer medications (e.g. in anaesthesia)
Monitoring Error	When a medicine is not monitored in the way that would be considered acceptable in routine medical practice, and applies both at initiation and continuation of treatment (Alldred et al., 2010)	Various healthcare professionals, namely doctors (e.g. when reviewing lab investigations or clinical signs) and nurses (e.g. observations during infusions)

2.3 Medication Errors: The Scale of the Problem

As outlined in the Introduction, medication errors remain one of the leading causes of preventable medical harm, contributing to increased rates of morbidity and mortality. Medical errors, with medication errors as one of the main causes, have been ranked as the third most common cause of mortality in the United States (US) (Makary and Daniel, 2016), with the WHO estimating that at least one death per day in the US occurs due to a medication error (WHO, 2017). In the United Kingdom (UK), over 237 million medication errors are estimated to occur each year, owing to a mistake along the medication use process, with over 180,000 bed days consumed annually due to errors (Elliott et al., 2021). Additionally, medication errors account for approximately 5% - 42% of hospital admissions and contribute to 22% of readmissions (Tariq et al., 2025), while a similar study in the Netherlands found that medication errors contributed to 16% of all readmissions (Uitvlugt et al., 2021). In more severe cases, medication errors may lead to serious consequences such as disability or death. A systematic review found that 16.3% of medication errors involving high alert medications caused patient harm, with 0.01% resulting in death (Sodré Alves et al., 2021).

The frequency of preventable medication harm varies by healthcare setting. A global meta-analysis found that the highest rate of potentially preventable medication harm occurred in elderly long-term care settings (11%), followed by in-hospital acute care environments, particularly intensive care units (ICU), highly specialised or surgical care and the emergency department, with rates of 7%, 6% and 5% respectively. In

contrast, the prevalence of preventable medication harm was only 1% in the primary care setting (Hodkinson et al., 2020).

Hospitalised patients are particularly vulnerable to medication errors, as nearly every patient is prescribed some form of medication during their stay, making the hospital environment ripe for medication errors to occur (Roughead, Semple and Rosenfeld, 2016).

Patients admitted into an ICU setting have a greater likelihood of experiencing a medication error in view of the complexity of the clinical picture and the volume of medications prescribed. Nearly 80% of preventable medical errors within the ICU setting are due to medication errors (Tully et al., 2019), with the European Association of Hospital Pharmacists (EAHP, 2024) finding that the prevalence of medication errors ranged from 9.2 to 967 medication errors per 1,000 bed-days. Latif et al. (2013) found that medication errors in the ICU setting were more likely to cause patient harm than in the non-ICU setting (3.7% vs 1.9% respectively), and had higher odds ratios of resulting in permanent harm, necessitating a life-saving intervention, or resulting in death. Transitions of care, particularly from the ICU setting to a general ward setting, represent a critical window during which medication errors can occur. A multicentre study conducted in the US and the Netherlands found that nearly half of patients experienced a medication error during this transition, while a study in China reported a rate of 58% (Tully et al., 2019; Wang et al., 2022).

The Emergency Department, being the first port of call for patients who are acutely unwell, is recognised as another area with a high likelihood of a patient suffering a medication error. Aside from the potential of medication errors at

transitions of care, this department is characterised by a fast-paced environment, associated with overcrowding, and with healthcare professionals tending to multiple patients simultaneously (Sartini et al., 2022). Nguyen et al. (2024) reported a medication error prevalence of 22.6%, with 42.6% of these errors resulting in patient harm and a further 0.2% resulting in death.

Paediatrics is a speciality which is also susceptible to medication errors due to specific factors such as a greater proportion of weight-based dosing calculations, off-label prescriptions and fewer paediatric-specific guidelines (Kuitunen, Saksa and Holmström, 2025). Within paediatric intensive care units, medication error rates have been reported at 14.6 errors for every 100 medication orders (Burns, Lal and Mc Donnell, 2023).

2.4 Prevalence of Medication Errors by Stage of the Medication Use Process

In a study using case reports from the EudraVigilance database over the period August 2012 to August 2015, Despott et al. (2023) found that 41% of classified medication errors were related to prescribing, 39% to administration and 20% to dispensing errors (Despott et al., 2023). Similar findings were reported in a systematic review and meta-analysis by Almalki et al. (2021), where prescribing errors accounted for 40.2% of cases, followed by administration errors (34.5%) and dispensing errors (28.2%) (Almalki et al., 2021).

Despite general trends, there is considerable variation in the reported prevalence of specific error types across studies and healthcare settings. A systematic review by Um, Clough and Tan (2024) identified that dispensing errors ranged widely from 0% to 33.3%, with a pooled prevalence across all studies calculated to be 1.6% (1.2% - 2.1%). Transcription errors also showed marked variability, ranging from 26.7% of patients who had at least one transcription error in one study to another study, which found that 88.6% of medication charts had at least one transcription error, with 22% containing three or more errors (Ratnapala et al., 2022; Ntani and Sangha, 2024). With respect to monitoring errors, Bosma et al. (2021) found that 4% of reported medication errors were monitoring errors, while in Alqenae et al. (2023) these accounted for 12% of reported errors.

2.5 Theoretical Frameworks Relevant to this Research

2.5.1 Introduction

The use of theoretical frameworks in research has been recognised as a core concept, with some authors describing it as a lens that can help frame and guide a study. The use of theoretical frameworks in research helps to situate the research undertaken within the existing body of research and supports the collection of different perspectives on the same phenomenon. Theoretical frameworks can also help reduce researcher subjectivity and may aid in the interpretation and analysis of the qualitative data collected (Anfara and Mertz, 2006).

This study is guided by two theoretical frameworks: Reason's Accident Causation Model (Reason, 2000) and the Theoretical Domains Framework (Cane, O'Connor and Michie, 2012), described hereunder.

2.5.2 Reason's Accident Causation Model

James Reason's Accident Causation Model describes that accidents and adverse events are not caused by a single factor, such as an individual's error, but rather occur due to a combination of weaknesses across the entire system. This model has been widely used in the healthcare field since its inception and has also been used in other sectors such as engineering and aviation. Reason divided the weaknesses into two: active failures and latent failures (Reason, 2000).

Active failures are defined as unsafe acts that are often carried out by the front-line workers who have direct system or patient contact. Reason further subdivided active failures into lapses, slips, violations or mistakes (Reason, 2000). Lapses tend to be associated with a failure in memory, such as forgetting to prescribe a medication during medicines reconciliation, whereas slips usually arise due to a momentarily decrease in a person's attention, such as choosing the incorrect medication from a cabinet. Both types of errors regularly occur when performing otherwise routine tasks in a near automatic manner. Violations happen when an individual makes a conscious decision not to follow a rule or protocol, not necessarily with the intention of causing harm, but at times simply to save time or work. Mistakes usually result from a lack of knowledge or when applying a rule or process incorrectly, such as prescribing the wrong dose of a medication (Reason, 2000; Higham and Vincent, 2021).

Latent failures refer to those underlying factors within a system, often long-standing, which may go unnoticed as they do not cause immediate harm but nevertheless have the potential to do so. These latent factors may then create error-provoking conditions or lead to long-term weaknesses in system defences (Reason, 2000). Reason (2000) describes these defences as the barriers or controls which a system implements to prevent, detect or mitigate against errors. *Figure 3* provides a graphical illustration of the main domains from Reason's framework, whereby latent failures create error-provoking conditions that, coupled with active failures by frontline staff, can penetrate a system's weakened defences and result in an error or patient safety incident.

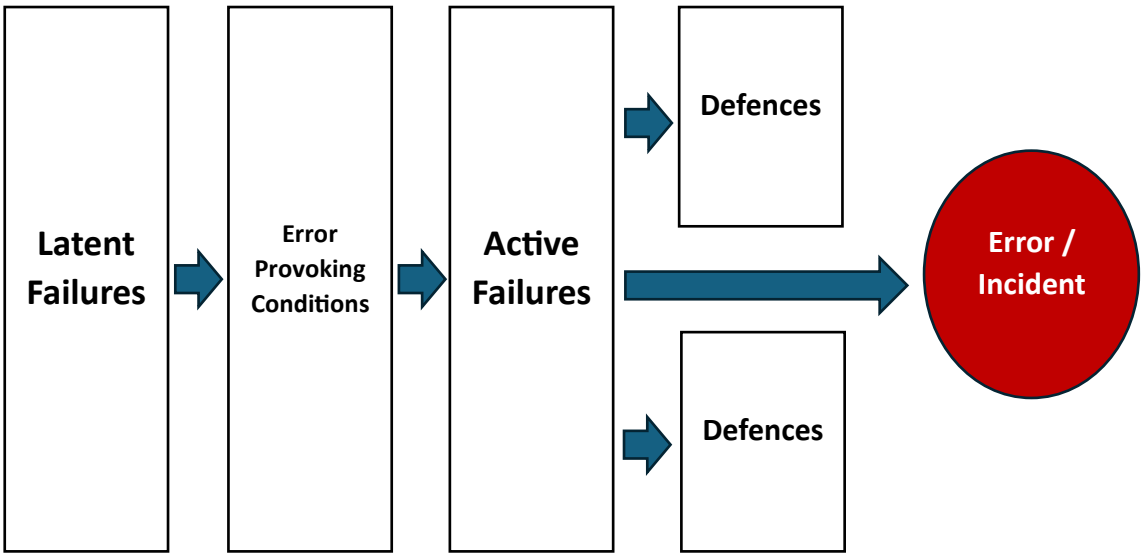

Figure 3 - Flowchart Illustrating Reason's Accident Causation Model (Adapted from Reason, 2000)

2.5.3 Theoretical Domains Framework

The Theoretical Domains Framework (TDF) is a theoretical framework first developed in 2005 and updated in 2012. It offers a structured and comprehensive approach to understanding the range of interconnected factors that influence

behaviour. The revised TDF is made up of the following 14 domains, encompassing social, cognitive, personal and environmental factors that influence behaviour (Cane, O'Connor and Michie, 2012):

(1) Knowledge

(2) Skills

(3) Social or professional role and identity

(4) Beliefs about capabilities

(5) Optimism

(6) Beliefs about consequences

(7) Reinforcement

(8) Intentions

(9) Goals

(10) Memory, attention and decision processes

(11) Environmental context and resources

(12) Social influence

(13) Emotion

(14) Behavioural regulation

The TDF is particularly useful as a theoretical framework as it enables the identification of the barriers and facilitators to behaviour changes. For this reason, it has been widely used in various healthcare studies in the healthcare field (Atkins et al., 2017).

2.6 Causes and Contributory Factors of Medication Errors

A structured literature search was conducted on the causes and contributory factors of medication errors. The findings from this search were grouped into active failures, error-provoking conditions and latent failures, as outlined by Reason's

Accident Causation Model and presented according to the stage of the medication use process in which they occur.

2.6.1 Search Strategy – Search 1

The aim of this structured systematic search was to explore the causes and contributory factors associated with medication errors made by healthcare professionals. A structured online search for relevant literature was carried out using academic databases, primarily PubMed and Scopus. The keywords and Boolean operators used included, but were not limited to:

"Medication error" OR "Drug error" OR "Medicine error" OR "Prescribing error" or "Prescription error" or "Transcribing error" or "Transcription error" OR "Dispensing error" OR "Administration Error" OR "Monitoring error"

AND

"Hospital" OR "Acute care" OR "Inpatient" OR "Tertiary care"

AND

"Cause" OR "Contributory" OR "Factor" OR "Reason"

An asterisk (*) at the end of keywords was used to increase the number of search results.

Inclusion criteria for the studies were that the included studies had to be in English (ensuring accurate interpretation of findings), published from 2015 onwards (thus representing the most recent available research), and the full text was available (to enable critical appraisal of results). The references from the included studies were also reviewed to identify any additional relevant publications.

The PRISMA flowchart (Page et al., 2021) in *Figure 4* graphically illustrates the number of articles initially identified, the subsequent selection and exclusion process, and the final number of articles included as part of the structured literature search on the stage-specific causes and contributory factors of medication errors. Initially, 1198 articles were found from database searching and 44 from other sources. Pertaining to those studies identified from database searching, after the removal of duplicates, 624 remained for title and abstract screening, of which 488 were excluded for not being related to the research topic. In total, 180 full-text sources were then reviewed, with 68 ultimately included in rest of section 2.6. Reasons for exclusion at the full-text stage included due to being undertaken not in real-world clinical settings, if the article did not provide information on error types, causes or contributory factors to medication errors, or if the descriptions of were not stage-specific.

Appendix A provides a tabulated overview of the main findings of the articles included as part of this structured search.

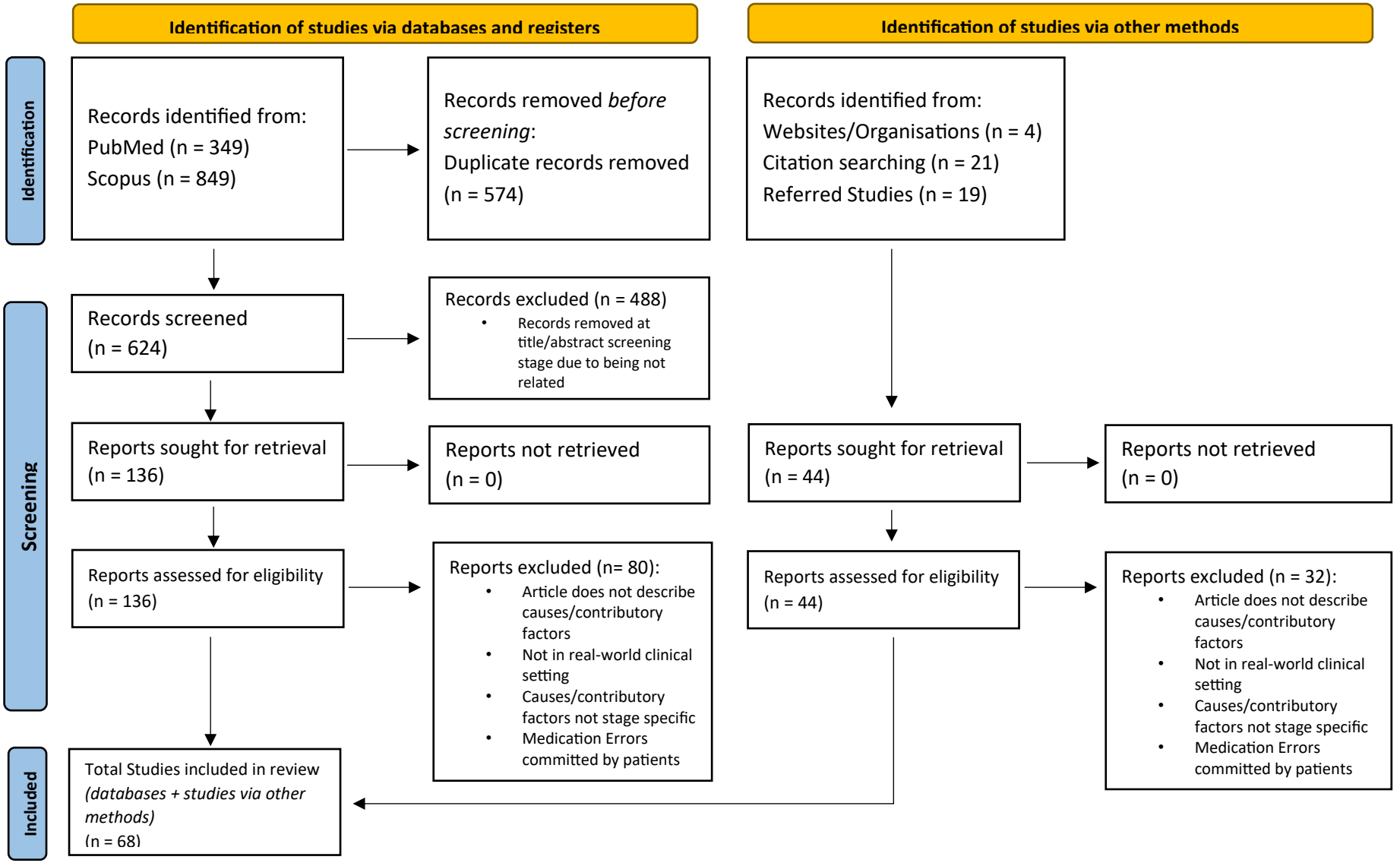

Figure 4 - PRISMA Flowchart Showing the Selection Process for the Literature on the Causes and Contributory Factors of Medication Errors

2.6.2 Prescribing

Error Types

Prescribing errors included wrong dose (Conn et al., 2019; Alharaibi et al., 2021; Anzan et al., 2021), wrong frequency (Alharaibi et al., 2021; Anzan et al., 2021) and medication omissions (Ashcroft et al., 2015; Bonella et al., 2023). Incomplete prescriptions and incorrect formulation were also observed, as well as the failure to specify maximum use for 'as required' medications (Khoo et al., 2017; Westbrook et al., 2018). Concerning fluid prescribing, most errors involved incorrect rates, either due to exceeding the maximum maintenance rate or wrong rate calculations (Conn et al., 2017).

The medication classes most frequently associated with prescribing errors were analgesics, especially opioids, and antimicrobials (Alharaibi et al., 2021; Anzan et al., 2021; Aldayyen et al., 2023).

Active Failures

Prescribing errors due to slips and lapses were identified in the literature review. Slips included errors such as incorrect decimal points when prescribing medications (Conn et al., 2019), while lapses in concentration, such as forgetting that a patient is allergic to a prescribed medication, prescribing on another patient's treatment chart, or forgetting to discontinue a prescription when no longer required, were identified (Conn et al., 2017; Alshahrani, Marriott and Cox, 2021; Bonella et al., 2023).

Slips and lapses were frequently observed with the use of electronic prescribing software, with one of the most common causes being simply the mis-selection of a

medication from the dropdown menu (Abdel-Qader et al., 2020; Alshahrani, Marriott and Cox, 2021; Anzan et al., 2021; Bonella et al., 2023).

Knowledge-based mistakes and rule-based mistakes were also identified. These included insufficient medication knowledge, incorrect dose calculations, and failure to amend prescriptions in response to drug interactions, antimicrobial sensitivities or patient clinical status (Conn et al., 2017, 2019; Puaar and Franklin, 2018; Sutherland, Ashcroft and Phipps, 2019; Anzan et al., 2021; Bonella et al., 2023).

Examples of violations included accepting a previous treatment chart without reviewing the patient's clinical condition (Bonella et al., 2023) and using adult treatment charts for paediatric patients to simply save time (Conn et al., 2017). Violations related to the electronic prescribing software included not following the protocol or guidelines for the proper use of the system (Alshahrani, Marriott and Cox, 2021).

Error Provoking Conditions

Workload, time pressures and low staff levels were the most frequently cited error-provoking conditions across multiple studies (Hansen, Bradley and Sahm, 2016; Puaar and Franklin, 2018; Conn et al., 2019; Sutherland, Ashcroft and Phipps, 2019; Abdel-Qader et al., 2020; Alharaibi et al., 2021; Alshahrani, Marriott and Cox, 2021; Anzan et al., 2021; Bonella et al., 2023; Mahomedradja et al., 2023, 2025; Alanzi, Tully and Lewis, 2024). Doctors felt that the workload was greatest during on-call or night duties, when they are responsible for all patients across multiple wards in the hospital (Alanazi, Tully and Lewis, 2016; Hansen, Bradley and Sahm, 2016; Puaar and Franklin, 2018).

The prescriber's physical and emotional state was also found to be associated with errors. Common factors included tiredness or fatigue, stress, lack of sleep, and hunger, all of which impacted decision making and contributed to errors (Khoo et al., 2017; Puaar and Franklin, 2018; Sutherland, Ashcroft and Phipps, 2019; Alshahrani, Marriott and Cox, 2021; Bonella et al., 2023; Mahomedradja et al., 2023; Alanzi, Tully and Lewis, 2024). Westbrook et al. (2018) found that when doctors had a below-average sleep duration, the risk of an error was more than 16 times higher (Risk Ratio [RR]: 16.4) compared to having an average sleep duration. The act of prescribing itself, particularly involving high-risk medications, was also associated with fear and anxiety, leading to overly cautious prescribing, such as by underdosing the medication (Alanzi, Tully and Lewis, 2024).

Distractions and interruptions were another major theme, particularly in high-pressure or chaotic environments such as the Emergency Department and surgical wards (Hansen, Bradley and Sahm, 2016; Khoo et al., 2017; Puaar and Franklin, 2018; Sutherland, Ashcroft and Phipps, 2019; Abdel-Qader et al., 2020; Alshahrani, Marriott and Cox, 2021; Bonella et al., 2023; Mahomedradja et al., 2025). One study found that when doctors were interrupted during prescribing, there was a nearly threefold increased risk of an error (RR: 2.82) (Westbrook et al., 2018). Anzan et al. (2021) specifically noted the effect of noise on doctors' ability to concentrate on prescribing tasks.

Patient-related factors could also give rise to error-provoking conditions. One common example was patient unfamiliarity during on-call shifts, when doctors were required to prescribe for patients not under their usual clinical care (Alshahrani,

Marriott and Cox, 2021; Bonella et al., 2023; Alanzi, Tully and Lewis, 2024). Other factors included the type of patient, such as paediatric cases (Alanazi, Tully and Lewis, 2016), patient complexity, either due to their clinical state, such as delirium or confusion (Puaar and Franklin, 2018; Bonella et al., 2023; Alanzi, Tully and Lewis, 2024) or due to rapid clinical deterioration (Conn et al., 2017), or due to polypharmacy (Abdel-Qader et al., 2020; Alshahrani, Marriott and Cox, 2021; Bonella et al., 2023).

Communication issues between doctors and nurses were also reported as contributing factors. These included miscommunications, such as referring to the patient by bed number instead of name or ID (Alharaibi et al., 2021; Alshahrani, Marriott and Cox, 2021; Bonella et al., 2023). In some instances, nurses did not provide sufficient background information for the prescriber (Alanzi, Tully and Lewis, 2024), while in others, doctors reported feeling pressured by nurses to prescribe medications, even if not clinically justified (Mahomedradja et al., 2023; Alanzi, Tully and Lewis, 2024).

Other less frequently cited error-provoking conditions included look-alike and sound-alike medications (Puaar and Franklin, 2018; Bonella et al., 2023), lack of medication knowledge (Sutherland, Ashcroft and Phipps, 2019; Mahomedradja et al., 2023, 2025) and limited clinical experience (Hansen, Bradley and Sahm, 2016; Conn et al., 2019; Mahomedradja et al., 2023, 2025).

Latent Failures

A lack of standardisation and issues with hospital protocols were common latent failures contributing to prescribing errors. Examples of lack of standardisation included the presence of different insulin sliding scales and treatment charts available

within the same hospital (Hansen, Bradley and Sahm, 2016; Alanzi, Tully and Lewis, 2024) and paediatric weighing scales calibrated in different units (with some reading in kilograms and others in pounds), which may lead to incorrect dose calculations (Khoo et al., 2017). The lack of, or difficulty accessing, hospital guidelines and protocols also contributed to errors (Khoo et al., 2017; Conn et al., 2019; Mahomedradja et al., 2023; Alanzi, Tully and Lewis, 2024). To address these latent factors, the implementation of a Safety Management System (SMS) provides a proactive approach to uncover and reduce these underlying risks through establishing defined safety guidelines and processes, thereby integrating patient safety within routine clinical practices (Chatzi and Kourousis, 2024; Zhelev et al., 2025).

Hospital culture was also identified as a latent risk contributing to prescribing errors. A hierarchical environment often discouraged junior doctors from seeking help or advice, due to the fear of being ridiculed or shouted at (Hansen, Bradley and Sahm, 2016; Sutherland, Ashcroft and Phipps, 2019; Bonella et al., 2023). In some cases, doctors refused to correct their prescriptions when an error was highlighted by a pharmacist (Abdel-Qader et al., 2020).

Latent issues were also seen with electronic prescribing systems. Various studies highlighted factors such as poor software design, a rigid, non-user-friendly interface, and excessive alerts leading to alert fatigue (Puaar and Franklin, 2018; Alshahrani, Marriott and Cox, 2021; Anzan et al., 2021; Bonella et al., 2023; Mahomedradja et al., 2025). Limited computer access was another issue raised (Puaar and Franklin, 2018). Despite these concerns, electronic prescribing was still associated with lower odds (Odds Ratio [OR]: 0.88) of a prescribing error compared to

handwritten prescribing (Ashcroft et al., 2015). Systematic reviews and meta-analyses also concluded that electronic prescribing systems, coupled with clinical decision support systems, reduce medication errors by 85% in patients admitted to the ICU setting (Prgomet et al., 2017) and 76% in general hospitalised patients (Roumeliotis et al., 2019). Additionally, Prgomet et al. (2017) also identified that mortality in the ICU was reduced by 12% following the introduction of these digital systems.

Lack of training was also highlighted. Participants felt that there was inadequate prescribing training from medical school through to specialty training, despite junior doctors having the greatest prescribing responsibility (Alanazi, Tully and Lewis, 2016; Bonella et al., 2023). Within specialisation training, prescribing is often overlooked in favour of clinical or surgical skill acquisition (Bonella et al., 2023). In some centres using electronic prescribing, doctors reported insufficient training on how to properly use the software (Puaar and Franklin, 2018; Abdel-Qader et al., 2020; Anzan et al., 2021; Mahomedradja et al., 2023, 2025).

The literature also identified that resource gaps, such as a lack of general and specialised staffing, and shortages of medications, contributed to prescribing errors. Medication shortages required clinicians to be well versed in multiple alternative options (Alharaibi et al., 2021), while high staff turnover and inadequate cover placed excessive responsibility on junior doctors to fill the gaps (Alshahrani, Marriott and Cox, 2021; Bonella et al., 2023). Conn et al. (2017) describe how, due to low staffing levels, non-specialist doctors were required to prescribe for certain patient groups, such as paediatrics, increasing the likelihood errors being committed. As a result of these resource gaps, a lack of supervision of junior doctors, particularly during on-call shifts,

further increased the likelihood of prescribing errors (Puaar and Franklin, 2018; Mahomedradja et al., 2023; Alanzi, Tully and Lewis, 2024). Another resource gap identified across several studies related to the presence of clinical pharmacists (Abdel-Qader et al., 2020; Anzan et al., 2021; Alanzi, Tully and Lewis, 2024). The literature provides evidence on the effectiveness of pharmacist interventions primarily on prescribing errors and at transitions of care. Batool et al. (2025) identified a significant reduction in prescribing errors due to clinical pharmacist interventions, particularly on wrong dose errors. Similarly, pharmacist interventions at transitions of care helped reduce discrepancies in prescribed medications by 66% and 42% in studies by Mekonnen et al. (2016) and Cheema et al. (2018), respectively. Redmond et al. (2018) however concluded that the effectiveness of pharmacist interventions was uncertain and based on low certainty evidence.

2.6.3 Transcribing

Fewer studies focused solely on transcription errors, compared to prescribing, dispensing and administration errors. Despite the increasing uptake of electronic systems for medication documentation in hospitals, many countries still rely on handwritten, paper-based documentation (Shawahna, Abbas and Ghanem, 2019).

Types of Errors

Multiple studies in the literature identified the omission of medication as one of the most common transcribing errors. A study by Abrishami et al. (2024) found that omissions during transcribing accounted for 29.3% of errors within this stage, while Ntani and Sangha (2024) reported a similar error rate for omissions of newly prescribed

medications, accounting for 28.9%. In contrast, a study within a hospital which predominantly used electronic software identified that omissions comprised only 3.7% of transcribing errors (Rahman et al., 2025).

The wrong dose transcribed was another common transcribing error seen, however variation on this type of error was noted depending on whether transcribing was done electronically or handwritten (Abrishami et al., 2024; Ntani and Sangha, 2024; Rahman et al., 2025). In a research setting using an electronic system, wrong dose errors accounted for 48.6% (Rahman et al., 2025), while only accounting for 18.4% in another study setting with solely paper-based treatment charts (Ntani and Sangha, 2024).

Incorrect medication name accounted for 80.9% of errors in the study by Ratnapala et al. (2022), mostly due to spelling mistakes, the use of trade names over generic names and incorrect or incomplete drug names. In contrast, these errors accounted for less than 15% of errors in studies by Ntani and Sangha (2024) and Rahman et al. (2025). Other less common transcribing errors included incorrect or missing frequency (Ntani and Sangha, 2024; Rahman et al., 2025), failure to discontinue a medication no longer clinically indicated (Ntani and Sangha, 2024) and a missing or incorrect route (Ratnapala et al., 2022).

Active Failures

Negligence by staff was cited as one of the main reasons for transcription errors, with 74% of participants in Ntani and Sangha (2024) attributing errors to negligence. Mistakes, such as forgetting to transcribe a medication from one treatment chart to another, or mistakenly adding a previously unordered medication, were other

causes of transcribing errors (Kinlay et al., 2021; Ratnapala et al., 2022; Rahman et al., 2025).

Specific to electronic systems, slips and lapses occurred when healthcare professionals did not amend the default administration times automatically generated by the system (Kinlay et al., 2021). Furthermore, complicated or rigid electronic platforms sometimes led staff to knowingly deviate from standard operation procedures, increasing the likelihood of errors (Kinlay et al., 2021; Rahman et al., 2025).

Error Provoking Conditions

Illegible handwriting on prescriptions was one of the most frequently identified error-provoking conditions, identified in multiple studies (Abrishami et al., 2024; Ntani and Sangha, 2024; Rahman et al., 2025). In one study, 90.7% of nurses reported that illegible prescriptions by doctors contributed to transcribing errors (Ntani and Sangha, 2024). Notably, there was general agreement that the implementation of electronic prescribing systems would largely eliminate this issue and markedly reduce transcribing errors (Kinlay et al., 2021; Abrishami et al., 2024; Ntani and Sangha, 2024; Rahman et al., 2025).

Similar to other stages of the medication use process, inadequate staffing levels, heavy workloads and time constraints were consistently identified as common contributory factors to transcribing errors (Ratnapala et al., 2022; Ntani and Sangha, 2024; Rahman et al., 2025) . Rahman et al. (2025) found that transcribing errors were most likely during peak hours when the workload is greatest, while Ratnapala et al.

(2022) described how low staffing worsened the already high workload, which further increased the probability of staff committing a transcribing error.

The presence of look-alike medication names also increased the likelihood of transcribing errors (Abrishami et al., 2024; Rahman et al., 2025). While this was less common than the previous contributory factors, it still accounted for 6.3% and 4.9% of transcribing errors in studies by Rahman et al. (2025) and Abrishami et al. (2024), respectively.

Other causes of transcribing errors included factors such as a patient's clinical condition, with a significantly increased likelihood of transcribing errors when admitted to ICU settings ($p < 0.01$) (Abrishami et al., 2024). A greater number of medications or complex regimes (Ratnapala et al., 2022; Ntani and Sangha, 2024) and frequent distractions during transcribing were also identified (Ntani and Sangha, 2024; Rahman et al., 2025).

Latent Failures

The most commonly identified latent failure was the presence of hybrid systems, whereby some units use paper-based treatment charts, while other units within the same hospital use electronic systems. These systems require healthcare professionals to copy the paper-based treatment charts onto the electronic software and vice versa, which, aside from causing duplication of work, also increases the risk of a transcribing error (Khoo et al., 2017). Kinlay et al. (2021) and Rahman et al. (2025) concluded that in healthcare settings with hybrid systems, there is a greater risk of transcribing errors, particularly medication omissions. A lack of standardisation of

medication charts within the same hospital was another latent factor that increased the likelihood of transcription errors (Ntani and Sangha, 2024).

Other common latent failures included a lack of sufficient training and knowledge, particularly when electronic systems were newly implemented, leading to a spike in medication errors (Kinlay et al., 2021; Rahman et al., 2025).

2.6.4 Dispensing

Types of Errors

One of the most common types of dispensing errors identified across multiple studies was the dispensing of the wrong medication. Aldhwaihi et al. (2016) reported that this type of error was present in all 14 studies included in their systematic review. This finding was echoed in Gao et al. (2023), where 85% of dispensing errors stemmed from either the wrong medication or an incorrect quantity being dispensed. Similarly, Tseng et al. (2018) found that 37.2% of dispensing near misses were due to the selection of the wrong drug, often caused by look-alike drug names, similar packaging, or simply grabbing the adjacent box from the one intended.

Dispensing errors involving the incorrect strength or formulation were also frequently reported, with such errors noted in most studies included in two systematic reviews (Aldhwaihi et al., 2016; Um, Clough and Tan, 2024). Dispensing the wrong quantity of medication was another common error. In Tseng et al. (2018) and Momo et al. (2022), the incorrect quantity of medication dispensed was the most frequently reported dispensing error or near-miss, accounting for 44.9% and 47.9% respectively, while being the second most common error in another study (Chou et al., 2024). The

failure to dispense a prescribed medication (dispensing omissions) was another routinely identified type of dispensing error (Aldhwaihi et al., 2016; Um, Clough and Tan, 2024).

Labelling errors were identified in fewer studies, but their potential impact is still significant. These errors include mislabelling a medication with the wrong patient's name, which could result in it being administered to the incorrect patient. Aldhwaihi et al. (2016) found that the most frequent labelling error was incorrect patient identification (reported in 5 out of 14 studies), though other types of labelling errors, such as incorrect instructions and wrong medicine names, also featured. Similarly, Um, Clough and Tan (2024) found that while labelling errors were less common than content errors, they still featured in one-third of the reviewed studies.

Active Failures

Several active failures were identified across the studies. Slips or lapses often occurred when pharmacists operated in a habitual or automatic manner, as well as due to a lack of concentration (Aldhwaihi et al., 2016; Gao et al., 2023). Under the sub-theme of mistakes, examples included staff failing to thoroughly read prescriptions and making errors in dose calculations (Aldhwaihi et al., 2016; Gao et al., 2023). Violations were also noted, whereby staff were found to have failed to adhere to written guidelines and policies, thereby increasing the likelihood of medication errors (Aldhwaihi et al., 2016; Al-Ahmadi et al., 2020).

Error Provoking Conditions

A high workload and time constraints were among the most consistently cited causative and contributory factors to dispensing errors (Aldhwaihi et al., 2016; Shire et

al., 2018; Al-Ahmadi et al., 2020; Gao et al., 2023; Chou et al., 2024; Tariq et al., 2025). When staff are faced with a persistently high workload for over an hour, typically during peak hours of the day, there is a greater likelihood of dispensing errors being committed (Shire et al., 2018; Gao et al., 2023). Furthermore, as more mistakes are made, a positive feedback loop can develop, requiring additional work to correct those errors, which further adds to the workload (Shire et al., 2018). Chou et al. (2024) found a statistically significant association ($p < 0.01$) between higher-than-average daily prescription volumes and dispensing errors. The use of technological solutions, such as barcode scanning and automated dispensing machines, was also found to help ease workload pressure and reduce error rates (Poole et al., 2021).

Fatigue compounded the effects of this high workload (Al-Ahmadi et al., 2020; Momo et al., 2022). Al-Ahmadi et al. (2020) described how, in addition to the heavy workload, healthcare professionals often have to balance academic commitments, along with social and family life, leading to exhaustion and a lack of sleep, both of which increase the likelihood of committing a medication error. Dispensing errors are also more likely to occur at the end of a shift, when fatigue typically sets in (Gao et al., 2023).

Staffing issues were another major contributor to dispensing errors. Aldhwaihi et al. (2016) noted that in some centres, staffing levels were so critical that at times, a single pharmacist was left to manage the hospital pharmacy. Aside from the lack of pharmacists, the lack of support staff, such as pharmacy technicians, further compounded the issue (Tariq et al., 2025). The important role of accredited pharmacy technicians was underscored by Poole et al. (2021), who found that accredited

pharmacy technicians could reduce dispensing errors by performing final checks before dispensing. Besides the shortage of staff, inexperience was another factor. During night shifts, less experienced staff were often left to manage duties, and these individuals were found to be statistically significantly more likely to be involved in an error than more experienced colleagues ($p = 0.04$) (Momo et al., 2022).

Look-alike and sound-alike medications were another leading cause of dispensing errors, identified in virtually all studies included (Aldhwaihi et al., 2016; Tseng et al., 2018; Al-Ahmadi et al., 2020; Momo et al., 2022; Gao et al., 2023; Chou et al., 2024; Sagawa et al., 2024; Tariq et al., 2025). Sagawa et al. (2024) found that medications with similar names, packaging and even a similar method of action had a higher likelihood of causing a dispensing error. This was backed up by Chou et al.'s (2024) findings, where 72% of medication errors were attributed to look-alike and sound-alike medications.

Interruptions and distractions were identified as key error-provoking conditions (Aldhwaihi et al., 2016; Al-Ahmadi et al., 2020; Gao et al., 2023; Chou et al., 2024; Tariq et al., 2025). Noise was noted to cause staff to lose concentration when working, with interruptions due to phone calls being a commonly cited gripe (Aldhwaihi et al., 2016; Al-Ahmadi et al., 2020).

Lack of teamwork and communication issues also play a role in contributing to dispensing errors. A lack of oral communication, especially between healthcare professionals of different professions, was highlighted, with examples of limited dialogue between the prescribing physicians and pharmacists, and vice versa, resulting in issues going unclarified, and medications being prescribed and dispensed regardless

(Aldhwaihi et al., 2016; Al-Ahmadi et al., 2020). Issues stemming from transcription may also contribute to dispensing errors, such as illegible prescriptions due to poor handwriting (Aldhwaihi et al., 2016; Tariq et al., 2025).

Emotional factors are further contributory factors. Low motivation or high stress can increase the risk of committing medication errors (Shire et al., 2018). Front-facing pharmacists may also need to deal with aggressive or difficult patients, potentially leading to flustered behaviour and low morale, increasing the risk of making an error (Aldhwaihi et al., 2016; Al-Ahmadi et al., 2020).

Other identified error-provoking conditions include multitasking (Gao et al., 2023) and increased task complexity, such as prescriptions requiring multiple medications to be dispensed at once (Momo et al., 2022).

Latent Factors

Poor organisational and management practices were consistently mentioned as contributory factors to dispensing errors. These included a lack of staff encouragement and empowerment from the management team, as well as unclear instructions regarding task assignments (Al-Ahmadi et al., 2020). Another recurring issue was poor staff distribution, where management failed to allocate sufficient personnel during particularly busy times or for more complex tasks (Shire et al., 2018; Al-Ahmadi et al., 2020). Similarly, management decisions surrounding vacation leave and time-off could result in a skeleton crew being left in some centres, placing excessive strain on the remaining healthcare professionals (Chou et al., 2024).

Lack of standardisation was another issue raised by Al-Ahmadi et al. (2020). One example given was that due to the hospital employing doctors from various

countries and professional backgrounds, prescribing practices were inconsistent, such as some doctors prescribing in milligrams and others in millimoles, thereby increasing the risk of error (Al-Ahmadi et al., 2020). The issue of staff training was another latent factor described as although training is provided during staff induction, participants felt that it was not comprehensive enough (Al-Ahmadi et al., 2020).

Organisational factors such as workplace layout, medication storage arrangements, and poorly lit workstations were also identified as potential contributors to errors (Al-Ahmadi et al., 2020; Momo et al., 2022). A SMS provides a structured framework to anticipate and control these risk factors related to medication errors. Through the principles of verifying safety and continuous monitoring, a SMS promotes the use of optimised physical layouts and safe medication storage to avert potential errors (Chatzi and Kourousis, 2024; NHS England, 2025; Zhelev et al., 2025).

2.6.5 Administration

Error Types

The most common type of medication administration errors pertains to administering the drug at the wrong time (Hammoudi, Ismaile and Abu Yahya, 2018; Zarea et al., 2018; Tsegaye et al., 2020; Wondmieneh et al., 2020; Assunção-Costa et al., 2022; Ramos, 2024). Other frequent types of errors include administering the incorrect dose, particularly seen with intravenous (IV) medications, omitted or missed doses, and the administration of the drug via the wrong route (Härkänen et al., 2019; Basil et al., 2023; Firde, 2023; Jessurun et al., 2023).

The medications often involved in administration errors include the anti-microbial class of drugs, cardiovascular drugs, and high alert medications, namely heparin, tramadol and insulin (Assunção-Costa et al., 2022).

Active Failures

Slips and lapses included the misidentification of a patient, selecting the wrong medication from the drug shelves or trolley, and forgetting to administer a medication at its scheduled time (Basil et al., 2022). Other slips and lapses occurred when nurses demonstrated casual attitudes to dose checks or were overconfident due to supposed patient familiarity (Keers et al., 2015).

Mistakes occurred when healthcare professionals neglected certain procedures, such as double-checking medications before administering them (Firde, 2023; Alotaibi, 2024), as well as mistakes in incorrect drug dilutions and dose calculations (Schroers, Ross and Moriarty, 2021).

The most common violations involved nurses knowingly ignoring hospital protocols despite being aware of them, which increases the likelihood of administration errors (Tsegaye et al., 2020; Ali et al., 2021; Basil et al., 2022). Firde (2023) found that nearly half of anaesthetists labelled syringes only after withdrawing the medication, which goes against established hospital guidelines.

Error Provoking Conditions

Consistent with the findings across the medication use process, inadequate staffing levels, heavy workloads and time constraints were identified as leading causes of administration errors. Nurses frequently reported feeling overstretched due to high nurse-to-patient ratios in their clinical settings, thus increasing the likelihood of errors

(Zarea et al., 2018; Ali et al., 2021; Alotaibi, 2024; Fathizadeh et al., 2024; Li et al., 2025). Brabcova et al. (2023) observed that heavy workloads hindered nurses' ability to adhere to scheduled drug administration times. In Basil et al. (2023), insufficient staff levels received the highest mean agreement score (5.14 out of 6), while Ramos (2024) reported it as the second-highest ranked factor (4.63/6).

Nurses' mental and physical state was identified as an important contributor to administration errors. The feelings of both physical and mental fatigue, as well as stress, often arising from long shifts and demanding workloads, were described in several studies (Zarea et al., 2018; Ali et al., 2021; Basil et al., 2022; Fathizadeh et al., 2024; Li et al., 2025). Additional academic commitments further exacerbated fatigue among nurses (Ali et al., 2021). Martin et al. (2024) found that sleep deprivation, particularly receiving fewer than seven hours of sleep, was a contributing factor. These effects were found to be more pronounced during night shifts (Firde, 2023; Fathizadeh et al., 2024; Martin et al., 2024), with Wondmieneh et al. (2020) reporting a fivefold increase in administration errors during these periods.

The presence of look-alike and sound-alike medications was another significant contributory factor (Zarea et al., 2018; Brabcová et al., 2023; Ishak and Ibrahim, 2024). Basil et al. (2023) reported moderate agreement among nurses on this issue, with mean scores of 4.65/6 for similar drug appearance and 4.41/6 for similar drug packaging. These findings were echoed in Hammoudi, Ismaile and Abu Yahya (2018), with mean scores of 4.43 and 4.45, respectively. Multiple interventions have been utilised to mitigate against look-alike and sound-alike medications. Among nurses, Lohmeyer et al. (2022) identified that the use of tall-man lettering, which is the use of

capital letters within certain parts of a drug name to better differentiate from a similar product, led to a significant decrease ($p < 0.05$) in administration errors. On the other hand, interventions such as colour coding, showed mixed effectiveness. While Larmene-Beld et al. (2018) identified no risk reduction through colour coding, Da Rocha et al. (2021) found that this intervention allowed staff to better recognise and differentiate look-alike products. These measures are not only applicable to the stage of medication administration, but to any stage impacted by similar-looking medications, such as dispensing (Da Rocha et al., 2021).

Issues with both written and oral communication were also prominent error-provoking factors. Nurses identified illegible handwriting on paper-based documentation and treatment charts as a key factor (Keers et al., 2015; Zarea et al., 2018; Basil et al., 2022; Alotaibi, 2024; Ishak and Ibrahim, 2024), supported by the highest mean agreement score of 4.67/6 in Ramos (2024). Nurses felt that verbal medication orders not recorded on treatment charts also predisposed to errors (Basil et al., 2022). In addition, frequent changes to medication instructions by doctors were another contributory factor (Keers et al., 2015; Ali et al., 2021; Brabcová et al., 2023), with Basil et al. (2023) reporting a mean agreement score of 4.19/6 for this issue.

Environmental issues also ranked highly as contributory factors to administration errors. Frequent distractions or interruptions during drug preparation or administration caused by other healthcare professionals or patients were often quoted (Ali et al., 2021; Schroers, Ross and Moriarty, 2021; Basil et al., 2022; Brabcová et al., 2023). Basil et al. (2023) found a mean agreement score of 4.33/6 regarding the impact of interruptions, while Tsegaye et al. (2020) reported a threefold higher chance of

committing an error (OR: 3.37). Other environmental concerns included excessive noise (Keers et al., 2015; Basil et al., 2022; Li et al., 2025) and poor lighting in treatment, preparation and patient areas (Schroers, Ross and Moriarty, 2021; Basil et al., 2022).

