Cyprus University of Technology

Faculty of Health Sciences

Doctoral Dissertation

AN EXPLANATORY SEQUENTIAL MIXED METHODS STUDY FOR ASSESSING MEDICATION ADMINISTRATION SAFETY IN MEDICAL WARDS OF A STATE TERTIARY HOSPITAL IN THE REPUBLIC OF CYPRUS

Georgios Savva

Limassol, May 2021

CYPRUS UNIVERSITY OF TECHNOLOGY
FACULTY OF HEALTH SCIENCES
DEPARTMENT OF NURSING

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Approval Form

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Limassol, May 2021

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The approval of the dissertation by the Department of Nursing does not imply necessarily the approval by the Department of the views of the writer.

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ABSTRACT

Background: Medication errors in hospitals are a leading cause of injury and avoidable harm that negatively affect the quality of the care provided. One-third of all medication errors causing harm to hospitalized patients occur in the administration stage of the medication process. For developing targeted interventions to reduce the risk of placing hospitalized patients at risk, it is crucial to first quantify the magnitude and dimensions of the problem and understand risk-related factors, such as working environment conditions, suboptimal problematic procedures drug-related factors and individual-related factors.

Objective: To record the prevalence and types of medication administration errors, with an emphasis on errors of omission. Also, to investigate error associated factors such as systematic and person-related factors, during administration of medicines to inpatients and explore nurses' perceptions of the medication error-related factors.

Methods: An explanatory sequential mixed methods design was followed. In particular, the study consisted of two phases: a descriptive observational phase and a focus group phase. In the first phase, the medication process in two medical wards of a tertiary hospital was observed by two observers using a structured observation form, to record the frequency and types of errors. Chi Square, and logistic regression analysis were used to explore associations between errors and potential factors. Subsequently, nurses' perceptions of medication administration error-related factors were explored in two focus group discussions, to explain and enrich the findings of the quantitative phase. Thematic analysis was employed for analyzing the data collected from the focus groups.

Results: A total of 665 drug administrations were observed involving 128 patients and administered by 24 nurses. From these administrations, 2371 errors were detected from which 81.2% were omissions and 18.8% were errors of commission. Omissions in the infection prevention guidelines (46.6%) and in the five rights of medication safety principles (35.8%) were more prevalent. In particular, omitting to hand wash before administering a drug (98.4%), omitting to disinfect the site of injection (37.7%), and omitting to confirm

patient's identity (74.4%) were the three most frequently observed omissions. Documentation errors (13.1%) and handling errors (4.5%) were also detected with lower frequency. Regression analysis showed that the therapeutic class of the drug administered (OR=4.11, 95% CI, 2.65-6.38, p<0.001) and the number of medicines taken per patient (OR=1.57, 95% CI, 1.08-2.27, p=0.04) were the two factors which statistically significantly increased the risk of a higher number of errors being detected. Particularly when a cardiovascular drug was administered, or when twelve or more drugs were prescribed for a patient, the risk of five or more errors being made per administration was increased by approximately 4 and 1.6 times respectively. Furthermore, regression analysis revealed that when the administration was carried out by a nurse with more than twelve years of working experience, the risk of five or more errors being made per administration was increased by approximately 48% than when a nurse with less than 12 years of experience was administering the drug (OR=1.48, 95% CI, 1.02-2.15, p=0.05). Four themes were identified from the analysis of the data collected in focus group discussions: (a) professional practice environment and related factors, (b) person related factors, (c) drug related factors, and (d) processes and procedures. Professional practice environment and related factors was the dominant theme. According to nurses' perceptions, factors like staffing, interruptions and/or distractions, communication lapses, processes and systems failures, management and leadership issues are associated with medication errors. Moreover, nurse being physically or mentally fatigued, the patient's condition and patients with polypharmacy or in a severely poor health condition were also perceived by nurses to be medication administration errors associated factors.