Other, less frequently cited error-provoking conditions included patient-related factors, such as absence during medication rounds or polypharmacy (Basil et al., 2022), prescribing the same medication to multiple patients within the same ward (Brabcová et al., 2023), lack of pharmaceutical or device knowledge (Zarea et al., 2018; Basil et al., 2022; Li et al., 2025), limited clinical experience (Wondmieneh et al., 2020; Fathizadeh et al., 2024) and technological issues such as malfunctioning devices and infusion pumps (Basil et al., 2022; Li et al., 2025).

Latent Failures

Lack of training was one of the most cited latent factors contributing to administration errors. Nurses felt that they were given insufficient training during their orientation sessions and that there was a lack of continuous education programmes focused on medication safety provided by their hospitals (Wondmieneh et al., 2020; Ali et al., 2021; Schroers, Ross and Moriarty, 2021; Basil et al., 2022). One study identified that nurses without sufficient training were more than twice as likely to make errors (OR: 2.20) (Tsegaye et al., 2020). Similarly, 87.5% of anaesthetists in one study felt inadequately trained in medication administration (Firde, 2023).

Several management decisions and organisational factors were identified as latent factors. These included procurement policies that led to frequent changes in medication stocks or substitutions with cheaper generic products (Brabcová et al., 2023; Firde, 2023). Additionally, while staffing shortages and high workload are error-

provoking conditions, these often stem from management-level decisions (Basil et al., 2022; Alotaibi, 2024). The lack of clinical pharmacists and systemic issues within the hospital pharmacy were also cited as underlying causes of administration errors (Hammoudi, Ismaile and Abu Yahya, 2018; Brabcová et al., 2023).

The absence of clear guidelines and protocols for medication reconstitution was another regularly cited factor predisposing to administration errors (Keers et al., 2015; Tsegaye et al., 2020; Wondmieneh et al., 2020). The lack of such guidance also contributed to unsafe practices and ingrained cultural and organisational norms (Schroers, Ross and Moriarty, 2021).

Other latent failures described included a hierarchical culture, which discouraged open communication due to fear of reprimand (Keers et al., 2015; Schroers, Ross and Moriarty, 2021), lack of supervision of recruits, the absence of efficient teamworking (Schroers, Ross and Moriarty, 2021; Li et al., 2025), and the lack of technology, which would otherwise help to prevent medication errors (Ali et al., 2021).

2.6.6 Monitoring

Comparatively few studies have specifically explored the causes and contributory factors of monitoring errors in medication use; however, their impact should not be underestimated. This is underscored by the findings of Bosma et al. (2021) and Alqenae et al. (2023), who found that virtually all monitoring errors reached the patient, with these errors generally associated with patient harm. Some examples of monitoring errors include the risk of uncontrolled infection or toxicity if antibiotic

levels are not kept within the therapeutic range (Alrasheed et al., 2025), the risk of bleeding or thrombus formation if INR is not within range (Shikdar et al., 2025), or organ damage if renal function is not monitored when initiating treatment with an ACE inhibitor (Chaumont et al., 2016).

The most common reason for monitoring errors was a lack of sufficient monitoring (85%), where tests were either not ordered or not performed. The remaining 15% of errors were due to either no action or incorrect remedial action being taken based on the available results (Bosma et al., 2021).

Bosma et al. (2021) attributed more than half of the monitoring errors (52%) to human factors, while 19% were due to organisational factors. Other contributory factors included technological and communication issues. No further details on the specific causes and contributory factors were provided however (Bosma et al., 2021).

2.6.7 Summary of the Main Literature Findings

Table 2 presents a summary of the main causes and contributory factors to medication errors identified from the structured literature search, categorised by stage of the medication use process.

Table 2 - Overview of the Main Causes and Contributory Factors to Medication Errors by Stage of the Medication Use Process

Causes and Contributory Factors	Prescribing	Transcribing	Dispensing	Administration	Monitoring
ACTIVE FAILURES					
Slips	✓	✓	✓	✓	
Lapses	✓	✓	✓	✓	
Mistakes	✓	✓	✓	✓	✓
Violations	✓	✓	✓	✓	✓
ERROR-PROVOKING CONDITIONS					
High Workload and Time Pressures	✓	✓	✓	✓	✓
Low Staff Levels	✓	✓	✓	✓	✓
Lack of Knowledge	✓			✓	✓
Environmental Factors (e.g. lighting, storage cabinets)			✓	✓	
Healthcare Professional's Physical and Emotional State	✓		✓	✓	
Distractions and Interruptions	✓	✓	✓	✓	
Patient-Related (e.g. clinical condition, patient attitudes)	✓	✓	✓	✓	
Written Communication (e.g. illegible handwriting)		✓	✓	✓	✓
Oral Communication (e.g. inter-professional issues, teamwork, verbal orders)	✓		✓	✓	✓
Look-alike and Sound-alike Medications	✓	✓	✓	✓	
Inexperience	✓		✓	✓	

Prescription Related (e.g. generic names, abbreviations, polypharmacy)		✓	✓	✓	
LATENT FAILURES					
Lack of Standardisation	✓	✓	✓		
Lack of or Outdated Policies/Protocols/Guidelines	✓			✓	✓
Hospital/Unit/Team Culture	✓		✓	✓	
Lack of Supervision	✓			✓	
Management Decisions on Staff Allocation and Staff Complement (incl. presence of specialised staff)	✓		✓	✓	
Lack of Training	✓	✓	✓	✓	
Electronic Software (e.g. user-interface, default settings)	✓				✓
Issues with Medical Devices (e.g. infusion pumps)				✓	
Medication Supply (e.g. shortages, frequent changes)	✓			✓	

2.7 Contributory Factors of Patient-Committed Medication Errors

While the previous section focused on the various causes and contributory factors that lead healthcare professionals to commit medication errors at different stages, this section focuses on the causes and contributory factors that lead to medication errors committed by patients themselves. Within the hospital environment, medicines are normally administered to patients by healthcare staff, but in the community, patients are largely responsible for managing and taking their own medications.

One major contributor to patient medication errors is low health literacy, whereby patients struggle to understand their medications, the instructions for administration and the importance to adhere with treatment regimens (Wali and Grindrod, 2016; Ghassab-Abdollahi et al., 2024). This issue is particularly prevalent among older adults, especially those on polypharmacy, where multiple medications increase the likelihood of an error occurring (Aldila and Walpola, 2021; Bieri et al., 2021). Closely related to this is the lack of appropriate patient education or training on how to take medications. Patients who are not properly advised by healthcare professionals may use medications ineffectively, such as through poor inhaler technique, or may follow a wrong dosing schedule (Ghassab-Abdollahi et al., 2024).

The effect of look-alike and sound-alike medications is another common cause of error. Some patients may rely solely on the appearance of physical packaging or the appearance of the drug, which can lead to confusion, especially when medications look

similar, or if external factors, such as frequent medication substitutions from the pharmacy, occur (Aldila and Walpola, 2021; Ghassab-Abdollahi et al., 2024).

Other factors that contribute to medication errors committed by patients include simply forgetting to take their medications, leading to missed doses, and incorrect personal beliefs, such as pill cutting or skipping medications due to being perceived as non-essential or not effective (Wali and Grindrod, 2016; Aldila and Walpola, 2021; Ghassab-Abdollahi et al., 2024). Social influences may also result in patients bypassing proper clinical or product advice (Ghassab-Abdollahi et al., 2024). Another issue that can contribute to errors is that patients may not afford to take their medication at the prescribed dose, leading them to skip doses to make them last longer (Ghassab-Abdollahi et al., 2024).

2.8 The Consequences of Medication Errors

Medication errors have far-reaching consequences that extend beyond just the individual patient directly affected by the error. The actors involved in an error can be categorised in several ways, with one commonly used framework being the victim phenomenon (ERNST, 2023). In this classification, the ‘first victims’ are the patients who have been exposed to the error, along with their immediate others, such as their family members or caregivers (ERNST, 2023). The healthcare professionals who are either directly or indirectly involved in the error are referred to as the ‘second victim’, while more recently, the term ‘third victims’ has been coined, which refers to the healthcare organisations involved in the incident (ERNST, 2023). This framework is a useful way to understand how each of these groups can experience significant and

potentially long-term consequences, underscoring the importance of addressing medication errors.

2.8.1 Impact of Medication Errors on Patients and Caregivers

Patients who experience a medication error suffer the direct physical and psychological consequences of these incidents. While many medication errors that reach the patient may go unnoticed or result in no harm, others can have more serious outcomes necessitating hospitalisation, readmission or extended hospital stays (Nguyen et al., 2024).

Beyond the physical harm to patients, medication errors can also lead to profound negative psychological consequences. Patients who experienced a medication error had significantly higher odds of adverse mental health outcomes compared to patients who did not (OR: 3.04) (van der Velden et al., 2020). Ottosen et al. (2021) found that more than a third of first victims experienced self-blame following an error, and 40% of participants reported experiencing persistent psychological scars such as depression, paranoia and post-traumatic stress disorder even a decade after the incident. Other reported effects include healthcare avoidance behaviour and lower reported trust in the healthcare system (Prentice et al., 2020).

While not directly impacted by the error, the patient's immediate family members or caregivers can face increased caregiver burden, emotional distress, shock and anxiety as they support the recovery of their loved one (Ottosen et al., 2021).

2.8.2 Impact of Medication Errors on Healthcare Professionals

Healthcare professionals involved in medication errors, either through action or association, also experience negative consequences. According to a systematic review by Seys et al. (2013), the prevalence of healthcare professionals who experience a detrimental cognitive or emotional burden ranges from 10.4% to 43.3% (Seys et al., 2013). In an Australian study, 76% of doctors who were involved in an actual medication error or a near-miss reported experiencing negative psychological effects following the incident (Harrison, Lawton and Stewart, 2014).

These healthcare professionals frequently experience adverse mental health outcomes such as guilt, anxiety, post-traumatic stress disorder and depression (Robertson and Long, 2018). Many professionals also report diminished confidence in their clinical abilities and having an increased fear of making future errors, which may potentially lead to overly cautious or defensive medical practices (Harrison, Lawton and Stewart, 2014).

In addition to the psychological distress experienced, healthcare professionals may also face serious professional consequences. These include lower levels of reported job satisfaction, a heightened risk of burnout, and some end up leaving the medical field altogether (Mira et al., 2015). The potential legal ramifications following a medication error may damage their professional reputation and further exacerbate the emotional toll (Mahat et al., 2022).

2.8.3 Impact of Medication Errors on Healthcare Organisations

The healthcare organisation where the medication error occurs also face significant consequences. Although there have been fewer publications on the impact

on healthcare organisations, studies suggest that institutions may face significant reputational and financial consequences following such patient safety incidents (Liukka et al., 2020). The resulting reputational damage may lead to a loss of patient trust, decreased service utilisation and a negative public perception. Financial repercussions due to legal costs, penalties or compensation to the affected individuals may also arise (Mira et al., 2015; Liukka et al., 2020).

2.9 The Costs of Medication Errors

Medication errors are associated with a significant financial burden on patients, healthcare providers and the healthcare system as a whole. When attributing costs in healthcare, costs are commonly subdivided into direct, indirect and intangible costs. In view of the multifaceted nature of identifying and managing medication errors, it is often challenging to accurately quantify the total costs attributed to these errors.

According to the WHO's "Medications Without Harm" report, the global costs attributed to medication errors were estimated to amount to approximately $42 billion annually (WHO, 2017). One report identified that in OECD countries alone, the costs of the otherwise avoidable hospital admissions and increased length of stay due to preventable medication-related harm were $54 billion annually (OECD, 2022). In the UK, a 2021 study by Elliot et al. estimated that medication errors cost the UK NHS over £98 million, including £75 million attributed to emergency department attendances following a medication error in the community and a further £5.4 million linked to cases requiring ICU-level care (Elliott et al., 2021).

A systematic review by Walsh et al. (2017) found that the mean cost per medication error ranged from €2.58 for minor vaccine-related errors up to €111,728 for severe drug errors occurring during anaesthesia (Walsh et al., 2017). Kirwan et al. estimated that the mean cost per discharge due to a medication error was €1,009 (95% CI: €726 – €1,585) (Kirwan et al., 2023). Similarly, Dalton and Byrne calculated that hospitalised patients who experience a medication error have an increased length of stay by an average of 2 days and an additional healthcare cost of between $2,000 - $2,500 (Dalton and Byrne, 2017).

Even in cases where a medication error does not result in actual harm to the patient, it still incurs a financial cost as it represents an inefficiency within the healthcare system. These costs are often under-represented in cost estimates and include the avoidable healthcare worker time spent assessing and managing the error, unnecessary laboratory investigations, and prescription of treatments that would not have otherwise been required, all of which contribute to the wastage of healthcare resources (Choi et al., 2016).

When discussing the costs of medication errors, it is also important to be aware of and consider the intangible costs. These include the psychological impact on patients, such as anxiety, pain or worry following an error (Yousefi et al., 2014). In addition, the social costs of medication errors, such as additional sick days and decreased work productivity, should also be considered when assessing the true impact of medication errors.

Conversely, implementing initiatives to address medication errors can yield substantial cost savings. A study conducted in the US identified that $1.4 million was

saved following clinical pharmacist interventions and comprehensive education to healthcare professionals (Odili, 2022). Similarly, Larson and Lo (2019) identified that the implementation of digital solutions, namely electronic prescribing and bar-code administration systems, would save an estimated 1.4 million CAD (roughly $1 million).

In view of the substantial costs associated with medication errors, and the potential cost savings by effectively mitigating them, understanding the underlying factors which contribute to their occurrence is crucial for informing policies aimed at addressing the root causes and reducing their frequency.

2.10 Methods of Detecting Medication Errors

A variety of methods for detecting medication errors have been described in the literature, with each method having advantages and disadvantages (Mulac and Granås, 2022). Strategies for the detection of medication errors can be subdivided as either prospective or retrospective in nature, depending on when the error is identified. Retrospective detection strategies enable the identification of errors that have already occurred and are useful for learning from past mistakes and therefore preventing similar errors in the future, while prospective methods of error detection aim to detect errors as they occur or before they reach the patient (Kessels-Habraken et al., 2010).

Table 3 lists some of the most common methods for detecting medication errors, which can be applied across the medication use process, and outlines the main advantages and limitations of each (Mulac and Granås, 2022).

Table 3 - Methods for Detecting Medication Errors (Adapted from Mulac and Granås, 2022)

Method	Prospective or Retrospective	Advantages	Limitations
Incident Reporting	Retrospective	May detect errors which are not identified by other means, as well as identify system failures. Requires relatively little training for healthcare professionals to report.	May be affected by under-reporting. Healthcare professionals may only report the most serious errors, leading to reporting bias. Healthcare professionals first need to be aware that an error has occurred to report it. An increased number of incident reports does not necessarily mean a greater quantity of errors, but only a culture of reporting.
Chart Review	Retrospective	Makes use of readily available data	Time-consuming and labour-intensive. Unable to detect any latent errors. Potential reviewer bias: dependent on reviewer training and experience, with potential reliability issues between reviewers.

Direct Observation	Prospective	Able to capture otherwise undocumented errors, as well as identify the contextual and human factors in the error environment.	Susceptible to the Hawthorne effect: the presence of an observer may affect healthcare workers' behaviour or practice. Time-consuming and labour-intensive. Requires training and experience in both observational technique and appropriate medical knowledge.
Computerised Monitoring	Prospective	May provide real-time alerts therefore prevent certain errors or adverse events. Able to integrate information from various data systems.	High initial costs to implement. Training is required. The software's user interface may affect adherence (e.g. due to alert fatigue).
Interviews (with both healthcare workers and the patients)	Retrospective	Detects a greater number of incidents. Offers unique perspectives.	Detection rates decrease as the time from the incident increases. Only applicable to patients who are able to participate

2.11 Reporting of Medication Errors

Another important aspect related to medication safety is the need for a comprehensive reporting system with high levels of engagement. The purpose of

medication error reporting is not to assign blame to a particular individual, but instead to serve as a potential learning opportunity to both healthcare professionals and the healthcare system as a whole (Abstoss et al., 2011).

Organisations such as the NCCMERP aim to encourage the use of reporting and evaluation systems and to encourage reporting practices so that effective strategies can be designed and implemented to prevent subsequent medication errors (NCCMERP, no date).

2.11.1 Legislative Background in Relation to Reporting of Medication Errors

As previously described, adverse drug events and medication errors have the potential to cause significant harm to patients. As a result, legislative measures have been implemented both at the international and national levels to safeguard against preventable medication-related harm.

At a European Union (EU) level, medication error reporting is incorporated as part of pharmacovigilance legislation. According to EMA, pharmacovigilance refers to those activities that lead "*to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem*" (EMA, 2024b). EMA has a leading role in coordinating, monitoring and supporting pharmacovigilance activities across the EU.

EU Directive 2010/84/EU (European Parliament & Council of the EU, 2010a) and Regulation No 1235/2010 (European Parliament & Council of the EU, 2010b), followed

by the Implementing Regulation No 520/2012 (European Commission, 2012), outline the responsibilities of both market authorisation holders and national competent authorities regarding the detection and reporting of adverse drug events and medication errors. EU Directive 2010/84/EU also specifies that any suspected medication error should be reported to the EudraVigilance Database, as well as the authorities responsible for patient safety within the Member State. The Good Pharmacovigilance Practices (GVP), which were published by the EMA, emerged from this legislation. Module VI of the GVP focuses primarily on medication errors and their reporting (EMA, 2017).

In Malta, the Medicines Act (Chap. 458) is the main legislation that transposes the relevant EU Directives into national law concerning the manufacture, importation, distribution and sale of medicinal products, and establishes and outlines the functions of the Malta Medicines Authority and the Licensing Authority (Government of Malta, 2003). The Pharmacovigilance Subsidiary Legislation (S.L. 458.35) states that healthcare professionals have the duty to report any suspected adverse reactions to the Medicines Authority. Those reactions that are suspected to be due to a medication error are entered on the EudraVigilance database by the Medicines Authority (Government of Malta, 2012).

2.11.2 Benefits of Medication Error Reporting

The benefits of medication error reporting are multiple, and include improving patient safety, enhancing professional practice, and facilitating organisational learning and continuous improvement (Stewart et al., 2018).

Error reporting has been described as a "*basic initiative in improving patient safety*" as it enables corrective actions to be taken, which help to prevent error recurrence, thus safeguarding patient wellbeing (AAnal and Seren, 2016). Medication error reporting should not only be limited to those errors which cause harm to the patient but also include those errors which cause no harm or are near misses, as in the future, repetition of these errors could potentially lead to actual patient harm (Sheikhtaheri, 2014).

Healthcare professionals will also benefit both individually and collectively from medication error reporting, as it allows them to learn from their mistakes and improve their own clinical practice through the feedback received (Rodziewicz et al., 2025).

The presence of a structured reporting system also helps to promote organisational learning and continuous improvement. When a medication error report is submitted, hospitals can then carry out root cause analysis and implement corrective changes to address system flaws. This ongoing cycle allows for continuous learning from patient safety incidents and contributes to improvements in the quality and safety of healthcare delivery (Moureaud, Hertig and Weber, 2021). Furthermore, error reporting and corrective actions are among the factors considered for ISO 9001 certification, which signifies a commitment to quality management (International Organisation for Standardisation [ISO], no date). These quality improvements have also been found in the literature as being beneficial for safeguarding and improving upon patient safety (Hussein et al., 2021).

2.11.3 Underreporting of Medication Errors

Despite the benefits of medication error reporting and healthcare workers' professional obligation to report such events, under-reporting remains a significant global issue (Al Meslamani, 2023).

NHS England cautions that organisations which have low rates of reported errors should not automatically be assumed as safer than those with higher reporting rates. This is because a low rate may instead imply a degree of under-reporting within an institution, whereas high reporting rates may suggest a more open reporting culture in another (NHS England, 2015).

One of the largest impacts that under-reporting has is that it leads to a paucity of data, with organisations or healthcare systems unaware of the gravity of the problem. This lack of insight then hinders the ability to competently and effectively address the root cause of the error, ultimately leading to future negative implications for healthcare quality system improvements and patient safety (Wolf and Hughes, 2008).

While no global figure can be attached to the prevalence of medication error underreporting, several studies in the literature have attempted to quantify its prevalence at an organisational or hospital level. A multi-regional study among doctors, nurses and pharmacists in Saudi Arabia found that 58% of participants did not report medication errors (Alshammari et al., 2021). Similarly, other studies identified that 45% of medication errors committed by nurses went unreported (Fathi et al., 2017), while the results of a meta-analysis found that just under 40% of nurses reported self-committed administration errors (Fathizadeh et al., 2024). A systematic review by

Vrbnjak et al. (2016) identified that medication error reporting ranged from just 37.4% up to 67%.

Specific to paediatrics, an audit conducted in two tertiary hospitals found that only 3.2 per 1,000 prescribing errors were accompanied by an incident report, and that an incident report was only submitted in 10% of the times that patient harm occurred (Li et al., 2024). A meta-analysis focused on anaesthesia-related medications suspected of significant under-reporting in paediatric patients, noting that the rate of administration errors was 10 times lower than that in adults (Feinstein, Pannunzio and Castro, 2018).

2.12 Barriers and Facilitators of Medication Error Reporting

The relatively high rates of medication error under-reporting reflected above are influenced by various barriers and facilitators to reporting, which are expanded upon in this section. Another structured literature search (listed as 'Search 2' in *Figure 1*) was carried out to identify these barriers and facilitators to medication error reporting, specifically in relation to the Theoretical Domains Framework, explained in *section 2.5.3*.

2.12.1 Search Strategy – Search 2

Academic databases, primarily PubMed and Scopus, were searched using the following keywords and Boolean operators:

"Medication error" OR "drug error" OR "prescribing error" OR "administration error" OR "medication incident"

AND

"hospital" OR "acute care" OR "inpatient"

AND

“report” OR "reporting" OR "incident reporting" OR "error reporting" OR "underreporting"

AND

"barrier" OR "facilitator" OR "enabler" OR "attitude" OR "motivation"

AND

“Theoretical Domain Framework” or “TDF”

For PubMed, the appropriate MeSH terms were also included where relevant. Additionally, the use of a * at the end of keywords was used to increase the number of search results.

The inclusion criteria for the studies were the same as the search strategy in *section 2.6.1*. The results of the literature search and the study selection process are summarised in the PRISMA flowchart (Page et al., 2021) in *Figure 5*, which shows that 5 studies were included in the review for the barriers and facilitators to error reporting. Appendix B provides an overview of the studies that were included as part of this second structured literature search.

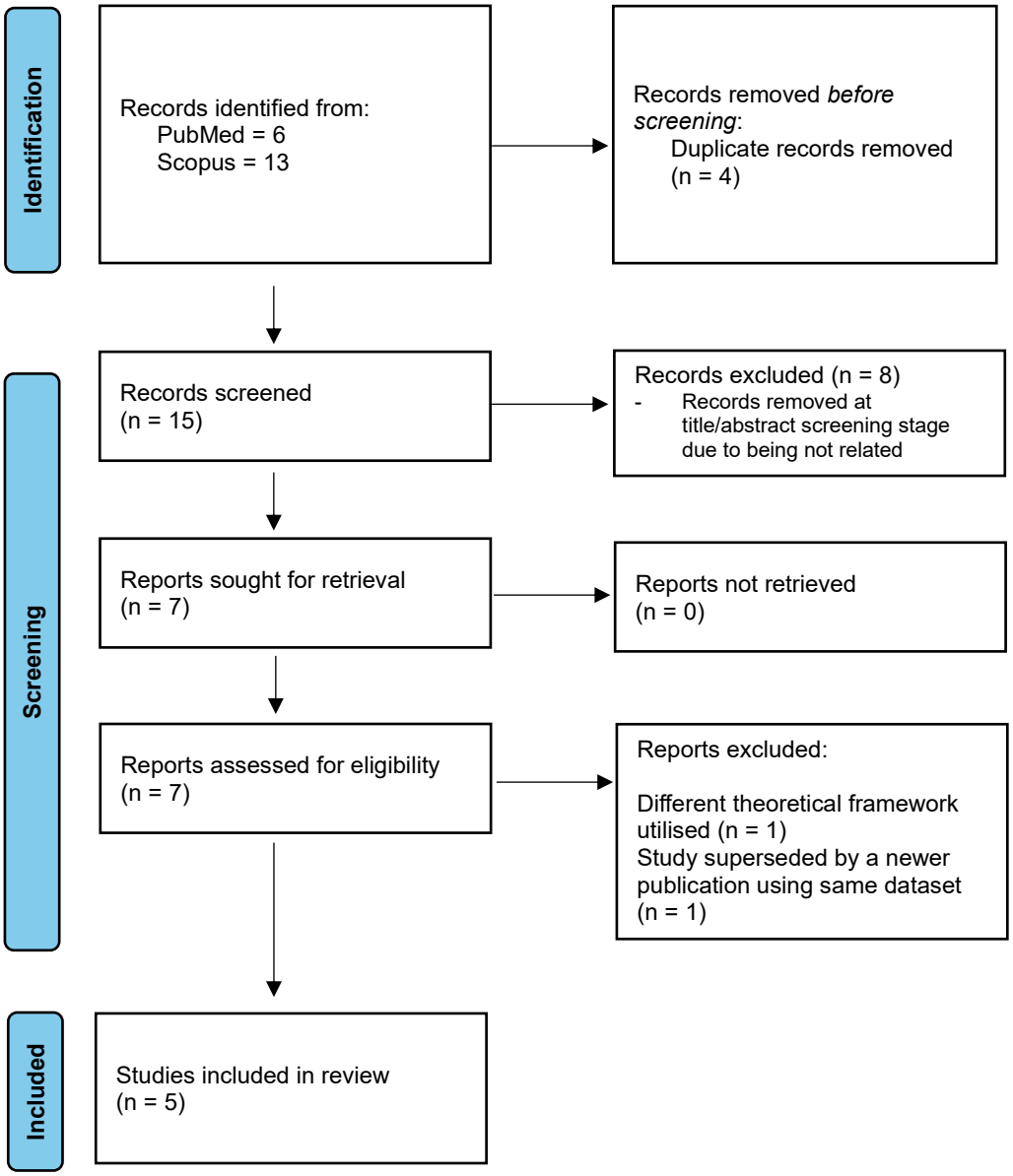

Figure 5 - PRISMA Flowchart Showing the Study Selection Process for the Literature on the Barriers and Facilitators to Medication Error Reporting

2.12.2 Mapping Barriers and Facilitators to the Theoretical Domains Framework

Domain 1 – Knowledge and Domain 2 – Skills

The domain of knowledge explores an individual's awareness and understanding of a particular topic, while the domain of skills relates to proficiency or ability, often acquired through regular use, to apply this knowledge effectively (Atkins et al., 2017). As these two domains often overlap, they are discussed together hereunder.

A common facilitator to medication error reporting identified across several studies related to healthcare professionals' generally strong awareness of the definitions of medication errors, and the distinctions between them and ADRs. In Stewart et al.'s (2018) study, 97.1% and 96.2% of participants, respectively, felt they had sufficient knowledge of the definitions and could distinguish between the two terms. Alqubaisi et al. (2016b) found similar findings, with 96.6% of respondents agreeing or strongly agreeing with these statements. Guo et al.'s (2025) qualitative study supported these quantitative findings, with participants well versed in discerning between medication errors and ADRs. In contrast, participants in Shaliviri et al. (2018) had misunderstandings in identifying the two.

The understanding of what constitutes a medication error did not translate into awareness about the organisation's reporting systems and associated procedures, representing a key barrier to reporting and a cause for under-reporting rates. One quantitative study showed that 21.7% of participants were unsure or unaware of their hospital's error reporting policy, and 16.3% were unsure or unaware of how to report

an error (Alqubaisi et al., 2016b). Another study by the same authors supported these findings, with doctors generally unaware of the reporting systems in place (Alqubaisi et al., 2016a). A lack of both general and specific knowledge of reporting procedures, with this sentiment particularly felt for doctors and new recruits, was described in the literature (Stewart et al., 2018). In Guo et al. (2025), some participants reported limited knowledge and "*uncertain[ty] about the specific reporting process*", with participants in Shalviri et al. (2018) also unclear on the steps involved to report a medication error.

Another barrier to reporting in Shalviri et al. (2018) was misunderstandings about which errors should be reported, with participants reporting conflicting views, with some believing that minor or non-serious errors need not be reported.

The concept of training and experience of using the system also emerged in three of the studies, with participants lamenting the lack of training and yearning for more skill-building training to improve safety awareness. Participants felt that training would act as a facilitator to increase medication error reports, while concurrently encouraging and reassuring staff about the reporting procedure (Alqubaisi et al., 2016a; Stewart et al., 2018; Guo et al., 2025).

Domain 3 - Social/Professional Role and Identity

Focusing on an individual's professional role and identity, this domain refers to the set of behaviours and personal qualities associated with fulfilling their role (Atkins et al., 2017).

A strong facilitator identified across all five studies was the perception of a healthcare professional's professional obligation and duty to report errors. Supporting this sentiment, 92.2% and 83.7% of participants acknowledged a sense of professional

duty to report medication errors as part of their role (Alqubaisi et al., 2016b; Stewart et al., 2018). Some studies, however, found that doctors were perceived not to report medication errors as much as nurses or pharmacists (Alqubaisi et al., 2016a; Guo et al., 2025).

Domain 4 – Beliefs about Capabilities

This domain refers to an individual's confidence in their own skills or abilities that can then be applied in an effective manner (Atkins et al., 2017).

Findings from this domain were represented in the studies by Guo et al. (2025) and Shalviri et al. (2018). Nurses and pharmacists expressed confidence in reporting errors, with one participant stating that "*I'm confident in my ability to report errors*"; however, the same confidence was not felt by the participating doctors, due to a lack of practical experience in reporting (Guo et al., 2025). The other study suggested that a lack of reporting was not necessarily stemming from an individual's capability to report, as participants find it relatively easy to report ADRs, whereas medication error reporting was felt to be more challenging due to various external factors (Shalviri et al., 2018).

Domain 5 – Optimism

Optimism is defined as having a positive outlook that future events will turn out positively or that one's objectives will be achieved (Atkins et al., 2017).

The domain of Optimism was only present in one of the studies, which found that nurses displayed a more optimistic outlook regarding medication error reporting, which could be seen as a facilitator to reporting. On the other hand, doctors had the

lowest levels of optimism, citing time and workload pressures as a reason for their low optimism (Guo et al., 2025).

Domain 6 – Beliefs about Consequences

Both barriers and facilitators to medication error reporting were identified under this domain, which refers to an individual's perception or conviction regarding the likely effects of engaging in a specific action (Atkins et al., 2017).

A major barrier noted in multiple studies was the perceived impact that medication error reporting may have on career progression and job security. In both the quantitative studies, around half of the participants agreed or strongly agreed with concerns related to their career and advancement (49.7% and 49.2% respectively) (Alqubaisi et al., 2016b; Stewart et al., 2018). These studies also raised concerns about potential reprimands in the workplace. Similarly, participants in the study by Shalviri et al. (2018) also identified the risk of negative consequences or punishments for those who report errors. This point was exemplified in an account of a healthcare professional being transferred to another unit as a potential consequence of reporting (Alqubaisi et al., 2016a).

Another frequently quoted barrier was the potentially damaging impact that medication error reporting could have on interpersonal workplace relationships, especially when it involves a close colleague or friend. This concern was expressed by the different groups of healthcare professionals across all levels of seniority (Stewart et al., 2018). In some cases, participants preferred to address errors informally in a face-to-face manner rather than submitting a formal report (Alqubaisi et al., 2016a). Loss of trust by both patients and colleagues could also be a barrier to medication error

reporting (Guo et al., 2025).

Concerns about confidentiality relating to both the patient, such as the documentation of the patient's name, and to the healthcare professional involved, were also raised. Lack of anonymity was specifically highlighted as a barrier to reporting during the focus group conducted by Stewart et al (2018). Participants also expressed a lack of trust and expressed concern that information would be revealed, as well as the risk of gossip, as other barriers (Stewart et al., 2018).

Despite these barriers, facilitators under this domain also emerged. These facilitators were closely aligned with the benefits of medication error reporting identified in *section 2.11.2*. Participants reported that medication error reporting contributes to improvements in patient safety within their hospital (Alqubaisi et al., 2016a; Guo et al., 2025). Another facilitator was the belief that error reporting not only helps improve one's own professional practice, but can also benefit other colleagues by raising awareness of potential mistakes, helping to prevent recurrence, and promoting collective learning (Alqubaisi et al., 2016b, 2016a; Stewart et al., 2018).

Domain 7 – Reinforcement

This domain is defined as the process of strengthening a specific behaviour by linking it to a specific stimulus (Atkins et al., 2017).

Incentives were discussed as a potential facilitator for medication error reporting. The types of incentives suggested in the literature included both symbolic incentives and material ones. Within one hospital, the title of reporter of the month was given out as a motivating factor to encourage reporting and to recognise an individual's efforts to report (Alqubaisi et al., 2016a). Other incentives mentioned in

the literature included work credits, contributions acknowledged in formal performance appraisals and financial rewards (Guo et al., 2025).

When a healthcare professional submits a report of a medication error, receiving feedback, especially constructive feedback, can help reinforce error-reporting behaviour and hence encourage reporting. In Stewart et al. (2018) and Alqubaisi et al. (2016b), 71.2% and 63.6% of respondents reported receiving feedback after submitting an error report; however, when it came to constructive feedback, the responses fell to 64.9% and 53.1% respectively.

Another reinforcement strategy outlined was that of providing encouragement and positive messaging. Fostering a culture where medication error reporting is framed in a positive light rather than as a punishment for anyone or with the intention to cause harm can also help break barriers and encourage professionals to report (Stewart et al., 2018).

Domain 8 – Intentions

Intentions are defined as a deliberate decision to carry out a specific action in a particular manner (Atkins et al., 2017).

Overall, the intention to report medication errors was high across all studies, wherein most study participants were determined to report medication errors occurring within their hospital (Shalviri et al., 2018). This is backed up by the quantitative findings of both Alqubaisi et al. (2016b) and Stewart et al. (2018) where 86% and 88.2% of participants, respectively, expressed a clear intention to report every medication error they witnessed or committed.

From the qualitative studies, the intention to report varied depending on

factors such as error severity and professional group. Guo et al. (2025) found that nurses demonstrated the highest intention and willingness to report errors, while pharmacists were more selective in their reporting practices. The intention to report errors based on severity was also seen in Stewart et al. (2018), with more serious or harmful events tending to be reported, while for "*a near miss, it never gets reported*".

Another theme that emerged was the concept of misaligned or negative intentions, whereby some healthcare professionals described reporting not with the goal of safeguarding patient safety, but to document and collect mistakes made by others (Stewart et al., 2018).

Domain 9 – Goals

Under the TDF, goals are defined as mental representations reflecting desired future objectives that a person strives to attain (Atkins et al., 2017).

Several of the facilitators previously described under Domain 6 (Beliefs about Consequences) also align with this domain. Across the studies, participants identified improving patient safety, preventing future medication errors, supporting system improvements and contributing to hospital policy development among the goals of medication error reporting (Alqubaisi et al., 2016b, 2016a; Stewart et al., 2018; Guo et al., 2025).

Domain 10 - Memory, Attention, and Decision Processes

This domain refers to an individual's capacity to store and recall information, concentrate on specific aspects, and make choices between different options (Atkins et al., 2017).

Forgetting to report medication errors was regularly acknowledged as a barrier in the studies identified. In the quantitative study by Alqubaisi et al (2016b), approximately one-third of respondents admitted that they sometimes forgot to report an error, while in Stewart et al.'s (2018) study, this figure rose to 48.8% of participants. In another study, pharmacists reported that, particularly during periods of high workload, they sometimes forget to report errors. In contrast, the nurses interviewed in the same study were less likely to forget to report due to team support that encourages the disclosure of medication errors (Guo et al., 2025). In Shalviri et al.'s (2018) study, participants claimed that they always remembered to report ADEs.

The severity of the medication error also influenced reporting practices. One study found that 77.3% of participants stated that if an error was perceived as severe, they prioritised reporting it (Alqubaisi et al., 2016b). The results from Guo et al. (2025) also supported this finding, with participants stating that errors causing patient harm were reported immediately, whereas less serious events or near misses were more likely to be reported at a later time or forgotten altogether.

Domain 11 - Environmental Context and Resources

This domain is defined as any scenario or setting that either promotes or inhibits the development of an individual's abilities or behaviour (Atkins et al., 2017).

A consistent barrier identified across multiple studies was a lack of time to complete error reports. Healthcare professionals described heavy workloads, time constraints and competing, often urgent, clinical responsibilities as major obstacles, with error reporting thus taking a secondary place to immediate patient care needs (Alqubaisi et al., 2016a). Similar concerns were echoed in the studies of Shalviri et al.

(2018) and Stewart et al. (2018), where staff viewed the reporting process as excessively time-consuming. This was also supported by both quantitative studies, which found that around half of the participants were unsure or outright disagreed that reporting takes little time or effort, yet over 80% of respondents answered that they still submitted reports despite time pressures (Alqubaisi et al., 2016b; Stewart et al., 2018). In addition to complaints about the time-consuming nature of the form itself, front-line clinical staff also said that submitting a report would lead to follow-up meetings, which they had no time to attend (Shalviri et al., 2018).

In addition to the time barriers, the design and accessibility of the reporting systems themselves were another factor which hindered reporting. In hospitals where a paper-based reporting system was still in use, inconveniences and difficulties in locating and submitting the physical forms were barriers to reporting. Participants also felt that the forms themselves were vague in parts (Alqubaisi et al., 2016a). Guo et al. (2025) described the barriers associated with using an electronic reporting system, whereby participants described the system as overly complex and lacking user-friendliness. Inadequate access to computers and other resources to submit error reports also acted as barriers (Shalviri et al., 2018; Guo et al., 2025).

Domain 12 – Social Influences

Social influences refer to the impact that relationships, social norms and group dynamics have on an individual's attitudes or actions (Atkins et al., 2017).

Professional hierarchy structures and power dynamics were identified as barriers to reporting in two out of the five studies (Alqubaisi et al., 2016a; Guo et al., 2025). Nurses and pharmacists expressed reluctance to report medication errors made

by doctors due to the perceived power dynamics within the hospital setting (Alqubaisi et al., 2016a). The effect of cultural norms that are present within the hospital setting, which emphasise hierarchical deference and the desire to maintain harmony in the workplace, may serve as a barrier for junior staff from reporting errors made by more senior colleagues, which further heightens underreporting (Guo et al., 2025).

In Alqubaisi et al. (2016b), 41.6% of participants agreed with the notion that others would think less of someone who reported a medication error made by themselves, or by another individual. Similarly, 35.6% of respondents felt uncomfortable reporting their own errors, and 40.3% expressed discomfort in reporting errors made by others (Stewart et al., 2018). These findings underscore the effect of social pressure and peer perception on medication error reporting.

The role and principles adopted by leaders and managers also influence reporting practices. Participants felt that in those units where the leader was seen to adopt a blame-free approach and is more focused on problem solving, staff then "*feel safe reporting errors – this approach is crucial*", which therefore helps facilitate error reporting (Guo et al., 2025). In the study by Shalviri et al. (2018), although managers approved of error reporting, they did not actively encourage or facilitate the process. The effect of the workplace culture was also mentioned, wherein participants who felt that the hospital culture was a punitive and blame-oriented one felt that this would hinder reporting (Stewart et al., 2018).

Other barriers related to this domain included a lack of collaboration and teamwork among different professional groups (Shalviri et al., 2018), as well as concerns about patient reactions when disclosing that a medication has occurred, potentially leading to confrontation or escalation of the issue (Guo et al., 2025).

Domain 13 – Emotions

This domain refers to the emotional responses, including constructs such as fear, anxiety and stress, to name a few, that can influence behaviour when confronting specific events (Atkins et al., 2017). There is a degree of overlap between this Domain and Domain 6 (Beliefs about Consequences).

Fear and worry were consistently identified as major barriers to medication error reporting within this domain. Questions on emotions generated the highest number of negative responses overall, with a median score of 20 out of 30 (IQR: 16-23). New recruits and younger individuals reported the highest levels of negative emotional responses, with respondents citing fear or reprimands and impacts to career progression as the major issues (Alqubaisi et al., 2016b). The qualitative study by the same author further supported these findings, with all professional groups interviewed (doctors, nurses and pharmacists) reporting experiencing fear and worry. Concerns raised by participants included fear of errors being reported to their superiors, negative performance reviews and fears about job security (Alqubaisi et al., 2016a). Similar emotional themes emerged in Stewart et al.'s (2018) focus groups, where fear of punishment following the reporting of an error was identified as one of the most significant barriers. Emotional states such as stress and mood fluctuations were also found to influence reporting behaviours (Guo et al., 2025).

Another emotional barrier identified was the difficulty that healthcare professionals may experience in accepting that they have made an error. This difficulty may be tied to feelings of guilt or shame. 41.9% and 40.5% of participants strongly agreed or agreed with this feeling (Alqubaisi et al., 2016b; Stewart et al., 2018).

In contrast to other studies, Shalviri et al. (2018) reported that emotional factors such as fear and worry did not influence reporting practices and that the emotional constructs within this domain were neither facilitators nor barriers to reporting.

Domain 14 – Behavioural Regulation

This domain refers to strategies or processes designed to adjust or modify observable and measurable actions to achieve desired outcomes (Atkins et al., 2017).

Among the studies reviewed, only Guo et al. (2025) explicitly addressed this domain. Participants highlighted the need to shift workplace habits toward more consistent and proactive reporting. This included fostering open dialogue among staff to clarify queries and enhancing individual competencies through training. Additionally, participants also felt that a culture shift within the hospital, coupled with supportive leadership, are necessary to facilitate medication error reporting (Guo et al., 2025).

Summary of the Main Literature Findings on the Barriers and Facilitators to Medication Error Reporting

The main barriers and facilitators to medication error reporting which emerged from the second structured literature search are summarised in *Table 4*, organised by each domain of the Theoretical Domains Framework.

Table 4 - Summary of the Main Barriers and Facilitators to Reporting Identified in the Literature

Domain	Barriers	Facilitators
Knowledge	Lack of awareness of reporting systems and procedures	Awareness of medication error definitions
Skills	Lack of training	Provision of training
Social/Professional Role and Identity	Perceptions that some professional groups report less than others	Sense of professional duty and obligation to report
Beliefs about Capabilities	Lack of confidence, especially among doctors	Confidence in own reporting abilities
Optimism	Low optimism (especially among doctors)	Optimistic outlook toward reporting (nurses/pharmacists)
Beliefs about Consequences	Impact on career progression and job security	Patient Safety Improvements
	Effect of reprimands or punishments	
	Damage to interpersonal workplace relationships	Promotes individual and collective learning leading to improved practice
	Loss of trust from patients and colleagues	Prevents error recurrence
	Concerns about confidentiality and anonymity	
Reinforcement	*Implied absence of positive reinforcement*	Incentives (symbolic and material)
		Provision of constructive feedback
		Encouragement and positive framing
Intentions	Selective reporting based on error severity	Intention to report errors witnessed or committed
	Misaligned intentions	
Goals	*Implied absence of positive goals*	Improved patient safety
		Prevents future errors
		Supports system improvements

		Contributes to hospital policy development
Memory, Attention, and Decision processes	Forgetting to report errors	Team support encouraging error disclosure
	Delayed or absent reporting of less serious events	Prioritising immediate reporting of serious errors resulting in patient harm
Environmental Context and Resources	Lack of time and time-consuming nature of reporting and follow-up meetings required	*No specific facilitators identified*
	Clinical priorities outweigh reporting needs	
	Design and accessibility of reporting system	
Social Influences	Professional hierarchy and power dynamics	Effect of positive leadership
	Social pressure and negative peer perception	
	Effect of negative leadership	
	Hospital culture (blame-oriented)	Hospital culture (blame-free approach)
	Concerns about patient reactions	
Emotions	Fear and worry	No specific facilitators identified
	Stress and mood fluctuations	
	Difficulty accepting personal error	
Behavioural Regulation	*No specific barriers identified*	Proactive reporting habits

2.13 Interventions to Improve Medication Error Reporting

Various interventions have been proposed to increase the uptake of medication error reporting; however, there remains limited evidence on their overall effectiveness.

A systematic review by Gleeson et al. (2020) emphasised the importance of having a reporting system in place, which does not place additional time pressure on

healthcare professionals who are already occupied with their various clinical commitments. Anonymous reporting systems have also been suggested to overcome the barriers related to the fear of consequences. While anonymity may encourage reporting, it can also limit the possibility of valuable follow-up actions. The establishment of a dedicated safety committee may further support reporting efforts (Gleeson et al., 2020).

Educational interventions have also been discussed as a potential strategy to improve reporting in both the review by Gleeson et al. (2020) and the Cochrane systematic review by Shalviri et al (2024). A lack of knowledge about how and when to report has been identified as one of the main barriers under Domain 1 of the TDF. Low-certainty evidence supports the use of educational sessions to address this gap (Gleeson et al., 2020; Shalviri et al., 2024). Educational interventions were particularly effective when combined with tools such as reminder cards and a dedicated reporting form, which together contributed to increased medication error reporting (Shalviri et al., 2024).

The importance of fostering a non-punitive culture is considered essential for facilitating error reporting. A learning-focused culture can help address barriers related to fear of consequences and social influences (Gleeson et al., 2020). One example of how this can be achieved is through a SMS, in which safety promotion serves as a core component (Chatzi and Kourousis, 2024; Zhelev et al., 2025). This involves providing specific education and encouraging transparent dialogue to cultivate the necessary environment for open error reporting (NHS England, 2025; Zhelev et al., 2025). This approach aligns with the principles of a just culture, as such a cultural shift helps to

decrease barriers to error reporting, as it differentiates between errors stemming from system shortcomings or unsafe practices and honest mistakes (Mira, 2023; Glarcher and Vaismoradi, 2025). This mitigates various barriers, such as those related to fear or belief of adverse consequences, thus strengthening reporting behaviours (Murray et al., 2023; Glarcher and Vaismoradi, 2025). While systematic reviews and meta-analyses on the impact of just culture on reporting rates are limited, individual studies have identified improvements following this cultural shift. Davis et al. (2025) identified that general error reporting increased by almost 38% ($p < 0.01$), while nurses in a study by El-Gazar et al. (2020) showed a statistically significant higher odds of reporting (OR: 1.074; $p < 0.01$).

The Cochrane review by Shalviri et al (2024) also found low certainty evidence showing that embedding reporting processes within existing clinical workflows, such as using discharge summaries that include a section specifically for documenting adverse drug events, may increase the number of reports submitted (Shalviri et al., 2024). Other interventions, including financial or non-financial incentives, the distribution of information letters, or deploying pharmacists in clinical areas, have shown uncertain levels of effectiveness so far and require further investigation (Shalviri et al., 2024).

2.14 The Malta Context

The previous sections provided an overview of recent international literature on the causes of medication errors and reporting practices. This section focuses on research conducted locally, including both peer-reviewed publications and academic

dissertations. These local studies offer valuable insights into current challenges, findings and trends specific to Malta's local healthcare situation.

In 2013, Tanti et al. published a study which aimed to identify and characterise the medication errors reported to the national pharmacovigilance database. This study found that between 2005 and 2010, 96 medication errors were registered on a national database, with nearly two-thirds (n = 62; 64.5%) of error reports having occurred in the community setting. Prescribing errors were the most frequently reported, accounting for just over half (n =50; 52%) of all entries, with dosage errors being the most frequent type of prescription error. The second and third most common types of errors were related to therapeutic monitoring (26%) and patient errors (12%), with 25 and 11 error reports, respectively. Notably, in contrast to international literature, administration errors were the least commonly reported type, comprising just 3% of entries (n = 3). Non-steroidal anti-inflammatory drugs (NSAIDs) were the most common medication class associated with an error (n = 27; 28.1%), followed by antibiotics (n = 10; 10.4%). The study also investigated the outcomes of these medication errors, finding that 56 ICSRs (58.3% of all errors) resulted in harm to the patient, including 8 cases (14.3% of all errors) which led to patients becoming hospitalised as a result. Additionally, 4% of the reported errors led to patient death (n = 4) (Tanti et al., 2013).

Tanti et al. (2017) published another study exploring the opinions of Maltese doctors and pharmacists on the causes of medication errors. This study found that hospital-based doctors experienced an average of 7.7 errors per doctor per year, and cited distractions from staff, a heavy workload and fatigue as the top three reasons for prescribing errors. Other reported causes included inexperience, a lack of medication-

related knowledge, low patient familiarity and the absence of a clinical pharmacist. From the pharmacists' responses, illegible prescriptions due to poor handwriting were the leading cause of dispensing errors, with 88% of hospital pharmacists citing this as the primary reason. Other causes of dispensing errors included look-alike and sound-alike medications, a high workload and fatigue. This study found a median error rate of 8 dispensing errors per pharmacist per year (Tanti et al., 2017).

In 2024, a student's dissertation (Vijidan, 2023) investigated nurses' perceptions on the causes of medication errors as well as the barriers and facilitators to their reporting in a long-term care facility. The main perceived causes of medication errors were staff shortages, long shifts, limited clinical or medication-related knowledge, caring for numerous acute patients simultaneously and frequent interruptions during medication administration. The main barriers to reporting were related to fear of consequences (62.8%) and fear of reprimand (33.1%). Participants felt that the workplace culture was another major barrier to reporting, with 62.2% of participants stating that blame is attributed to the individual rather than systemic issues, and 59.3% of participants feeling that if a harm resulted to the patient, the nurse will be blamed. Other barriers to reporting included the perception that nurses would be viewed as incompetent, the error not being sufficiently important to report, and the time-consuming nature of the reporting process. On the other hand, more than half of the participants indicated that they would report a medication error if this resulted in patient harm, and around 41% said that they would be highly likely to report an error if the reporting process was truly anonymous and free from repercussions or potential retaliation in the workplace (Vijidan, 2023).

In 2023, Ward and Mangion published a study exploring nurses' attitudes and perceived barriers to incident reporting in Malta's main acute general teaching hospital. The study found that over 70% of participants knew how to access and complete the hospital's incident report form. The main barriers to reporting identified included a lack of feedback after submitting a report, a belief that no system changes or corrective action would take place, and concerns about confidentiality, with participants expressing worry over who might have access to the information provided in the report and a fear that the reporter's identity would be exposed (Ward and Mangion, 2023).

Another student's dissertation, Schiavone (2024), investigated nurses' perceptions and attitudes towards medication errors, and their reporting at Mater Dei Hospital. Reported causes of errors included written and oral communication issues with the prescribing physician, such as illegible prescriptions and frequent changes in instructions, respectively. Other contributory factors to errors were interruptions during medication administration and staffing issues. Regarding reporting practices, this study found a statistically significant ($p = 0.003$) association between more years of professional experience and an increased likelihood of reporting medication errors. While 88% of respondents admitted to having made a medication error during their career, over half (54%) said they never reported it, underscoring under-reporting locally. The barriers to reporting included a fear of consequences or potential lawsuits, concern over being viewed as incompetent, and a loss of trust from patients or relatives. More than 80% of participants had apprehension over the hospital administration's response, believing that blame tends to be placed on the individual rather than the system, echoing the findings from the dissertation conducted within

the same long-term care facility. 78% of respondents stated they would not report a medication error in which they had no direct involvement, and only 34% said they would report an error if no harm resulted to the patient (Schiavone, 2024).

Section Summary

This section highlighted the specific causes and contributory factors to medication errors seen within Malta's healthcare sector. While many of these factors were common across all professional groups, such as heavy workload, fatigue and frequent interruptions or distractions (Tanti et al., 2017; Vijidan, 2023; Schiavone, 2024), there were also profession-specific reasons, such as doctors reporting inexperience and the absence of a clinical pharmacist (Tanti et al., 2017), nurses identifying limited clinical knowledge and communication issues with doctors (Vijidan, 2023; Schiavone, 2024) and pharmacists prioritising illegible prescriptions and look-alike and sound-alike medications (Tanti et al., 2017).

Triangulation of the local research highlighted the challenges to medication error reporting. Across multiple studies, fear of consequences, a prevalent blame culture, lack of feedback, the belief that reporting would not lead to system changes and concerns about confidentiality were identified as deterrents to reporting (Vijidan, 2023; Ward and Mangion, 2023; Schiavone, 2024).

The findings from these local studies complement and resonate with the international literature and provide context-specific insights that form a basis for informing this dissertation.

2.15 Chapter Conclusion

This chapter provided a comprehensive review of the recent literature on medication errors, including the choice of definitions to guide this dissertation. The literature review also explored the prevalence of medication errors, highlighted their wide-ranging impacts, including the consequent costs, effect on the healthcare system and the preventable morbidity and mortality associated with them.

This literature review then systematically outlined the various causes and contributory factors to medication errors across the entire medication use process, utilising Reason's Accident Causation Model to categorise errors into active failures, error-provoking conditions and latent failures. The findings from the literature underscore the multifactorial nature of medication errors, which often result from a combination of these causative and contributory factors.

The chapter also delved into medication error reporting, highlighting the global issue of under-reporting. Literature which utilised the Theoretical Domains Framework provided a comprehensive overview of the barriers and facilitators to medication error reporting.

The two aforementioned frameworks guided this study's methodology and analysis to similarly uncover the most common causes and contributory factors of medication errors, as well as the main barriers and facilitators to their reporting, in the local acute hospital setting.

Chapter 3: Methodology

3.1 Introduction

The comprehensive literature review in the previous chapter revealed key gaps that informed the methodology of this study. Firstly, while under-reporting of medication errors is acknowledged in the literature, there is a lack of studies comparing medication error reporting rates across different countries. Secondly, a critical review of local studies reveals an evidence gap which this dissertation intends to fill. As noted in the *section 2.14*, existing research conducted in Malta has adopted a primarily quantitative approach with limited qualitative insights. While this has been effective in identifying what the contributory factors and reporting barriers are, it offers limited insights into the underlying reasons why these issues occur from the direct perspectives of front-line healthcare professionals. Furthermore, as far as the author is aware, this is the first local study to gather insights from professionals across different acute hospital settings in Malta. This study will therefore employ a mixed methodology to attempt to address these gaps, as described in more detail in the following sections.

3.2 Overall Study Design

Cresswell (2009) outlined different approaches towards conducting mixed methods research that have been widely utilised in research (Creswell, 2009). This study employed an explanatory-sequential mixed methods design, in which the quantitative phase was first conducted, followed by the qualitative phase, which was informed by the initial quantitative findings.

The quantitative phase involved a retrospective analysis of Individual Case Safety Reports (ICSRs) from the EudraVigilance database to comprehensively map the causes and contributory factors to medication errors, as well as their reporting practices, from across the European Economic Area (EEA) and the United Kingdom (UK). These findings then guided the qualitative phase, which sought to gain in-depth insights into the local factors influencing medication errors and the barriers and facilitators to error reporting in the local context. *Figure 6* provides a graphical illustration summarising the main steps of the methodology.

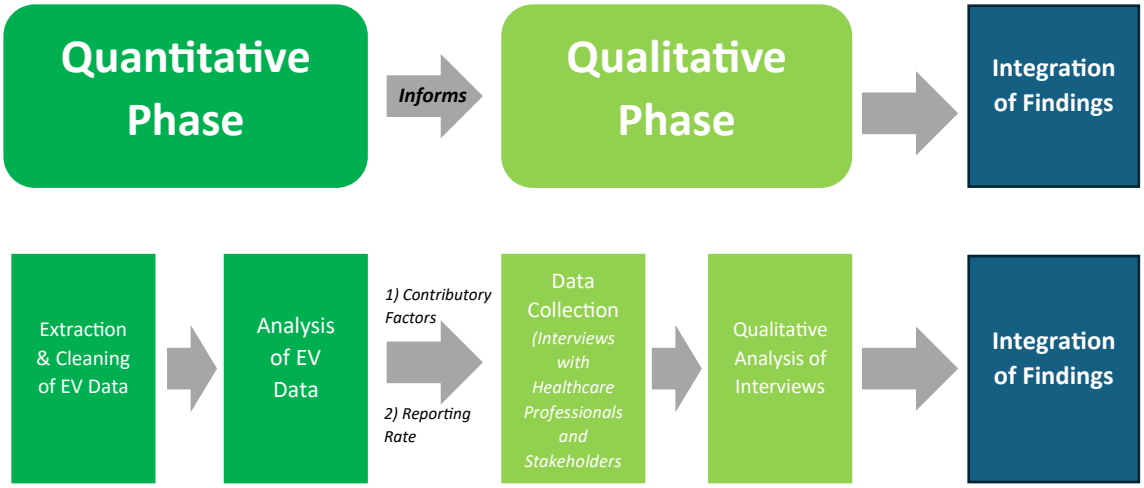

Figure 6 - Flowchart Summarising the Main Steps of the Explanatory-Sequential Mixed-Methods Approach (Adapted from Cresswell et al., 2009) and its Application in this Study

3.3 Phase 1: Quantitative Method

The quantitative phase of the study involved the use of secondary data from the EudraVigilance database. A retrospective analysis of the anonymised ICSRs submitted to this database was undertaken. Permission to access this data was granted by the Malta Medicines Authority, the local entity responsible for EudraVigilance data.

Using the EudraVigilance Data Analysis System (EVDAS), an official from the Medicines Authority extracted all the ICSRs submitted to the EudraVigilance database between 27th March 2022 and 27th March 2025, representing the most recent three-year period available at the time of extraction. Only reports that included the term "medication error" were extracted.

The initial dataset consisted of 5,352 ICSRs and was provided in Microsoft Excel format. The dataset was subsequently cleaned in accordance with the inclusion and exclusion criteria. Reports originating from clinical trials or cases from the literature (n = 587) were excluded as these did not represent spontaneous, real-world reporting and clinical scenarios. A further 238 ICSRs were removed due to the report type being unspecified. Reports originating from outside the EEA and the UK were also excluded (n = 565). Lastly, duplicate or follow-up reports (n = 253) were removed. Following this process, 3,709 unique ICSRs remained.

The final dataset included both structured fields (e.g. age, gender, reporter type, seriousness of outcome, among others) and unstructured free-text narratives. The structured data was analysed using the entire dataset, while a simple random, representative sample of eligible ICSRs was used for the analysis of the unstructured narratives. The sample size was calculated to be approximately 349 ICSRs using a 95% confidence interval and a 5% margin of error. Each ICSR was assigned a unique random number using Microsoft Excel's built-in randomisation functions, and those reports with a number between 1 and 349 were analysed further.

Figure 7 provides a graphical illustration showing the data cleaning process and how the ICSRs were subsequently used for the two phases of the EudraVigilance analysis.

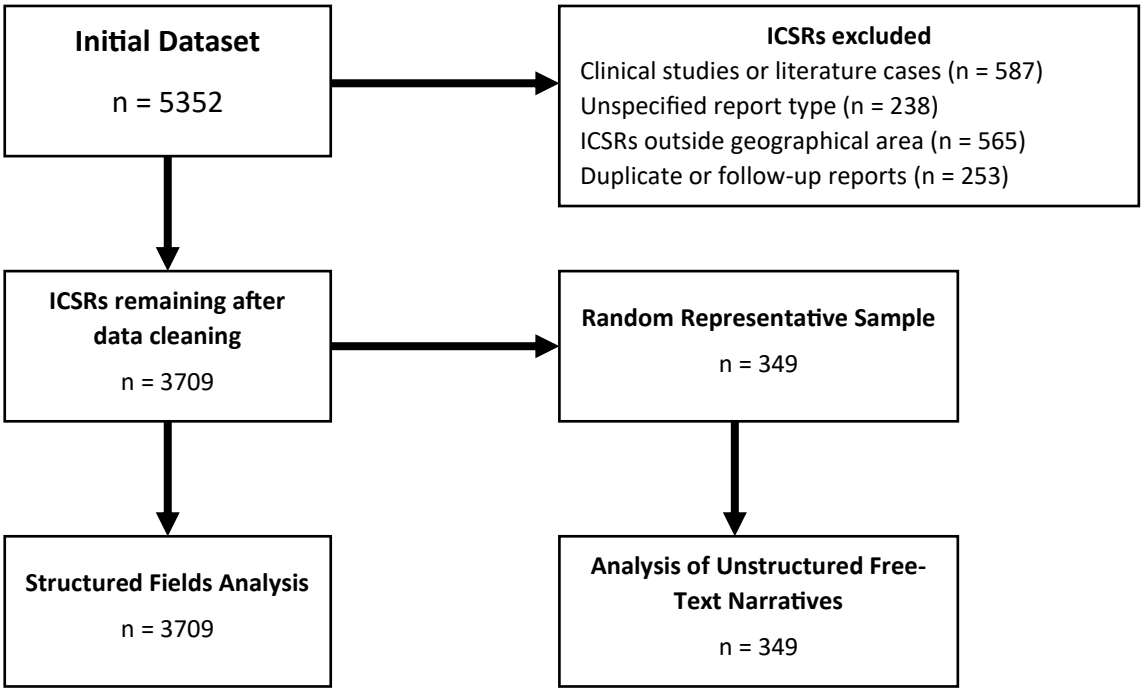

Figure 7 - Flowchart Illustrating the Data Cleaning and Selection of Individual Case Safety Reports for Analysis

Descriptive statistical analysis of the structured fields was first conducted using Microsoft Excel. Due to the variability in data completeness, denominator values differed across variables. Inferential statistical analysis was subsequently conducted using R version 4.3.2. The free-text narratives from the sampled ICSRs were manually reviewed and coded to determine the stage at which the medication error occurred within the medication-use process (refer to *Figure 2* and *Table 1* for the stages of the medication use process and the respective error definitions by stage). To reduce the risk of interpretation or coding bias during the free-text analysis, the pre-established

error definitions (outlined in Chapter 2) were used as a standard for classifying the sampled ICSRs.

3.4 Phase 2: Qualitative Approach

3.4.1 Setting

The qualitative phase of the study was conducted in two acute hospital settings in Malta.

3.4.2 Design

The qualitative phase was guided by a theory-driven approach utilising the two theoretical frameworks previously outlined in *Section 2.5*. Reason's Accident-Causation Model was used to identify and analyse the causes and contributory factors leading to medication errors, while the Theoretical Domains Framework (TDF) was used to explore participants' reporting practices, and to identify and categorise the barriers and facilitators to medication error reporting.

Data collection was conducted through semi-structured, individual (one-to-one) interviews with healthcare professionals from both hospitals. The choice of one-to-one interviews minimised potential social desirability bias as it enabled participants to freely share any personal experiences, therefore fostering more open and honest responses due to the anonymity and confidentiality of the interview modality. This was particularly important given the sensitive nature of the research topic, as participants may feel more comfortable admitting to issues such as not reporting errors in a confidential setting rather than in front of their colleagues. According to Adams, Khan

and Raeside (2014), another advantage of individual interviews is that they enable a more thorough exploration of emerging themes, and by going back and focusing on certain responses, the researcher can obtain a detailed explanation and understanding of the participant's views, which ultimately helps improve the quality of the qualitative data. Compared to focus groups, the literature also describes how individual interviews reduce the risk of bias due to group dynamics, wherein more vocal or senior participants may shape the discussion, instead ensuring that each participant's voice and perspective was equally heard (Acocella, 2012; Adams, Khan and Raeside, 2014). Individual interviews also have practical advantages, such as clearer audio for transcription due to the absence of cross-talking between participants, as well as easier scheduling given the various working hours and clinical duties of study participants (Kitzinger and Barbour, 1999).

The choice of individual interviews has disadvantages, however. The literature describes the risk of interviewer influence which may shape participant responses (Acocella, 2012). Furthermore, this interviewing modality lacks the interaction driven insights and the co-creation of ideas possible in a focus group setting (Acocella, 2012; Adams, Khan and Raeside, 2014). Individual interviews had the practical disadvantage of necessitating a greater number of interviews to be conducted by the researcher of this study, however.

3.4.3 Participants and Data Collection

A purposive, maximal variation sampling approach was used to recruit a heterogeneous group of healthcare professionals, including doctors, nurses and pharmacists, working within the acute hospital settings. In the literature, this sampling

strategy is identified as a method that enhances the richness of the data collected by capturing a wide range of perspectives on a topic (Miles, Huberman and Saldana, 2013; Campbell et al., 2020). This sampling approach was therefore considered ideal for capturing the diverse perspectives on both the causes of medication errors and the barriers associated with their reporting from healthcare professionals of different professions and levels of experience. The literature describes certain limitations with this method, such as the potential for researcher bias in participant selection, the increased difficulty in achieving thematic saturation due to the variation in perspectives, and thus the potential of not fully capturing the complexity of the issue (Miles, Huberman and Saldana, 2013; Ahmed, 2025).

Participants were identified and informed about the study by intermediaries, such as senior nursing managers or a representative from the hospital's management, who had access to the complete list of potential participants. Individuals who consented to participate were then approached by the primary researcher. Inclusion criteria to take part in the study were the ability to communicate in either English or Maltese and working in a clinical area with direct patient contact.

Interviews were then conducted with consenting participants. The combined information letter and informed consent sheet used is available in Appendix C. The interviews were held either in person, at a location chosen by the participant, or virtually via Zoom. The semi-structured interview guide (found in Appendix D) was developed using an iterative approach. Initially, the interview guide was constructed by identifying key themes and prominent findings from the studies presented in the literature review (Chapter 2), thereby ensuring that the questions were grounded in

recent international research on the topic. The interview guide was then refined and augmented based on the preliminary results from Phase 1 of the study (section 3.3), to deeply explore the underlying reasons for the identified findings. The interviews were audio-recorded with the participant's consent for the subsequent transcription and data analysis.

In addition to interviewing frontline healthcare professionals, selected key stakeholders involved in the field of patient and medication safety were also contacted to gain their views on the topic. These included representatives from patient safety and quality team set-ups of one acute care hospital, and a representative from the Malta Medicines Authority, the regulatory agency for medicines for human use.

Data collection took place predominantly throughout Q2 of 2025 and the start of Q3 2025. In this study, a total of 13 interviews were conducted with healthcare professionals, in addition to those held with the key stakeholders. Qualitative interview-based studies rely on smaller samples to allow for detailed exploration of experiences, prioritising depth and richness of data over statistical generalisation (Hennink and Kaiser, 2022; Wutich, Beresford and Bernard, 2024). According to Wutich, Beresford, and Bernard (2024), an average of 12-13 interviews is typically sufficient for the saturation of themes, while a systematic review by Hennink and Kaiser (2022) identified that saturation is commonly achieved within a range of 9-17 interviews. Participant recruitment for this study was therefore finalised once thematic saturation was achieved. Thematic saturation was defined as the point at which no new themes or insights emerged (Ahmed, 2025).

3.4.4 Data Analysis

All interviews were manually transcribed by the primary researcher and then analysed thematically. Data familiarisation was achieved through repeated listening to the audio recordings, followed by multiple readings of the transcripts, to be fully immersed in the material.

During the initial coding phase, meaningful sections from each interview were assigned to the overarching domains of Reason's Accident Causation Model and the Theoretical Domains Framework. Following this initial coding, a second review was conducted in which the initial codes were then grouped together into specific themes. The grouping under the specific domains and themes were then revisited to ensure coherence and resolve any significant overlaps. The application of the two theoretical frameworks helped guide the data analysis, thereby mitigating interpretation bias, minimise subjective variability in coding and ultimately enhance overall rigor. Lastly, illustrative quotes were selected to support and enrich the narrative presentation of the results.

3.4.5 Measures taken to enhance Quality and Trustworthiness

Miles, Huberman and Saldana, drawing on the foundational work carried out by Lincoln and Guba (1985), identified several key criteria for enhancing the quality and trustworthiness of qualitative research. These criteria included confirmability, dependability, credibility, and transferability (Miles, Huberman and Saldana, 2013).

To support reflexivity and confirmability, the primary researcher's background as a medical doctor and a specialist trainee in Public Health was disclosed to participants to acknowledge any positional views and possible researcher influence,

and this background was also considered when analysing and interpreting the transcripts. Dependability and credibility were addressed using a clearly defined sampling strategy and ongoing reflexive practice undertaken during data analysis. Furthermore, multiple rounds of review by the dissertation supervisors served as a form of peer debriefing, wherein the themes and interpretation of findings were reviewed against the selected illustrative quotes to challenge any potential positionality bias, ensuring that the results were logically derived according to the theoretical frameworks utilised. To promote the transferability and generalisability of this study, a detailed description of the study setting and participant recruitment process was outlined above. Additionally, participant demographics and professional characteristics are presented in the Results chapter to help contextualise the findings.

3.5 Ethical Considerations

This research study was approved by the Faculty Research Ethics Committee (FREC) of the Faculty of Medicine and Surgery of the University of Malta (REDP Application ID: MED-2025-00049) (Appendix E).

All participants were provided with a written information letter and were required to sign a consent form prior to their participation. Participant confidentiality was safeguarded using pseudonyms and participant codes, with all identifiable information removed during transcription. This involved assigning each participant a unique code (e.g. P1, P2) and storing these codes and personal identifiers separate from the research data. The names of the participating hospitals were likewise pseudonymised as ‘Hospital 1’ and ‘Hospital 2’. To ensure participant anonymity, all

details regarding the professional group and the names of the hospitals were omitted from the results in *section 4.4.2* and *section 4.4.3* and the pseudonymised codes were used instead.

The data protection requirements of each entity and of the General Data Protection Regulation (GDPR (EU) 2016/679) were fully adhered to throughout the data collection process and thereafter.

3.6 Chapter Summary

This chapter detailed the methodology used in this research and the rationale for its choice. A mixed-methods explanatory-sequential design was used, whereby the quantitative phase involved the retrospective analysis of ICSRs from the EudraVigilance, followed by the qualitative phase informed by these findings. The qualitative component sought to explain the quantitative results and gain in-depth perspectives from healthcare professionals regarding the causes of medication errors and the barriers to their reporting.

Chapter 4: Results

4.1 Chapter Overview

This chapter presents the findings obtained from the study and is divided into three main sections. The first section presents the results from the analysis of the Individual Case Safety Reports (ICSRs) from the EudraVigilance database, divided into two sub-sections, namely the structured fields and the unstructured free-text narratives. The second section presents the results from the qualitative phase of the study, which examines the causes and contributory factors to medication errors, grouped according to Reason's Accident Causation Model. It also explores the barriers and facilitators to medication error reporting, organised thematically using the Theoretical Domains Framework (TDF). The third section provides insights into these issues from representatives of the existing quality and safety set-ups within one acute care hospitals and the Malta Medicines Authority.

4.2 EudraVigilance Results – Quantitative Structured Fields Analysis

4.2.1 Overview of the dataset from EudraVigilance

A total of 5,352 ICSRs containing the term medication error were submitted to the EudraVigilance database between 27th March 2022 and 27th March 2025[1]. After the

[1] The EudraVigilance data presented in Section 4.2 and 4.3 reflects all healthcare settings, and not just the acute hospital setting. This is a limitation of the dataset, as expanded upon in Section 5.4.2.

data cleaning process (refer to *Section 3.3, Figure 7*) the final dataset consisted of 3,709 ICSRs, which formed the basis for all subsequent analysis within this section.

4.2.2 Temporal Distribution of Individual Case Safety Reports

Table 5 provides a breakdown of the number of ICSRs which were recorded in each calendar year from the dataset.

Table 5 - Count of Individual Case Safety Reports by Calendar Year

Year	Number of ICSRs
2022 (27/03 – 31/12 only)	1001
2023	1227
2024	1209
2025 (01/01 – 26/03 only)	272

Figure 8 shows the quarterly distribution of ICSRs, highlighting that the highest number of reports were submitted in Q4-2024 (n = 374), while Q2-2024 had the least number of ICSRs submitted to EudraVigilance (n = 237). No consistent seasonal pattern is apparent when comparing the same quarters across different years.

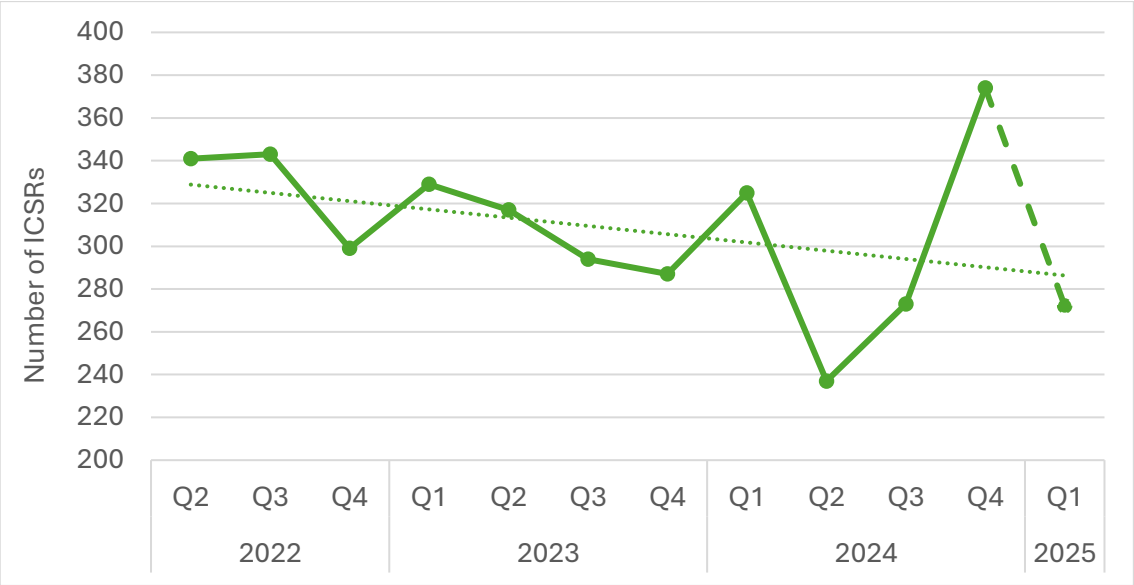

Figure 8 - Number of Individual Case Safety Reports by Quarter and Calendar Year[2]

For ease of comparison, the data was then reorganised into three equal 12-month periods as shown in *Figure 9* . The number of ICSRs over the three-year study period showed a gradual downward trend. The average monthly reporting rate declined from 110 ICSRs per month in Year 1 (27/03/22 – 26/03/23) to 98 ICSRs per month in Year 3 (27/03/24 – 26/03/25), representing an 11% decrease. Year 1 accounted for the highest proportion of reports, comprising 35.5% (n = 1315) of all ICSRs in the dataset, followed by Year 2 with 32.9% (n = 1221) and Year 3 with 31.6% (n = 1173).

[2] Q1-2025 covers the period from 1st January 2025 to 26th March 2025 only

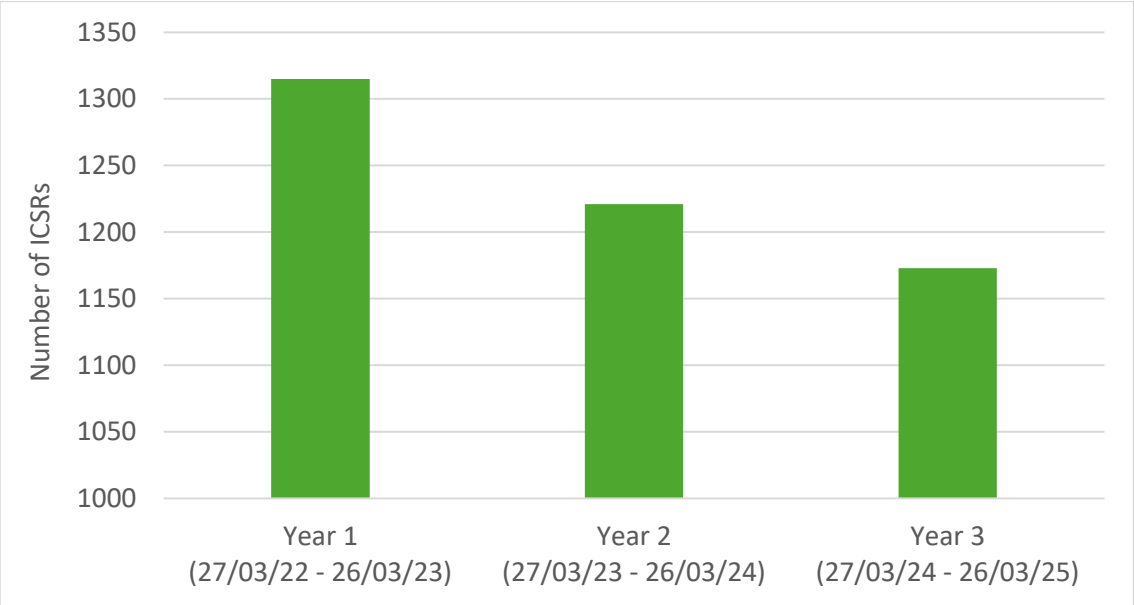

Figure 9 - Number of Individual Case Safety Reports Received Over Three 12-Month Periods (March 2022 - March 2025)

A Chi-Squared test was then conducted, which revealed a statistically significant difference in the number of ICSRs across the three 12-month periods ($\chi^2 = 8.44$, $p = 0.015$).

4.2.3 Country of Report Origin

The United Kingdom (UK) was the country with the highest number of ICSRs reported in the EudraVigilance database during the study period, with 2,353 reports (63.4%), followed by France (n = 450; 12.1%) and Italy (n = 258; 7.0%). Due to the wide variation in reporting volumes, a logarithmic bar chart was used to visualise the distribution across all countries within the EEA, and the UK *(Figure 10).*

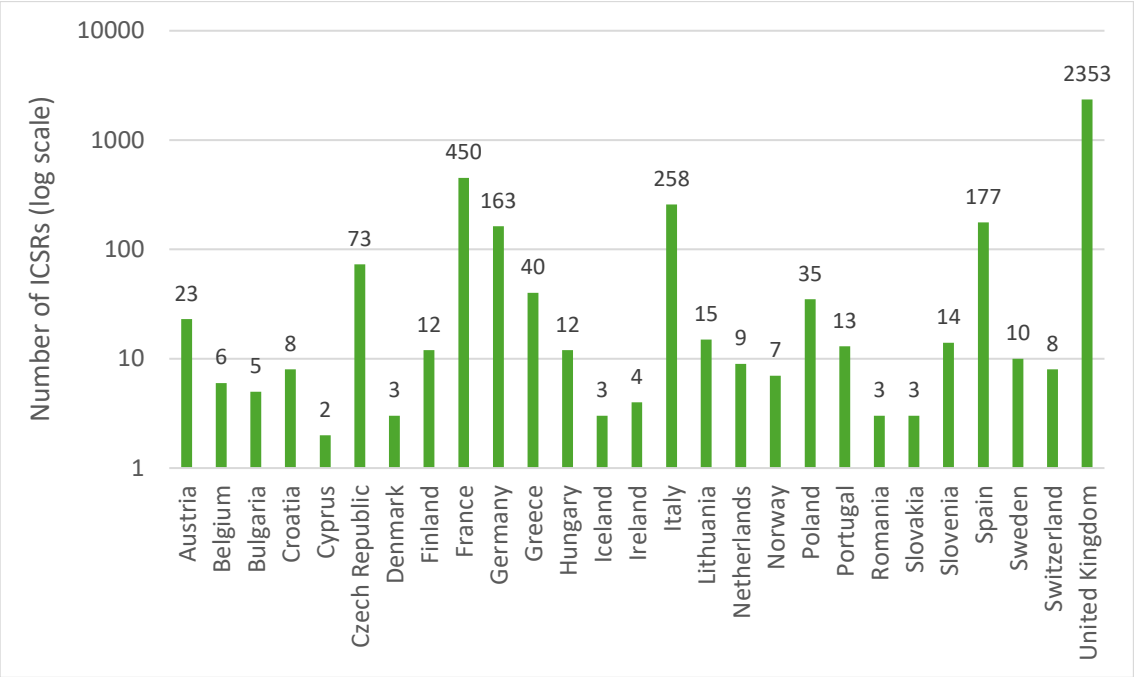

Figure 10 - Number of Individual Case Safety Reports by Country

Over the three-year period, no ICSRs originating from Malta, Luxembourg, Liechtenstein, Lativia or Estonia were present within the EudraVigilance dataset.

The reporting rate per 100,000 population was then calculated using Eurostat population estimates (Eurostat, 2025), as shown in *Table 6* below. The UK also had the highest reporting rate among all countries, with a rate of 3.51 ICSRs per 100,000 population, followed by Iceland (0.78 per 100,000) and then the Czech Republic (0.67 per 100,000 population).

Table 6 - Top 10 Countries by Reporting Rate per 100,000 Population

Rank	Country	Reporting Rate (per 100,000 population)
1	United Kingdom	3.51
2	Iceland	0.78
3	Czech Republic	0.67
4	Slovenia	0.66
5	France	0.66
6	Lithuania	0.52
7	Italy	0.44
8	Greece	0.38
9	Spain	0.36
10	Austria	0.25

4.2.4 Patient Demographics

An analysis of ICSRs by gender revealed that 58.8% (n = 2,179) of reports were submitted for female patients, while 37.3% (n = 1,382) were for male patients. The remaining 3.9% (n = 144) did not have a gender specified, as shown in *Figure 11* .

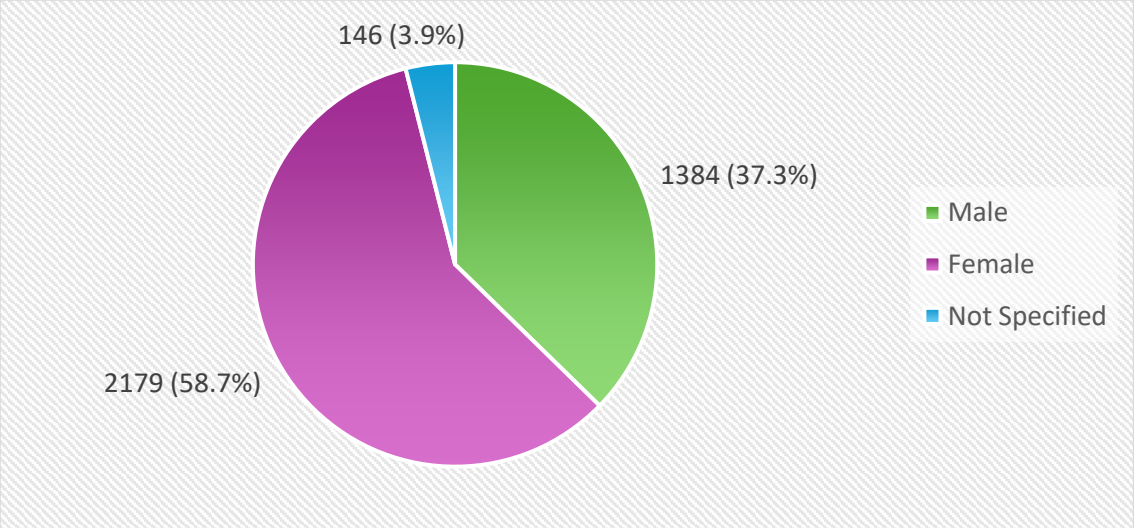

Figure 11 - Distribution of Individual Case Safety Reports by Gender

The ages of patients ranged from less than 1 year of age in 65 separate ICSRs up to 1 case occurring in a patient aged 105 years. The mean age was calculated to be 49.9 years (Standard Deviation [SD]: 23.8), and the median was found to be 53 years (Inter Quartile Range [IQR]: 37).

A breakdown of the reports by 10-year age groups was then conducted. A total of 657 entries were missing age information. Among the remaining ICSRs, the highest number of reports occurred in the 50-59 age group (n = 464, 15.2%), followed closely by the 60-69-year age group and then the 70-79-year age group, accounting for 14.9% and 14.8% respectively. The full distribution across all age categories is shown in *Figure 12.*

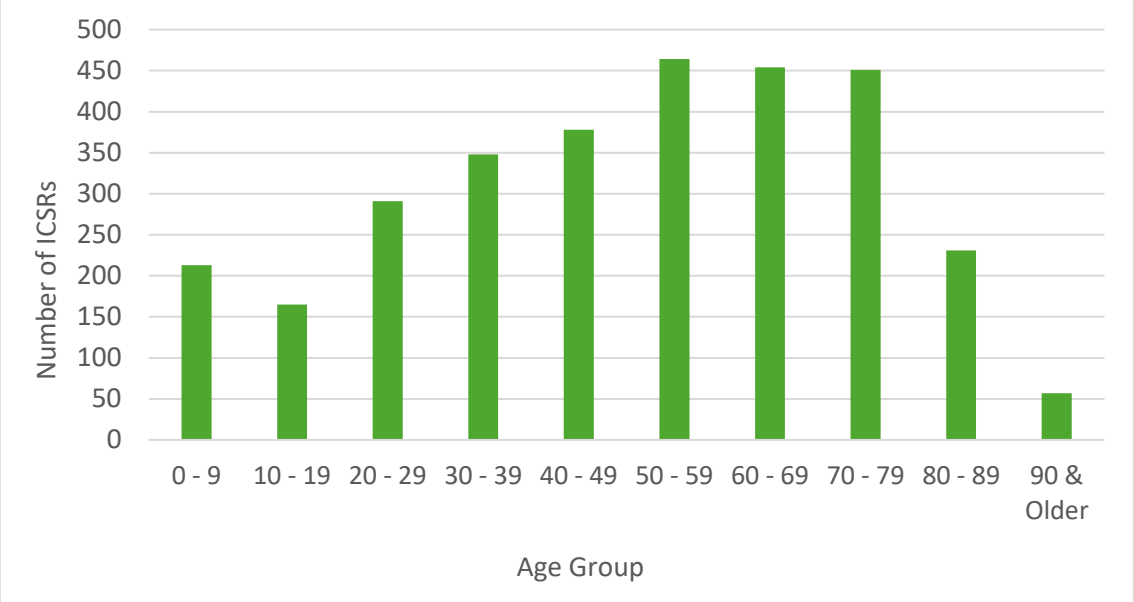

Figure 12 - Distribution of Individual Case Safety Reports by 10-Year Age Groups

To explore gender differences across age groups, only those ICSRs where both age and gender information were available (n = 2,980) were included in a stratified analysis (*Figure 13*). Female reports (n = 1,789) outnumbered male reports (n = 1,191)

in every age category. Among females, the highest number of reports was observed in the 50 – 59 age group (n = 271), followed by the 70 – 79 (n = 256) and 30 – 39 (n = 249) groups. For males, the highest number of reports was seen in the 60 – 69 age group (n = 210), with the 70 -79 (n = 183) and 50 – 59 (n = 182) closely behind.

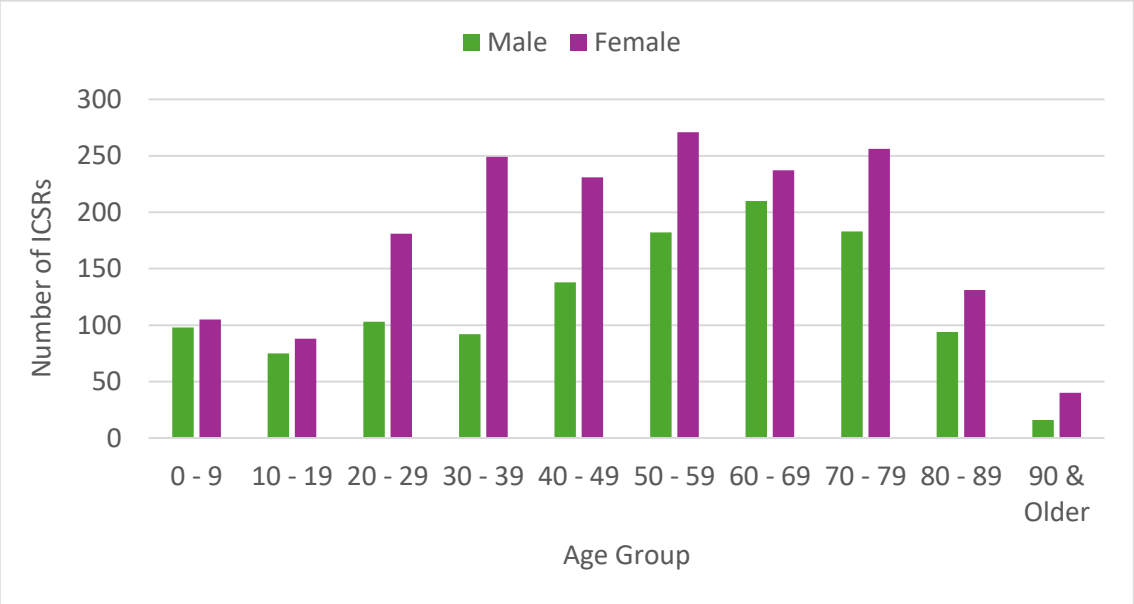

Figure 13 - Gender Differences in Individual Case Safety Reports Stratified by 10-Year Age Groups

As shown in *Table 7*, the overall gender gap was calculated to be 50.2%, favouring females. This gender gap was most pronounced in the 30-39-year age group (170.7%) and the 90 and older cohort (150%). Conversely, the narrowest gap was in the youngest age group (7.1%), followed by the 60–69-year age group (12.9%).