Conclusions: Medication administration errors is a multifactorial and multidimensional problem that requires collective effort to be minimized, thereby improving patient safety. Taking into account nurses' perceptions of medication errors can help enlightening the underlying conditions contributing to errors. Errors during drug administration are common in clinical practice, with omissions being the most common type of error. The risk of a higher number of errors being made is increased when a cardiovascular drug is administered or when the number of medicines administered per patient is increased. Nurses' years of work experience is also related to drug administration errors. Staff's perceptions of the causes of

medication errors, when supplemented with evidence derived from observational studies, can provide a comprehensive picture of the factors that contribute to errors and thus inform and shape targeted interventions for preventing medication errors in hospitals wards.

Keywords: drug safety, medication administration errors, hospital wards, observation, thematic analysis

ΠΕΡΙΛΗΨΗ

Εισαγωγή: Τα λάθη κατά τη διαδικασία της φαρμακευτικής αγωγής στα νοσοκομεία αποτελούν την κύρια αιτία βλάβης που θα μπορούσε να είχε αποφευχθεί και επηρεάζουν αρνητικά την ποιότητα της παρεχόμενης φροντίδας. Το ένα τρίτο όλων των λαθών κατά τη φαρμακευτική αγωγή που προκαλούν βλάβη σε νοσοκομειακούς ασθενείς συμβαίνουν στο στάδιο χορήγησης των φαρμάκων. Για την ανάπτυξη στοχευμένων παρεμβάσεων για τη μείωση του κινδύνου έκθεσης των εσωτερικών ασθενών σε κίνδυνο, είναι σημαντικό πρώτα να προσδιοριστεί το μέγεθος και οι διαστάσεις του προβλήματος, να εντοπιστούν οι παράγοντες που σχετίζονται με τον κίνδυνο εμφάνισης λαθών, όπως οι συνθήκες του εργασιακού περιβάλλοντος, οι προβληματικές διαδικασίες, άλλοι παράγοντες που σχετίζονται με το χορηγούμενο φάρμακο ή και παράγοντες που σχετίζονται με τα άτομα.

Στόχος: Η καταγραφή του αριθμού και του είδους των λαθών που συμβαίνουν κατά τη χορήγηση φαρμάκων, με έμφαση στα λάθη παράλειψης. Επίσης, η διερεύνηση των παραγόντων που σχετίζονται με λάθη κατά τη χορήγηση φαρμάκων σε εσωτερικούς ασθενείς, όπως συστηματικοί και σχετιζόμενοι με το άτομο παράγοντες, και η διερεύνηση των αντιλήψεων των νοσηλευτών ως προς τους παράγοντες που σχετίζονται με το λάθος.

Μέθοδος: Εφαρμόστηκε ένας επεξηγηματικός, διαδοχικός, μικτός ερευνητικός σχεδιασμός. Συγκεκριμένα, η μελέτη περιελάβανε δύο φάσεις. Μια περιγραφική μελέτη παρατήρησης σε πρώτη φάση και ακολούθως μία μελέτη με τη μέθοδο των ομάδων εστίασης. Στην πρώτη φάση, η διαδικασία της χορήγησης φαρμάκων σε δύο παθολογικά τμήματα ενός τριτοβάθμιου νοσοκομείου παρατηρήθηκε από δύο παρατηρητές χρησιμοποιώντας μια δομημένη φόρμα παρατήρησης, προκειμένου να καταγραφεί η συχνότητα και οι τύποι σφαλμάτων. Για τη διερεύνηση συσχετίσεων μεταξύ λαθών και πιθανών παραγόντων χρησιμοποιήθηκε η στατιστική δοκιμασία X^2 και η λογιστική παλινδρόμηση. Στη συνέχεια, διερευνήθηκαν οι αντιλήψεις των νοσηλευτών σχετικά με τους παράγοντες που σχετίζονται με λάθη κατά τη χορήγηση φαρμάκων με ημι-δομημένες συζητήσεις σε δύο ομάδες εστίασης, προκειμένου να εξηγηθούν και να εμπλουτιστούν τα ευρήματα της ποσοτικής φάσης, δηλαδή της μελέτης παρατήρησης που προηγήθηκε των ομάδων εστίασης. Για την

ανάλυση των δεδομένων που συλλέχθηκαν από τις ομάδες εστίασης χρησιμοποιήθηκε η μέθοδος της θεματικής ανάλυσης.