Table 7 – Gender Gap in Individual Case Safety Reports Stratified by Age Group

Age Group (Years)	Gender Gap (% Higher in Females)
0 – 9	7.1%
10 – 19	17.3%
20 – 29	75.7%
30 – 39	170.7%
40 – 49	67.4%
50 – 59	48.9%
60 – 69	12.9%
70 - 79	39.9%
80 – 89	39.4%
90 & Older	150.0%
Total	50.2%

4.2.5 Reporter Type

The majority of ICSRs reported to the EudraVigilance database were submitted by non-healthcare professionals, accounting for 2,248 reports (60.6%). Among reports submitted by healthcare professionals, doctors contributed the highest number, with 583 reports (15.7%), followed by pharmacists, who submitted 440 reports (11.9%). A further 11.9% of reports submitted by healthcare professionals were marked as 'Other', where the professional group was not specified. The dataset did not contain a structured field or code specifically for nurses. *Figure 14* provides a visual representation of ICSRs by reporter type.

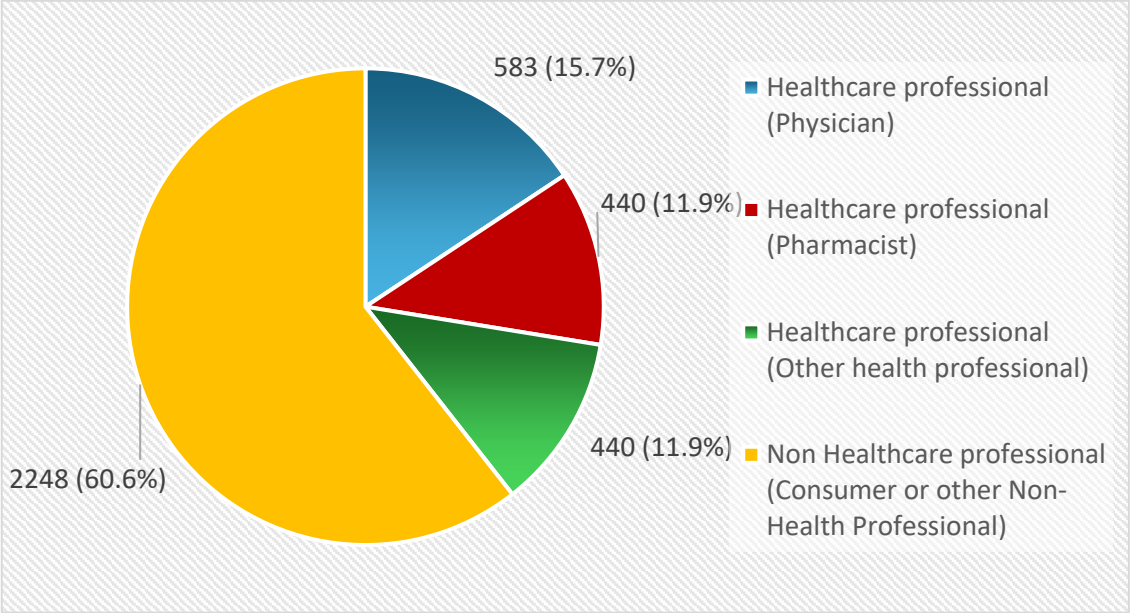

Figure 14 - Distribution of Individual Case Safety Reports by Reporter Type

An analysis to understand the high reporting rate seen in the UK compared to the other countries showed a substantial difference in the source of ICSRs compared to the collective reports by all other countries. In the UK, non-healthcare professionals accounted for the majority of reported ICSRs (79.8%; n = 1876), whereas healthcare professionals were the primary source for reports from the other countries combined (72.6%; n = 982).

4.2.6 Seriousness of Errors

Distribution of Serious vs Non-Serious Individual Case Safety Reports

Out of the 3,709 ICSRs included in the analysis, 2,880 (77.6%) were classified as serious, while the remaining 829 (22.4%) were considered non-serious, as shown in *Figure 15* which illustrates this distribution.

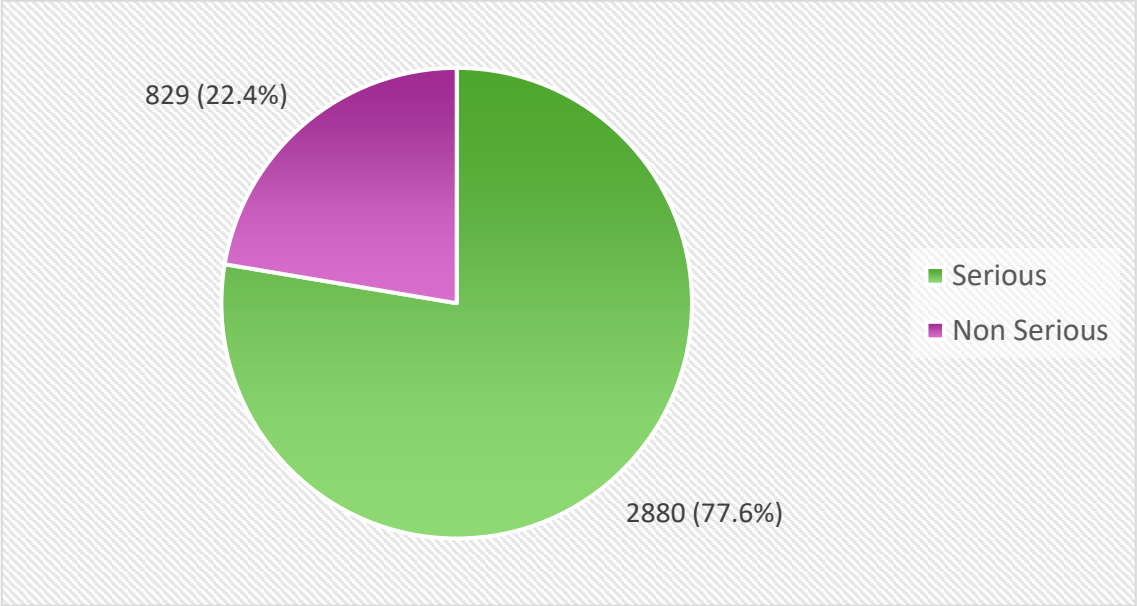

Figure 15 - Proportion of Serious and Non-Serious Individual Case Safety Reports

Relationships between Age, Gender, Reporter Type and Seriousness of Report

To further explore the association between demographic variables (age and gender) and the overall seriousness of the report, inferential statistical analysis was carried out. A chi-squared test found no significant association between patient gender and seriousness of report ($\chi^2 = 0.25$, $p = 0.62$).

The Chi-Squared test was then conducted to assess the statistical relationship between age group and seriousness. Following this analysis, a significant association between the two was found ($\chi^2 = 162.92$, $p < 0.001$). To further understand this association, post-hoc tests using standardised residuals were conducted. This test compared the observed number of serious and non-serious ICSRs in each age group with the number that would be expected if age and seriousness were unrelated. The results of this post-hoc test are shown in *Figure 16*, where redder hues indicate more

reports than expected for that age-group and bluer hues depicting fewer reports than expected.

Figure 16 - Heatmap Showing Standardised Residuals for Seriousness by 10-Year Age Groups

As shown above, the youngest age groups (0-9 and 10-19) and the 70 – 79 age group had significantly fewer serious reports than expected if age and seriousness were not related. Conversely, the 20 – 29, 40 – 49 and 50 – 59 age groups showed significantly higher numbers of serious reports than expected.

An analysis of ICSR seriousness by type of reporter was then conducted for those ICSRs reported by a single reporter (n = 3703). A statistically significant difference

was found, whereby ICSRs by non-healthcare professions had a higher proportion of serious outcomes (84.9%) compared with those submitted by healthcare professionals (66.6%) (Chi-squared: $\chi^2 = 168.52$, $p < 0.01$).

Further analysis then examined patterns of report seriousness within different healthcare professions (n = 1456). Doctor-reported ICSRs had the highest proportion of serious outcomes (70.3%), followed by those submitted by non-specified/other healthcare professionals (69.6%) and pharmacists (59.2%). A chi-squared test was carried out and demonstrated a statistically significant difference in the proportion of serious reports across these groups ($p < 0.01$).

4.2.7 Breakdown of Individual Case Safety Reports by Outcome

The serious reports were then analysed by outcome, with individual reports potentially listing more than one outcome each. Among the 2,880 serious reports, the most commonly assigned subtype of seriousness was ‘Seriousness Other’, appearing in 2,236 cases. This was followed by hospitalisation in 910 cases and life-threatening events in 403 cases.

Disability was reported in 639 cases, although the data set does not specify whether this disability was permanent or temporary. There were 64 reports where the outcome was death, and 16 cases involved congenital anomalies. *Table 8* provides a summary of these outcomes, expressed both as a percentage of serious reports and of the total dataset.

Table 8 - Distribution of Seriousness of Outcomes Among Serious and All Individual Case Safety Reports

Outcome	Count (Yes)	% of Serious Reports (N= 2,880)	% of All Reports (N = 3,709)
Death	64	2.2%	1.7%
Disability	639	22.2%	17.2%
Life-threatening	403	14.0%	10.9%
Congenital Anomaly	16	0.6%	0.4%
Hospitalisation	910	31.6%	24.5%
Other/Not Specified	2236	77.6%	60.3%

4.2.8 Characteristics of Reported Medications

The majority of ICSRs in the dataset involved only a single suspected medication (n = 3,327), representing 89.7% of the total entries. Further analysis by the WHO Anatomical Therapeutic Chemical (ATC) Level 1 and Level 2 codes was carried out on those reports involving a single suspected agent.

From the 3,327 single-agent ICSRs, 14 entries could not be mapped to an ATC code due to incomplete, ambiguous or unknown foreign drug names. Among the classified reports, medications within the 'J' ATC code (anti-infectives for systemic use) were the most frequently associated with errors, comprising 23.1% of the total. This was closely followed by medications within the 'N' class (nervous system agents), accounting for 22.8%, and then drugs in the 'A' class (alimentary tract and metabolism), with 14.9%. The full distribution of medications by ATC Level 1 Category is shown in *Figure 17.*

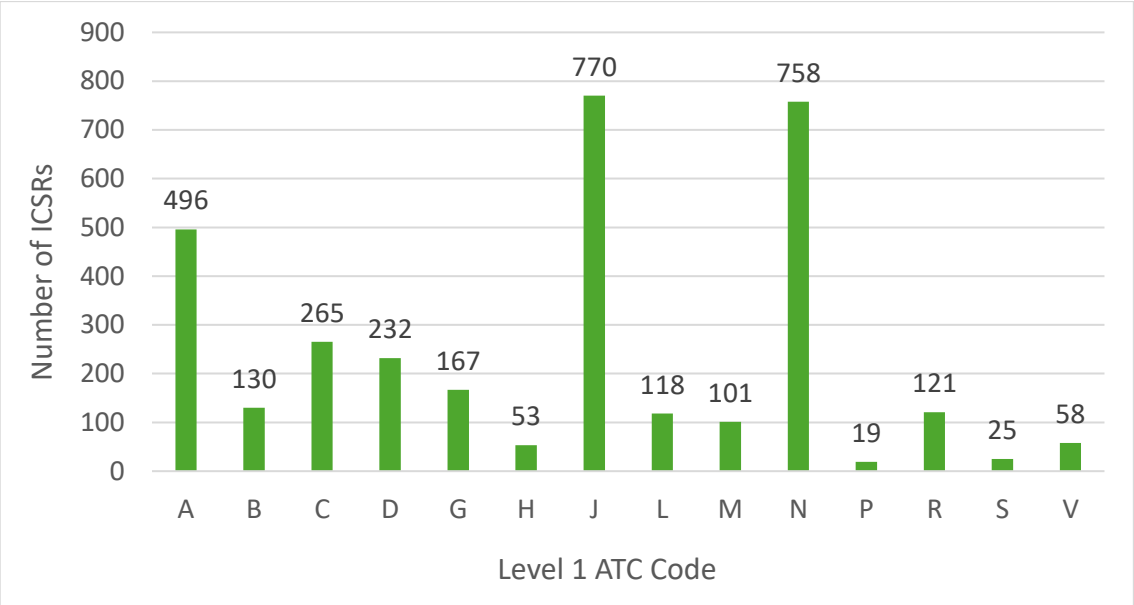

Figure 17 - Distribution of Single Agent Individual Case Safety Reports by Anatomical Therapeutic Chemical Level 1 Code

To provide greater granularity, the Level 2 ATC classification was used to identify the most frequently implicated subgroups (*Table 9*). Vaccines (J07) were the most commonly represented subgroup (n = 445), followed by systemic antibacterials (J01), with 308 reports and psycholeptics (N05), with 221 reports.

Table 9 - Top 10 Anatomical Therapeutic Chemical (ATC) Level 2 Codes Among Single-Agent Individual Case Safety Reports

Rank	Level 2 ATC Code	Description	Count
1	J07	Vaccines	445
2	J01	Antibacterials for Systemic Use	308
3	N05	Psycholeptics	211
4	N06	Psychoanaleptics	192
5	N02	Analgesics	185
6	A10	Drugs used in Diabetes	184
7	G03	Sex Hormones and Modulators	107
8	A01	Stomatological Preparations	106
9	N03	Antiepileptics	85
10	B01	Anti-thrombotic Agents	81

The field for route of administration had the greatest gaps in data, with 54.5% of ICSRs not having the route specified. From the remaining 1687 ICSRs with a listed route, oral medications were the commonest reported route of administration (n = 946), followed by the intramuscular (IM) route (n = 337) and then the intravenous (IV) route (n = 123), as shown in *Figure 18*.

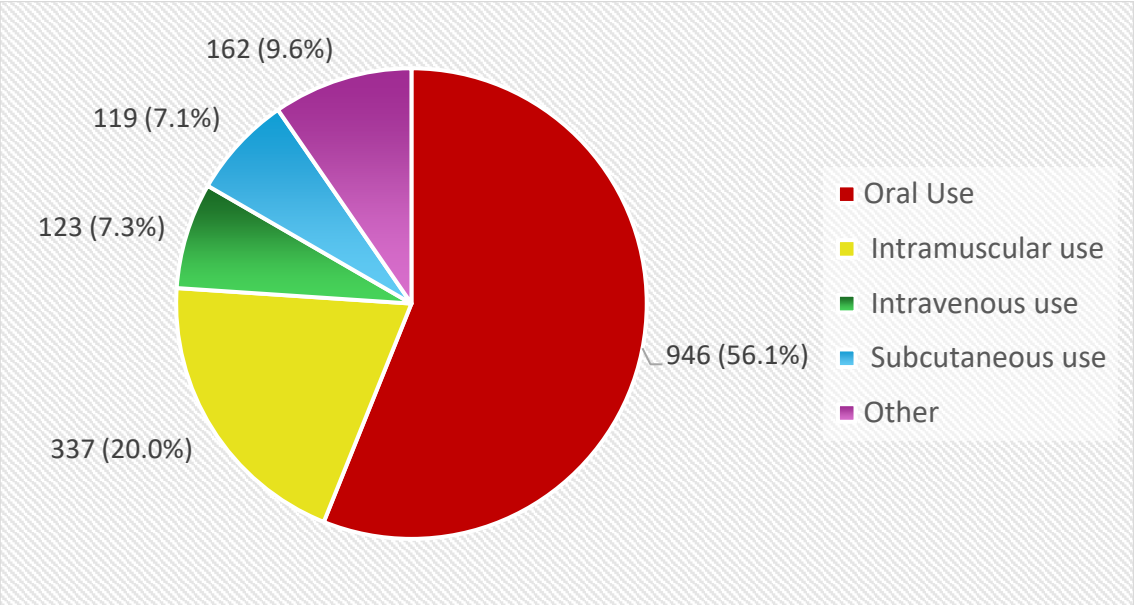

Figure 18 - Distribution of Individual Case Safety Reports with a Known Route of Administration

4.3 EudraVigilance Results – Analysis of Unstructured Free-Text Narratives

4.3.1 Medication Errors by Stage of the Medication Use Process

As mentioned in Chapter 3: Methods, a random representative sample of 349 ICSRs was analysed to classify each report by stage of the medication use process, based on the free-text narrative section. As shown in *Figure 19*, the highest number of reported errors occurred during the prescribing stage, accounting for 27.2% of errors, followed by administration errors (24.4%) and then errors committed by the patient themselves (patient errors), which accounted for 20.6%. Errors at the dispensing, monitoring and transcribing stages were relatively less frequent. Approximately 12% of the ICSRs sampled did not contain sufficient information to assign them to one specific stage.

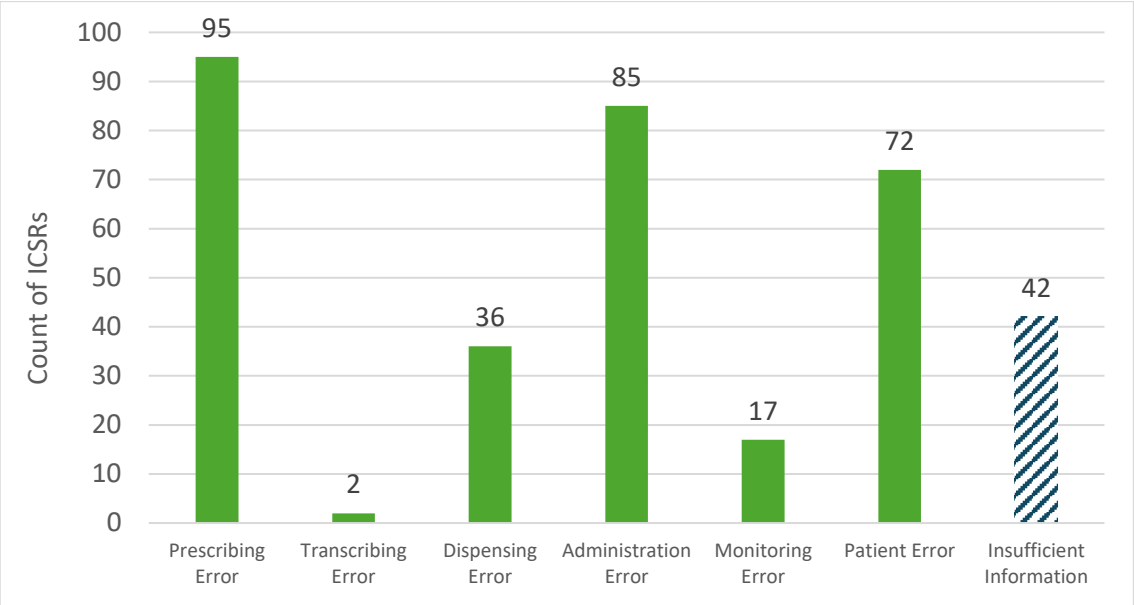

Figure 19 - Distribution of Individual Case Safety Reports by Stage (n = 349)

The type of errors in ICSRs from the sample that were attributed to a specific stage (n = 307) were then categorised as shown in *Table 10*.

Within the prescribing stage, the most common type of error was wrong dose (29.5%), followed by wrong drug prescribed (24.2%). 21.1% of prescribing errors were due to prescribing a medication to a patient with a known allergy or contraindication to its use.

The two errors identified within the transcribing stage were the lack of documentation of a patient's allergy status and the failure to hide previously discontinued prescriptions on an electronic prescribing software.

In the dispensing stage, more than one-third of ICSRs were due to the wrong drug being dispensed, including errors involving the brand (36.1%). The next most common dispensing errors were failure to provide appropriate advice and instructions,

as well as dispensing the wrong strength of the medication, each accounting for 16.7% of cases within this stage.

Within the administration stage, the most frequently reported errors were the administration of the wrong medication and failure to follow administration guidelines or protocols, each contributing to 14.1% of administration-related ICSRs. Other common administration errors included wrong dose, wrong time and an incorrect administration technique, each accounting for 12.9% of cases.

Inadequate or delayed clinical monitoring was identified as the most common error type within the monitoring stage, accounting for over half of the errors in this stage. The second most frequent error was Inadequate or delayed laboratory monitoring (17.6%), followed by failure to act on abnormal results or lack of documentation, which together accounted for 11.6% of monitoring errors.

Patient errors were predominantly due to wrong dose errors, including both overdoses and underdoses, which accounted for 34.7% of patient-related errors. Other common factors included non-adherence or non-compliance and a failure to understand instructions, with 16.7% and 11.1% of errors under this category, respectively.

Table 10 - Types of Medication Errors by Stage of the Medication Use Process

Error Type	Count	% of Class	% of Total
Prescribing			
Inappropriate Drug Selection	12	12.6	3.9
Known Allergy or Contraindication	20	21.1	6.5
Wrong Dose	28	29.5	9.1
Wrong Drug	23	24.2	7.5
Wrong Frequency or Duration	5	5.3	1.6
Others[3] (Duplication of Drug, Incomplete Prescription, Wrong Formulation, Prescribing Error Unspecified)	7	7.4	2.3
Transcribing			
Failure to document allergy status	1	50.0	0.3
Electronic software issue	1	50.0	0.3
Dispensing			
Expired Medication Dispensed	2	5.6	0.7
Failure to provide advice when dispensing	6	16.7	2.0
Labelling error	4	11.1	1.3
Wrong Constitution	3	8.3	1.0
Wrong Drug (incl. wrong brand)	13	36.1	4.2
Wrong Strength	6	16.7	2.0
Others[3] (Defective/Substandard Product Dispensed, Unspecified Dispensing Error)	2	5.6	0.7
Administration			
Failure to follow guidelines	12	14.1	3.9
Incorrect Technique	11	12.9	3.6

[3] Includes error types that individually account for < 5% of errors within their stage

Administration Error Unspecified	11	12.9	3.6
Wrong Dose	11	12.9	3.6
Wrong Medication	12	14.1	3.9
Wrong Route	7	8.2	2.3
Wrong Time	11	12.9	3.6
Others[4] (Omissions, Wrong Formulation/ Frequency/ Infusion Rate/ Patient/ Preparation)	10	11.8	3.3
Monitoring			
Failure to Act on Abnormal Result	2	11.8	0.7
Failure to Document or Communicate Monitoring Results	2	11.8	0.7
Inadequate Clinical Monitoring	9	52.9	2.9
Inadequate or Delayed Lab Monitoring	3	17.6	1.0
Monitoring Error Unspecified	1	5.9	0.3
Patient-Related			
Incorrect Use of Device	4	5.6	1.3
Lack of Understanding of Instructions	8	11.1	2.6
Non-Adherence/Non-Compliance	12	16.7	3.9
Wrong Dose	25	34.7	8.1
Wrong Drug	6	8.3	2.0
Wrong Frequency	6	8.3	2.0
Wrong Route	7	9.7	2.3
Others[4] (Expired Drug, Self-Medication, Patient Error Unspecified)	4	5.6	1.3

[4] Includes error types that individually account for < 5% of errors within their stage

Summary of Key Findings from the EudraVigilance Analysis

The most notable finding was the absence of medication error reports originating from Malta over the 3 years. Across the dataset, patient demographic data indicated that 58.8% of errors occurred in females, with a mean age of just under 50 years. A chi-squared test showed a statistically significant association ($p < 0.01$) between age group and the seriousness of the event, with standardised residual analysis revealing higher rates of serious reports than expected if age and seriousness were unrelated in the 20-29, 40-49 and 50-59 age groups. Overall, 77.6% of all ICSRs were classified as serious, with a large proportion of these reports classified under the "other/non-specified" seriousness category. Healthcare professionals were the source of reports in only 39.4% of cases, which was particularly attributable to the UK, which had substantially higher reporting rates compared to other countries and where non-healthcare professionals accounted for 79.8% of reports. Overall, a statistically significant association was found between the reporter type and the seriousness of the outcome ($p < 0.01$), with non-healthcare professionals reporting a higher proportion of ICSRs with a serious outcome compared to healthcare professionals. The medication classes most frequently implicated with ICSRs were anti-infectives for systemic use (ATC code J) and nervous system agents (ATC code N), accounting for 23.1% and 22.8% of ICSRs, respectively. Errors most often occurred at the prescribing stage (27.2%), followed by the administration stage (24.4%) of the medication use process.

4.4 Qualitative Results

4.4.1 Overview of Background Characteristics of Participants

A total of thirteen (13) healthcare professionals participated in the interviews, which had an average duration of just under 40 minutes. Thematic saturation was achieved in this study, as no new themes emerged during the analysis of the final interviews. This indicated that sufficient data had been collected. The participants interviewed stemmed from a range of professions, grades, clinical specialities and levels of experience, thus providing perspectives from across hospital settings. In order to safeguard participant anonymity while still providing the necessary context, the data about the participants was presented in a pseudonymised and aggregated form. Additionally, the names of the hospitals were also pseudonymised.

Demographic Details

As illustrated in *Figure 20*, 8 out of the 13 participants were male, while the remaining 5 were female.

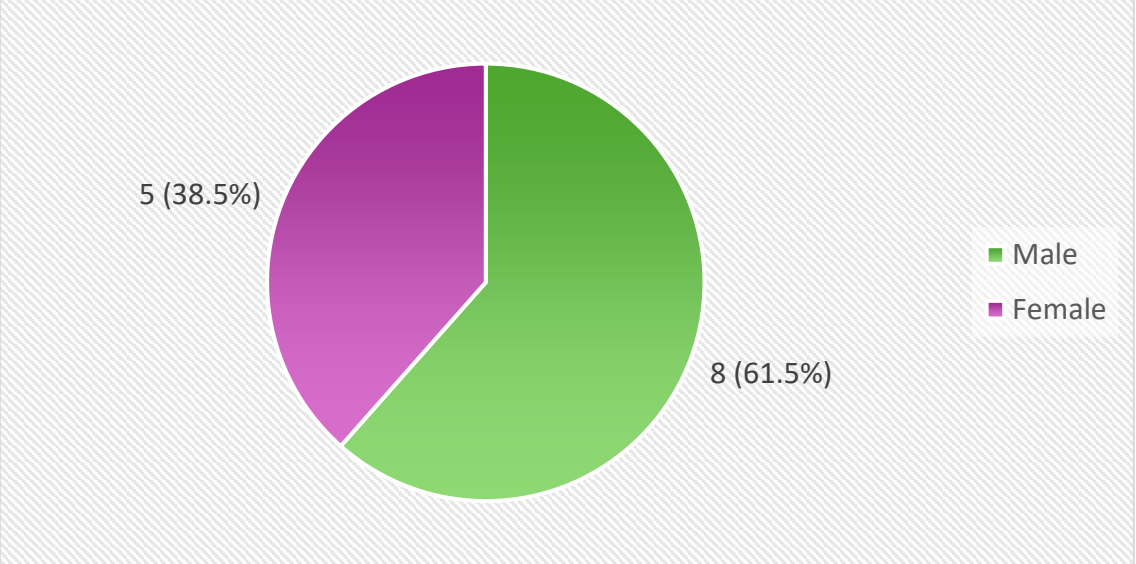

Figure 20 - Distribution of the Participants at the interview by Gender

The participants had an average age of 36.5 years, ranging from 28 to 45 years. Most participants were Maltese (n = 12), with one participant hailing from Asia but working locally for several years.

Professional Group and Grade

Table 11 shows the breakdown of participants by professional group and grade. The participants in the study consisted of nurses (n = 8), doctors (n = 4) and a pharmacist (n = 1). Participants represented a wide range of seniority, from entry-level positions to senior clinical grades.

Table 11 - Breakdown of Participants by Professional Group and Grade

Professional Group	Grade	Count
Nurse	Nursing Officer (NO) / Deputy NO	1
	Practice Nurse	2
	Registered Nurse	2
	Other / Not Specified	2
Doctor	Consultant / Resident Specialist	1
	Specialist Trainee	2
	Resident Medical Doctor	1
	Foundation Doctor	1
Pharmacist	Managing Pharmacist	1

Clinical Specialty

Participants were recruited from a range of acute care specialities, thus allowing for a varied and diverse set of perspectives on the causes of medication errors

and the barriers and facilitators associated with their reporting. *Figure 21* illustrates the range of specialities participants predominantly worked in.

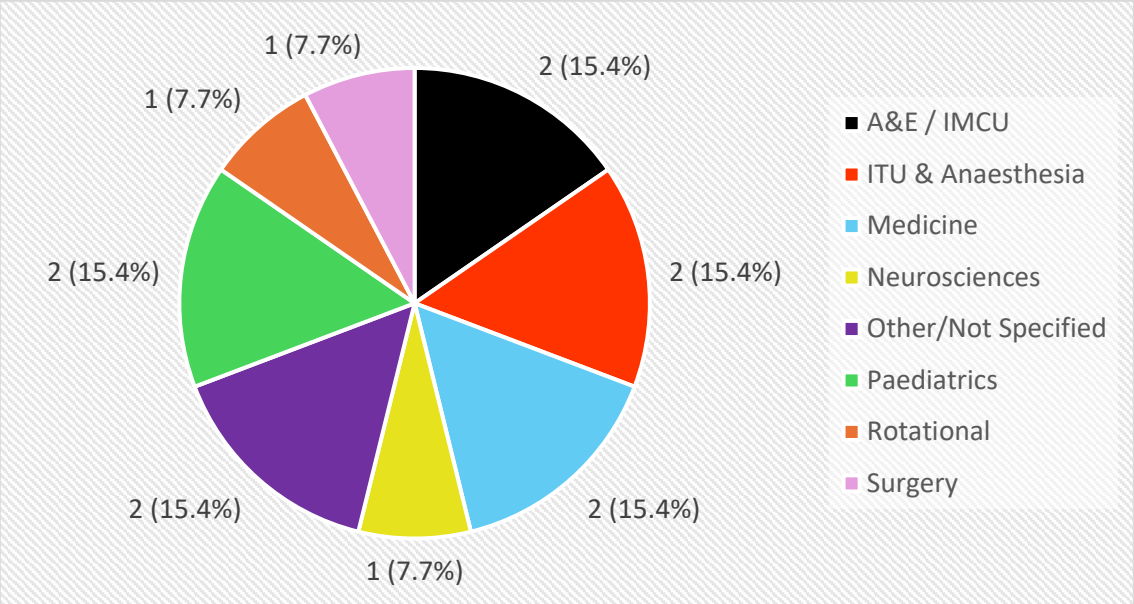

Figure 21 - Distribution of Participants by Speciality

Years of Professional Experience

Participants reported between 2 and 23 years of experience in their profession within the healthcare sector, with an average of 12.6 years. Just under half of participants (46.2%) had between 15 – 19 years of experience. *Figure 22* illustrates the distribution of clinical experience of the study participants.

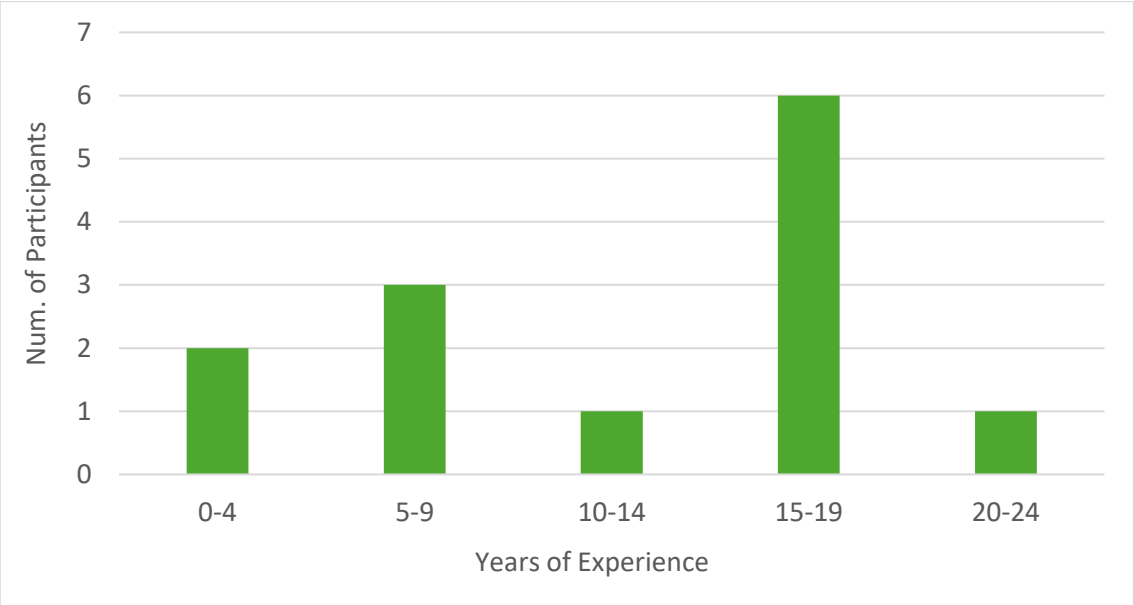

Figure 22 - Distribution of Participants by Years of Experience (in 5-Year Groups)

4.4.2 Causes and Contributory Factors for Medication Errors

The interview transcripts were first analysed to identify the causes and the contributory factors that participants felt led to medication errors. These were then grouped into active failures, error-provoking conditions or latent failures, in accordance with Reason's Accident-Causation Model (refer to *section 2.5.2).*

Active Failures

When describing the causes and contributory factors of medication errors, participants mentioned active failures less frequently than error-provoking conditions and latent factors.

Most of the active failures reported were slips, often precipitated by lookalike medications, with one participant recounting an incident where the wrong medication

was selected because "*the vial was similar to another drug that she wanted to give*" (P7). Lapses in concentration were also mentioned, although less frequently, and were mostly associated with drug omissions. One participant described how anti-coagulation was forgotten to be prescribed following surgery:

"*He had been in for some orthopaedic procedure…and he was not anticoagulated for 72 hours. So not having been prescribed what he needed*" (P11)

Mistakes were also identified as a cause for medication errors by participants from both hospitals. These were most apparent when staff lacked the appropriate knowledge for the clinical setting or scenario, leading to an incorrect medication or dose ultimately being administered:

"*…in paediatrics, [paracetamol is] given by weight. And we had issues, we had problems even recently that someone gave a whole bottle, so 10 times, 12 times as much the dose that he [the patient] should have been prescribed*" (P13)

"*a patient was to be prescribed Depo-Provera…as a birth control drug, and instead, the doctor, due to his inexperience with the drug, prescribed Prontogest [progesterone]*" (P2)

Participants also described violations which contribute to medication errors. The most common violations mentioned were staff knowingly deviating from hospital standard operating procedures, raising the likelihood of an error:

"*…we skip corners, we cut corners, basically, and we try to facilitate the process more, and by doing that, errors happen*" (P13)

"[double-checking] should be done with every medication, but unfortunately, it is not" (P9)

Error-Provoking Conditions

Error-provoking conditions were the most frequently mentioned causes and contributory factors to medication errors, with multiple distinct themes emerging following the qualitative analysis.

Heavy Workload and Time Pressures

The most frequently described cause and contributory factor to medication errors among participants was the impact of high workload and time pressure experienced at both hospitals. Participants noted that the sheer volume of work increased the risk of errors occurring, as one participant explained:

"*If you have a lot of work, there is more risk of having an error*" (P4)

This phenomenon was particularly apparent among the junior grade participants working within Hospital 2, who were often required to work long hours and numerous night duties, which adversely affected their judgment and actions, increasing the likelihood of committing a mistake. One participant described how "*the other week I had four duties in a week…I didn't have time to rest, I was always working*" (P4), with another participant reinforcing how this workload affected his decision-making:

"*When you have a [professional] who's on two hours of sleep on his 30th hour of the duty and they're asked to prescribe something for a patient…it's not always easy*" (P3)

Staffing Levels

Multiple respondents also brought up the issue of low staffing levels, which exacerbate and give rise to the heavy workload and associated time pressures, contributing to staff committing error. A participant aptly described the effect of low staff levels:

"*If you are understaffed, if you're stressed, you're more likely to commit…an error*" (P8)

The issue of low staffing levels was a theme that was predominantly highlighted by nurses. Participants from both hospitals described instances in whereby staff had to juggle the clinical needs of multiple patients simultaneously, negatively affecting their performance and safe clinical practice:

"*Honestly, we have too many patients...you have five or six patients a day that you have to deal with. And you might have more because you're in lack of staff*" (P9)

"*He was the only nurse on his own trying to deal with three different cases. That is what I believe contributed to the mistake*" (P6)

Fatigue and Emotional Strain

Many participants identified fatigue, tiredness and emotional strain as factors that increased the likelihood of committing a mediation error. They described various

moments when errors were more likely to occur. The night shift was identified as one such high-risk period, with one participant stating that "*the human body, at night, suffers because of the lack of sleep*" (P7), illustrating how reduced rest can impair focus and cognitive ability. Another participant noted that errors were more likely to occur "*between 11 am and 1 pm. And then…between 5 pm and midnight*" (P6), citing increased patient presentations to the Casualty Department and increasing fatigue, particularly during the latter period. A participant also believed that errors tended to happen "*towards the end of the shift*" (P1), attributing this to accumulated fatigue and the mental preparation to go home, which can lead to staff becoming more lax or rushing to finish their pending tasks.

Beyond physical fatigue, several participants also highlighted how emotional exhaustion and burnout, stemming from high workload, time pressure and insufficient staff, were other contributory factors to medication errors:

"*With the burnout, with the fatigue, these are all factors that contribute to medication errors*" (P7)

"*If you burn out, you're going to make mistakes*" (P6)

Also, within this theme, participants emphasised that a professional's working life cannot be separated from their private life. Participants from both hospitals gave multiple examples of how personal challenges or difficulties outside of work could lead to increased stress, reduced concentration or altered mood, thereby increasing the likelihood of committing a medication error. Similarly, sometimes healthcare

professionals attend work while sick or become unwell during their shift, which may also impair their abilities and make them more prone to committing an error:

"*If you have issues at home, you can easily make mistakes*" (P6)

"*a mistake…could have happened to anyone. Maybe you were having a bad day, or you weren't feeling very well, and you weren't thinking as clearly*" (P2)

"*If a person is going through a bad patch, for example, it affects their performance, definitely*" (P7)

Lookalike and Soundalike Medications

Lookalike and soundalike medications were one of the most frequently raised error-provoking conditions.

Participants at both hospitals described how similar packaging or names of medications led to near misses or actual errors. One participant referred to an incident involving potassium replacement, and as "*the vial was similar to another drug that she wanted to give*" (P7), a medication error occurred. Similarly, another participant recounted almost administering chlorhexidine instead of sterile water because "*they were the same bottle, the same label*" (P9), with only the product name differing. An interviewee also referred to when a wrong antibiotic was administered, stating that "*it came down to the packaging being very similar*" (P8).

To mitigate this risk, in Hospital 1, the hospital pharmacy "*marks soundalike, lookalike drugs with stickers to sort of grab your attention more…so they are more in-your-face*" (P8). Another mitigation measure that was carried out within this hospital

was that the staff "*asked the nursing manager to rearrange [the medications] in the treatment room, so any packaging that is the same is not next to each other to avoid this mistake [from happening] again*" (P8).

Distractions and Environmental Factors

While less regularly noted as a contributory factor to medication errors by the study participants, several participants identified the working environment, particularly distractions and workplace features, as another factor that may contribute to errors.

One interviewee noted how the environment itself predisposed to committing an error, as the environment is often chaotic and noisy, making it difficult to maintain focus on critical tasks such as medication preparation and administration, with there being "*a lot of equipment, a lot of pumps, beeping…these are all distractions*" (P7). This is particularly challenging in chaotic, busy and already stressful environments such as the Intensive Care Unit, where high-risk medications such as adrenaline and opioid infusions need to be reconstituted and administered by the same professional, which may increase the likelihood of errors:

"*I do have to reconstitute a lot of medications…I think that is a drawback. Because in a stressful environment, such as in ITU, such medication…should be reconstituted in another environment, such as pharmacy, and ITU should receive them ready reconstituted, ready to administer to the patients*" (P7)

Interruptions from patients and visitors were also mentioned as a possible source of distraction during medication preparation. One participant shared that:

"*Our patients are so demanding. They ask too many questions. They don't let you work…I am measuring the dose of Augmentin for a paediatric [patient]…you can easily mistake the dose because they are stopping you all the time*" (P6)

Another environmental factor that was described as potentially contributing to medication errors was the reduced lighting present in the hospital during night shifts. One participant working in ITU explained how the lights are normally dimmed to promote patient rest; however, this sometimes posed challenges to the staff, firstly, due to having the same, unintended effect on staff, and secondly, the reduced visibility makes it more difficult to prepare and verify medication accurately:

"*At night, the environment changes a bit...there is reduced lighting...the patients at ITU are very, very sleep-deprived, especially those patients who are conscious...we try...to create more of a sleeping environment...if you have to give an antibiotic or treatment at 4 o'clock in the morning, what do you do?*" (P7)

Transcribing Issues

Another frequently described theme was issues related to transcribing, particularly the continued reliance on handwritten documentation. While one hospital had adopted electronic prescribing within some departments and clinics, both hospitals have continued to use paper-based treatment charts for their inpatients.

Consequently, issues regarding illegible handwriting were frequently raised, and a participant expressed that he came across handwriting issues "*all the time*" (P3). The use of electronic prescribing has been viewed as a valuable asset in reducing medication errors:

"*We have electronic prescribing for the emergency department, which is great, and which helps to reduce incorrect dispensing as a result of not clearly identifying the doctor's handwriting*" (P2)

"*The automatic systems that we have…totally eliminates the handwriting issues*" (P1)

The healthcare professionals who do not have access to such systems, namely those within Hospital 2, believed that these systems would be beneficial in eliminating transcribing issues, stating that "*having an online treatment chart…removes the issue of illegible handwriting…it would be out of the picture*" (P3). Another participant felt that such software "*should be introduced and it would help because it's definitely legible*" (P9).

Other contributory factors included the use of trade names instead of generic names, which is particularly problematic in the current local healthcare settings, consisting of healthcare professionals from across the globe who may be unfamiliar with the brands used in Malta:

"*in the multinational, multicultural environment the doctors or the nurses might not be used to the brand names which are used in Malta, and they might associate that with something similar…in their countries, totally different in medication, but similar name…that can be avoided by using the actual medical name because that's worldwide, Ciprofloxacin is Ciprofloxacin*" (P1)

Other practices that may contribute to errors highlighted by participants included the incorrect use of decimal points, abbreviations, and unclear symbols, as illustrated by one participant:

"*Even the way that they prescribe, decimal points, digoxin .25, not 0.25. Also…not writing the full word, just writing the symbol - that is increasing the risk of errors as well*" (P2)

Communication Issues

Communication issues were identified by a few participants as contributing to medication errors. One specific factor was the use of verbal medication orders, especially in emergency situations. While often viewed as necessary in time-critical situations, verbal instructions can easily be misunderstood, or the dose or type of medication administered may be forgotten. One participant described that "*there were rare instances, but there were instances…slight miscommunication*" [where a doctor gave a verbal instruction, and the dose was misunderstood] (P5). Another communication issue arose in post-operative prescribing, where some doctors failed to document medications on the treatment chart, assuming nurses were familiar with post-operative instructions. One participant noted that "*Sometimes there are issues between nurses and the doctors…they don't prescribe some medications on the treatment chart and assume the nurse knows and administers it*" (P10), potentially leading to medication not being given, especially if the nurse is new or unfamiliar with the routine processes in that department.

Another participant also highlighted the effect that informal messaging platforms such as WhatsApp may have when communicating medication-related instructions. Although seemingly convenient, these methods may lead to misunderstandings or patient misidentification, ultimately making "*us more vulnerable to mistakes*" (P11) according to one participant.

Latent Failures

Participants identified various latent factors which cause and contribute to medication errors. Some of the error-provoking conditions described in the previous section may also be borne out of specific management decisions that are taken, such as issues pertaining to low staffing and heavy workload.