Αποτελέσματα: Παρατηρήθηκαν συνολικά 665 χορηγήσεις φαρμάκων σε 128 ασθενείς οι οποίες χορηγήθηκαν από 24 νοσηλευτές συνολικά. Από αυτές τις χορηγήσεις, εντοπίστηκαν 2371 λάθη από τα οποία το 81,2% ήταν παραλείψεις και το 18,8% ήταν σφάλματα εκτέλεσης. Οι παραλείψεις στις οδηγίες πρόληψης των λοιμώξεων (46,6%) και στην τήρηση των 5 βασικών αρχών ορθής χορήγησης φαρμάκων (35,8%) ήταν τα πιο συχνά είδη λαθών. Συγκεκριμένα, η παράλειψη της απολύμανσης των χεριών πριν από τη χορήγηση ενός φαρμάκου (98,4%), η παράλειψη απολύμανσης του σημείου της ένεσης (37,7%) και η παράλειψη επιβεβαίωσης της ταυτότητας/στοιχείων του ασθενούς (74,4%) ήταν οι τρεις πιο συχνές παραλείψεις που καταγράφηκαν. Εντοπίστηκαν επίσης λάθη στην καταγραφή της χορήγησης (13,1%) και λάθη στον τρόπο χορήγησης (4,5%) αλλά με χαμηλότερη συχνότητα. Η ανάλυση λογιστικής παλινδρόμησης έδειξε ότι η θεραπευτική κατηγορία του χορηγούμενου φαρμάκου (OR = 4,11, 95% CI, 2,65-6,38, p <0,001) και ο αριθμός των φαρμάκων που ελήφθησαν ανά ασθενή (OR = 1,57, 95% CI, 1,08-2,27, p = 0,04) ήταν οι δύο παράγοντες που αύξησαν στατιστικά σημαντικά τον κίνδυνο εντοπισμού μεγαλύτερου αριθμού σφαλμάτων. Ιδιαίτερα όταν χορηγήθηκε ένα καρδιαγγειακό φάρμακο, παρά ένα φάρμακο από άλλη θεραπευτικής τάξης ή όταν συνταγογραφήθηκαν δώδεκα ή περισσότερα φάρμακα ανά ασθενή, ο κίνδυνος πέντε ή περισσότερων σφαλμάτων ανά χορήγηση αυξήθηκε κατά περίπου 4 και 1,6 φορές αντίστοιχα. Επίσης, σημαντική συσχέτιση φαίνεται να είχε και η εργασιακή εμπειρία του νοσηλευτή. Η ανάλυση παλινδρόμησης έδειξε ότι όταν η χορήγηση γινόταν από νοσηλευτή με περισσότερα από δώδεκα χρόνια εργασιακής εμπειρίας, ο κίνδυνος πέντε ή περισσότερων σφαλμάτων ανά χορήγηση αυξανόταν κατά περίπου 48% από ό, τι όταν νοσηλευτής με λιγότερο από 12 χρόνια εμπειρίας χορηγούσε το φαρμάκο (OR = 1,48, 95% CI, 1,02-2,15, p = 0,05). Όσο αφορά τις συζητήσεις στις ομάδες εστίασης εντοπίστηκαν από την ανάλυση των δεδομένων που συλλέχθηκαν τα ακόλουθα θέματα: (α) εργασιακό περιβάλλον και συναφείς παράγοντες, (β) παράγοντες που σχετίζονται με το άτομο, (γ) παράγοντες που σχετίζονται με τα φάρμακα και (δ) διαδικασίες. Το εργασιακό περιβάλλον και οι σχετιζόμενοι παράγοντες ήταν το κυρίαρχο θέμα. Σύμφωνα με τους νοσηλευτές, παράγοντες όπως το προσωπικό, οι διακοπές ή/και οι παρεμβάσεις κατά

τη χορήγηση φαρμάκων, η προβληματική επικοινωνία ανάμεσα στο προσωπικό, οι αστοχίες των λειτουργικών διαδικασιών και των συστημάτων, τα θέματα διοίκησης και ηγεσίας σχετίζονται με την εμφάνιση λαθών κατά τη χορήγηση των φαρμάκων. Επιπλέον, όταν οι νοσηλευτές που χορηγούν τα φάρμακα είναι σωματικά ή ψυχικά κουρασμένοι, ή όταν οι ασθενείς λάμβαναν μεγάλο αριθμό φαρμάκων (πολυφαρμακία) ή η κατάσταση της υγείας τους ήταν κακή, θεωρήθηκαν επίσης από τους νοσηλευτές ως παράγοντες που σχετίζονται με λάθη κατά τη χορήγηση φαρμάκων.