Staff Allocation

One of the most commonly cited latent failures that participants believed contributed to medication errors was management decisions regarding staff allocation. The effect of high staff turnover was described by participants from both hospitals, whereby experienced staff often left after a few years, leading to the loss of institutional knowledge and skills, and then being replaced by less experienced recruits:

"*People, after five years, maybe ten, a maximum of ten years, they start to see that maybe it's time…to leave*" (P5)

"*Some doctors, they come to work with us, then after two, three years they go to another job or training post, so then we have to replace them… we have a kind of relatively young, new staff*" (P1)

Another issue raised regarding staff resource allocation was the practice of replacing absent or specialist staff with non-specialised personnel in Hospital 2. This was seen with respect to nursing care in areas such as paediatrics, which, due to not having the specific knowledge related to the patient cohort, may more likely lead to a medication error:

"*They tend to replace them by someone …not specialised in the area…when someone works most of the time with adults, they tend to…have the line of thought of administering treatment to an adult. Whereas in paediatrics, it's different*" (P13)

One healthcare professional highlighted that they are often required to perform additional tasks that may fall outside their core professional responsibilities, due to gaps in staffing, thus leading to an increased workload and increasing the likelihood of medication errors occurring:

"…we have to do additional tasks, like bloodletting, doing ECGs ourselves, booking appointments as we don't have a clerk after office hours" (P10)

Participants from both hospital settings described the absence of clinical pharmacists on wards or other acute patient care areas as a missed opportunity that

could otherwise help to identify and prevent medication errors from occurring. Participants from one hospital described that "*on the wards there aren't pharmacists*" (P2), while at the other hospital, due to a lack of human resources (HR), the clinical pharmacist service is very limited and confined mainly to the Intensive Treatment Unit (ITU) and the Neonatal Paediatric Intensive Care Unit (NPICU).

"*During the day, there will be someone who comes around once a day or twice a day to check the treatment charts of the patients and who comes on the ward round*" (P7)

One participant contrasted this service with their experience in a UK NHS hospital, where clinical pharmacists were widespread throughout the hospital and highlighted the benefits of this service:

"*I remember when I was in a specific hospital [in the UK], there used to be clinical pharmacists during office hours, and they checked all the inpatient drug charts…and the number of mistakes they used to find was impressive…I think we are a bit weak on the clinical pharmacy aspects…it's very limited*" (P11)

Many participants believed that the implementation of hospital-wide clinical pharmacy services would help reduce a number of medication errors. Owing to their specific expertise, these clinical pharmacists can "*check the treatment chart and…correct when necessary*" (P9), thereby preventing errors before they reach the patient.

A participant felt that the management decision for resource allocation with respect to break allocations also had a negative effect on keeping staff well rested and cognitively alert, with staff only given a 1-hour break in a 12-hour shift:

"*So, you can imagine starting the shift at 7 am, then you take the break at around 2 pm, then another 4-5 hours [working] after that, so that 1 hour break is gone, the effect of it*" (P1)

Lack of Supervision

Another of the latent factors that was described by participants was the lack of supervision provided to junior staff. Two junior healthcare professionals explained how, despite being responsible for documenting any changes to a patient's treatment chart, they were not given adequate supervision in this task:

"*Supervision, again, sometimes consultants or seniors just say, I'll give him this and leave and you're like, okay, but I don't know what the dose is, I don't know what the frequency is*" (P3)

"*…especially in junior staff, when there is so much work here, the supervisors don't have enough time to actively supervise*" (P12)

Inadequate Training

Deficiencies in training were noted by many participants and were considered a latent factor contributing to medication errors. Participants described how inadequate

training with respect to medication safety was an issue since their undergraduate education. One junior participant reflected on how unprepared he felt in prescribing knowledge upon starting clinical work:

"*We're only given the PSA [Prescribing Safety Assessment] ... But again, it's not enough exposure, I feel, and when we're doing our training as students, we're not really involved in how to prescribe medication even though it's one of the core procedures*" (P3)

The same participant also expressed concern about the limited training offered in the workplace:

"*We had a lecture once about safe prescribing…the lectures are held during, in inverted commas, 'protected time' which is not always given priority*" (P3)

However, not all participants shared this view. One participant felt that for them, training was adequately supported through hands-on experience and other optional courses offered:

"*To be fair, you learn the most as you go along. You ask the experienced professionals to guide you, and by practice, you get there. But there are some courses, yes... they do courses periodically, and there is the option*" (P7)

Hospital Culture

The effect of the hospital's culture was another latent factor that was described as potentially contributing to medication errors. Participants from one hospital described a blame culture, where participants described the potential negative repercussions, such as punishment or adverse effects on career progression. This environment discouraged error reporting and hindered organisational learning. In contrast, staff from the other hospital consistently described a no-blame culture, wherein staff were encouraged to openly discuss and report mistakes and near misses, with the overarching aim of system improvement. This theme is further explored in the upcoming *section 4.4.3, which* focuses on the barriers and facilitators towards medication error reporting.

Organisational Factors – Protocols and Policies

Some participants noted that organisational factors related to medication protocols or policies also contributed to medication errors. Participants from Hospital 2 felt that the hospital protocols in place were not updated regularly to match the drug products being procured and were not kept up to date with the latest international guidelines:

"We have this chart, which has been in place from 2016, supposed to be updated every two years. It was updated back in 2017, it was in 2019...from that time onwards, it was never updated" (P13)

On the other hand, Hospital 1 had a dedicated team to ensure regular policy review and staff dissemination:

"*we're going through the policies…word by word…so they know what the content is, and they go back to their staff…ask them to read the policies, [and] make sure they know [them]"* (P8)

Another participant felt that in Hospital 2 there was difficulty in accessing certain resources, such as the British National Formulary (BNF), which may increase the risk for a healthcare professional to commit an error:

"*The BNF is so inaccessible. It used to be at the tip of our fingers... I don't know why it's so laborious [to access]*" (P11)

Procurement of Medications and Equipment

Management decisions over drug procurement were a latent factor that was raised as a contributory factor to medication errors by the two senior healthcare professionals who were interviewed. These participants described how the cheaper products that were being procured often had foreign (non-English) labels and information sheets, increasing the likelihood of an error, particularly in acute, time-critical situations:

"[The hospital] gets medicines from the cheapest countries…they bring…from Greece, from Turkey…and it is in the language of Turkey or Greece, which we don't understand. Supposedly...they should insert a leaflet in English...But this is not always done" (P13)

"I don't know if it's a question of standards...but there are drugs...which are in Italian...it can be Greek...or it can be Japanese...I don't think there are standards" (P5)

In addition to medication procurement issues, problems with the procurement of equipment and its maintenance were other contributing factors to medication errors. Participants from one hospital described various scenarios in which faulty or substandard equipment contributed to medication errors or near misses:

"*We have loads of problems with equipment… we had one type of equipment, which was not adhering to the time. So, a drug was given, instead of over 24 hours, it was given over 20 hours*" (P13)

"*I increased the dose of the propofol, and the patient was waking up...we found out that the three-way tap that you have to attach the line to the central line was leaking…So that would have had repercussions on the patient*" (P7)

Aside from procurement issues, one participant described latent issues related to the drug packaging itself, which may also contribute to causing a medication error:

"*Everyone knows that labelling is a contributing factor…to this day and age, for some unknown reason…the dose is written very small in the packaging. The labelling…I feel that we still haven't found a way how to make it clearly and easily readable to cater for these stressful environments*" (P7)

Patient Medication and Health Literacy

One participant highlighted how patients' attitudes and level of knowledge may also contribute to medication errors. This relates to broader cultural and systemic issues surrounding health literacy, where some patients may be unwilling or unable to provide their full medication list or medical history to healthcare professionals, thus increasing the likelihood of an error occurring:

"*Sometimes it's hard for them [patients] to understand why…they see our questions as being very intrusive and very personal…If the patient doesn't provide you with the information or doesn't have all of their medical records with them, then there's only so much that you can know… That basic understanding that it isn't there. Patients…don't take an active role in their health…I think this…something that needs to be enforced on a, suppose, on a national scale*" (P2)

The perceived low patient health literacy was further illustrated by instances where patients denied having underlying medical conditions despite taking treatment for them: "*I mean, it's not the first time [a patient says] I'm perfectly healthy, I'm fine. But I take this for blood pressures, I take this for diabetes"* (P2)

Summary of the Causes and Contributory Factors Mapped According to Reason's Accident-Causation Model

The main themes on the causes and contributory factors to medication errors, as identified by healthcare professionals from both hospitals, are summarised in *Table 12.*

Table 12 - Summary of the Main Causes and Contributory Factors

Reason's Domain	Theme
Active Failures	Slip (selecting the wrong medication)
	Lapse (omitting a required medication
	Mistake (incorrect drug or dose calculation)
	Violation (ignoring protocols or skipping steps)
Error Provoking Conditions	Workload & Time Pressures
	Staffing Shortages
	Fatigue, Burnout & Emotional Strain
	Look-alike & Sound-alike Medications
	Distractions & Interruptions
	Working Environment
	Transcribing & Documentation Issues
	Communication Breakdowns
Latent Failures	Staff Allocation
	High Staff Turnover
	Lack of Supervision
	Inadequate Training
	Hospital Culture
	Issues with Protocols & Policies
	Procurement of Medication & Equipment
	Low Patient Health Literacy

4.4.3 Facilitators and Barriers to Medication Error Reporting

Using the same set of interview transcripts used for the first part of the qualitative analysis, this section focuses on and presents the factors that participants feel facilitate or hinder medication error reporting, mapped to the 14 domains of the Theoretical Domains Framework (TDF).

Domain 1 – Knowledge and Domain 2 - Skills

Since themes within the domains of knowledge and skills often overlapped and

occurred together in participants' accounts, the findings from these domains are presented jointly hereunder.

A key barrier under the knowledge domain was participants' limited awareness of the existence of a formal reporting system. This was best illustrated by a junior participant who admitted *"I don't know that there was a system*" (P3), while another was aware of the presence of a reporting system but was "*unsure how to complete the form and to who to send it to due to a lack of education*" (P12), thus also falling under the domain of skills. Contributing to this lack of awareness was the observation that staff were not sufficiently trained or informed about the system or its use. One healthcare professional claimed that knowledge of the reporting process is many times acquired informally, such as from peers when an incident occurs, rather than from management. The lack of formal training was also noted by another participant in Hospital 2, who emphasised the need for targeted intervention on these matters:

"…we need to train people on how to actually…report those incidents" (P13)

"*I think [this information] should be taught in the induction period*" (P4)

Clear guidance and systematic training were conversely described as important facilitators to medication error reporting. Several interviewees from Hospital 1 reported how new employees are given specific training during induction, including how to access the reporting system:

"*One of the main things we show them physically is where to find the incident reporting portal. I get a new employee and say, [do] you know how to report an incident? No, obviously, he doesn't know. So, I say, look, on the computer…incident reporting [icon]"* (P1)

"*On induction, yes, they have training on everything – systems and the policies*" (P8)

In addition to training during induction, staff are provided with "*constant reminders, constant updates*" (P8), with pertinent findings from reported incidents disseminated amongst staff, helping them to keep abreast of any changes or recommendations, and maintaining their awareness of the reporting system and its function.

Besides the lack of procedural knowledge on how to report, there was a lack of knowledge around what constitutes a medication error and what should be reported. One participant felt that some professionals have a "*poor understanding of medication errors, and what constitutes a medication error*" (P2), which could prevent them from actually reporting. Another healthcare professional stated, *"I don't have the competence to know all this"* (P11), reinforcing the lacuna in training and education. To address this, one participant felt that there needed to be structured "*lectures [on] how to report, what can be reported*" (P5).

Domain 3 - Social/Professional Role and Identity

Many participants believed that, as individuals who safeguard patients' welfare, healthcare professionals have a professional duty and moral responsibility to report medication errors, with this being an integral part of their professional role. One interviewee explained that "*as a professional, you should feel accountable enough to report*" (P7), while another added "*I think it's very important for the same reason that we have to report due to the patient's safety and our safety*" (P9). This notion of

professional responsibility was also reinforced by the belief that failing to report an error would constitute a moral and professional failure to fulfil one's duty, with one participant expressing:

"*I wouldn't sleep well if something happened and I didn't say anything, and it may have affected the patient*" (P10)

However, one participant expressed concern that the increased administrative burden of completing error reports would conflict with their clinical role by reducing their time spent as a caregiver at the bedside and hindering their ability to perform other clinical duties:

"*If we are burdened with more reporting, the problem…is we have too much admin and we're not on the ground with the patients*" (P11)

Domain 4 – Beliefs about Capabilities

Following the qualitative analysis, no barriers or facilitators specifically relating to this domain were identified from the interviews.

Domain 5 – Optimism

No distinct barriers or facilitators were explicitly identified in relation to this domain.

Domain 6 – Beliefs about Consequences

Participants described how the perceived consequences of medication error

reporting reduced the likelihood of engaging in the process. The dominant barrier within this domain was the belief that reporting an error could lead to negative professional repercussions, including the risk of formal disciplinary action, damage to their reputation and the effects it may have on career progression. One healthcare professional summarised this sentiment by saying:

"*This will affect their career, it will affect their promotions…If no one saw me, the easier way out is not to report*" (P7)

Facilitators under this domain included themes such as the belief that medication error reporting could lead to improving patient safety, individual professional practice, and wider hospital systems in place. These themes are closely aligned and overlap with Domain 3 – Social/Professional Role and Identity, and Domain 8 – Intentions, where they are explored further.

Domain 7 – Reinforcement

The main barrier identified under this domain by several participants was the lack of follow-up after submitting a medication error report. One participant noted that "*there is no closing of the loop*" (P7), referring to instances when an individual actually submitted a report but then received no feedback or saw no changes implemented. This results in discouragement and reduces the likelihood of future reporting:

"*…if there's a lack of feedback, so I'm sending my reports, and I never get an acknowledgement for it*" (P2)

"*Obviously, if you don't have enough feedback, I think you're a bit discouraged to report it*" (P4)

Another participant noted that while the reports are taken seriously and initially acted upon, the changes are not always sustained and that "*after a few months, the same problem happens again*" (P11).

A key facilitator identified from the interviews was being provided with prompt and constructive feedback, which reassures individuals that their reports are being taken seriously and acted upon. Providing follow-up may validate the reporter's effort and reinforce positive reporting behaviours. One interviewee explained how:

"*The people involved will get feedback for that error*" and "*some form of acknowledgement and follow up that, yes, we're going to take this up and this wasn't something silly that you did… to validate that would definitely help*" (P8).

Domain 8 – Intentions

Within this domain, several themes were identified that both positively and negatively influenced participants' reporting behaviours. Most of the participants expressed strong intentions to report, with motivations primarily linked to safeguarding patient safety, overlapping with Domain 3. When discussing their motivation to report, one participant stated that "*patient safety is the primary thing, of course*" (P2). Borne out of the various potential consequences, environmental, cultural and social influences experienced within their work environment, a minority of participants, however, described an overall lax or lack of intention to report, representing a significant barrier that needs to be overcome:

"*…you totally ignore it because you just are not bothered*" (P9)

"*I'd rather not get involved in that, if I can… I'll only report if it's obligatory*" (P11)

All interviewed participants felt that all medication errors should be reported, regardless of whether the error reached the patient and caused harm or not, and participants also felt that near-miss reporting was just as important:

"*Not necessarily if there is harm to the patient, because any medication error could have potentially caused harm*" (P3)

"*…the goal is to learn from mistakes, to prevent it from happening again. It's a near miss, but another time it can be an inpatient death*" (P5)

"*…near misses, 100%, I believe, should be reported as well*" (P2)

One participant drew a comparison with the aviation industry, noting that "*all the aircraft accidents led to some new recommendations…so I believe every incident should be reported*" (P1). This analogy underscores the belief that improving medication safety similarly depends on learning from all incidents, including near misses.

Despite overall consensus among study participants that every error should be reported, what happens on the clinical shopfloor is different, wherein errors which do not lead to harm to the patient or are near misses tend to go unreported:

"*…some nurses or doctors have done mistakes, and they keep them for themselves…because they are not that serious*" (P6)

"*Believe me, there are loads of near misses. But near misses…they are near misses, so they are just put underneath the carpet…and no one knows about them…probably 90% of the time of the medication errors that happen in hospital, we're not informed*" (P13)

Domain 9 – Goals

Under the domain of Goals, two key facilitators of medication error reporting emerged, although there is also a degree of overlap with the previous domain (Intentions).

One of the facilitators was that several study participants described how error reporting was an opportunity for professional development. One participant explained that it helps to "*improve your own knowledge or practices*" (P9), while another added that through reporting "*they teach us, so it will not happen again. That is…the benefits of medication error reporting*" (P6).

The participants who had teaching or administrative roles highlighted the benefits of medication error reporting to improve hospital systems and organisational improvement:

"*You have to report. You have to document in order to know where you are, in order to measure and in order to improve. Because by reporting you will be getting a picture of what is happening*" (P7)

"*It's a lesson, a learning lesson for not only the person who did the medication error, but for everyone in general, because…maybe we find gaps in our processes, in our guidelines, in our policies. So, we can improve on those*" (P8)

Domain 10 - Memory, Attention, and Decision Processes

No distinct barriers nor facilitators were identified from this domain following

the qualitative analysis.

Domain 11 - Environmental Context and Resources

Several healthcare professionals highlighted the environmental and resource-related factors that may influence medication error reporting. The most prominent issue cited among participants was the time-consuming nature of the reporting process and the perceived effort to report an error, particularly within the context of high clinical workloads and staff shortages, as illustrated in *section 4.4.2* on the contributory factors to medication errors. One participant demonstrated the reasoning why some professionals do not report due to time constraints:

"*They could find it time-consuming… I'm so busy. I hardly have time to have my own break. I'm going to stay wasting time typing a report?*" (P2)

However, not all participants agreed that time was the main reason for not reporting. One interviewee, while acknowledging that reporting takes time, believed that other factors play a more prominent role:

"*But at the end of the day, I think that time is not the actual issue*" (P13)

Another routinely discussed barrier was related to the design, nature and accessibility of the reporting systems. Participants working at one hospital described the paper-based reporting form as overly lengthy and at times vague, with one participant comparing it to writing an "*essay*" (P7). Participants within this hospital felt that to facilitate reporting, there should be a transition to electronic reporting systems, with the option of choosing to remain anonymous:

"*We are not using technology here, we are using papers… if we make better use of*

technology… if there is a reporting system which is easily accessible on a computer or on [a tablet], and you remain anonymous, I think the uptake will be better" (P7)

"*I think that from a time constraint point of view, it would be better to report. I think that everything that comes to my mind should be anonymous*" (P4)

In the other hospital, there is an electronic reporting system in place, which has been described by one participant as "*very straightforward, user-friendly, very easy to use*" (P6), demonstrating that if the system is simple to use and easily accessible, it could increase the likelihood of reporting.

Domain 12 – Social Influences

Social influences emerged as a significant factor affecting medication error reporting both positively and negatively. One prominent barrier was the fear of social repercussions and stigmatisation at the workplace. A healthcare professional working within one of the hospitals reflected on the social label peers may place on him from reporting, such as "*being known as the person who reports*" (P3). The effect of stigma was suspected of being particularly impactful on new recruits, with a participant stating that "*a relatively new employee…is really trying to fit in, to understand the system…might feel a little bit intimidated to just go ahead and make a report*" (P2).

Another key influence was the prevailing hospital culture, which was seen to differ markedly between the two institutions. In Hospital 2, multiple participants cited the culture within the hospital as a barrier to reporting. One participant bluntly stated that "*it's very much a blame culture in [name of hospital]*" (P3), while another

participant echoed his sentiments by claiming that "*we always say that it's not finger-pointing. It's always sort of like we are trying to improve the system. And sometimes it's like that. However, when it comes to the actual thing...I don't know, we always tend to point fingers*" (P13). Interviewees from different professional groups within Hospital 1 acknowledged that a blame culture may lead to under-reporting, whereas the presence of a no-blame culture was seen as facilitating error reporting. They felt that the environment in their settings was more conducive to reporting for this reason:

"*Obviously, when there's a blame culture, the incidents may not be reported. But thankfully, I'm talking about this hospital now, we have no blame culture in incident reporting*" (P1)

"*With regards to the culture, I mean, if you have a no-blame culture, people are obviously going to be more willing to come forward with any mistakes that they make*" (P8)

"*I feel, yes, there's no blame culture… it's non-punitive*" (P2)

Another factor that was identified as both a barrier and a facilitator was the influence of senior staff and management on reporting practices. Supportive leadership and leading by example were seen as facilitators to error reporting, particularly when the leaders actively created a psychologically safe environment, with one participant feeling that "*it's really important for managers to lead by example, to emphasise the importance of this*" (P2). One of the more experienced healthcare professionals interviewed underlined the importance of leadership buy-in, including from hospital management, stating that "*it needs to be tackled from a top-down approach. And I say top-down approach because everyone needs to be involved*" (P13).

The need for a strong culture of safety driven from the top was echoed by another participant, who noted that admitting to errors early in one's career requires significant bravery: *"I think it has to be a little bit top down because as a junior, you need to be really courageous to say, 'I did my second case, and this has happened', you know?"* (P11).

Coupled with this top-down approach, the value of peer support and non-hierarchical team dynamics were also described by another participant as facilitating open communication and reporting:

"*We don't have that hierarchy. So junior doctors are not afraid to report or ask questions if they make mistakes*" (P1).

While peer support was seen as enabling reporting, the same participant cautioned against the presence of gossip within the clinical setting, emphasising the need to distinguish between reporting through the official channels and informal conversations between staff, with the latter seen as potentially harmful due to spreading negative information without initiating corrective action or the appropriate root cause analysis into the error.

The role of external bodies, such as trade unions, was also highlighted as an influence which may prevent medication error reporting. One participant noted their union's influence in discouraging medication error reporting, stating that "*when a union is involved, they try to safeguard whoever the person is, and they sort of like limit the person, or they tell them not to file an incident report*" (P13), thus contributing to

under-reporting.

Domain 13 – Emotions

Emotions were reported by more than half of the participants as significant influences on medication error reporting practices. The most frequently cited emotion was that of fear, which acted as a strong barrier to reporting. This included fear of being blamed, punished, or suffering negative repercussions, which closely aligned with the barriers identified under Domain 6 (Fear of Consequences). Participants across both hospitals identified fear as a barrier that discourages individuals from reporting:

"…because of fear, because of shame… these incidents tend to go unreported. Because people are scared" (P7)

"*People might be afraid that they will get in trouble if they report*" (P9)

"*The number two barrier, I think, is they are scared to report [the number one barrier was a lack of awareness of the reporting system]*" (P1)

One participant felt that the emotional barrier may be more pronounced in the younger healthcare professionals, who may lack the confidence to report errors and become overwhelmed by the situation:

"*I think the biggest barrier is that the young [healthcare professionals] would…be scared to report errors…I think the young ones would be terrified*" (P10)

Conversely, when individuals feel emotionally safe and well supported by their colleagues and managers, this helps to reduce any feelings of fear and, in turn,

encourages medication error reporting practices. One interviewee aptly described this psychological safety:

"*I'm rarely stressed out or in a state of panic that I am going to be chucked out or shouted at… So, I feel safe, I feel happy. I don't feel afraid reporting it*" (P6).

Other emotional barriers that participants mentioned included guilt and anxiety, which hindered error reporting. One participant reflected on how this guilt had ultimately led a healthcare professional to leave the profession entirely:

"*I think any nurse that I know would feel guilty if they made a medication error…there had been a medication error where a [healthcare professional] had quit eventually because of the guilt that he felt over what had happened*" (P8).

One participant commented that stress, burnout and emotional fatigue, often linked to workload pressures, resulted in staff becoming disengaged and simply "*not bothered*" (P9) to report medication errors.

Domain 14 – Behavioural Regulation

Following the qualitative analysis, no barriers or facilitators were identified under this theme.

Summary of the Barriers and Facilitators mapped according to the Theoretical Domains Framework

Table 13 provides a summary of the main barriers and facilitators to medication error reporting outlined by the participants. As described previously, there is a degree of overlap between the different domains, however in the below table, each theme is listed only once for ease of understanding.

Table 13 - Summary of the Main Barriers and Facilitators to Medication Error Reporting

TDF Domain	Theme	Facilitator	Barrier
Domain 1 - Knowledge Domain 2 - Skills	Lack of awareness of the reporting system		✓
	Training on medication error reporting	✓	✓
	Lack of knowledge on what a medication error is		✓
Domain 3 – Social/Professional Role & Identity	Professional Duty & Responsibility	✓	
	Safeguarding Patient Safety	✓	
	Role Conflict		✓
Domain 6 – Belief About Consequences	Negative professional repercussions		✓
Domain 7 - Reinforcement	Feedback on Error Reports	✓	✓
	Lack of Sustained Change		✓
Domain 8 - Intentions	Attitudes to Reporting	✓	✓
	Selective Reporting		✓
Domain 9 - Goals	Professional Learning & Improvement	✓	
	Organisational & System Improvement	✓	
Domain 11 - Environmental Context & Resources	Time Constraints & Workload		✓
	Nature of Reporting System	✓	✓
	Anonymity of Reporting	✓	
Domain 12 – Social Influences	Hospital Culture	✓	✓
	Peer & Management Support	✓	
	Gossiping & Labelling		✓
	External Influences (e.g. Unions)		✓
Domain 13 - Emotions	Fear		✓
	Other Negative Emotions (Guilt, Anxiety, Stress, Burnout)		✓

4.4.4 Discussions with Selected Key Stakeholders

This section outlines unstructured interviews which were held with selected key stakeholders involved in medication safety locally. Interviews were conducted with representatives from the patient safety and quality team from one hospital, and an official from the Malta Medicines Authority.

Representatives from the Hospital Patient Safety and Quality Set-Up

During the interviews with members of a hospital patient safety and quality set-up, it was highlighted that medication errors are among the least reported incidents within their hospital, with doctors in particular reporting "*close to nothing*". Nurses, on the other hand, tended to be more proactive in reporting, especially regarding missed doses, illegible prescriptions, wrong doses, and issues arising from look-alike products. Nonetheless, representatives from this team felt that the reports they received do not even represent the "tip of the iceberg" regarding actual incidents, with even fewer concerning near-misses.

According to an interviewee, some of the main reasons for this under-reporting included factors such as the culture of blame and bullying, preference to keep issues within teams, the general attitude that reporting errors is not important, and many more. To address this, the team increased outreach activities over the past few years; however, they feel that more needs to be done. Suggestions for improvement included: being involved during the induction sessions of recruits to raise awareness, providing formal training on how to use the system, which is currently absent, the development of patient safety champions within wards, and securing management support and

dedicated resources to prioritise patient safety and to embed it within the hospital culture.

Medicines Authority

An official from the Malta Medicines Authority was contacted and he/she responded to a series of questions. The official explained that, regarding medication errors, the Authority is only legally mandated to collect, process, and transmit reports of medication errors that result in an adverse reaction to the patient. In contrast, errors not associated with an adverse reaction are not legally required to be reported to them.

The current system in place allows reports to be submitted by any healthcare professional, consumer or marketing authorisation holder, either electronically or through physical means. For a report to be valid and processed, however, it must include an identifiable and contactable reporter, certain patient details, and specific details about the suspected drug and reaction.

The representative of the Medicines Authority acknowledged that underreporting is a major limitation of the current spontaneous reporting systems in place, and this is a common limitation with this type of reporting globally. The official referenced various outreach activities that were conducted by the Authority over recent years, including face-to-face and online sessions, as well as social media educational campaigns aimed at healthcare professionals and the public to increase awareness on medication error reporting.

4.5 Chapter Summary

This chapter presented the key findings emerging from the study's mixed-methods approach. The EudraVigilance analysis revealed the absence of medication error reports originating from Malta over the three years under study. This data showed that errors most commonly occurred at the prescribing and administration stages.

The qualitative interviews with study participants provided insights into the situation in Malta. The main contributory factors to medication errors were error-provoking conditions, such as heavy workload, time pressures and lookalike medications, as well as latent failures, including inadequate training and issues with staff allocation. The qualitative phase also highlighted key barriers to medication error reporting. These barriers included fear of negative professional consequences, the presence of a blame culture and a lack of awareness of reporting systems in place.

Chapter 5: Discussion

5.1 Introduction

Building on the previous chapter, which presented the findings of the study, the discussion presents an interpretation of the key results from both the quantitative and qualitative phases. This chapter is structured to systematically address the main study objectives, to integrate the quantitative and qualitative findings obtained and to assess how the study findings align with or differ from the existing literature on the topic. The comprehensive literature review presented in Chapter 2 fulfilled the study's first objective and provided the theoretical models and the necessary evidence, enabling the comparison of this study's findings with those in the established literature.

The chapter first discusses the findings in relation to Objective 2, which was to conduct a retrospective analysis of Individual Case Safety Reports (ICSRs) submitted to the EudraVigilance database over the latest available three-year period.

Thereafter, Objective 3 is addressed in the two subsequent sections, the first of which discusses healthcare professionals' perspectives on the main causes and contributory factors to medication errors using Reason's Accident Causation Model as the theoretical framework, and the second examines the major barriers and facilitators to medication error reporting through the use of the Theoretical Domains Framework (TDF).

In this chapter, the findings from the analysis of the EudraVigilance database and the qualitative interviews are contextualised together with the international literature to strengthen their overall analysis and interpretation. While the

EudraVigilance database did not include any ICSRs from Malta, the correlation of this data with the qualitative results from the interviews gives a structured framework for contextualising the lack of reporting in Malta and uncovering similar contributory factors to medication errors.

Within this chapter, a dedicated section also appraises the strengths, limitations and potential biases of the study, along with suggestions for future research on these topics. The conclusion of the chapter assesses whether the study's aim was achieved.

5.2 Objective 2: Analysis of the EudraVigilance Database

5.2.1 Absence of Individual Case Safety Reports originating from Malta

In addressing the study's second objective, the most striking finding emanating from the quantitative analysis of the EudraVigilance database was the complete lack of Individual Case Safety Reports (ICSRs) originating from Malta during the three-year study period (March 2022 – March 2025). Malta was one of five countries which did not have any ICSRs recorded in EudraVigilance during this period, alongside Luxembourg, Liechtenstein, Latvia and Estonia. While these countries have among the lowest population figures within the European Economic Area (EEA), which could naturally lead to fewer events, this finding is unlikely to indicate a complete absence of medication errors occurring locally, but instead suggests a substantial degree of underreporting in Malta. This is supported by the integration with the qualitative interview findings, where both frontline healthcare professionals and key stakeholders believed that errors do occur regularly locally. However, they explained that the

multiple barriers present prevent these errors from actually being reported, as discussed and interpreted in more detail in *section 5.3.2*.

While spontaneous reporting systems, like the EudraVigilance database, have been described in the literature as being inherently prone to underreporting (Henriksen et al., 2005), the complete absence of reports suggests wider, more deeply rooted issues, rather than simply a lack of engagement. The absence of ICSRs from Malta directly addresses the study's aim of exploring medication error reporting practices locally and highlights a potential gap between the occurrence of errors and their formal reporting. This has immediate and serious implications for the local healthcare system's ability to identify threats to medication safety, benchmark against international standards and implement evidence-based interventions that could prevent serious patient harm.

The lack of error reports from Malta within the EudraVigilance database for the period March 2022 to March 2025 contrasts with the findings of Tanti et al. (2013), who found 96 medication errors reported between 2006 and 2010 in Malta from a national pharmacovigilance database (Tanti et al., 2013). This suggests that the practice of medication error reporting has decreased over the subsequent 15 years, which may reflect a deterioration in formal error reporting or increased barriers to error disclosure.

5.2.2 Other Findings from Analysis of the EudraVigilance Database

In line with the study's second objective, the retrospective analysis of the EudraVigilance database provided insights into patient demographics, commonly

involved medication classes and the stages of the medication use process most associated with errors, offering a comprehensive mapping of the reporting. Despite the absence of error reports from Malta, the analysis of international EudraVigilance data revealed important, though not directly generalisable, findings that may still be useful in informing local medication safety initiatives and risk reduction strategies.

Medication errors predominantly occurred during the prescribing and administration stages, accounting for more than half of the reported cases sampled. This mirrors the findings of Despott et al. (2023), which had data from August 2012 to 2015, but contrast somewhat with the study by Tanti et al. (2013), spanning the period 2006 to 2010, which found that administration errors were the least often reported category in Malta at the time, comprising only 3% of reports.

With respect to medication classes, anti-infective agents (Anatomical Therapeutic Chemical (ATC) code J) and nervous system agents (ATC code N) were the most frequently identified classes in error reports from the EudraVigilance database. These findings are consistent with the findings in other studies, where vaccines (J07) also ranked as the most common ATC Level 2 class in error reports (Newbould et al., 2017; Pera et al., 2025). Eight of the other nine most frequently implicated ATC level 2 classes identified in this study (refer to *Table 9*) overlapped with those identified by Newbould et al. (2017), the only difference being the presence of anti-neoplastic medications compared to stomatological preparations, the latter identified in this study. These overlaps suggest that certain medication classes may have a higher likelihood of errors, either due to complex dosing regimens, narrow therapeutic windows, high usage rates, or the clinical context in which they are used.

Following the analysis of the EudraVigilance dataset, a median patient age of 53 years was identified, with ICSRs for females more common than for males. These findings align with those of Pera et al. (2025), in which the median age was 50 years, and female reports also outnumbered male reports. While female reports were more common, this study found no statistically significant association between gender and seriousness. Despott et al. (2023) also concluded that gender was not a predictor of error seriousness.

In contrast, a statistically significant association between patient age group and error severity was identified in this study. More serious outcomes were observed in patients in the 40 – 59 year age cohort, which aligns with Despott et al.'s (2023) findings of a statistically significant ($p < 0.01$) association between seriousness and age group for patients aged 41 – 60.

While differences in healthcare systems, medication usage patterns and reporting cultures mean these international patterns cannot be assumed to directly reflect the local situation, particularly considering the absence of local data in the EudraVigilance database. Such findings can nonetheless provide a valuable evidence base for informing local safety initiatives, targeting high-risk medication classes or stages where errors are most likely to occur.

5.3 Objective 3: Local Perspectives on the Causes and Contributory Factors of Medication Errors and the Barriers to Reporting

5.3.1 Causes and Contributory Factors to Medication Errors

The qualitative findings achieved the study's third objective, identifying healthcare professionals' perspectives on the causes and contributory factors to medication errors within Malta's acute hospital setting. As the majority of interview participants were doctors and nurses, the two professional groups predominantly carrying out prescribing and administration tasks respectively, the interview data provides a strong basis for contextualising the findings and identifying the main contributory factors at the most frequently reported error stages previously identified.

The study findings aligned consistently with the literature, suggesting that many hospitals and healthcare systems globally share common underlying vulnerabilities, such as high workload, time pressures, lack of medication-related knowledge and poor communication, among others (Aldhwaihi et al., 2016; Hansen, Bradley and Sahm, 2016; Puaar and Franklin, 2018; Alshahrani, Marriott and Cox, 2021; Bonella et al., 2023). Reason's Accident Causation model was used as the theoretical framework to categorise these findings, through which the study identified contributory factors within each of the 3 main domains outlined (active failures, error-provoking conditions, latent failures). According to Elliott, Page and Worrall-Carter (2012), this model is applicable for research into causes and contributory factors of adverse patient safety incidents, as it categorises the underlying causes of errors into various domains. This approach extends beyond the immediate failures of frontline staff to include the

underlying latent and error-provoking factors which result in the error (Elliott, Page and Worrall-Carter, 2012). The applicability of Reason's Accident Causation Model was supported through this study as it allowed for understanding and categorisation of the root causes that led to medication errors in the local setting.

Major Error Provoking Conditions

The convergence with the literature was particularly evident in the identification of various error-provoking conditions, where the themes of heavy workload, time pressures and staff shortages were the primary contributors across both hospitals. These findings are strongly in alignment with previous studies conducted both locally (Tanti et al., 2017; Schiavone, 2024) and in other healthcare systems globally (Abdel-Qader et al., 2020; Alharaibi et al., 2021; Bonella et al., 2023; Alanzi, Tully and Lewis, 2024), reinforcing the universal nature of these factors and suggesting that these issues extend beyond isolated local problems. Additionally, the identification of fatigue and emotional strain as contributing factors to medication errors, particularly during night shifts, corresponds to the findings by Westbrook et al. (2018), which showed that below-average sleep duration markedly increases the risk of errors. From this evidence, it is therefore unsurprising that participants overall believed that fatigue and tiredness increased the likelihood of committing a medication error due to lapses in concentration that naturally ensue. This suggests that current duty rostering practices may be an important latent factor that gives rise to error-provoking conditions. Specific to night duties, the literature suggests that measures such as shorter shift lengths, particularly during night shifts, could help in mitigating this (Mutair et al., 2021).

Erosion of Safety Practices Under System Pressures

Administration errors resulting from deviations from hospital protocols were one of the most common error types identified in the analysis of the EudraVigilance database. This finding also emerged from the qualitative interviews, where local participants acknowledged that at times, staff deviated from established hospital safety protocols, such as skipping steps or not double-checking medications, due to the pressures of the various error-provoking and latent factors. These pressures transformed protective barriers into perceived obstacles to completing clinical tasks. Similar descriptions appeared in the literature, whereby safety protocols, which were designed to prevent errors, instead became the casualties of the operational pressures they were meant to counteract (Al-Ahmadi et al., 2020; Alshahrani, Marriott and Cox, 2021; Bonella et al., 2023). The implementation of a Safety Management System (SMS) is one mitigation strategy identified in the literature to counteract this effect. The SMS would proactively and systematically identify and address latent factors and error provoking conditions, such as those identified in this study, which cause deviations from safety practices (Godec et al., no date; Zhelev et al., 2025). The implementation of a SMS requires leadership commitment, risk management and continuous monitoring to directly target the root causes that lead staff to deviate from safety protocols when under pressure, as well as instil safe practices across the organisation (Zhelev et al., 2025).

This deprioritisation of safety practices is also exemplified in participants' descriptions that protected time for lectures for junior doctors is compromised due to heavy workload and daily clinical pressures. This suggests a challenge to maintain balance between service delivery and professional development and continuing

education. In light of the backdrop provided by the EudraVigilance data, where prescribing errors, especially those due to wrong drug or dose were frequently recorded, this is concerning as it suggests that opportunities to mitigate the most prevalent type of errors are being compromised. A systematic review by Manias, Kusljic and Wu (2020) identified that targeted education, in particular pharmacist-led training for junior doctors, was effective at reducing prescribing errors. Similarly, Khalil, Kynoch and Hines (2020) found that multifaceted educational sessions with both students and healthcare professionals led to a statistically significant reduction in medication errors. This evidence, combined with the need for further training for local healthcare professionals that emerged from the qualitative findings, underscores the importance of implementing solutions which safeguard patient safety initiatives despite the considerable operational demands present.

Effect of Look-alike and Sound-alike Medications

The identification of look-alike and sound-alike medications as a common contributory factor identified from the qualitative interviews strongly resonates with published literature on the topic (Puaar and Franklin, 2018; Bonella et al., 2023; Sagawa et al., 2024). The interplay between the different domains in Reason's model becomes apparent here, whereby participants described slips in selecting the wrong medication due to the error-provoking effect of look-alike and sound-alike medications. The organisational response to these risks varies between different hospitals. While participants from Hospital 1 highlighted the beneficial effect of colour coding in reducing the risk of errors due to look-alike and sound-alike products, a systematic review by Larmene-Beld, Alting and Taxis (2018) found little evidence that this measure reduced the risk of look-alike errors in isolation. This suggests that while the use of

coloured stickers is a positive step, it may represent an incomplete mitigation strategy. The literature identified that other mitigation measures, such as the use of tall man lettering, have been shown to significantly reduce error rates by better capturing professionals' visual attention (Da Rocha et al., 2021; Lohmeyer et al., 2022). The combination of measures, such as tall man lettering with bold-text or colour coding, further improved recognition and reduced errors (Larmené-Beld, Alting and Taxis, 2018; Da Rocha et al., 2021).

Product Quality and Procurement Challenges

A notable issue identified by the respondents within the public sector stemmed from problems participants attributed to 'the procurement process'. When the responses were analysed, the issues were more specifically related to the quality of the medications and medical devices being purchased. While Alharaibi et al. (2021) described procurement-related issues as pertaining to medication shortages and staff needing to be aware of various brands or alternative drugs with the same clinical effect, locally, the main concern was more on the quality of the products themselves. Participants identified the increasing trend in foreign labelled medications without accompanying English documentation as a notable contributory factor to medication errors. Aside from the immediate implication of increasing the likelihood of medication error, these approaches to procurement may inadvertently create hidden costs through increased errors, time and effort for clinical resolution of errors and system inefficiency, which further exacerbate the impact of the errors, as previously described.

The implementation of a SMS is one strategy that could be used to address the identified issues with product quality and foreign labelling. The SMS seeks to identify

risks that could cause harm, followed by corrective actions to mitigate against them (Zhelev et al., 2025). In the context of the study's findings, this structure could identify low-quality products or those with non-English labelling and rectify the issue at source or once present in the clinical area.

The Shift to Electronic Prescribing Systems

Participants highlighted the effect that illegible prescriptions and other transcribing issues have on increasing the likelihood of medication errors. These findings were also central contributory factors identified within the other studies conducted in Malta (Tanti et al., 2017; Schiavone, 2024).

The partial shift to electronic prescribing systems in one of the hospitals where the interviews were conducted was seen by staff as a positive step forward in improving medication safety. This view is supported by systematic reviews and meta-analysis which show that electronic prescribing systems can significantly reduce medication error rates, with one study reporting an 85% decrease in prescribing errors (Prgomet et al., 2017) and another a relative risk of 0.24 for overall medication errors (Roumeliotis et al., 2019). However, the authors of these reviews caution that the quality of the underlying evidence is low. Additionally, this potential improvement is contrasted by other studies, which identify the emergence of new, system-related slips and highlight how rigid, non-user-friendly interfaces may be significant barriers to their uptake (Abdel-Qader et al., 2020; Alshahrani, Marriott and Cox, 2021; Bonella et al., 2023; Mahomedradja et al., 2025). The most frequently associated active failure following the introduction of electronic prescribing highlighted from the literature was inadvertently selecting the incorrect medication from the dropdown menu (Abdel-

Qader et al., 2020; Alshahrani, Marriott and Cox, 2021; Anzan et al., 2021; Bonella et al., 2023). The EudraVigilance analysis also identified new error types introduced by electronic systems, such as the failure to hide previously discontinued prescriptions, which created the risk of a medication being administered twice or when no longer indicated. These integrated findings illustrate that while electronic systems can reduce errors due to illegible handwriting, they may in turn, introduce new types of medication errors that may still result in patient harm.

In view of the potential benefits of these electronic tools, the transition toward digitalisation of prescribing practices should be considered by local healthcare institutions; however, their implementation requires careful consideration of risk minimisation measures and stakeholder engagement.

The Challenges of Non-Standardised Practices in a Multinational Health Workforce

Another aspect that was identified from the qualitative interviews was the effect of non-standardised prescribing or transcribing patterns, namely the use of brand names over generic names and the use of abbreviations for routes of administration and for frequencies of administration. Participants noted that these practices are especially challenging in view of the increasingly multinational healthcare staff working within local hospitals, highlighting the growing importance of addressing this situation. Issues regarding unclear or incorrect documentation have been established in the literature as heightening the risk of medication errors (Ratnapala et al., 2022; Ntani and Sangha, 2024). Al-Ahmadi et al. (2020) describe similar challenges faced within their study setting, given that foreign doctors make up a significant

proportion of their workforce. To mitigate against these risks, measures such as education on standardised prescribing behaviours and locally available medications, as well as the use of electronic prescribing systems that flag unavailable medications, brand names and inconsistent units or frequencies, were proposed to prevent these errors (Al-Ahmadi et al., 2020).

Staffing Levels, Recruitment and Allocation

Of the most prominent latent factors contributing to medication errors identified in this study were staffing levels and staff allocation decisions made by management. One direct consequence of such issues is reflected in the findings from the EudraVigilance analysis, which identified that errors due to administering drugs at the wrong time were common. Local participants' responses contextualised this finding, revealing that due to staffing issues, nurses often had to care for many patients simultaneously, and at times also carry out tasks outside their usual remit, potentially resulting in delays to medication administration.

Previous research has shown that high staff turnover and inadequate cover place excessive pressure on junior staff on duty (Alshahrani, Marriott and Cox, 2021; Bonella et al., 2023). This mirrors the views of study participants, who identified the loss of institutional knowledge and the replacement of specialist staff with personnel not routinely working in that area. O'Connor and Dugan (2017) describe how 'floating' or temporary staff working in unfamiliar wards or departments may not have the necessary skills to cater for the needs of the patients in that area, ultimately compromising patient safety. This directly links to this study's findings, where a

mismatch in clinical expertise was highlighted as increasing the risk of patient safety incidents, especially in departments like paediatrics.

Participants from both hospitals also highlighted the lack of clinical pharmacists, whose role would include the early identification and correction of potential medication errors. The literature provides evidence for clinical pharmacists' ability to markedly reduce medication errors, such as through medication reconciliation interventions (Batool et al., 2025). These interventions have been shown to be effective in addressing prescribing errors, including issues related to the choice of medication, identifying any interactions or contraindications, as well as errors involving the wrong route, frequency or dose (Mekonnen, McLachlan and Brien, 2016; Cheema et al., 2018). The implementation of such initiatives would be particularly beneficial, given that prescribing errors were the most common error type identified in the EudraVigilance data. Integrating this quantitative finding with the gap observed by local healthcare professionals supports the need to consider local recruitment into this role to enhance medication safety and consequently improve patient outcomes.

Divergence from the Literature

While themes from the domains of active failures, error-provoking conditions and latent failures emerged from the qualitative responses, there were some themes which did not feature in the replies from the interviews but were noted in the literature. The literature highlighted to patient-related factors, such as a patient's clinical state, especially if this was associated with a complex, rapidly evolving clinical picture, and the number of medications on the patient's treatment chart (Conn et al., 2017; Puaar and Frankin, 2018; Bonella et al., 2023; Alanzi, Tully and Lewis, 2024). The

local literature also identified healthcare professionals' unfamiliarity with patients, particularly in the context of night duties as a risk factor (Tanti et al., 2017). During the interviews, none of the participants directly attributed medication errors to a patient's clinical scenario. This could be due to the framing of the questions asked during the interviews, due to selection bias in the choice of the healthcare professionals included for interviewing or a preference by the study participants to attribute causes to latent or error-provoking conditions, believing that the patient-related factors should not be associated with errors.

Another gap between this study and the literature was the theme pertaining to emotions when prescribing. In the literature, some studies identified emotions such as fear or anxiety affecting prescribing duties, which result in defensive practice and potentially underdosing errors (Alanzi, Tully and Lewis, 2024). Within this dissertation, while emotional responses were described, these were limited to fatigue, tiredness or wellbeing in the case of contributory factors to errors, while anxiety and fear only arose when discussing the barriers to reporting.

The identification of the vast causes and contributory factors spanning Reason's three main domains, active failures, error-provoking conditions and latent failures, suggests that effective error reduction initiatives require concurrent interventions across all these domains. The prominent overlap with international literature suggests that successful global medication safety practices can be applied locally, while being tailored to address some of the unique local factors identified in this study. The gaps identified in the responses from the local healthcare professionals should be analysed

further to establish the cause for these omissions and whether these are areas requiring intensive training or a culture shift.

5.3.2 Barriers and Facilitators to Medication Error Reporting

The qualitative findings from this study provided a crucial explanatory context for the absence of medication error reports from Malta within the EudraVigilance database, shedding light on the various determinants that positively and negatively influence reporting practices among healthcare professionals at local acute hospitals. These findings directly addressed part of the third study objective by identifying the various barriers and facilitators to error reporting, which were thematically grouped according to the Theoretical Domains Framework. When compared with published literature on the topic, the results obtained broadly aligned with the established themes, while certain divergences and insights, as well as themes unique to the local context were also identified.

Impact of Hospital Culture

Differences in organisational culture emerged clearly between the two acute hospitals involved in the study. Participants working at Hospital 2 described a prevailing blame culture that discouraged reporting, and consequently prevented system-level learning, whereas participants from the other hospital felt that the open, non-punitive culture at their hospital fostered positive reporting behaviours. These contrasting views support previous research, which emphasised the role of learning-oriented cultures and supportive leadership in meaningfully promoting reporting behaviour (Guo et al., 2025). Over recent years, the World Health Organisation (WHO) has similarly

advocated for the shift away from punitive cultures to those that encourage learning, recognising it as a key foundation for improving reporting practices (WHO, 2024b).

While the presence of a culture that fosters positive reporting behaviours at one hospital indicates that such cultural change is achievable within our local context, it is important to acknowledge that each hospital faces unique macro-, meso- and micro- level pressures and challenges depending on the sector within which it operates, such as socio-political pressures, differences in funding sources and operational demands. The literature strongly supports the implementation of a just culture, which goes beyond simply a no-blame culture by promoting system-level learning and balanced accountability (Murray et al., 2023). In a just culture, the organisation takes responsibility for system flaws and the individual remains accountable for their intentional choices (Murray et al., 2023; Glarcher and Vaismoradi, 2025). The principles of a just culture are in line with Reason's Accident-Causation model, emphasising that healthcare professionals should not be held responsible for latent failures or error-provoking conditions beyond their control (Mira, 2023). This is of particular importance locally, given that the key contributory factors for medication errors identified in this study related to these domains.

For a just culture to be established, there needs to be strong and visible leadership commitment to patient safety, comprehensive staff education on just culture principles, open and trustworthy communication and follow-up processes that provide feedback (Gleeson et al., 2020; Mira, 2023; Murray et al., 2023; Glarcher and Vaismoradi, 2025). When reporting is reframed as a constructive learning opportunity and systemic learning, a meaningful increase in reporting is seen (Murray et al., 2023;

Glarcher and Vaismoradi, 2025). Adopting these principles would help local healthcare settings with a blame culture to move towards more open, learning oriented environments, thus addressing the central barriers to medication error reporting identified in this study.

Fear of Consequences and Emotional Barriers

The most prominent barriers to reporting identified in this study fell within the domains of 'beliefs of consequences' and 'emotions', which are closely interlinked, and also shaped by the prevailing hospital culture as previously described. The widespread fear of negative repercussions following an error report, such as potential disciplinary action, damage to workplace relationships and the effect on career progression, were identified across different professional groups and seniority levels, indicating that these beliefs stem from wider systemic issues rather than isolated concerns. These findings were closely supported by literature findings that similarly identified fear and emotional deterrents as major obstacles to reporting, particularly amongst junior staff (Alqubaisi et al., 2016a, 2016b; Stewart et al., 2018). Addressing these barriers requires wider organisational-level changes, and not solely from individual-level interventions. The fostering of a just culture is an example of organisation-level change that could bring about a meaningful improvement to reporting, as it promotes replacing the feelings of shame and fear of consequences with a safe environment where professionals are encouraged to report errors (Mira, 2023; Glarcher and Vaismoradi, 2025).

External Stakeholder Influence – Effect of Trade Unions

A unique barrier that was identified in this study was the influence of external stakeholders, specifically trade unions, on reporting practices. Some participants perceived union direction not to do formal reporting in order to protect members in blame-oriented environments. It is important to acknowledge that such action by unions may arise as a defensive response to management decisions or hospital cultures where individuals are scapegoated or blamed for an incident, rather than tackling the more pertinent system issues. This theme was absent from the reviewed literature, suggesting that it may be specific to the local industrial relations landscape.

This finding is significant as it highlights how the internal safety culture of a hospital (referred to as the meso-level) is not in isolation, but it is also shaped by these broader, external macro-level and micro-level forces. While these influences stem from outside the direct hospital environment, they ultimately still impact hospital practices. Addressing this barrier requires a collaborative and integrated approach, where hospital management or higher authorities and union representatives and society at large work together to build trust and foster a just culture, effectively addressing the safety of all the stakeholders within the healthcare system for the good of all.

Knowledge, Training and Role Conflict

Other common barriers that emerged from the interviews included limited awareness regarding formal reporting procedures and a sense of insufficient training on how or what to report, highlighting deficiencies in professional development, organisational communication and staff preparedness. This barrier was particularly pronounced among doctors working within Hospital 2 and echoes the findings within

the literature, which showed a widespread lack of awareness, knowledge and training on the systems, policies and procedures in place for reporting medication errors, with these issues also most frequently seen in doctors (Alqubaisi et al., 2016a; Guo et al., 2025).

Related to these knowledge gaps, some doctors who participated in this study viewed reporting as more of an administrative task that would detract from already time-pressured clinical work. Insights from patient safety and quality set-up in this study identified that doctors tend to prefer informal peer discussion rather than formally reporting the error. While such informal discussion may resolve immediate clinical issues and acute situations, this behaviour demonstrates a lack of appreciation or awareness of the importance for continuous, system-level improvements and limits the opportunity for broader organisational learning that formal reporting enables, with similar situations noted in Alqubaisi et al. (2016a) and Stewart et al. (2018).

The practical implications of these barriers become apparent when contextualising these findings. Evidence from Tanti et al. (2017) shows that prescribing errors by hospital doctors are relatively high, with an average of 7.7 errors per doctor per year, while the analysis of the EudraVigilance database conducted in this study also identified prescribing errors as the most common type of error occurring within the EEA and the UK. In view of these points, the discrepancy between error occurrence and the views from representatives of the patient safety set-up from one hospital, who revealed minimal submissions from doctors, becomes apparent. This suggests that there is a need for clear guidance, informative training sessions and active reinforcement of reporting policies, with a specific focus on doctors, to enhance

engagement with formal reporting systems. Systematic reviews by both Shalviri et al. (2024) and Gleeson et al. (2020) support this as they identified that the provision of knowledge and training through combined initiatives, such as educational sessions, workshops and reminder cards, increased the rate of reporting; however, the certainty of evidence on their effectiveness is low. While such training is not a guarantee for behaviour change in isolation, the literature suggests that improving clarity and competence in reporting processes are necessary preconditions (Guo et al., 2025).

Impact of Error Severity on Reporting

The effect of error severity on reporting behaviours is a barrier that can be contextualised from the findings of the EudraVigilance analysis and local healthcare professionals' responses from the interviews. The EudraVigilance data showed that over 77% of reported ICSRs had a serious outcome. This aligns with local healthcare professionals' insights, who felt that many healthcare professionals would be unlikely to report those errors that do not have a visible or harmful effect on the patient, or are simply near misses, despite study participants themselves believing that every medication error, irrespective of severity, should be reported. This was further supported by the representatives from the patient safety set-up within one hospital, who highlighted that near-miss reporting for medication errors is virtually non-existent. These findings from the qualitative data suggest that in Malta, reporting behaviours are also influenced by the severity of the error.

These views are in common with the literature, which also shows that healthcare professionals tend to prioritise and more readily report those errors which are serious or lead to patient harm, while minor errors or near-misses more often end

up being overlooked or under-reported (Alqubaisi et al., 2016a, 2016b; Shalviri et al., 2018; Stewart et al., 2018; Guo et al., 2025). Alqubaisi et al. (2016a) suggest that hospital policies should mandate the reporting of both actual errors and near misses, ensure that staff are made aware of these policies, and a particular emphasis on educating staff on the value of near-miss reporting.

Reporting System Design

Participants' views on the reporting systems in place in the two hospitals contrasted sharply. The paper-based system at Hospital 2 was perceived by many participants as time-consuming and laborious, which deterred reporting. Similar complaints on paper-based reporting systems were also described in the literature (Alqubaisi et al., 2016a).

In contrast, the electronic reporting system at Hospital 1 was praised for its accessibility and ease of use. A systematic review by Gleeson et al. (2020) identified that individual studies demonstrated that the transition to electronic reporting systems leads to a greater number of reports; however, due to low-certainty evidence, the overall effectiveness could not be assessed. Nonetheless, any transition to electronic reporting systems should be carefully planned and implemented, as studies have also shown that poor design, complexity, and inadequate IT infrastructure can, in turn, hinder reporting (Shalviri et al., 2018; Guo et al., 2025). This indicates that a reporting system's success does not depend solely on the chosen modality, but also on its local adaptation and implementation, and its interaction with the various other barriers and facilitators present within the hospital setting.

Predominant Facilitators of Reporting

During the interviews the domain of 'social/professional role and identity' emerged predominantly as a facilitator, with participants viewing medication error reporting as part of their ethical and moral duty to safeguard patient safety. Studies conducted in other countries documented comparable values, illustrating the fundamental duty towards the patient common amongst healthcare professionals (Alqubaisi et al., 2016b; Stewart et al., 2018; Guo et al., 2025).

Within the domains of 'intentions' and 'goals', reporting was viewed as an opportunity for learning, both personally and for system improvement. Consistent with literature findings, framing medication error reporting as an investment in professional growth, system improvement and better patient outcomes may strengthen and promote positive reporting behaviours by healthcare professionals (Alqubaisi et al., 2016b, 2016a; Stewart et al., 2018; Guo et al., 2025).

The effect of leadership, discussed within the domain of 'social influences', was identified as a factor that can potentially facilitate medication error reporting. Participants attributed that visible leadership commitment and the cultivation of environments where staff felt safe and secure to report errors would increase reporting likelihood. These views are also supported by Guo et al.'s (2025) study, which found that positive leadership attitudes improved staff reporting behaviours. In contrast, the literature presents various examples of how poor leadership attitudes in turn hinder reporting behaviours (Alqubaisi et al., 2016a, 2016b; Stewart et al., 2018; Shalviri et al., 2018). Another facilitator of reporting, particularly seen in the context of Hospital 1, was the presence of non-hierarchical team dynamics. These team dynamics, often

fostered by leadership attitudes and beliefs, can also improve the likelihood of error reporting by flattening communication structures (Guo et al., 2025), whereas hierarchical teams can instead introduce power dynamics between junior and senior grades or between different professional groups, which may reduce reporting (Alqubaisi et al., 2016a).

Domains and Themes Not Addressed

Some of the domains from the TDF, namely 'beliefs about capabilities', 'optimism', 'memory, attention and decision processes', and 'behavioural regulation', did not emerge from the qualitative analysis. Some of these domains were also largely unaddressed in the literature, perhaps suggesting that not all domains of the TDF are relevant or applicable in every context or study. However, the absence of these domains may also reflect assumptions made in the local setting, such as healthcare professionals being presumed capable of reporting (Domain 4) without formal audit or monitoring.

A notable divergence from the literature was the absence of barriers or facilitators under the domain of 'memory, attention and decision processes', with the theme of forgetting to report a medication error being a common barrier in the literature (Alqubaisi et al., 2016b; Stewart et al., 2018; Guo et al., 2025). The absence of this theme in this study may be due to more dominant barriers overshadowing this domain, or healthcare professionals' reluctance to attribute non-reporting to their own personal lapses, by instead framing barriers due to organisational factors, which could reflect a degree of social desirability bias, as expanded upon in *Section 5.4.2*.

In addition to the domains common to both this study and the literature, participants did not discuss several themes identified in previous research. One of these themes within the domain of ‘reinforcement’ was the effect of incentives for reporting. In studies by Alqubaisi et al. (2016a) and Guo et al. (2025), the concept of either monetary or symbolic incentives was raised as a possible facilitator to error reporting. This theme was not mentioned by any of the interviewees in this study. Furthermore, the literature on the effectiveness of providing financial compensation to professionals who report errors is very mixed, with some studies claiming that some professionals end up filing reports which are either frivolous or blatantly made-up, detracting from root-cause investigations into true errors (Mutair et al., 2021; Shalviri et al., 2024). Moreover, incentivised reporting may also have the negative effect of some professionals reporting for the wrong reasons, such as to list the mistakes made by colleagues (Stewart et al., 2018). The absence of this theme may be due to the fact that in Malta, by law, reporting is part of the duties of a healthcare professional and therefore an expected professional responsibility.

Given the context of a small country, the barriers to reporting identified as part of domain 6, ‘beliefs about consequences’, were mainly focused on professional reputation and judgment from peers. Within this domain, however, other themes identified in the literature were absent from this study’s findings. One such barrier was the loss of trust by patients or their caregivers when disclosing an error, as highlighted in Guo et al. (2025). Similarly, while fear of litigation and compensation claims are other barriers related to this domain (Mahat et al., 2022), these reasons did not feature in the interviews conducted. The absence of these themes may possibly be

explained due to the tendency towards informal negotiation by the institution with the injured party, or due to limitations in the sample, as expanded upon in *section 5.4.2*.

Alqubaisi et al. (2016a) noted a preference for informally addressing errors face-to-face over formally reporting these errors. This practice of informal resolution of errors did not emerge from the interviews with the thirteen frontline professionals, however the patient safety team representatives did believe that there was this tendency within their hospital set-up, thus aligning with the literature.

5.4 Strengths, Limitations and Biases of the study

5.4.1 Strengths

A major strength of this study lies in its explanatory-sequential mixed methods design to explore the causes of medication errors and the associated reporting practices. This approach is recognised in the literature for allowing the research to achieve both breadth and depth, as the quantitative findings can inform and be further studied and explained through the subsequent qualitative phase (Dawadi, Shrestha and Giri, 2021). The initial quantitative analysis of the EudraVigilance database provided a broad overview of error characteristics, causes and reporting patterns across the EEA. This was followed by a qualitative phase that provided insights into the Maltese acute hospital care setting, uncovering the deeper, context-specific details of these topics. The mixed methods design was particularly insightful for answering the study's aim, as this approach highlighted the absence of error reports from Malta in the EudraVigilance database, a finding that would have otherwise been missed with a

solely qualitative design. This result acutely underscored the pressing need to address the barriers towards reporting.

Another strength of this study was the inclusion of interviewees from different acute hospital settings, including a public and a private hospital, which enabled comparative insights into the unique strengths and challenges faced by each sector.

The use of a purposive, maximal variation sampling strategy has been described in the literature for enhancing the richness of qualitative findings by ensuring that a wide range of perspectives are captured (Palinkas et al., 2015). This sampling strategy has often been used in public health research (Ahmed, 2025). In line with these reasons, this sampling approach was therefore used to ensure representation across different healthcare professionals, thereby capturing the diverse perspectives on medication error causes and reporting behaviours.

The exclusive use of one-to-one interviews for data collection in the study's second phase was a key strength in securing participation from healthcare professionals. This method was chosen over other qualitative methods, such as focus groups, due to the highly sensitive nature of the research topic, whereby participants may otherwise not feel comfortable or be hesitant to openly discuss such issues in front of peers from the same or different professional groups. Individual interviews also had logistical advantages, as outlined in Chapter 3 (refer to *section 3.4.3*), and were therefore identified as the preferred data collection modality for this study.

The use of theory is a recognised method in the literature for strengthening a study's rigour, by providing a theory-driven framework for analysing and interpreting qualitative data (Anfara and Mertz, 2006). For this reason, this study utilised two

theoretical frameworks, Reason's Accident Causation Model and the Theoretical Domains Framework, to guide the analysis of the qualitative findings. The two frameworks were used to enable the identification and categorisation of the various causes, contributory factors and barriers which emerged from the qualitative data, and to interpret their significance within the local context.

5.4.2 Limitations and Biases

While every effort was made to minimise the limitations and biases in the study, it is important to acknowledge these areas, as described below.

Limitations of the Mixed Methods Approach

A limitation of the study was that there was a mismatch between certain aspects of the quantitative and the qualitative phases of the study. The EudraVigilance database did not contain any error reports from Malta, which, while a significant finding, meant that the subsequent analysis of this dataset focused on the wider European perspectives on medication error findings and reporting patterns, while the qualitative phase focused just on healthcare professionals working in Malta. While this may affect the significance and applicability of these quantitative findings to the local scenario, the findings from the EudraVigilance analysis and the qualitative interviews were integrated in a complementary manner. The European data served as a baseline, resulting in the qualitative findings providing an explanation and the local context for the patterns, and particularly the local data gap, noted in the wider quantitative phase.

Limitations of the Quantitative Phase

The quantitative analysis relied on the analysis of secondary data from the EudraVigilance database. The use of secondary data for answering a research question carries certain inherent limitations, such as lack of certain desired variables and not being an exact match for answering the research question in isolation (Wickham, 2019).

Several key limitations specific to the EudraVigilance database are also important to acknowledge. Firstly, a key limitation in using data from the EudraVigilance for this study was that those incidents which do not result in an observable patient harm or are near misses are not mandated to be included as ICSRs, and such events are therefore likely underrepresented in the dataset (Newbould et al., 2017). Secondly, the EudraVigilance database is based on spontaneous error reporting, with such spontaneous reporting systems prone to under-reporting (Henriksen et al., 2005; Sundaran et al., 2018; Routledge and Bracchi, 2023), potentially reflecting only a fraction of the actual medication errors taking place in practice. Furthermore, the quality of the data within each ICSR is highly variable, as reports may be submitted by both healthcare professionals and patients; therefore, there can be inconsistencies in the information supplied, as well as missing data which may influence the accuracy of the presented results (Toki and Ono, 2020). Another inherent limitation of the dataset was that the structured fields did not contain information on the healthcare setting where they occurred, and while a representative sample of the free-text narratives was reviewed, the healthcare setting was not a required variable and was only mentioned incidentally, if at all. Therefore, this information could not be confidently analysed across the dataset.

The practice of a single individual carrying out the coding of qualitative or free-text data is recognised in the literature as a potential source of interpretation and classification bias (McAlister et al., 2017). This was a potential limitation of this study, as the coding and analysis of the free-text narratives were conducted by the primary researcher alone. To mitigate against the potential problems with interpretation, the definitions outlined in Chapter 2 were used to guide the classification following the error definitions of each stage of the medication use process.

While the 3-year period resulted in a considerable quantity of ICSRs from countries within the chosen European regions, the absence of Malta-specific reports represents a limitation as it prevented detailed analysis of local error characteristics and patterns. This necessitated using the broader EEA and UK data as a baseline for comparison with local findings. However, the absence of ICSRs from Malta also represents a notable finding, providing evidence of underreporting behaviours locally, which the qualitative interviews then sought to give insights into.

Another possible limitation of the dataset was that the initial period overlaps with the final stages of the COVID-19 pandemic. This extraordinary situation may have influenced results due to factors unique to that time, particularly the possible higher rates of vaccine use, and any associated changes in prescribing practices and reporting behaviours.

Limitations of the Qualitative Phase

One of the limitations of the qualitative phase was that participant recruitment was facilitated by intermediaries. According to the literature, this practice may inadvertently introduce potential selection bias (Lamprianou, 2022). The literature also

recognises that individuals with a strong interest in a particular research topic may be more likely to take part, while those who are indifferent or plainly uninterested do not, potentially skewing the findings towards a particular perspective (Houghton et al., 2020). This tendency may have been a factor in this study, as the overwhelming positive beliefs expressed towards medication error reporting may not fully align with actual reporting behaviours and barriers in clinical practice.

Social desirability bias is another potential limitation described in the literature, where participants may focus on one particular area, such as the effect of systemic or latent factors, while downplaying the role of others, such as individual or human factors (Bispo Júnior, 2022). In this study, participants may have been influenced by professional considerations when discussing the strengths and barriers seen within their own clinical area, potentially presenting their clinical setting in a particular light. This risk is greater in Malta due to the small number of acute hospitals, where it is more difficult to maintain full anonymity. To mitigate this, interviews were conducted on an individual basis, and their individual responses were strictly pseudo-anonymised. To further safeguard participant confidentiality, professional grades and the names of the hospitals were also not disclosed, and no link between individual participants and the specific hospital they worked in was retained.

Another limitation was that, due to time constraints, the study was conducted in only two acute hospital settings in Malta, which may limit the generalisability and the transferability of the findings to other healthcare settings or institutions. Including additional hospitals would have led to a greater number of interviews and manual

transcriptions needing to be carried out, which would have been unfeasible within the timeframe to complete the study.

Despite the strengths of a purposive, maximal variation sampling approach which allows for a range of perspectives, it may limit the ability to obtain more nuanced insights from some subgroups within the sample (Andrade, 2021). This may have been a limitation in this study, as the maximal variation approach might have prevented the identification of some unique causes of medication errors or reporting barriers specific to certain professional groups or grades. While the qualitative data covered various contributory factors within all main domains of Reason's model, four out of the fourteen TDF domains were not highlighted by participants, with the most notable absence being responses pertaining to the domain of 'memory, attention and decision processes'. This limitation may not have been particularly significant, however, as the saturation of themes was achieved in the qualitative phase, particularly for the causes and contributory factors to errors and the majority of domains within the TDF. Furthermore, three out of the four domains that did not emerge in this study were also largely absent from similar research in the literature.

Finally, interviewer and researcher bias must also be acknowledged. The use of a single individual for qualitative data collection and analysis has been identified in the literature as potentially introducing bias into qualitative research (Pannucci and Wilkins, 2010). This was a potential limitation in this study as all interviews, coding and thematic analysis were conducted by the primary researcher alone. To mitigate this, the analysis and interpretation of data were guided by the two theoretical frameworks outlined previously. Despite the use of theory, the influence of individual subjectivity

and prior assumptions, including potential preconceptions about error causes from the primary researcher's own clinical experience working within one of the healthcare settings, may have had an effect. This was mitigated through reflexive practices during data analysis through note-taking and review of initial theme categorisation.

5.5 Suggestions for Future Research

Considering the study's findings and the limitations discussed above, some proposed suggestions for future research on the topic are outlined below.

A quantitative follow-up study using an anonymous questionnaire could be conducted to quantify the prevalence of identified causes of medication errors, as well as key attitudes, beliefs and barriers to reporting. This type of study could explore associations between these variables and predictors of under-reporting, and, owing to its anonymous nature, may promote greater engagement.

A quantitative study could also be conducted to analyse medication error reporting trends in Malta by using data from the start of the EudraVigilance database. This research would provide temporal insights into how reporting behaviours have evolved over time.

Further qualitative research may also be beneficial, particularly if it targets specific professional groups separately. This approach could capture more in-depth, specific insights from each profession, thereby enabling more tailored interventions to be instituted.

In view of the differences in reporting culture and patient safety culture between the different healthcare settings identified in this study, future research could consider expanding on the research setting to include a wider range of healthcare institutions locally. In addition, the study could also be extended to primary care settings and healthcare institutions in Gozo, which may have their own unique challenges not captured in this current study.

Given the findings from the EudraVigilance database showed that just over 60% of received reports were by non-healthcare professionals, a similar study may be conducted locally with a specific focus on reporting by patients. Such a study could help uncover the patient-specific factors contributing to medication errors locally and explore the knowledge, awareness and barriers to their reporting by the general public.

Lastly, future research could also focus on studying the impact of specific interventions that are aimed at increasing medication error reporting rates to determine which are the most effective.

5.6 Chapter Summary

This chapter presented the integration of results from both the quantitative analysis of the EudraVigilance database and the qualitative interviews with local healthcare professionals. The integration of findings highlighted the strength of the explanatory-sequential mixed methods approach undertaken, with each phase complementing the other to provide comprehensive insights into medication error causes, contributory factors and reporting practices.

The retrospective quantitative analysis of the EudraVigilance database fulfilled the second objective and identified the notable finding that no error reports originating from Malta were recorded during the most recent three-year period. While the absence of local medication error reports may be considered a limitation, it also emerged as a key finding, revealing critical reporting gaps and the substantial and widespread degree of underreporting locally.

The qualitative phase of the study subsequently achieved the third objective by identifying several underlying causes and contributory factors to medication errors, as well as the most pertinent barriers and facilitators to medication error reporting in Malta. These findings demonstrated consistent alignment with international literature, indicating that many common causes of errors and barriers to reporting are shared across healthcare systems globally, while also identifying some specific factors unique to the local setting.

This MSc Dissertation, therefore, successfully fulfilled its overarching aim of exploring the causes of medication errors and their reporting practices within Malta's acute hospital setting. The findings from this study directly inform the recommendations presented in *Chapter 6*, fulfilling the study's fourth objective of proposing strategies to reduce the occurrence of medication errors and improve reporting practices.

Chapter 6: Conclusions and Recommendations

6.1 Conclusions

This dissertation concludes that medication errors represent an important public health concern locally, requiring urgent measures to address the systemic causes and contributory factors to medication errors, and the widespread reporting gaps identified.

The analysis from the EudraVigilance most notably revealed that no medication error reports originating from Malta were submitted to this database within the 3-year study period (March 2022 – March 2025), highlighting a substantial reporting gap. The qualitative data confirms that this absence indicates systematic under-reporting rather than a lack of errors, representing both a significant patient safety risk and a missed opportunity for organisational learning and quality improvement. The analysis also highlighted that internationally, errors most likely occurred during prescribing and administration, and that anti-infective medications and nervous system agents were the most frequently implicated medication classes.

The qualitative interviews with healthcare professionals revealed that medication errors stemmed from a mixture of active failures, error-provoking conditions and latent failures, most often driven by factors in the latter two domains. Error-provoking conditions were the most frequently identified contributory factors, with heavy workload and time pressures mentioned by virtually all participants. Staffing shortages, fatigue and emotional strain, the effect of look-alike and sound-alike medications, and transcribing issues emerged as other noteworthy error-provoking conditions. The latent factors uncovered included issues with staff allocation, the

absence of clinical pharmacists, the presence of low-quality medications and devices, and inadequate training and supervision.

The study also revealed multiple barriers which explain the lack of medication error reports recorded, particularly the prevailing blame culture, fear of professional repercussions, and lack of awareness regarding both what should be reported and the use of the reporting system itself. In contrast, reported facilitators to reporting included a sense of professional duty towards patients, the belief that reporting serves as a means for both individual and organisation learning and improvement, psychological safety, a positive hospital culture and receiving feedback following incident reporting.

The study findings provide important evidence for developing tailored strategies and corrective measures to foster the pressing and overdue shift in mentality needed to promote and sustain a supportive, learning oriented culture. This requires a multi-faceted approach targeting training and education, organisational processes and workplace culture to address the identified causes, contributory factors and reporting barriers of medication errors, ultimately strengthening the healthcare system and protecting both patients and healthcare professionals.

6.2 Recommendations

This section translates the findings of the study into key recommendations aimed at reducing the causes and contributory factors leading to medication errors and improving reporting practices. These recommendations are structured across three distinct levels: the micro-level, addressing the individual healthcare professional; the meso-level, targeting the hospital or organisation; and the macro-level, concerning

national regulatory and policy-writing bodies. The recommendations described below are prioritised to establish the necessary systemic governance structures and culture first, as these are prerequisites for ensuring safe clinical processes and workforce support, which then enable effective innovation and patient engagement. These recommendations are therefore intended to inform decision-making and guide improvement across all levels.

6.2.1 Cultivate and Consolidate a Patient Safety Culture

The impact of hospital culture and the fear of repercussions on reporting were clearly evident from the findings of the study. One key recommendation, therefore, is for healthcare institutions to actively move away from a punitive culture and instead cultivate, champion and sustain a just culture that promotes learning from errors. This culture shift is a long-term commitment that requires a change in organisational philosophy, driven by both a top-down and bottom-up approach. Fostering such a culture would help to break down barriers such as a fear of blame or consequences and increase positive social influences, ultimately leading to a greater quantity and quality of medication error reports. This cultural shift must be implemented in practice to build the trust needed to effectively enable the identification of causative and contributory factors leading to medication errors and support the implementation of corrective action, thus benefiting both professionals and patients.

Meso-Level Actions

Healthcare organisations must make a long-term commitment to fostering cultural change within their institutions. This requires a top-down approach that must

be led by senior hospital leadership, comprising both administrative management, such as CEOs and directors, as well as senior clinical leaders such as clinical chairpersons and nursing managers. These individuals must lead by example and themselves be designated as patient safety champions. Furthermore, hospital management should also empower frontline staff by creating appropriate forums for open and clear discussion and provide them with opportunities to take on active roles in patient safety initiatives.

Micro-Level Actions

The meso-level commitment must be complemented by a bottom-up approach, as healthcare professionals have a key responsibility in fostering a positive shift towards a just culture. Frontline clinical staff should therefore take an active role in patient safety initiatives and demonstrate behaviours that reinforce this cultural change, such as by demonstrating positive reporting behaviours, including open error disclosure, while avoiding negative ones, such as gossiping and an overly hierarchical firm-based structure.

6.2.2 Enhance and Strengthen Compliance with the Regulatory Framework for Medication Error Reporting

The study identified a critical discrepancy between the acknowledged frequency of medication errors and the actual reporting practices. While reporting is already mandated in local legislation, it is recommended that the relevant regulatory authorities take active steps to improve compliance with these regulations, as well as widen their scope.

Macro-Level Actions

The relevant regulatory authorities should launch a targeted educational and awareness campaign for all healthcare professionals, reinforcing their legal and professional obligations to report under the existing regulations, based on the principles of just culture by protecting healthcare professionals who report in good faith, and clearly distinguishing between system failures and individual negligence.

There should be a concurrent trust-building exercise, assuring the confidentiality of the process, as while reporter details are required, the identity is known solely to the regulatory authority for potential follow-up, but deleted once the evaluation process is concluded, ensuring long-term confidentiality.

The relevant authorities should consider expanding the scope of local legislation to also include the reporting of near-miss events.

6.2.3 Address Staff Shortages and Workload Issues

This recommendation addresses the study's findings where heavy workload, time constraints and staff shortages were identified by participants as both contributing factors to medication errors and barriers to their reporting. The central principle is to mitigate these pressures through improved staffing, resource allocation and work practices to safeguard patient safety and employee wellbeing.

Meso-Level Actions

Hospital management must prioritise strategic recruitment and staff retention. Staff allocation should be guided with patient safety as the primary focus, meaning that

staff assigned to highly specialised areas must possess the necessary training, qualifications and experience to work safely and effectively within those settings, even on a temporary or reliever basis.

Dedicated investment to develop or expand upon the current complement of human resources is also required. The presence of clinical pharmacists within acute care settings has been shown to be of considerable value, and greater recruitment in this area is required. Furthermore, the recruitment and utilisation of allied healthcare professionals to ease the burden on nurses and doctors performing tasks outside their direct clinical remit may also help to ease these high-risk situations. Changes in work practices, such as the preparation and reconstitution of medications within the hospital pharmacy rather than within acute care areas, should also be considered.

Beyond the investment in human resources, hospital management should strive to safeguard employee wellbeing by providing the appropriate support, adequate break times and rest facilities for both day and night duty staff. Collectively, these measures would help relieve workload and time pressures, enabling staff to remain alert and focused, adhere to hospital protocols without skipping steps and have sufficient time to report incidents.

6.2.4 Enhance Training on Medication Safety and Error Reporting Systems

A lack of knowledge and awareness regarding what constitutes a medication error, what should be reported, and the reporting system itself were identified as key barriers to error reporting. The recommendations below seek to address healthcare

professionals' knowledge and ability gaps, as well as raise awareness and reinforce good medication and reporting practices. Collectively, the below micro-, meso- and macro-level educational initiatives would enhance professional knowledge and competency, promote error reporting and reduce errors stemming from knowledge deficits.

Macro-Level Actions

National healthcare authorities and educational bodies should collaborate to provide more robust theoretical and practical modules on medication safety, prescribing practices and instil the importance of error reporting in healthcare undergraduate curricula, particularly for doctors and nurses. This would ensure the necessary competence before professionals enter the workforce.

Meso-Level Actions

Hospitals should implement comprehensive and continuous education and training programmes to healthcare professionals. This must start from the new employee induction period, whereby the teams responsible for patient safety initiatives in hospitals are given a slot during these sessions to provide a practical demonstration of the incident reporting systems, also highlighting their role and importance. Hospitals should also provide mandatory continuous medical education (CME) sessions focused on correct and safe medication practices, irrespective of speciality or department. This should also be supplemented by periodic refresher courses on the use of hospital reporting systems, and for healthcare professionals to receive direct updates on the findings and ensuing corrective actions from the root cause investigations following medication-related incidents.

Micro-Level Actions

Healthcare professionals should have personal accountability for patient safety by participating in all necessary training on good medication practices and all informational sessions on error reporting systems. Furthermore, healthcare professionals should have the personal agency to familiarise themselves with their hospital's specific protocols to ensure that they practice safely.

6.2.5 Optimise Procurement Processes

In view of the findings surrounding the quality of medications and devices, and medicinal products with non-English labels, a key recommendation emerging from this study is that procurement processes must prioritise the purchasing of high-quality products which enhance and safeguard patient safety.

Macro-Level Actions

At a national level, the appropriate regulatory framework should be continuously reviewed to ensure it strikes an effective balance between standards for quality and safety, managing costs, and maintaining access to necessary medications. Organisations are responsible for ensuring that regulatory standards are secured at the point of procurement. Procurement processes must shift away from cost-driven practices towards a more comprehensive approach that also considers the quality, clarity and usability of the products. To implement this, a dedicated and qualified procurement team, with expertise or input of the clinical environment, should be responsible for the careful drafting of tender specifications which explicitly incorporate requirements for quality and safety.

6.2.6 Address Look-alike and Sound-alike Products

Based on this study's findings that look-alike and sound-alike products are a frequent source of error-provoking conditions, it is recommended that healthcare organisations draft policies and implement effective, evidence-based measures to better differentiate between these products.

Macro-Level Actions

At a national level, regulatory frameworks should be reviewed to include specific standards for packaging and labelling of medicinal products. This would help minimise similarities between look-alike and sound-alike products before they enter circulation within the healthcare system.

Meso-Level Actions

Hospitals must implement a combination of measures to mitigate against the effect of look-alike and sound-alike products, such as colour coding in combination with tall-man lettering, to more accurately differentiate between medications with similar appearances or names.

Furthermore, hospital policy must mandate and provide guidance on the appropriate storage of medications in treatment rooms and on trolleys, such as by separating similar looking or named products. To ensure that policies are effective and consistently applied, regular spontaneous checks should also be conducted by the patient safety team or clinical pharmacists to assess how medications are stored and provide suggestions for improvement to support ward staff.

6.2.7 Implement Interventions to Target Risks for Errors During the Medication Use Process

The analysis of the EudraVigilance database revealed that over half of the reported errors occurred during the prescribing and administration stages, and that anti-infectives for systemic use and nervous system agents were the medication classes most commonly involved in errors. Furthermore, both the EudraVigilance analysis and the qualitative interviews highlighted that a lack of adherence to established protocols was a significant contributory factor. Therefore, actions targeting these specific areas of risk are recommended.

Meso-Level Actions

Due to poor reporting practices, hospitals should proactively conduct internal audits of their medication use processes and clinical practices. This would provide the necessary data to guide the development of specific measures and interventions based on their own hospital findings.

A dedicated team within the hospital should also be responsible for updating any protocols in accordance with the latest medications, equipment and best practices identified. Furthermore, the importance of adhering to hospital standard operating procedures (SOPs) should be reinforced with staff, coupled with regular competency assessments, particularly related to prescribing and administration. In addition, for medications frequently involved in errors, namely the classes of anti-infective and nervous system agents, specialised training modules and awareness campaigns should be provided.

6.2.8 Evaluate the Use of Digital Tools to Support the Medication Use Process and Reporting of Adverse Events

A key recommendation emerging from this study is the transition towards digital solutions. Electronic prescribing software can address some recurring issues, particularly those related to illegible handwriting. The system's features, such as automated alerts for suspected errors and mandatory fields for information such as known drug allergies, can help prevent certain types of medication errors. Similarly, a well-designed and easy-to-use electronic reporting system could facilitate more error reporting. The shift to digital tools should be carefully considered, weighing the benefits against the potential to inadvertently introduce new system-related risks, such as poorly designed user interfaces, emergence of new types of errors or low uptake by clinical staff.

Meso-Level Actions

When transitioning to digital systems, the healthcare organisation must provide the frontline healthcare professionals with the necessary training on how to use the system safely and effectively. The digital solution that is implemented should also have ongoing corrective and preventative actions based on user feedback in order to be adopted and utilised by healthcare professionals on the shop floor. Furthermore, the shift to electronic systems must be complemented by the availability of sufficient IT resources and infrastructure for busy healthcare professionals to quickly and effectively access the systems.

Micro-Level Actions

Healthcare providers should actively participate in providing user feedback that is essential for the improvement and tailoring of any electronic system to be introduced.

6.2.9 Promote Patient Health Literacy and Engagement

This recommendation is based on the findings that patient errors are a common cause of medication errors in the EudraVigilance database and that patients' medication and health literacy are perceived to be low by healthcare professionals in Malta. These findings, therefore, underscore the need for targeted health promotion efforts.

Macro-Level Actions

A national education campaign should be launched to improve patients' understanding of their medications, including the importance of maintaining an up-to-date list of medications, and encourage active participation in their care. The campaign should also seek to normalise and encourage patient reporting of suspected errors. Improved patient engagement and knowledge not only reduces the likelihood of errors and non-adherence but also provides healthcare professionals with a more accurate and complete medication history. This, in turn, supports safer prescribing practices and contributes to overall medication safety.

6.2.10 Summary of Recommendations

Table 14 provides a summary of the key recommendations presented in this chapter, outlining the specific areas for intervention and indicating the level at which action is required to effectively address the causes of medication errors and mitigate the barriers to their reporting.

Table 14 - Summary of the Key Recommendations Emerging from the Study

Recommendation	Level of Action		
	Micro-Level	Meso-Level	Macro-Level
Cultivate and Consolidate a Patient Safety Culture	✓	✓	
Enhance and Strengthen Compliance with the Regulatory Framework for Medication Error Reporting			✓
Address Staff Shortages and Workload Issues		✓	
Enhance Training on Medication Safety and Error Reporting Systems	✓	✓	✓
Optimise Procurement Processes			✓
Address Look-alike and Sound-alike Products		✓	✓
Implement Interventions to Target Risks for Errors During the Medication Use Process		✓	
Evaluate the Use of Digital Tools to Support the Medication Use Process and Reporting of Adverse Events	✓	✓	
Promote Patient Health Literacy and Engagement			✓

References

AAnal, A. and Seren, S. (2016) 'Medical Error Reporting Attitudes of Healthcare Personnel, Barriers and Solutions: A Literature Review,' *Journal of Nursing & Care*, 05(06). Available at: https://doi.org/10.4172/2167-1168.1000377.

Abdel-Qader, D.H. et al. (2020) 'Investigating prescribing errors in the emergency department of a large governmental hospital in Jordan,' *Journal of Pharmaceutical Health Services Research,* 11(4), pp. 375–382. Available at: https://doi.org/10.1111/jphs.12376.

Abrishami, R. et al. (2024) 'Assessment of Transcription Errors and their Effects on Medical Approach, Hospitalization Duration, and Financial Costs of Traumatic Patients: How Can We Prevent Them?,' *Epidemiology and Health System Journal*, 11(3), pp. 121–127. Available at: https://doi.org/10.34172/ehsj.26193.

Abstoss, K.M. et al. (2011) 'Increasing medication error reporting rates while reducing harm through simultaneous cultural and system-level interventions in an intensive care unit,' *BMJ Quality & Safety*, 20(11), pp. 914–922. Available at: https://doi.org/10.1136/bmjqs.2010.047233.

Acocella, I. (2012) 'The focus groups in social research: advantages and disadvantages,' *Quality & Quantity,* 46(4), pp. 1125–1136. Available at: https://doi.org/10.1007/s11135-011-9600-4.

Adams, J., Khan, H. and Raeside, R. (2014) *Research methods for business and social science students*. 2nd ed. Sage Publications.

Agency for Healthcare Research and Quality (2024) *Never Events*. Available at: https://psnet.ahrq.gov/primer/never-events (Accessed: September 10, 2025).

Ahmed, S.K. (2025) 'Sample size for saturation in qualitative research: Debates, definitions, and strategies,' *Journal of Medicine, Surgery, and Public Health*, 5, p. 100171. Available at: https://doi.org/10.1016/j.glmedi.2024.100171.

Al Meslamani, A.Z. (2023) 'Underreporting of Adverse Drug Events: a Look into the Extent, Causes, and Potential Solutions', *Expert Opinion on Drug Safety*, 22(5), pp. 351–354. Available at: https://doi.org/10.1080/14740338.2023.2224558

Al-Ahmadi, R.F. et al. (2020) 'Categorizing and understanding medication errors in hospital pharmacy in relation to human factors,' *Saudi Pharmaceutical Journal*, 28(12), pp. 1674–1685. Available at: https://doi.org/10.1016/j.jsps.2020.10.014.

Alanazi, M.A., Tully, M.P. and Lewis, P.J. (2016) 'A systematic review of the prevalence and incidence of prescribing errors with high-risk medicines in hospitals,'

Journal of Clinical Pharmacy and Therapeutics, pp. 239–245. Available at: https://doi.org/10.1111/jcpt.12389.

Alanzi, M.A., Tully, M.P. and Lewis, P.J. (2024) 'Exploring the challenges faced by foundation doctors when prescribing high risk medicines safely during the on-call period: A qualitative study,' *British Journal of Clinical Pharmacology*, 90(2), pp. 548–556. Available at: https://doi.org/10.1111/bcp.15928.

Aldayyen, A.M. et al. (2023) 'Types, trends, and patterns of the reported antimicrobial errors to the eastern region's medical centers in Saudi Arabia: A cross-sectional study,' *Saudi Pharmaceutical Journal*, 31(4), pp. 569–577. Available at: https://doi.org/10.1016/j.jsps.2023.02.009.

Aldhwaihi, K. et al. (2016) 'A systematic review of the nature of dispensing errors in hospital pharmacies,' *Integrated Pharmacy Research and Practice*, p. 1. Available at: https://doi.org/10.2147/iprp.s95733.

Aldila, F. and Walpola, R.L. (2021) 'Medicine self-administration errors in the older adult population: A systematic review,' *Research in Social and Administrative Pharmacy*, 17(11), pp. 1877–1886. Available at: https://doi.org/10.1016/j.sapharm.2021.03.008.

Alharaibi, M.A. et al. (2021) 'Prescribing errors among adult patients in a large tertiary care system in Saudi Arabia,' *Annals of Saudi Medicine*, 41(3), pp. 147–156. Available at: https://doi.org/10.5144/0256-4947.2021.147.

Ali, L. et al. (2021) 'Nurses' perceptions toward factors that cause medication errors in Jordan: A qualitative study,' *Perspectives in Psychiatric Care*, 57(3), pp. 1417–1424. Available at: https://doi.org/10.1111/ppc.12707.

Alldred, D.P. et al. (2010) 'Development and validation of criteria to identify medication-monitoring errors in care home residents,' *International Journal of Pharmacy Practice*, 16(5), pp. 317–323. Available at: https://doi.org/10.1211/ijpp.16.5.0007.

Almalki, Z.S. et al. (2021) 'Evaluation of medication error rates in Saudi Arabia,' *Medicine*, 100(9), p. e24956. Available at: https://doi.org/10.1097/MD.0000000000024956.

Alotaibi, J.S. (2024) 'Causes of medication administration errors and barriers to reporting as perceived by nurses in Saudi Arabia: A qualitative study,' *Belitung Nursing Journal,* 10(2), pp. 215–221. Available at: https://doi.org/10.33546/BNJ.3249.

Alqenae, F.A. et al. (2023) 'Analysis of the nature and contributory factors of medication safety incidents following hospital discharge using National

Reporting and Learning System (NRLS) data from England and Wales: a multi-method study,' *Therapeutic Advances in Drug Safety*, 14. Available at: https://doi.org/10.1177/20420986231154365.

Alqubaisi, M. et al. (2016a) 'Exploring behavioural determinants relating to health professional reporting of medication errors: a qualitative study using the Theoretical Domains Framework,' *European Journal of Clinical Pharmacology*, 72(7), pp. 887–895. Available at: https://doi.org/10.1007/s00228-016-2054-9.

Alqubaisi, M. et al. (2016b) 'Quantifying behavioural determinants relating to health professional reporting of medication errors: a cross-sectional survey using the Theoretical Domains Framework,' *European Journal of Clinical Pharmacology*, 72(11), pp. 1401–1411. Available at: https://doi.org/10.1007/s00228-016-2124-z.

Alrasheed, M.A. et al. (2025) 'Therapeutic drug monitoring of vancomycin: A retrospective cross-sectional study of blood draw timing and clinical outcomes.,' *Medicine*, 104(25), p. e42952. Available at: https://doi.org/10.1097/MD.0000000000042952.

Alshahrani, F., Marriott, J.F. and Cox, A.R. (2021) 'A qualitative study of prescribing errors among multi-professional prescribers within an e-prescribing system,' *International Journal of Clinical Pharmacy*, 43(4), pp. 884–892. Available at: https://doi.org/10.1007/s11096-020-01192-0.

Alshammari, F.M. et al. (2021) 'Medication Error Concept and Reporting Practices in Saudi Arabia: A Multiregional Study Among Healthcare Professionals,' *Risk Management and Healthcare Policy,* 14, pp. 2395–2406. Available at: https://doi.org/10.2147/RMHP.S281154.

Andrade, C. (2021) 'The Inconvenient Truth About Convenience and Purposive Samples,' *Indian Journal of Psychological Medicine*, 43(1), pp. 86–88. Available at: https://doi.org/10.1177/0253717620977000.

Anfara, V. and Mertz, N. (2006) *Theoretical Frameworks in Qualitative Research*. Thousand Oaks, CA: SAGE Publications, Inc. Available at: https://doi.org/10.4135/9781412986335.

Anzan, M. et al. (2021) 'Prescribing errors and associated factors in discharge prescriptions in the emergency department: A prospective cross-sectional study,' *PLoS ONE*, 16(1). Available at: https://doi.org/10.1371/journal.pone.0245321.

Ashcroft, D.M. et al. (2015) 'Prevalence, Nature, Severity and Risk Factors for Prescribing Errors in Hospital Inpatients: Prospective Study in 20 UK Hospitals,'

Drug Safety, 38(9), pp. 833–843. Available at: https://doi.org/10.1007/s40264-015-0320-x.

Assunção-Costa, L. et al. (2022) 'Drug administration errors in Latin America: A systematic review,' *PLoS ONE*. Available at: https://doi.org/10.1371/journal.pone.0272123.

Atkins, L. et al. (2017) 'A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems,' *Implementation Science*, 12(1), p. 77. Available at: https://doi.org/10.1186/s13012-017-0605-9.

Basil, J.H. et al. (2022) 'Prevalence, Causes and Severity of Medication Administration Errors in the Neonatal Intensive Care Unit: A Systematic Review and Meta-Analysis,' *Drug Safety*, pp. 1457–1476. Available at: https://doi.org/10.1007/s40264-022-01236-6.

Basil, J.H. et al. (2023) 'Nurses' perception of medication administration errors and factors associated with their reporting in the neonatal intensive care unit', *International Journal for Quality in Health Care*, 35(4). Available at: https://doi.org/10.1093/intqhc/mzad101.

Batool, A. et al. (2025) 'Role of clinical pharmacist in ensuring safe medication practices for pediatric cardiac care in low- and middle-income countries,' *Antimicrobial Stewardship & Healthcare Epidemiology,* 5(1), p. e67. Available at: https://doi.org/10.1017/ash.2025.35.

Bieri, M. et al. (2021) 'Beliefs about Polypharmacy among Home-Dwelling Older Adults Living with Multiple Chronic Conditions, Informal Caregivers and Healthcare Professionals: A Qualitative Study', *Healthcare* (Basel, Switzerland), 9(9). Available at: https://doi.org/10.3390/healthcare9091204.

Bispo Júnior, J.P. (2022) 'Social desirability bias in qualitative health research,' *Revista de Saúde Pública*, 56, p. 101. Available at: https://doi.org/10.11606/s1518-8787.2022056004164.

Bonella, G.F. et al. (2023) 'Prescribing errors in a Brazilian teaching hospital: Causes and underlying factors from the perspective of junior doctors', *PLoS ONE*, 18(4). Available at: https://doi.org/10.1371/journal.pone.0284071.

Bosma, B.E. et al. (2021) 'Voluntarily reported prescribing, monitoring and medication transfer errors in intensive care units in The Netherlands,' *International Journal of Clinical Pharmacy*, 43(1), pp. 66–76. Available at: https://doi.org/10.1007/s11096-020-01101-5.

Boysen, P.G. (2013) 'Just culture: a foundation for balanced accountability and patient safety.', *Ochsner journal*, 13(3), pp. 400–6. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC3776518/

Brabcová, I. et al. (2023) 'Reasons for medication administration errors, barriers to reporting them and the number of reported medication administration errors from the perspective of nurses: A cross-sectional survey,' *Nurse Education in Practice*, 70. Available at: https://doi.org/10.1016/j.nepr.2023.103642.

Burns, D., Lal, R. and Mc Donnell, C. (2023) 'Paediatric harmful adverse drug events (PHADE),' *Paediatrics & Child Health*, 28(5), pp. 299–304. Available at: https://doi.org/10.1093/pch/pxac132.

Campbell, S. et al. (2020) 'Purposive sampling: complex or simple? Research case examples', *Journal of research in nursing*, 25(8), pp. 652–661. Available at: https://doi.org/10.1177/1744987120927206.

Cane, J., O'Connor, D. and Michie, S. (2012) 'Validation of the theoretical domains framework for use in behaviour change and implementation research,' *Implementation Science*, 7(1), p. 37. Available at: https://doi.org/10.1186/1748-5908-7-37.

Chatzi, A. V. and Kourousis, K.I. (2024) 'Clarifying misconception of quality and safety in healthcare,' *International Journal of Health Governance*, 29(4), pp. 377–384. Available at: https://doi.org/10.1108/IJHG-06-2024-0064.

Chaumont, M. et al. (2016) 'Acute Kidney Injury in Elderly Patients With Chronic Kidney Disease: Do Angiotensin-Converting Enzyme Inhibitors Carry a Risk?,' *Journal of clinical hypertension*, 18(6), pp. 514–521. Available at: https://doi.org/10.1111/jch.12795.

Cheema, E. et al. (2018) 'The impact of pharmacists-led medicines reconciliation on healthcare outcomes in secondary care: A systematic review and meta-analysis of randomized controlled trials,' *PLoS ONE*, 13(3). Available at: https://doi.org/10.1371/journal.pone.0193510.

Choi, I. et al. (2016) 'Incidence and treatment costs attributable to medication errors in hospitalized patients,' *Research in Social and Administrative Pharmacy*, 12(3), pp. 428–437. Available at: https://doi.org/10.1016/j.sapharm.2015.08.006.

Chou, H. et al. (2024) 'Exploring susceptibility factors to medication dispensing errors through a retrospective study of patient-reported dispensing errors over 11 years: are dispensing errors indeed due to personal reasons for pharmacists?,' *European Journal of Hospital Pharmacy*. Available at: https://doi.org/10.1136/ejhpharm-2023-004064.

Claffey, C. (2018) 'Near-miss medication errors provide a wake-up call,' *Nursing*, 48(1), pp. 53–55. Available at: https://doi.org/10.1097/01.NURSE.0000527615.45031.9e.

Conn, R.L. et al. (2017) 'Intravenous fluid prescribing errors in children: Mixed methods analysis of critical incidents,' *PLoS ONE*, 12(10). Available at: https://doi.org/10.1371/journal.pone.0186210.

Conn, R.L. et al. (2019) 'What causes prescribing errors in children? Scoping review,' *BMJ Open*, 9(8). Available at: https://doi.org/10.1136/bmjopen-2018-028680.

Cooper, J. et al. (2017) 'Nature of Blame in Patient Safety Incident Reports: Mixed Methods Analysis of a National Database', *The Annals of Family Medicine*, 15(5), pp. 455–461. Available at: https://doi.org/10.1370/afm.2123.

Creswell, J.W. (2009) *Research design: Qualitative, quantitative, and mixed methods approaches*. 3rd ed. Sage Publications.

Da Rocha, B.S. et al. (2021) 'Interventions to reduce problems related to the readability and comprehensibility of drug packages and labels: A systematic review,' *Journal of Patient Safety*, pp. E1494–E1506. Available at: https://doi.org/10.1097/PTS.0000000000000619.

Dalton, K. and Byrne, S. (2017) 'Role of the pharmacist in reducing healthcare costs: current insights,' *Integrated Pharmacy Research and Practice*, 6, pp. 37–46. Available at: https://doi.org/10.2147/IPRP.S108047.

Davis, T.R. et al. (2025) 'Promoting a Culture of Patient Safety: Using the Principles of Just Culture to Improve Transparency and Risk Reporting in the Hospital Setting,' *PATIENT SAFETY*, 7(2). Available at: https://doi.org/10.33940/001c.137737.

Dawadi, S., Shrestha, S. and Giri, R.A. (2021) 'Mixed-Methods Research: A Discussion on its Types, Challenges, and Criticisms,' *Journal of Practical Studies in Education*, 2(2), pp. 25–36. Available at: https://doi.org/10.46809/jpse.v2i2.20.

Dean, B. (2000) 'What is a prescribing error?,' *Quality in Health Care*, 9(4), pp. 232–237. Available at: https://doi.org/10.1136/qhc.9.4.232.

Despott, R. et al. (2023) 'Risk management of medication errors: a novel conceptual framework,' *Expert Opinion on Pharmacotherapy*, 24(4), pp. 523–534. Available at: https://doi.org/10.1080/14656566.2023.2178899.

Edwards, I.R. and Aronson, J.K. (2000) 'Adverse drug reactions: definitions, diagnosis, and management,' *The Lancet*, 356(9237), pp. 1255–1259. Available at: https://doi.org/10.1016/S0140-6736(00)02799-9.

El-Gazar, H.E. et al. (2020) 'Effect of Just Culture on Nurses' Willingness to Report Medication Errors,' *Egyptian Journal of Health Care*, 11(1), pp. 1223–1235. Available at: https://doi.org/10.21608/ejhc.2020.255687.

Elliott, M., Page, K. and Worrall-Carter, L. (2012) 'Reason's accident causation model: Application to adverse events in acute care,' *Contemporary Nurse*, 43(1), pp. 22–28. Available at: https://doi.org/10.5172/conu.2012.43.1.22.

Elliott, R.A. et al. (2021) 'Economic analysis of the prevalence and clinical and economic burden of medication error in England,' *BMJ Quality & Safety*, 30(2), pp. 96–105. Available at: https://doi.org/10.1136/bmjqs-2019-010206.

European Association of Hospital Pharmacists (2024) *Special Interest Group for The Investigation of Medication Errors in Intensive Care Units*. Available at: https://eahp.eu/wp-content/uploads/2024/03/report_sig_for_the_investigation_of_medication_errors_in_intensive_care_units.pdf (Accessed: February 26, 2025).

European Commission (2012) *Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC*. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:159:0005:0025:EN:PDF (Accessed: March 8, 2025).

European Medicines Agency (2017) *Guideline on good pharmacovigilance practices (GVP)*. Available at: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-collection-management-and-submission-reports-suspected-adverse-reactions-medicinal-products-rev-2_en.pdf (Accessed: March 8, 2025).

European Medicines Agency (2024a) *Guideline on good pharmacovigilance practices (GVP) Annex I - Definitions (Rev 5).* Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-annex-i-definitions-rev-5_en.pdf (Accessed: August 18, 2025).

European Medicines Agency (2024b) *Pharmacovigilance: Overview.* Available at: https://www.ema.europa.eu/en/human-regulatory-overview/pharmacovigilance-overview (Accessed: March 8, 2025).

European Medicines Agency (no date) *Medication Errors*. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/medication-errors (Accessed: February 20, 2025).

European Medicines Agency (no date) *EudraVigilance*. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/pharmacovigilance-research-development/eudravigilance (Accessed: 8 March 2025).

European Parliament & Council of the EU (2010a) *Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use*. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:348:0074:0099:EN:PDF (Accessed: March 8, 2025).

European Parliament & Council of the EU (2010b) *Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004, and Regulation (EC) No 1394/2007*. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:348:0001:0016:EN:PDF (Accessed: March 8, 2025).

European Researchers' Network Working on Second Victims (ERNST) (2023) *The victims of patient safety incidents*. Available at: https://trainingmanual.cost-ernst.eu/index/the-victims-of-patient-safety-incidents/ (Accessed: February 15, 2025).

Eurostat (2025) *Population on 1 January (tps00001)*. Available at: https://ec.europa.eu/eurostat/databrowser/view/tps00001/default/table?lang=en&category=t_demo.t_demo_pop (Accessed: June 24, 2025).

Fathi, A. et al. (2017) 'Medication errors among nurses in teaching hospitals in the west of Iran: what we need to know about prevalence, types, and barriers to reporting,' *Epidemiology and Health*, 39, p. e2017022. Available at: https://doi.org/10.4178/epih.e2017022.

Fathizadeh, H. et al. (2024) 'Prevalence of medication errors and its related factors in Iranian nurses: an updated systematic review and meta-analysis,' *BMC Nursing*, 23(1), p. 175. Available at: https://doi.org/10.1186/s12912-024-01836-w.

Feinstein, M.M., Pannunzio, A.E. and Castro, P. (2018) 'Frequency of medication error in pediatric anesthesia: A systematic review and meta-analytic estimate,' *Pediatric Anesthesia*, 28(12), pp. 1071–1077. Available at: https://doi.org/10.1111/pan.13521.

Firde, M. (2023) 'Incidence and root causes of medication errors by anesthetists: a multicenter web-based survey from 8 teaching hospitals in Ethiopia,' *Patient*

Safety in Surgery, 17(1). Available at: https://doi.org/10.1186/s13037-023-00367-8.

Gao, Y. et al. (2023) 'A refined management system focusing on medication dispensing errors: A 14-year retrospective study of a hospital outpatient pharmacy,' *Saudi Pharmaceutical Journal*, 31(12). Available at: https://doi.org/10.1016/j.jsps.2023.101845.

Ghassab-Abdollahi, N. et al. (2024) 'Exploring the reasons for self-administration medication errors among illiterate and low-literate community-dwelling older adults with polypharmacy: a qualitative study,' *BMC Geriatrics*, 24(1), p. 1010. Available at: https://doi.org/10.1186/s12877-024-05595-w.

Glarcher, M. and Vaismoradi, M. (2025) 'Promoting just culture in nursing education: A systematic integrative review on enhancing patient safety,' *Nurse Education Today*. Available at: https://doi.org/10.1016/j.nedt.2025.106776.

Gleeson, L. et al. (2020) 'Interventions to improve reporting of medication errors in hospitals: A systematic review and narrative synthesis,' *Research in Social and Administrative Pharmacy*, 16(8), pp. 1017–1025. Available at: https://doi.org/10.1016/j.sapharm.2019.12.005.

Godec, S. et al. (no date) *Developing whole-organisation Quality Management Systems in health care: learning from practice and recommendations for progress*. Available at: https://q.health.org.uk/assets/resources/QMS-full-report_FINAL.pdf?v=1741354582 (Accessed: August 29, 2025).

Government of Malta (2003) *Medicines Act (Chap. 458).* Available at: https://legislation.mt/eli/cap/458/eng/pdf (Accessed: March 9, 2025).

Government of Malta (2012) *Pharmacovigilance Regulations (S.L. 458.35)*. Available at: https://legislation.mt/eli/sl/458.35/eng (Accessed: March 9, 2025).

Guo, H. et al. (2025) 'Exploring multidimensional determinants of medication error reporting in China: a qualitative study using the theoretical domains framework,' *Frontiers in Pharmacology*, 16. Available at: https://doi.org/10.3389/fphar.2025.1590794.

Hammoudi, B.M., Ismaile, S. and Abu Yahya, O. (2018) 'Factors associated with medication administration errors and why nurses fail to report them,' *Scandinavian Journal of Caring Sciences,* 32(3), pp. 1038–1046. Available at: https://doi.org/10.1111/scs.12546.

Hansen, R., Bradley, C. and Sahm, L. (2016) 'Factors Influencing Successful Prescribing by Intern Doctors: A Qualitative Systematic Review,' *Pharmacy*, 4(3), p. 24. Available at: https://doi.org/10.3390/pharmacy4030024.

Härkänen, M. et al. (2019) 'Medication administration errors and mortality: Incidents reported in England and Wales between 2007–2016,' *Research in Social and Administrative Pharmacy,* 15(7), pp. 858–863. Available at: https://doi.org/10.1016/j.sapharm.2018.11.010.

Harrison, R., Lawton, R. and Stewart, K. (2014) 'Doctors' experiences of adverse events in secondary care: the professional and personal impact', *Clinical medicine*, 14(6), pp. 585–590. Available at: https://doi.org/10.7861/clinmedicine.14-6-585.

Hennink, M. and Kaiser, B.N. (2022) 'Sample sizes for saturation in qualitative research: A systematic review of empirical tests', *Social Science & Medicine*, 292. Available at: https://doi.org/10.1016/j.socscimed.2021.114523

Henriksen, K. et al. (2005) *Advances in Patient Safety: From Research to Implementation (Volume 4: Programs, Tools, and Products*). Rockville, MD: Agency for Healthcare Research and Quality (US).

Higham, H. and Vincent, C. (2021) *Textbook of Patient Safety and Clinical Risk Management.* Edited by L. Donaldson et al. Cham: Springer International Publishing. Available at: https://doi.org/10.1007/978-3-030-59403-9.

Hirshon, J.M. et al. (2013) 'Health systems and services: the role of acute care', *Bulletin of the World Health Organization*, 91(5), pp. 386–388. Available at: https://doi.org/10.2471/BLT.12.112664.

Hodkinson, A. et al. (2020) 'Preventable medication harm across health care settings: a systematic review and meta-analysis,' *BMC Medicine*, 18(1), p. 313. Available at: https://doi.org/10.1186/s12916-020-01774-9.

Houghton, C. et al. (2020) 'Factors that impact on recruitment to randomised trials in health care: a qualitative evidence synthesis', *The Cochrane database of systematic reviews*, 10(10), p. MR000045. Available at: https://doi.org/10.1002/14651858.MR000045.pub2.

Hussein, M. et al. (2021) 'The impact of hospital accreditation on the quality of healthcare: a systematic literature review.,' *BMC health services research*, 21(1), p. 1057. Available at: https://doi.org/10.1186/s12913-021-07097-6.

Institute of Medicine (2000) *To Err Is Human*. Washington, D.C.: National Academies Press. Available at: https://doi.org/10.17226/9728.

Ishak, M.S. and Ibrahim, M.I. (2024) 'Critical Care Nurses' Perception of Medication Administration Errors in Kelantan, Malaysia: A Cross-Sectional Study,' *Journal of Nursing Management*, 2024. Available at: https://doi.org/10.1155/2024/3055826.

International Organisation for Standardisation (no date) *Management system guidance.* Available at: https://www.iso9001help.co.uk/10.2%20Non-Conformity%20&%20Corrective%20Action.html (Accessed: July 1, 2025).

Jessurun, J.G. et al. (2023) 'Prevalence and determinants of medication administration errors in clinical wards: A two-centre prospective observational study,' *Journal of Clinical Nursing*, 32(1–2), pp. 208–220. Available at: https://doi.org/10.1111/jocn.16215.

Keers, R.N. et al. (2015) 'Understanding the causes of intravenous medication administration errors in hospitals: a qualitative critical incident study,' *BMJ Open*, 5(3), p. e005948. Available at: https://doi.org/10.1136/bmjopen-2014-005948.

Kessels-Habraken, M. et al. (2010) 'Prospective risk analysis prior to retrospective incident reporting and analysis as a means to enhance incident reporting behaviour: A quasi-experimental field study,' *Social Science & Medicine*, 70(9), pp. 1309–1316. Available at: https://doi.org/10.1016/j.socscimed.2010.01.035.

Khalil, H., Kynoch, K. and Hines, S. (2020) 'Interventions to ensure medication safety in acute care: an umbrella review,' *International journal of evidence-based healthcare*, 18(2), pp. 188–211. Available at: https://doi.org/10.1097/XEB.0000000000000232.

Khoo, T.B. et al. (2017) 'Paediatric in-patient prescribing errors in Malaysia: a cross-sectional multicentre study,' *International Journal of Clinical Pharmacy*, 39(3), pp. 551–559. Available at: https://doi.org/10.1007/s11096-017-0463-1.

Kinlay, M. et al. (2021) 'Medication errors related to computerized provider order entry systems in hospitals and how they change over time: A narrative review,' *Research in Social and Administrative Pharmacy*, pp. 1546–1552. Available at: https://doi.org/10.1016/j.sapharm.2020.12.004.

Kirwan, G. et al. (2023) 'Potential costs and consequences associated with medication error at hospital discharge: an expert judgement study,' *European Journal of Hospital Pharmacy,* 30(2), pp. 86–91. Available at: https://doi.org/10.1136/ejhpharm-2021-002697.

Kitzinger, J. and Barbour, R.S. (1999) 'Introduction: The Challenge and Promise of Focus Groups', in *Developing Focus Group Research*. London: SAGE Publications Ltd, pp. 1–20. Available at: https://doi.org/10.4135/9781849208857.n1.

Kuitunen, S., Saksa, M. and Holmström, A.-R. (2025) 'Medication Errors and Error Chains Involving High-Alert Medications in a Paediatric Hospital Setting: A Qualitative Analysis of Self-Reported Medication Safety Incidents,' *Drugs - Real*

World Outcomes, 12(1), pp. 45–61. Available at: https://doi.org/10.1007/s40801-024-00469-4.

Lamprianou, I. (2022) 'Surveying through gatekeepers in social research: methodological problems and suggestions,' *International Journal of Social Research Methodology*, 25(6), pp. 783–795. Available at: https://doi.org/10.1080/13645579.2021.1940775.

Larmené-Beld, K.H.M., Alting, E.K. and Taxis, K. (2018) 'A systematic literature review on strategies to avoid look-alike errors of labels,' *European Journal of Clinical Pharmacology*, pp. 985–993. Available at: https://doi.org/10.1007/s00228-018-2471-z.

Larson, K. and Lo, C. (2019) *Potential Cost Savings and Reduction of Medication Errors Due to Implementation of Computerized Provider Order Entry and Bar-Coded Medication Administration in the Fraser Health Authority*. Available at: https://med-fom-ubcmj.sites.olt.ubc.ca/files/2019/03/Commentary-14.pdf (Accessed: August 29, 2025)

Latif, A. et al. (2013) 'National Study on the Distribution, Causes, and Consequences of Voluntarily Reported Medication Errors Between the ICU and Non-ICU Settings,' *Critical Care Medicine*, 41(2), pp. 389–398. Available at: https://doi.org/10.1097/CCM.0b013e318274156a.

Li, B. et al. (2025) 'Analysis of the Incidence and Factors Influencing Medication Administration Errors Among Nurses: A Retrospective Study,' *Journal of Clinical Nursing*, 34(7), pp. 2852–2863. Available at: https://doi.org/10.1111/jocn.17483.

Li, L. et al. (2024) 'Paediatric medication incident reporting: a multicentre comparison study of medication errors identified at audit, detected by staff and reported to an incident system,' *BMJ Quality & Safety*, 33(10), pp. 624–633. Available at: https://doi.org/10.1136/bmjqs-2023-016711.

Lisby, M. et al. (2010) 'How are medication errors defined? A systematic literature review of definitions and characteristics,' *International Journal for Quality in Health Care*, 22(6), pp. 507–518. Available at: https://doi.org/10.1093/intqhc/mzq059.

Liukka, M. et al. (2020) 'Action after Adverse Events in Healthcare: An Integrative Literature Review', *International Journal of Environmental Research and Public Health*, 17(13), p. 4717. Available at: https://doi.org/10.3390/ijerph17134717.

Lohmeyer, Q. et al. (2022) 'Effects of tall man lettering on the visual behaviour of critical care nurses while identifying syringe drug labels: a randomised in situ

simulation,' *BMJ Quality and Safety*, 32(1), pp. 26–33. Available at: https://doi.org/10.1136/bmjqs-2021-014438.

Mahat, S. et al. (2022) 'Negative emotions experienced by healthcare staff following medication administration errors: a descriptive study using text-mining and content analysis of incident data,' *BMC Health Services Research*, 22(1), p. 1474. Available at: https://doi.org/10.1186/s12913-022-08818-1.

Mahomedradja, R.F. et al. (2023) 'Factors influencing in-hospital prescribing errors: A systematic review,' *British Journal of Clinical Pharmacology*, pp. 1724–1735. Available at: https://doi.org/10.1111/bcp.15694.

Mahomedradja, R.F. et al. (2025) 'Hospital-wide interventions for reducing or preventing in-hospital prescribing errors: a scoping review,' *Expert Opinion on Drug Safety,* pp. 529–546. Available at: https://doi.org/10.1080/14740338.2025.2467831.

Makary, M.A. and Daniel, M. (2016) 'Medical error—the third leading cause of death in the US,' *BMJ*, p. i2139. Available at: https://doi.org/10.1136/bmj.i2139.

Malta Independent (2012) 'MUMN Calls for investigation', *Malta Independent*, 24 April. Available at: https://www.independent.com.mt/articles/2012-04-24/local-news/MUMN-Calls-for-investigation-309107 (Accessed: September 12, 2025).

Manias, E., Kusljic, S. and Wu, A. (2020) 'Interventions to reduce medication errors in adult medical and surgical settings: a systematic review,' *Therapeutic Advances in Drug Safety*. Available at: https://doi.org/10.1177/2042098620968309.

Martin, C.V. et al. (2024) 'Sleep deprivation and medication administration errors in registered nurses—A scoping review,' *Journal of Clinical Nursing*, pp. 859–873. Available at: https://doi.org/10.1111/jocn.16912.

McAlister, A. et al. (2017) 'Qualitative Coding: An Approach to Assess Inter-Rater Reliability', *2017 ASEE Annual Conference & Exposition Proceedings*. Available at: https://doi.org/10.18260/1-2--28777.

Mekonnen, A.B., McLachlan, A.J. and Brien, J.A.E. (2016) 'Pharmacy-led medication reconciliation programmes at hospital transitions: A systematic review and meta-analysis,' *Journal of Clinical Pharmacy and Therapeutics*, pp. 128–144. Available at: https://doi.org/10.1111/jcpt.12364.

Miles, M.B., Huberman, M.A. and Saldana, J. (2013) *Qualitative Data Analysis: A Methods Sourcebook*. 3rd ed. SAGE Publications.

Ministry for Health (2022) *A National Health Systems Strategy for Malta 2023 - 2030*. Available at: https://health.gov.mt/wp-content/uploads/2023/04/A_National_Health_Systems_Strategy_for_Malta_20

23_-_2030_Investing_Successfully_for_a_Healthy_Future_EN.pdf (Accessed: 22 August 2025).

Ministry for Health and Active Ageing (2025) *National Patient Safety Strategy 2025-2035*. Available at: https://health.gov.mt/wp-content/uploads/2025/09/National-Patient-Safety-Strategy-2025-2035.pdf (Accessed: September 10, 2025).

Mira, J.J. (2023) 'Understanding Honest Mistakes, Second Victims and Just Culture for Patient Safety', *Journal of Healthcare Quality Research*, 38(5), pp. 259–261. Available at: https://doi.org/10.1016/j.jhqr.2023.08.001.

Mira, J.J. et al. (2015) 'Interventions in health organisations to reduce the impact of adverse events in second and third victims', *BMC health services research*, 15, p. 341. Available at: https://doi.org/10.1186/s12913-015-0994-x.

Momo, K. et al. (2022) 'A Survey of Near-Miss Dispensing Errors in Hospital Pharmacies in Japan: DEPP-J Study—Multi-Center Prospective Observational Study—,' *Biological and Pharmaceutical Bulletin*, 45(10), pp. b22-00355. Available at: https://doi.org/10.1248/bpb.b22-00355.

Moureaud, C., Hertig, J.B. and Weber, R.J. (2021) 'Guidelines for Leading a Safe Medication Error Reporting Culture.,' *Hospital pharmacy*, 56(5), pp. 604–609. Available at: https://doi.org/10.1177/0018578720931752.

Mulac, A. and Granås, A.G. (2022) 'Detecting Medication Errors and Adverse Drug Events: A Review of Current Methodologies', in *Medication Safety in Municipal Health and Care Services.* Cappelen Damm Akademisk/NOASP, pp. 135–160. Available at: https://doi.org/10.23865/noasp.172.ch7.

Murray, J.S. et al. (2023) 'Requirements for implementing a 'just culture' within healthcare organisations: an integrative review,' *BMJ Open Quality*. Available at: https://doi.org/10.1136/bmjoq-2022-002237.

Mutair, A. Al et al. (2021) 'The Effective Strategies to Avoid Medication Errors and Improving Reporting Systems,' *Medicines*, 8(9), p. 46. Available at: https://doi.org/10.3390/medicines8090046.

Naseralallah, L. et al. (2022) 'An umbrella review of systematic reviews on contributory factors to medication errors in health-care settings', *Expert Opinion on Drug Safety*, 21(11), pp. 1379–1399. Available at: https://doi.org/10.1080/14740338.2022.2147921.

National Coordinating Council for Medication Error Reporting and Prevention (no date) *Vision and Mission*. Available at: https://www.nccmerp.org/vision-and-mission (Accessed: June 29, 2025).

National Coordinating Council for Medication Error Reporting and Prevention (no date) *About Medication Errors*. Available at: https://www.nccmerp.org/about-medication-errors (Accessed: February 20, 2025).

Nebeker, J.R., Barach, P. and Samore, M.H. (2004) 'Clarifying Adverse Drug Events: A Clinician's Guide to Terminology, Documentation, and Reporting,' *Annals of Internal Medicine*, 140(10), pp. 795–801. Available at: https://doi.org/10.7326/0003-4819-140-10-200405180-00009.

Newbould, V. et al. (2017) 'Medication Errors: A Characterisation of Spontaneously Reported Cases in EudraVigilance,' *Drug Safety*, 40(12), pp. 1241–1248. Available at: https://doi.org/10.1007/s40264-017-0569-3.

Nguyen, P.T.L. et al. (2024) 'Medication errors in emergency departments: a systematic review and meta-analysis of prevalence and severity,' *International Journal of Clinical Pharmacy,* 46(5), pp. 1024–1033. Available at: https://doi.org/10.1007/s11096-024-01742-w.

NHS England (2015) *Patient safety incident reporting continues to improve*. Available at: https://www.england.nhs.uk/2015/09/patient-safety-reporting/ (Accessed: July 3, 2025).

NHS England (2025) *Safety management: accountability across organisational boundaries*. Available at: https://www.hssib.org.uk/patient-safety-investigations/safety-management/investigation-report/pdf/ (Accessed: September 14, 2025).

Ntani, S.N. and Sangha, Y.M.N. (2024) 'Prevalence and causes of medication transcription errors among hospitalized patients: An observational study and survey of nurses at a faith-based hospital in Cameroon,' *Global Health Economics and Sustainability*, 2(3), p. 2457. Available at: https://doi.org/10.36922/ghes.2457.

O'Connor, K. and Dugan, J.L. (2017) 'Addressing floating and patient safety,' *Nursing*, pp. 57–58. Available at: https://doi.org/10.1097/01.NURSE.0000511820.95903.78.

Odili, A. (2022) *Exploring Strategies Hospital Leaders Use to Reduce Costs of Medication Administration Errors*. [Doctoral dissertation], Walden University.

Organisation for Economic Co-operation and Development (2022) *The economics of medication safety*. Available at: https://doi.org/10.1787/9a933261-en.

Organisation for Economic Co-operation and Development (2023) *Malta: Country Health Profile 2023.* OECD. Available at: https://doi.org/10.1787/2a821e8a-en.

Ottosen, M.J. et al. (2021) 'Long-Term Impacts Faced by Patients and Families After Harmful Healthcare Events', *Journal of Patient Safety*, 17(8), pp. e1145–e1151. Available at: https://doi.org/10.1097/PTS.0000000000000451.

Page, M.J. et al. (2021) 'The PRISMA 2020 statement: an updated guideline for reporting systematic reviews', *BMJ*, p. n71. Available at: https://doi.org/10.1136/bmj.n71.

Palinkas, L.A. et al. (2015) 'Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research.,' Administration and policy in mental health, 42(5), pp. 533–44. Available at: https://doi.org/10.1007/s10488-013-0528-y.

Panagioti, M. et al. (2017) Preventable Patient Harm across Health Care Services: A Systematic Review and Meta-analysis. *BMJ*. Available at: https://doi.org/10.1136/bmj.l4185

Pannucci, C.J. and Wilkins, E.G. (2010) 'Identifying and avoiding bias in research.,' *Plastic and reconstructive surgery*, 126(2), pp. 619–625. Available at: https://doi.org/10.1097/PRS.0b013e3181de24bc.

Paradiso, L. and Sweeney, N. (2019) 'Just culture: It's more than policy', *Nursing management*, 50(6), pp. 38–45. Available at: https://doi.org/10.1097/01.NUMA.0000558482.07815.ae.

Parker, J. and Davies, B. (2020) 'No Blame No Gain? From a No Blame Culture to a Responsibility Culture in Medicine', *Journal of Applied Philosophy*, 37(4), pp. 646–660. Available at: https://doi.org/10.1111/japp.12433.

Pera, V. et al. (2025) 'Disproportionality Analysis and Characterisation of Medication Errors in EudraVigilance: Exploring Findings on Sexes and Age Groups,' *Drug Safety*, 48(1), pp. 59–74. Available at: https://doi.org/10.1007/s40264-024-01478-6.

Poole, S.G. et al. (2021) 'Interventions to decrease the incidence of dispensing errors in hospital pharmacy: a systematic review and meta-analysis,' *Journal of Pharmacy Practice and Research*, pp. 7–21. Available at: https://doi.org/10.1002/jppr.1709.

Prentice, J.C. et al. (2020) 'Association of open communication and the emotional and behavioural impact of medical error on patients and families: state-wide cross-sectional survey,' *BMJ Quality & Safety*, 29(11), pp. 883–894. Available at: https://doi.org/10.1136/bmjqs-2019-010367.

Prgomet, M. et al. (2017) 'Impact of commercial computerized provider order entry (CPOE) and clinical decision support systems (CDSSs) on medication errors,

length of stay, and mortality in intensive care units: A systematic review and meta-analysis,' *Journal of the American Medical Informatics Association*, pp. 413–422. Available at: https://doi.org/10.1093/jamia/ocw145.

Puaar, S.J. and Franklin, B.D. (2018) 'Impact of an inpatient electronic prescribing system on prescribing error causation: A qualitative evaluation in an English hospital,' *BMJ Quality and Safety*, 27(7), pp. 529–538. Available at: https://doi.org/10.1136/bmjqs-2017-006631.

Rahman, N.A. et al. (2025) 'A retrospective study on prevalence, characteristics, and outcomes of transcribing error: analysis of data from the National Medication Error Reporting System in Malaysia', *Journal of Pharmaceutical Policy and Practice*, 18(1). Available at: https://doi.org/10.1080/20523211.2025.

Ramos, R.R. (2024) 'Perceptions on Medication Administration Errors (MAEs) among nurses at a tertiary government hospital,' *Applied Nursing Research*, 79. Available at: https://doi.org/10.1016/j.apnr.2024.151822.

Rasool, M.F. et al. (2020) 'Risk Factors Associated With Medication Errors Among Patients Suffering From Chronic Disorders', *Frontiers in Public Health*, 8. Available at: https://doi.org/10.3389/fpubh.2020.531038.

Ratnapala, U.S. et al. (2022) 'Medication transcription errors at a tertiary healthcare facility in Uva province, Sri Lanka: A retrospective study,' *Ceylon Medical Journal*, 67(4), pp. 184–188. Available at: https://doi.org/10.4038/cmj.v67i4.9748.

Reason, J. (2000) 'Human error: models and management,' *BMJ*, 320(7237), pp. 768–770. Available at: https://doi.org/10.1136/bmj.320.7237.768.

Reason, J. (2016) *Managing the Risks of Organizational Accidents*. Routledge. Available at: https://doi.org/10.4324/9781315543543.

Redmond, P. et al. (2018) 'Impact of medication reconciliation for improving transitions of care', *The Cochrane database of systematic reviews*, 8(8), p. CD010791. Available at: https://doi.org/10.1002/14651858.CD010791.pub2.

Reis, C.T., Paiva, S.G. and Sousa, P. (2018) 'The patient safety culture: a systematic review by characteristics of Hospital Survey on Patient Safety Culture dimensions', *International Journal for Quality in Health Care*, 30(9), pp. 660–677. Available at: https://doi.org/10.1093/intqhc/mzy080.

Robertson, J.J. and Long, B. (2018) 'Suffering in Silence: Medical Error and its Impact on Health Care Providers', *The Journal of Emergency Medicine*, 54(4), pp. 402–409. Available at: https://doi.org/10.1016/j.jemermed.2017.12.001.

Rodziewicz, T.L. et al. (2025) *Medical Error Reduction and Prevention*. Treasure Island (FL): StatPearls Publishing

Routledge, P.A. and Bracchi, R. (2023) 'Improving the spontaneous reporting of suspected adverse drug reactions: An overview of systematic reviews,' *British Journal of Clinical Pharmacology*, 89(8), pp. 2377–2385. Available at: https://doi.org/10.1111/bcp.15791.

Roughead, E.E., Semple, S.J. and Rosenfeld, E. (2016) 'The extent of medication errors and adverse drug reactions throughout the patient journey in acute care in Australia,' *International Journal of Evidence-Based Healthcare*, 14(3), pp. 113–122. Available at: https://doi.org/10.1097/XEB.0000000000000075.

Roumeliotis, N. et al. (2019) 'Effect of Electronic Prescribing Strategies on Medication Error and Harm in Hospital: a Systematic Review and Meta-analysis,' *Journal of General Internal Medicine*. Springer New York LLC, pp. 2210–2223. Available at: https://doi.org/10.1007/s11606-019-05236-8.

Rutledge, D.N., Retrosi, T. and Ostrowski, G. (2018) 'Barriers to medication error reporting among hospital nurses', *Journal of Clinical Nursing*, 27(9–10), pp. 1941–1949. Available at: https://doi.org/10.1111/jocn.14335.

Sagawa, H. et al. (2024) 'Analyzing the Impact of Drug Name Similarity on Dispensing Errors: An Examination Using a Drug Name Similarity Index,' *Biological and Pharmaceutical Bulletin*, 47(8), pp. b24-00365. Available at: https://doi.org/10.1248/bpb.b24-00365.

Sartini, M. et al. (2022) 'Overcrowding in Emergency Department: Causes, Consequences, and Solutions-A Narrative Review', *Healthcare* (Basel, Switzerland), 10(9). Available at: https://doi.org/10.3390/healthcare10091625.

Schiavone, N. (2024) Exploring Nurses' Knowledge, Attitudes, and Perceptions on Medication Errors In Mater Dei Hospital. [Masters dissertation], University of Malta.

Schroers, G., Ross, J.G. and Moriarty, H. (2021) 'Nurses' Perceived Causes of Medication Administration Errors: A Qualitative Systematic Review', *Joint Commission Journal on Quality and Patient Safety*, pp. 38–53. Available at: https://doi.org/10.1016/j.jcjq.2020.09.010.

Sears, K., Scobie, A. and MacKinnon, N.J. (2012) 'Patient-Related Risk Factors for Self-Reported Medication Errors in Hospital and Community Settings in 8 Countries', *Canadian Pharmacists Journal / Revue des Pharmaciens du Canada*, 145(2), pp. 88–93. Available at: https://doi.org/10.3821/145.2.cpj88.

Seys, D. et al. (2013) 'Health Care Professionals as Second Victims after Adverse Events,' *Evaluation & the Health Professions*, 36(2), pp. 135–162. Available at: https://doi.org/10.1177/0163278712458918.

Shalviri, G. et al. (2018) 'Choosing Appropriate Theories for Understanding Hospital Reporting of Adverse Drug Events, a Theoretical Domains Framework Approach', *Iranian Journal of Pharmaceutical Research* 17(2): 811-821. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC5985197/

Shalviri, G. et al. (2024) 'Improving adverse drug event reporting by healthcare professionals,' *Cochrane Database of Systematic Reviews*, 2024(10). Available at: https://doi.org/10.1002/14651858.CD012594.pub2.

Shawahna, R. et al. (2016) 'Medication administration errors from a nursing viewpoint: a formal consensus of definition and scenarios using a Delphi technique,' *Journal of Clinical Nursing*, 25(3–4), pp. 412–423. Available at: https://doi.org/10.1111/jocn.13062.

Shawahna, R., Abbas, A. and Ghanem, A. (2019) 'Medication transcription errors in hospitalized patient settings: a consensual study in the Palestinian nursing practice,' *BMC Health Services Research*, 19(1), p. 644. Available at: https://doi.org/10.1186/s12913-019-4485-3.

Sheikhtaheri, A. (2014) 'Near Misses and Their Importance for Improving Patient Safety', *Iranian journal of public health*, 43(6), pp. 853–854. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4475608/

Shikdar, S. et al. (2025) *International Normalized Ratio: Assessment, Monitoring, and Clinical Implications*. Treasure Island (FL): StatPearls Publishing

Shire, M.I. et al. (2018) 'A System Dynamics Approach to Workload Management of Hospital Pharmacy Staff: Modeling the Tradeoff between Dispensing Backlog and Dispensing Errors,' *IISE Transactions on Occupational Ergonomics and Human Factors*, 6(3–4), pp. 209–224. Available at: https://doi.org/10.1080/24725838.2018.1555563.

Slawomirski, L. and Klazinga, N. (2022) *The economics of patient safety*. OECD. Available at: https://doi.org/10.1787/761f2da8-en.

Sodré Alves, B.M.C. et al. (2021) 'Harm Prevalence Due to Medication Errors Involving High-Alert Medications: A Systematic Review,' *Journal of Patient Safety*, 17(1), pp. e1–e9. Available at: https://doi.org/10.1097/PTS.0000000000000649.

Stewart, D. et al. (2018) 'Exploring facilitators and barriers to medication error reporting among healthcare professionals in Qatar using the theoretical

domains framework: A mixed-methods approach,' *PLoS ONE*, 13(10). Available at: https://doi.org/10.1371/journal.pone.0204987.

Sundaran, S. et al. (2018) 'Study on the Classification, Causality, Preventability and Severity of Adverse Drug Reaction Using Spontaneous Reporting System in Hospitalized Patients,' *Pharmacy*, 6(4), p. 108. Available at: https://doi.org/10.3390/pharmacy6040108.

Sutherland, A., Ashcroft, D.M. and Phipps, D.L. (2019) 'Exploring the human factors of prescribing errors in paediatric intensive care units,' *Archives of Disease in Childhood*, 104(6), pp. 588–595. Available at: https://doi.org/10.1136/archdischild-2018-315981.

Tanti, A. et al. (2013) 'Medication errors through a national pharmacovigilance database approach: A study for Malta,' *International Journal of Risk & Safety in Medicine*, 25(1), pp. 17–27. Available at: https://doi.org/10.3233/JRS-120582.

Tanti, A. et al. (2017) 'Opinions of Maltese doctors and pharmacists on medication errors,' *International Journal of Risk & Safety in Medicine*, 29(1–2), pp. 81–99. Available at: https://doi.org/10.3233/JRS-170741.

Tariq, R.A. et al. (2025) *Medication Dispensing Errors and Prevention*. Treasure Island (FL): StatPearls Publishing.

Times of Malta (2025) 'Emergency services outsourced to three private hospitals in new deal', *Times of Malta*, 9 January. Available at: https://timesofmalta.com/article/emergency-services-outsourced-three-private-hospitals-new-deal.1103492 (Accessed: 17 August 2025).

Toki, T. and Ono, S. (2020) 'Assessment of factors associated with completeness of spontaneous adverse event reporting in the United States: A comparison between consumer reports and healthcare professional reports,' *Journal of Clinical Pharmacy and Therapeutics*, 45(3), pp. 462–469. Available at: https://doi.org/10.1111/jcpt.13086.

Tsegaye, D. et al. (2020) 'Medication administration errors and associated factors among nurses,' *International Journal of General Medicine*, 13, pp. 1621–1632. Available at: https://doi.org/10.2147/IJGM.S289452.

Tseng, H.Y. et al. (2018) 'Dispensing errors from look-alike drug trade names,' *European Journal of Hospital Pharmacy*, 25(2), pp. 96–99. Available at: https://doi.org/10.1136/ejhpharm-2016-001019.

Tully, A.P. et al. (2019) 'Evaluation of Medication Errors at the Transition of Care From an ICU to Non-ICU Location,' *Critical Care Medicine*, 47(4), pp. 543–549. Available at: https://doi.org/10.1097/CCM.0000000000003633.

Uitvlugt, E.B. et al. (2021) 'Medication-Related Hospital Readmissions Within 30 Days of Discharge: Prevalence, Preventability, Type of Medication Errors and Risk Factors,' *Frontiers in Pharmacology*, 12. Available at: https://doi.org/10.3389/fphar.2021.567424.

Um, I.S., Clough, A. and Tan, E.C.K. (2024) 'Dispensing error rates in pharmacy: A systematic review and meta-analysis,' *Research in Social and Administrative Pharmacy*, 20(1), pp. 1–9. Available at: https://doi.org/10.1016/j.sapharm.2023.10.003.

van der Velden, P.G. et al. (2020) 'Victims of medical errors and the problems they face: a prospective comparative study among the Dutch population,' *European Journal of Public Health,* 30(6), pp. 1062–1066. Available at: https://doi.org/10.1093/eurpub/ckaa106.

Vest, T.A. et al. (2024) 'Practice-enhancing publications about the medication-use process in 2023,' *American Journal of Health-System Pharmacy*, 81(24), pp. 1305–1312. Available at: https://doi.org/10.1093/ajhp/zxae269.

Vijidan, V. (2023) Barriers and Facilitators in Reporting Medication Errors among Nurses in a Long-Term Facility in Malta. [Masters dissertation], University of Malta.

Vrbnjak, D. et al. (2016) 'Barriers to reporting medication errors and near misses among nurses: A systematic review,' *International Journal of Nursing Studies*, 63, pp. 162–178. Available at: https://doi.org/10.1016/j.ijnurstu.2016.08.019.

Wali, H. and Grindrod, K. (2016) 'Don't assume the patient understands: Qualitative analysis of the challenges low health literate patients face in the pharmacy,' *Research in Social and Administrative Pharmacy*, 12(6), pp. 885–892. Available at: https://doi.org/10.1016/j.sapharm.2015.12.003.

Walsh, E.K. et al. (2017) 'Economic impact of medication error: a systematic review,' *Pharmacoepidemiology and Drug Safety*, 26(5), pp. 481–497. Available at: https://doi.org/10.1002/pds.4188.

Wang, Yao et al. (2022) 'Evaluation of medication risk at the transition of care: a cross-sectional study of patients from the ICU to the non-ICU setting,' *BMJ Open*, 12(4), p. e049695. Available at: https://doi.org/10.1136/bmjopen-2021-049695.

Ward, C.S. and Mangion, D. (2023) 'Nurses' attitudes and barriers to incident reporting in Malta's acute general hospital,' *British Journal of Nursing,* 32(4), pp. 194–200. Available at: https://doi.org/10.12968/bjon.2023.32.4.194.

Westbrook, J.I. et al. (2018) 'Task errors by emergency physicians are associated with interruptions, multitasking, fatigue and working memory capacity: A

prospective, direct observation study,' *BMJ Quality and Safety*, 27(8), pp. 655–663. Available at: https://doi.org/10.1136/bmjqs-2017-007333.

Wickham, R.J. (2019) 'Secondary Analysis Research.,' *Journal of the advanced practitioner in oncology*, 10(4), pp. 395–400. Available at: https://doi.org/10.6004/jadpro.2019.10.4.7.

Wolf, Z.R. and Hughes, R.G. (2008) 'Error Reporting and Disclosure', in Hughes, R.G. (ed.) *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*. Rockville, MD: Agency for Healthcare Research and Quality (US).

Wolff, J. et al. (2021) 'Polypharmacy and the risk of drug–drug interactions and potentially inappropriate medications in hospital psychiatry', *Pharmacoepidemiology and Drug Safety*, 30(9), pp. 1258–1268. Available at: https://doi.org/10.1002/pds.5310.

Wondmieneh, A. et al. (2020) 'Medication administration errors and contributing factors among nurses: A cross-sectional study in tertiary hospitals, Addis Ababa, Ethiopia*,' BMC Nursing*, 19(1). Available at: https://doi.org/10.1186/s12912-020-0397-0.

World Health Organisation (2005) *WHO Draft Guidelines for adverse event reporting and learning systems*. Available at: https://iris.who.int/bitstream/handle/10665/69797/?sequence=1 (Accessed: February 20, 2025).

World Health Organisation (2017) *Medications Without Harm - WHO Global Patient Safety Challenge*. Available at: https://iris.who.int/bitstream/handle/10665/255263/WHO-HIS-SDS-2017.6-eng.pdf?sequence=1 (Accessed: 18 February 2025).

World Health Organisation (2019a) *Medication Safety in High-risk Situations*. Available at: https://www.who.int/publications/i/item/medication-safety-in-high-risk-situations (Accessed: 19 March 2025).

World Health Organisation (2019b) *Medication Safety in Polypharmacy*. Available at: https://www.who.int/publications/i/item/medication-safety-in-polypharmacy-technical-report (Accessed: 19 March 2025).

World Health Organisation (2019c) *Medication Safety in Transitions of Care*. Available at: https://www.who.int/publications/i/item/WHO-UHC-SDS-2019.9 (Accessed: 19 March 2025).

World Health Organisation (2021) *GLOBAL PATIENT SAFETY ACTION PLAN 2021–2030: Towards eliminating avoidable harm in health care*. Available at:

https://www.who.int/teams/integrated-health-services/patient-safety/policy/global-patient-safety-action-plan (Accessed: 12 March 2025).

World Health Organisation (2022) *KEY FACTS ABOUT MEDICATION ERRORS (MEs) IN THE WHO EUROPEAN REGION*. Available at: https://cdn.who.int/media/docs/librariesprovider2/country-sites/medication-error-wpsd-final.pdf?sfvrsn=e5853e2a_1&download=true (Accessed: 19 August 2025).

World Health Organisation (2023) *Patient Safety*. Available at: https://www.who.int/news-room/fact-sheets/detail/patient-safety#:~:text=Common%20sources%20of%20patient%20harm,Surgical%20errors. (Accessed: 17 August 2025).

World Health Organisation (2024a) *Global burden of preventable medication-related harm in health care: A systematic review*. Available at: https://www.who.int/publications/i/item/9789240088887 (Accessed: 12 March 2025).

World Health Organisation (2024b) *Global patient safety report 2024*. Available at: https://iris.who.int/bitstream/handle/10665/376928/9789240095458-eng.pdf (Accessed: 12 March 2025).

Wutich, A., Beresford, M. and Bernard, H.R. (2024) 'Sample Sizes for 10 Types of Qualitative Data Analysis: An Integrative Review, Empirical Guidance, and Next Steps'. *International Journal of Qualitative Methods*. Available at: https://doi.org/10.1177/16094069241296206.

Yousefi, M. et al. (2014) 'Household Health Costs: Direct, Indirect and Intangible.,' *Iranian journal of public health*, 43(2), pp. 202–9. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4450688/

Yu, W.-N. et al. (2025) 'Implementation of Medication-Related Technology and Its Impact on Pharmacy Workflow: Real-World Evidence Usability Study,' *Journal of Medical Internet Research*, 27, p. e59220. Available at: https://doi.org/10.2196/59220.

Yusof, A.N.M. and Razali, H.Y.H. (2024) 'Moving Away from the Blame Culture: The Way Forward to Manage Medical Errors.,' *The Malaysian journal of medical sciences: MJMS*, 31(6), pp. 126–132. Available at: https://doi.org/10.21315/mjms2024.31.6.10.

Zarea, K. et al. (2018) 'Iranian nurses' medication errors: A survey of the types, the causes, and the related factors,' *International Journal of Africa Nursing Sciences*, 8, pp. 112–116. Available at: https://doi.org/10.1016/j.ijans.2018.05.001.

Zhelev, Z. et al. (2025) 'The implementation of Safety Management Systems in healthcare: a systematic review and international comparison,' *Health and Social Care Delivery Research*, 13(7). Available at: https://doi.org/10.3310/QPLF8546.

Appendices

Appendix A – Summary of Studies Used in the Structured Literature Search on the Causes and Contributory Factors to Medication Errors

Title of Study	Authors & Year	Country	Type of Study & Sample Size	Main Findings
A systematic review of the prevalence and incidence of prescribing errors with high-risk medicines in hospitals	Alanazi, M.A. et al. (2016)	UK	Systematic Review n = 9 studies	The most frequent prescribing error types were due to wrong doses, with opioids being the most common medication class. Errors were more common in children
Types, trends and patterns of reported antimicrobial errors to the eastern region's medical centers in Saudi Arabia: A cross-sectional study	Aldayyen, A.M. et al. (2023)	Saudi Arabia	Quantitative (cross-sectional) n = 1422 antimicrobial errors	The main contributory factors to errors were lack of experience and lack of hospital policies. Other factors included high workload and complexity of prescribing of antimicrobials
Prescribing errors among adult patients in a large tertiary care system in Saudi Arabia	Alharaibi, M.A. et al. (2021)	Saudi Arabia	Quantitative (retrospective database review) n = 315166 prescriptions	Contributory factors to errors were mainly due to a lack of sufficient information in electronic health records. Other factors were stress, tiredness and a lack of competence.

A qualitative study of prescribing errors among multi-professional prescribers within an e-prescribing system	Alshahrani, F. et al. (2020)	UK	Qualitative (semi-structured interviews) n = 23 participants	The various contributory factors were due to system failures (e.g. alert fatigue, default auto-population), prescriber issues (lack of knowledge, tiredness, workload) and environmental factors (poor communication, distractions, time pressures)
Prevalence, Nature, Severity and Risk Factors for Prescribing Errors in Hospital Inpatients: Prospective Study in 20 UK Hospitals	Ashcroft, D.M. et al. (2015)	UK	Quantitative (prospective) n = 124260 medication orders	Causes of errors identified included complex systems, busy and stressful working environments and a lack of knowledge. Errors were twice as likely in foundation doctors compared to consultants
Prescribing errors in a Brazilian teaching hospital: Causes and underlying factors from the perspective of junior doctors	Bonella, G.F. et al. (2023)	Brazil	Qualitative (semi-structured interviews) n = 34 doctors	The most common attributed cause was a high workload and time pressures, leading to participants to commit violations. The study also identified latent failures, such as a lack of supervision, hospital culture and the electronic prescribing system, as contributory factors.

Exploring the challenges faced by foundation doctors when prescribing high risk medicines safely during the on-call period: A qualitative study	Alanzi, M.A., Tully, M.P. and Lewis, P.J. (2024)	UK	Qualitative (focus groups) n = 40 participants	The study identified multiple challenges that doctors face particularly within the night shift which contributed to errors. These included lack of senior support, pressure from nurses, complex prescribing tasks and individual factors (e.g. lack of knowledge and fatigue).
Prescribing errors and associated factors in discharge prescriptions in the emergency department: A prospective cross-sectional study	Anzan, M. et al. (2021)	Saudi Arabia	Quantitative (prospective) n = 504 prescriptions	This study identified that the most common prescribing errors were wrong dose, wrong frequency and wrong strength, accounting for 23.2%, 20.7% and 14.6% of errors respectively. The main causes for prescribing errors were a lack of knowledge and mis-selection from the electronic software.
Intravenous fluid prescribing in children: Mixed methods analysis of critical incidents	Conn, R.L. et al. (2017)	UK	Mixed-Methods n = 40 incidents	The study identified that the wrong rate of IV fluids was the most common error type (39%), followed by wrong choice of fluid (24%). The contributory factors to errors were active failures, non-specialist settings, complex patients and poor communication.

Factors Influencing Successful Prescribing by Intern Doctors: A Qualitative Systematic Review	Hansen, R., Bradley, C. and Sahm, L. (2016)	Global	Systematic Review N = 7 publications	This systematic review described how prescribing errors occurred due to factors in three main domains: Environment (including time pressure and hierarchical structures), Individual (lack of knowledge, fatigue, stress) and Patient (e.g. patient complexity)
Paediatric in-patient prescribing errors in Malaysia: a cross-sectional multicentre study	Khoo, T.B. et al. (2017)	Malaysia	Quantitative (cross-sectional) n = 17889 prescribed medications	Most prescribing errors in this study's cohort were due to human factors. Contributory factors to errors were a lack of supervision and a lack of knowledge, accounting for 51.7% and 33.7% respectively. Electronic prescribing systems were also associated with a higher rate of medication errors.
Hospital-wide interventions for reducing or preventing in-hospital prescribing errors: a scoping review	Mahomedradja, R.F., et al. (2025)	Global	Scoping Review n = 14 studies	This study focused on interventions to reduce prescribing errors in view of common contributory factors. The included studies in this review focused on interventions for inadequate drug knowledge and prescriber skills. The review concluded by stating that a multidisciplinary approach and organisational reform was needed to tackle prescribing errors

What causes prescribing errors in children? Scoping review	Conn, R.L. et al. (2019)	UK	Scoping Review + Qualitative Interviews n = 68 articles in review n = 6 stakeholders in focus group	The most common type of prescribing error in children was dosing errors. The study also identified that the causes of prescribing errors in children were healthcare professional's experience working with this cohort communication with children, off-license prescribing, dose calculations and drug formulation.
Factors influencing in-hospital prescribing errors: A systematic review	Mahomedradja, R.F. et al. (2023)	Global	Systematic Review n = 19 articles	This systematic review identified contributory factors across multiple domains, including prescriber-related, organisation-related, prescription-related and technological related, among others. Within the systematic review, the themes of lack of sufficient knowledge, prescribing skills and experience were the most common contributory factors leading to errors.

Impact of an inpatient electronic prescribing system on prescribing error causation: a qualitative evaluation in an English hospital	Puaar, S.J. and Frankling, B.D. (2018)	UK	Qualitative (semi-structured interviews) n = 25 interviews	The errors identified in this study focusing on electronic prescribing were slips (e.g. selecting the wrong medication) and mistakes. Various latent conditions associated with the software were highlighted as contributing to errors, including system design, decisions around its implementation and over-reliance on clinical decision support systems
Investigating prescribing errors in the emergency department of a large governmental hospital in Jordan	Abdel-Qader, D.H. et al. (2020)	Jordan	Quantitative (retrospective) n = 3740 medication orders	The study found an incidence of prescribing errors of 12.5% in the study setting, with wrong drug errors and wrong dose errors being the most common types. The main causative factor identified was poor skills in using the electronic system
Exploring the human factors of prescribing errors in paediatric intensive care units	Sutherland, A. et al. (2019)	UK	Qualitative (semi-structured interviews) n = 11 interviews	Participants in this study identified that fatigue, interruptions, distractions, poor information transfers, inexperience and a high workload increased the likelihood of medication errors.

Task errors by emergency physicians are associated with interruptions, multitasking, fatigue and working memory capacity: a prospective, direct observation study	Westbrook, J.I., et al. (2018)	Australia	Quantitative (prospective) n = 239 medication orders	This study found that reduced sleep showed a 15 times greater increase in medication errors (RR 16.44). Other factors which led to a notable increase in errors were interruptions and multitasking.
A retrospective study on prevalence, characteristics, and outcomes of transcribing error: analysis of data from the National Medication Error Reporting System in Malaysia	Rahman, N.A. et al. (2025)	Malaysia	Quantitative (retrospective analysis of data) n = 12049 transcribing errors	The most common error types recorded were wrong dose (48.6%) followed by wrong frequency transcribed (19.9%). The main contributory factors to errors identified were high workload, especially during peak hours, and distractions
Assessment of Transcription Errors and their Effects on Medical Approach, Hospitalization Duration, and Financial Costs of Traumatic Patients: How Can We Prevent Them?	Abrishami, R. et al. (2024)	Iran	Quantitative (observational) n = 312 patients	The most common transcription error in this study were omissions and incorrect dose transcribed. Among the most common contributory factors to medication errors within this stage were patient related factors, such as clinical severity and underlying diseases, as well as the hospital ward (ICU settings had a greater likelihood of transcribing errors). The study also found that transcribing errors were more likely in particular shifts.

Medication errors related to computerized provider order entry systems in hospitals and how they change over time: A narrative review	Kinlay, M. et al. (2021)	Global	Narrative review n = 31 studies	This study focused on errors related to electronic systems, with the most common error types being incorrect information, omissions and duplicate medications. The factors which contributed to these errors were predominantly due to the software interface (e.g. poor display of information, inflexible system design) and inappropriate use of the system.
Prevalence and causes of medication transcription errors among hospitalized patients: An observational study and survey or nurses at a faith-based hospital in Cameroon	Ntani, S.N. and Sangha, Y.M.N. (2024)	Cameroon	Quantitative (prospective) n = 578 medication orders (observation) n = 54 nurses (survey)	The most frequent transcription errors identified in this study were omissions of new medications. From the survey results, nurses cited illegible prescription (90.7%), distractions (87%) and high workload (77.8%) as the most likely cause of errors in their hospital setting.
Medication transcription errors at a tertiary healthcare facility in Uva province, Sri Lanka: A retrospective study	Ratnapala, U.S. et al. (2022)	Sri Lanka	Quantitative (cross-sectional) n = 272 drug charts	From the drug charts reviewed as part of this study, just over 88% of charts had a transcription error. Most of the errors were in the medication name (80.9%), mainly due to spelling errors. The study found a statistically significant associated with the presence of errors and the number of medications prescribed ($p < 0.01$)

Categorizing and understanding medication errors in hospital pharmacy in relation to human factors	Al-Ahmadi, R.F. et al. (2020)	Saudi Arabia	Qualitative (semi-structured interviews) n = 19 participants	Pharmacists and pharmacy technicians who participated in this study described various contributory factors to dispensing errors, including organisational factors, stress, high workload and poor communication, among others.
A systematic review of the nature of dispensing errors in hospital pharmacies	Aldhwaihi, K. et al. (2016)	Global	Systematic Review n = 15 studies	The systematic review identified both common dispensing error types (e.g. wrong drug, wrong strength, wrong formulation) and common contributory factors (e.g. high workload, low staff, look-alike/sound-alike medications, distractions).
Exploring susceptibility factors to medication dispensing errors through a retrospective study of patient-reported dispensing errors over 11 years: are dispensing errors indeed due to personal reasons for pharmacists?	Chou, H. et al. (2024)	China	Quantitative (retrospective) n = 376 patient-reported errors	This study identified that within its setting, almost half of errors were due to look-alike and sound-alike medications. Factors such as high workload, manual preparation of medications and length of vacation time were identified as increasing the likelihood of committing an error.

A refined management system focusing on medication dispensing errors: A 14-year retrospective study of a hospital outpatient pharmacy	Gao, Y. et al. (2023)	China	Quantitative (retrospective) n = 1326 dispensing errors	The study found that dispensing the incorrect quantity of medication and dispensing the wrong drug were the most frequent error types. Causes of errors were subdivided into human (e.g. habitual tasks, poor concentration) and non-human (e.g. look-alike/sound-alike, environmental) factors.
A System Dynamics Approach to Workload Management of Hospital Pharmacy Staff: Modeling the Tradeoff between Dispensing Backlog and Dispensing Errors	Shire, M.I. et al. (2018)	UK	Other	This study identified that a high workload in the hospital pharmacy led to increases in dispensing errors. As a result of having to correct these errors, backlog increases and further exacerbates the issue. The study also identified the more effective staffing allocations
A Survey of Near-Miss Dispensing Errors in Hospital Pharmacies in Japan: DEPP-J Study - Multi-Center Prospective Observational Study	Momo, K. et al. (2022)	Japan	Quantitative (prospective) n = 53039 prescriptions	This study focused specifically on near-miss errors. Most of these errors were due to the incorrect number of drugs. The factors which increased the likelihood of these near-misses were a higher number of drugs in the prescription, inexperienced staff and particular shift times

Interventions to decrease the incidence of dispensing errors in hospital pharmacy: a systematic review and meta-analysis	Poole, S.G. et al. (2021)	Global	Systematic Review and Meta-analysis n = 11 studies	This meta-analysis/systematic review identified that poor design of the pharmacy, low staff levels, poor training, inexperience and the effect of look-alike and sound-alike medications were associated with errors. The study then described various interventions (including training and technological solutions) as significantly reducing errors.
Analyzing the Impact of Drug Name Similarity on Dispensing Errors: An Examination Using a Drug Name Similarity Index	Sagawa, H. et al. (2024)	Japan	Quantitative (retrospective) n = 563 dispensing errors	This study found that aside from similarities in drug name and appearance, even when medications had similar efficacy contributed to dispensing errors.
Medication Dispensing Errors and Prevention	Tariq, R.A. et al. (2025)	N/A	Book Chapter	This publication listed a number of common causes of pharmacy errors, which included workload, look-alike/sound-alike medications, interruptions, illegible handwriting, among others.

Dispensing errors from look-alike drug trade names	Tseng, H.Y. et al. (2018)	Taiwan	Quantitative (prospective) n = 478 near-misses	The study identified that the most common near-misses were due to dispensing the wrong quantity and wrong drug, with the main contributory factor being look-alike drug names (66.3% of errors). The study also described how tall-man lettering significantly reduced these errors.
Dispensing error rates in pharmacy: A systematic review and meta-analysis	Um, I.S., Clough, A. and Tan, E.C.K. (2024)	Global	Systematic Review and Meta-Analysis n = 62 studies	The study identified the global pooled prevalence of dispensing errors as 1.6%. The most common types of dispensing errors were wrong drug dispensing, wrong strength and labelling errors.
Analysis of the nature and contributory factors of medication safety incidents following hospital discharge using National Reporting and Learning System (NRLS) data from England and Wales: a multi-method study	Alqenae, F.A. et al. (2023)	UK	Mixed-Methods n = 1121 medication incidents	This study identified that monitoring errors were associated with a higher proportion of harmful incidents when compared to incidents that occurred at the prescribing stage. The predominant contributory factors to these errors were organisational factors.

Voluntarily reported prescribing, monitoring and medication transfer errors in intensive care units in The Netherlands	Bosma, B.E. et al. (2021)	Netherlands	Quantitative (retrospective data analysis) n = 27 monitoring errors	The findings on monitoring errors were used from this study. The authors identified that the most common error type in this stage was due to insufficient monitoring (85% of errors). The study identified that monitoring errors were mainly due to human, but technical, organisational and communication factors also had a role.
Nurses' perceptions toward factors that cause medication errors in Jordan: A qualitative study	Ali, L. et al. (2021)	Jordan	Qualitative (semi-structured interviews) n = 24 nurses	The main study findings pertaining to the causes of administration errors were classified into human factors (e.g. lack of knowledge, inexperience and stress/tiredness) and systemic issues (e.g. heavy workload, interruptions, a lack of technology and communication issues).
Causes of medication administration errors and barriers to reporting as perceived by nurses in Saudi Arabia: A qualitative study	Alotaibi, J.S. (2024)	Saudi Arabia	Qualitative (semi-structured interviews) n = 43 nurses	This study was used in the literature review for the causes of administration errors. The main study findings on this aspect were divided into three main categories: malpractice (when staff fail to adhere to policies), high workloads and staff shortages, and issues with the prescription (e.g. poor handwriting, abbreviations).

Prevalence, Causes and Severity of Medication Administration Errors in the Neonatal Intensive Care Unit: A Systematic Review and Meta-Analysis	Basil, J.H. et al. (2022)	Global	Systematic Review and Meta-Analysis n = 20 studies	The most common types of administration errors identified were wrong technique, wrong drug preparation and wrong time administered. The study utilised Reason's Accident-Causation model and identified active failures, error-provoking conditions and latent failures
Reasons for medication administration errors, barriers to reporting them and the number of reported medication administration errors from the perspective of nurses: A cross-sectional survey	Brabcova, I. et al. (2023)	Czech Republic	Quantitative (cross-sectional) n = 1205 nurses	The main findings emerging from this study were that look-alike and sound-alike drugs, substitution with generic products, interruptions during medication administration, illegible prescriptions, staff shortages and a lack of clinical pharmacists were among the most common reasons for errors to occur.
Drug administration errors in Latin America: A systematic review	Assuncao-Costa, L. et al. (2022)	South America	Systematic Review n = 10 studies	This systematic review identified that the most common types of administration errors were wrong time, wrong dose and omission errors.

Nurses' perception of medication administration errors and factors associated with their reporting in the neonatal intensive care unit	Basil, J.H. et al. (2023)	Malaysia	Quantitative (cross-sectional) n = 143 nurses	While this study explored both the causes of errors and their reporting, the findings of the former were included as part of the structured search. This study found that the most common causes of administration errors in their study setting were low staff levels, and the effect of look-alike and sound-alike products
Prevalence of medication errors and its related factors in Iranian nurses: an updated systematic review and meta-analysis	Fathizadeh, H. et al. (2024)	Iran	Systematic Review and Meta-Analysis n = 36 studies	According to this systematic review/meta-analysis, the most common error types identified were wrong time and wrong dose errors. The main causes of administration errors were attributed to high workload, fatigue and nursing shortages.
Incidence and root causes of medication errors by anesthetists: a multicenter web-based survey from 8 teaching hospitals in Ethiopia	Firde, M. (2023)	Ethiopia	Quantitative (cross-sectional) n = 104 participants	The perspectives of anaesthetists regarding administration errors identified that failure to double-check medications and the use of medications prepared by someone else were among the most common causes of errors Administration by the wrong route was the most common error type.

Factors associated with medication administration errors and why nurses fail to report them	Hammoudi, B.M. et al. (2018)	Saudi Arabia	Quantitative (cross-sectional) n = 367 nurses	The main study findings with respect to the contributory factors to administration errors were that similar drug packaging, poor interprofessional communication, transcribing issues and low staffing levels were the main reasons for these errors.
Medication administration errors and mortality: Incidents reported in England and Wales between 2007 – 2016	Harkanen, M. et al. (2019)	UK	Quantitative (retrospective analysis of incidents) n = 229 errors resulting in deaths	This study identified the most common administration error types resulting in patient deaths, with nearly one-third being due to a medication omission. Cardiovascular drugs were the most commonly implicated medication class.
Critical Care Nurses' Perception of Medication Administration Errors in Kelantan, Malaysia: A Cross-Sectional Study	Ishak, M.S. and Ibrahim, M.I. (2024)	Malaysia	Quantitative (cross-sectional) n = 424 participants	The primary contributory factor to medication errors identified in this study were illegible prescriptions. Other reasons for administration errors were look-alike and sound-alike medications.

Prevalence and determinants of medication administration errors in clinical wards: A two-centre prospective observational study	Jessurun, J.G. et al. (2023)	Netherlands	Quantitative (cross-sectional) n = 2576 medication administrations	From the medication administrations observed as part of this study, errors occurred at a in 13.7% of administrations, with the leading cause being omissions (22.9%). The study found that administering complex pharmaceutical forms or administering drugs during specific time periods increased the likelihood of an error.
Understanding the causes of intravenous medication administration errors in hospitals: a qualitative critical incident study	Keers, R.N. et al. (2015)	UK	Qualitative (semi-structured interviews) n = 20 nurses	The study identified that intravenous administration errors resulted from active failures interacting with latent failures. The main contributory factors to this were lack of dose-checking, high workload, interruptions and equipment/devices used during administration.

Analysis of the Incidence and Factors Influencing Medication Administration Errors Among Nurses: A Retrospective Study	Li, B. et al. (2025)	China	Quantitative (retrospective) n = 342 errors	The most common error types described in this study were wrong medication and wrong dose administered. The study findings highlighted the interplay of various personal (e.g. lack of knowledge, physical state), environmental (e.g. workload, equipment) and behavioural (e.g. communication issues, lack of supervision) factors resulting in administration errors.
Sleep deprivation and medication administration errors in registered nurses – A scoping review	Martin, C.V. et al. (2024)	Global	Scoping Review n = 18 studies	The main study finding was that while nurses regularly attribute fatigue, tiredness and shift work as major factors to administration errors, there was insufficient evidence to confirm a direct relationship between reduced sleep duration and increased error rates.
Perceptions on Medication Administration Errors (MAEs) among nurses at a tertiary government hospital	Ramos, R.R. (2024)	Philippines	Quantitative (cross-sectional) n = 190 nurses	The two most common types of administration errors were wrong time of administration and omitted medication. The major perceived causes according to nurses in this study were illegible or unclear orders from doctors and inadequate ward staffing levels.

Nurses' Perceived Causes of Medication Administration Errors: A Qualitative Systematic Review	Schroers, G., Ross, J.G. and Moriarty, H. (2021)	Global	Systematic Review n = 16 studies	This systematic review identified that the causes of errors are often multifactorial and interconnected. The study divided the contributory factors into three main domains: contextual factors (e.g. interruptions and heavy workload), knowledge-based factors (e.g. lack of knowledge) and personal factors (e.g. fatigue and complacency).
Medication administration errors and associated factors among nurses	Tsegaye, D. et al. (2020)	Ethiopia	Quantitative (cross-sectional) n = 414 nurses	The study found that the most common error types were due to administration at the incorrect time (38.6%). Notable factors contributing to errors were a lack of training, lack of hospital guidelines, interruptions and poor communication.
Medication administration errors and contributing factors among nurses: A cross sectional study in tertiary hospitals, Addis Ababa, Ethiopia	Wondmieneh, A. et al. (2020)	Ethiopia	Quantitative (cross-sectional) n = 298 nurses	57.8% of medication administration errors identified in this study were due to administration at the wrong time. Common causes of administration errors were lack of training, unavailability of guidelines, inexperience, interruptions and the night shift.

Iranian nurses' medication errors: A survey of the types, the causes, and the related factors	Zarea, K. et al. (2018)	Iran	Quantitative (cross-sectional) n = 225 nurses	The most common type of administration error identified in this study was administering a drug at the incorrect time (both earlier and later than scheduled), accounting for 55.6% of errors. The three most common causes of errors were a high patient-nurse ratio, increased workload and fatigue.
Role of clinical pharmacist in ensuring safe medication practices for pediatric cardiac care in low- and middle- income countries	Batool, A. et al. (2025)	Pakistan	Quantitative (retrospective) n = 260 pharmacist interventions in 2754 patients	The study assessed the role that clinical pharmacists have in mitigate against medication errors. The study found that clinical pharmacists addressed various errors (e.g. wrong dose, wrong frequency, incorrect duration), with the authors concluding that their involvement significantly reduced medication errors in this study cohort.
Clarifying misconception of quality and safety in healthcare	Chatzi, A.V. and Kourousis, K.I. (2024)	Ireland	Other	The authors of this article describe safety management systems, differentiate with quality management systems and outline the requirements in order to institute such a system in healthcare, which is lacking.

The impact of pharmacists-led medicines reconciliation on healthcare outcomes in secondary care: A systematic review and meta-analysis of randomized controlled trials	Cheema, E. et al. (2018)	Global	Systematic Review and Meta-Analysis n = 18 RCTs included	The study identified that pharmacist led interventions effectively reduced medication discrepancies, however these interventions did not lead to a significant reduction in preventable ADEs or healthcare utilisation following discharge.
Interventions to Reduce Problems Related to the Readability and Comprehensibility of Drug Packages and Labels: A Systematic Review	Da Rocha, B.S. et al. (2021)	Global	Systematic Review n = 17 studies	The study identified that interventions such as colour-coding, font changes and the use of tall-man lettering for look-alike and sound-alike medications, especially when used in combination, improved recognition and differentiation of different drugs.
A systematic literature review on strategies to avoid look-alike errors of labels	Larmene-Beld, K.H.M et al. (2018)	Global	Systematic Review n = 16 studies	This review identified that tall-man lettering improved the readability and reduced error rates associated with look-alike and sound-alike products, however further evidence is required from real-world settings particularly on other interventions such as colour-coding.

Effects of tall man lettering on the visual behaviour of critical care nurses while identifying syringe drug labels: a randomised in situ simulation	Lohmeyer, Q. et al. (2022)	Switzerland	Randomised Simulation (prospective) n = 30 nurses	This study identified that tall man lettering significantly reduced the error rate among critical care nurses in identifying different syringes (from 5.3% to 0.7%), suggesting that this intervention could help reduce error rates.
Pharmacy-led medication reconciliation programmes at hospital transitions: a systematic review and meta-analysis	Mekonnen, A.B. et al. (2016)	Global	Systematic Review and Meta-Analysis n = 19 studies	The main findings of this study was that interventions by pharmacists at a single point of transitions of care significantly reduce medication discrepancies by 66% compared to the usual pathway.
Impact of commercial computerized provider order entry (CPOE) and clinical decision support systems (CDSSs) on medication errors, length of stay, and mortality in intensive care units: A systematic review and meta-analysis	Prgomet, M. et al. (2017)	Global	Systematic Review and Meta-Analysis n = 20 studies	This systematic review/meta-analysis identified that the use of electronic software for prescribing reduced medication error rates by 85% and decreased mortality rates. However, there was no significant change in hospital length of stay or overall mortality.

Impact of medication reconciliation for improving transitions of care	Redmond, P. et al. (2018)	Global	Systematic Review and Meta-Analysis n = 25 randomised trials	This study found very low certainty evidence that by implementing medication reconciliation, there was a reduction in at least 1 discrepancy. Other evidence on the impact on readmissions or clinical outcomes was unreliable.
Effect of Electronic Prescribing Strategies on Medication Error and Harm in Hospital: a Systematic Review and Meta-analysis	Roumeliotis, N. et al. (2019)	Global	Systematic Review and Meta-Analysis n = 38 studies	The main findings that emerged from this study relevant to the literature review was that electronic prescribing significantly reduced medication errors.
The implementation of Safety Management Systems in healthcare: a systematic review and international comparison	Zhelev, Z. et al. (2025)	Global	Systematic Review n = 53 studies	This review used evidence from a number of high-income countries to assess the adoption and impact of Safety Management Systems (SMS) in healthcare institutions. From the countries reviewed, the Netherlands had a SMS in place which resulted in improvements in some aspects of patient safety.
Safety management: accountability across organisational boundaries	NHS England (2025)	UK	Other	This publication was an investigation of safety accountability across the UK NHS. The publication also provided the necessary background on the main pillars of a SMS.

Appendix B - Summary of Studies Used in the Structured Literature Search on the Barriers and Facilitators to Medication Error Reporting

Title of Study	Authors & Year	Country	Type of Study & Sample Size	Main Findings
Exploring behavioural determinants relating to health professional reporting of medication errors: a qualitative study using the Theoretical Domains Framework	Alqubaisi, M. et al. (2016a)	United Arab Emirates	Qualitative (semi-structured interviews) n = 29 interviews	The key barriers identified in this qualitative study included themes associated with beliefs of consequences, emotions and environmental context, the latter including time taken to report. The facilitators to reporting included improving patient safety, and positive goals and intentions for organisational improvement
Quantifying behavioural determinants relating to health professional reporting of medication errors: a cross-sectional survey using the Theoretical Domains Framework	Alqubaisi, M. et al. (2016b)	United Arab Emirates	Quantitative (cross-sectional) n = 294 responses	This study identified that emotional related issues were the main barriers to medication error reporting, with this notion identified across different professional groups.

Exploring multidimensional determinants of medication error reporting in China: a qualitative study using the theoretical domains framework	Guo, H. et al. (2025)	China	Qualitative (semi-structured interviews) n = 27 participants	Utilising the Theoretical Domains Framework, the main barriers to reporting in this study included themes within the domains of knowledge, beliefs about capabilities and consequences, emotions, social influences and environmental context.
Choosing Appropriate Theories for Understanding Hospital Reporting of Adverse Drug Events, a Theoretical Domains Framework Approach	Shalviri, G. et al. (2018)	Iran	Qualitative (focus groups) n = 45 participants	This study identified six main domains that were barriers to reporting, including the domains of knowledge, skills, beliefs about consequences, motivation and goals, environmental context and social influences.
Exploring facilitators and barriers to medication error reporting among healthcare professionals in Qatar using the theoretical domains framework: A mixed-methods approach	Stewart, D. et al. (2018)	Qatar	Mixed-Methods n = 1604 survey responses n = 54 focus group participants	Through mixed-methods research, this study quantified and explained the key barriers and facilitators to medication error reporting. Barriers were predominantly identified within the domains of emotions and belief of consequences

Appendix C – Copy of the Combined Information Letter and Informed Consent Sheet for Participation in the Study

L-Università ta' Malta

Combined Information Sheet & Consent Form - English

Information about the study

My name is Terence Micallef, and I am a student at the University of Malta, currently reading for a MSc in Public Health. As part of the course requirements of this MSc, I am presently conducting my dissertation titled *'Medication Errors and their Reporting: an insight into acute care practice'*; this is being supervised by Dr Patricia Vella-Bonanno (email: patricia.vella-bonanno@um.edu.mt) and Dr John Cachia (john.cachia@um.edu.mt). The aim of my study is to investigate the causes of medication errors and their reporting practices using a mixed-methods approach.

Your Participation

Any data collected from this research will be used solely for purposes of this study.

Should you choose to participate, you will be asked to take part in a semi-structured qualitative interview to explore your perspectives on the causes and contributory factors of medication errors, as well as any barriers to reporting these errors.

The interview will be carried out on a one-to-one basis and the interview will take place either online (using Zoom) or in-person, the latter at a venue of your preference. Each participant will be interviewed once, with the interview expected to last between 45 to 60 minutes.

Before the interview begins, you will be asked to sign an informed consent form. The interview will then be conducted in a confidential manner, using pseudonyms to ensure your anonymity. Data will be collected through audio recording in order to maintain maximal accuracy during the transcription of the interview at a later stage.

Participation in this study is entirely voluntary; in other words, you are free to accept or refuse to participate, without needing to give a reason.

You are also free to withdraw from the study at any time, without needing to provide any explanation and without any negative repercussions for you. Should you choose to withdraw, any data collected from you will be erased as long as this is technically possible (for example, before it is published), unless erasure of data would render impossible or seriously impair achievement of the research objectives, in which case it shall be retained in an anonymised form.

If you choose to participate, please note that there are no direct benefits to you

Your participation does not entail any known or anticipated risks.

Data Management

The data collected will be pseudonymized to ensure confidentiality. All personal data and research data will be securely stored on a password-protected laptop, while backups of the data will be maintained on an encrypted external hard drive. Only my supervisors, examiners, and I will have access to the pseudo-anonymized transcribed data. No personally identifiable information will be included in the final dissertation or any publications arising from the research.

Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said Regulation, you have the right to obtain access to, rectify, and where applicable ask for the data concerning them to be erased.

All raw audio data collected will be deleted following transcription, while all other data will be permanently deleted after 3 years from the successful completion of the dissertation.

Should there be any incidental findings that arise during the course of the research, we will inform you accordingly.

Participant's consent

- ☐ I hereby declare to have read the information about the nature of the study, my involvement and data management.
- ☐ I have had the opportunity to ask questions about the study and my questions have been satisfactorily answered.
- ☐ I declare that I am 18 years or older.
- ☐ I understand that should I have any further queries, I can contact either the researcher on terence.micallef.15@um.edu.mt and/or the supervisor on patricia.vella-bonanno@um.edu.mt.
- ☐ I agree to participate in this research study.

MARK ONLY IF APPLICABLE

- ☐ I agree to be identified in the research records.
- ☐ I agree to be identified in the research publications.

_____ _____

Participant's name (in block) Researcher's name (in block)

Appendix D – Copy of the Semi-Structured Interview Guide used for the Qualitative Interviews

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Interview Guide – English

The below interview guide will be used during the interview process. They are displayed as bullet points to help guide the interview process, however at the same time allow for a degree of flexibility.

Introduction

At the start of the interview, participants will be welcomed and thanked for participating in the study. Following this brief introduction, participants will be given a brief verbal overview and explanation of the topics that will be discussed (i.e. the causes and contributory factors of medication errors and their reporting practices), the structure of the interview, and the information previously provided in the participant information sheets and consent forms. Participants will be encouraged to reply honestly and that there are no right or wrong answers. Before commencing with the interview, participants will be asked whether they have any further questions prior to starting.

Once the participant is satisfied with the explanation and ready to proceed, they will be informed that from this point onwards the interview will formally begin, and the audio-recording **started**.

Participants will first be asked questions about their background and participants will therefore be asked about their:

- Age
- Gender
- Professional group & professional grade
- Length of time working within the healthcare sector
- Department

Medication Errors: Causes & Contributory Factors

Participants will then be informed that we will be moving to the second part of the interview which will deal with the causes and contributory factors of medication errors, and asked the following questions:

- Have you ever seen or experienced a medication error within your work setting? Any example that you would like to share?
- Do you think these errors could be prevented?
- Can you describe what you feel the culture regarding errors is within your unit/hospital?
    - Prompt: is the culture blame oriented or is there a just-culture?
- What do you think are the causes and contributory factors to medication errors?
    - Prompts: Any environment related factors? *[E.g. staffing, day of week, time of shift, work schedule, noise/distractions]*

    - Prompt: Any individual related factors? *[E.g. experience, fatigue, illness, patient state/behaviour]*
    - Prompt: Any other factors? *[e.g. equipment, medication itself]*
- Do you have any recommendations that you feel would reduce the frequency/occurrence of medication errors?

Medication Errors: Reporting Practices:

Participants will then be informed that we will be moving to the third part of the interview which will deal with medication error reporting practices, and asked the following questions:

- Are you aware of how to report medication errors within your hospital/unit? Can you briefly describe it?
- Have you ever been given training on how to report medication errors using this pathway?
- Have you ever reported medication errors using this pathway?
    - If yes, did you receive any feedback following this report? Did any change result following the medication error report?
- From the examples given earlier on in the interview, were these errors reported/do you believe these errors should be reported?
- Do you feel that medication error reporting is important? Why or why not?
- What do you feel are the barriers to reporting medication errors?
- What are the factors that encourage you to report medication errors?
- What do you believe are the benefits to medication error reporting?
- What can be done to improve reporting practices?
- Do you have any opinion on how the medication error reporting process can be improved?

Conclusions:

At this stage the participants will be informed that we are reaching the end of the interview. Participants will be asked to reflect on today's interview and asked one final question:

- Do you have any other comments/feedback regarding the causes of medication errors or their reporting that you would like to add?

At this point, the participants will be informed that the recording will be **stopped**.

The participants will be once again thanked for participating in the interview and provided with the interviewer's (i.e. the student's) contact information should they have any follow-up questions in the future.

Appendix E – Ethical Approval from the University of Malta's Faculty Research Ethics Committee

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Ref No: MED-2025-00049

6 March 2025

Dr Terence Micallef
[redacted]

With reference to your application submitted to the Faculty Research Ethics Committee in connection with your research entitled:

Medication Errors and their Reporting: an insight into acute care practice

The Faculty Research Ethics Committee is granting ethical approval for the above-mentioned application.

[redacted]
Professor Anthony Serracino Inglott
Chair
Faculty Research Ethics Committee