Συμπεράσματα: Τα σφάλματα κατά τη χορήγηση φαρμάκων αποτελούν ένα πολύπλευρο, πολυδιάστατο πρόβλημα που απαιτεί συλλογική προσπάθεια προκειμένου να αντιμετωπιστεί και επομένως να βελτιωθεί η ασφάλεια των ασθενών. Όταν λαμβάνονται υπόψη οι αντιλήψεις των νοσηλευτών για τα λάθη στη χορήγηση φαρμάκων, μπορεί να συμβάλει στον εντοπισμό των παραγόντων που συμβάλλουν στην εμφάνιση των λαθών. Τα λάθη κατά τη χορήγηση φαρμάκων είναι συχνά στην κλινική πρακτική, με τις παραλείψεις να είναι ο πιο συνηθισμένο είδος λάθους. Ο κίνδυνος υψηλότερου αριθμού σφαλμάτων αυξάνεται όταν χορηγείται ένα καρδιαγγειακό φάρμακο ή όταν αυξάνεται ο αριθμός των φαρμάκων που χορηγούνται ανά ασθενή. Πολυετής εργασιακή εμπειρία των νοσοκόμων φαίνεται να σχετίζεται επίσης με λάθη. Οι αντιλήψεις του προσωπικού για τις αιτίες των σφαλμάτων φαρμάκων, όταν εμπλουτίζονται με στοιχεία που προέρχονται από την μέθοδο της απευθείας παρατήρησης, συνθέτουν μια πιο ολοκληρωμένη εικόνα για τους παράγοντες που συμβάλλουν στα λάθη και επομένως επιτρέπουν τον σχεδιασμό πιο στοχευμένων παρεμβάσεων για μείωση των λαθών και παραλείψεων κατά την χορήγηση φαρμάκων στο νοσοκομειακό περιβάλλον.

Λέξεις κλειδιά: ασφάλεια στη χρήση φαρμάκων, λάθη στη χορήγηση φαρμάκων, τμήματα νοσοκομείου, παρατήρηση, θεματική ανάλυση

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LIST OF ABBREVIATIONS

AHQR	:	Agency for Healthcare Research and Quality
AMA	:	American Medical Association
ANOVA	:	Analysis of Variance
APSS	:	Actionable Patient Safety Solutions
BCMA	:	Bar Code Medication Administration
COREQ	:	Consolidated Criteria for Reporting Qualitative Studies
ECDC	:	European Center for Disease Prevention
EMA	:	European Medicines Agency
EU	:	European Union
FDA	:	Food and Drug Administration
ICU	:	Intensive Care Unit
IfPS	:	Institute for Patient Safety (Bonn)
IM	:	Intramuscular
IV	:	Intravenous
JBI	:	Johanna Briggs Institute
LPN	:	Liscenced Practice Nurse
MA	:	Medication Administration
MAEs	:	Medication Administration Errors
MEs	:	Medication Errors
MeSH	:	Medical Subject Headings
NCC MERP	:	National Coordination Council for Medication Errors Reporting and Prevention
NHS	:	National Health System
NICE	:	National Institute for Health and Care Excellence
NMC	:	Nursing and Midwifery Council
NPSF	:	National Patient Safety Foundation
OE	:	Opportunities for Error
PFs	:	Procedure Failures
PRISMA	:	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
PSNet	:	Patient Safety Network
PSQIA	:	Patient Safety and Quality Improvement Act

RNs	:	Registered Nurses
SEIPS	:	Systems Engineering Initiative for Patient Safety
SPSS	:	Statistical Product and Service Solutions
UK	:	United Kingdom
US	:	United States
WHA	:	World Health Assembly
WHO	:	World Health Organization
WMA	:	World Medical Association

Introduction

When the report "To Err Is Human: Building a Safer Health System" published by the United States' (US) Institute of Medicine, it resulted in increased awareness of medical errors in US. It included alarming statistics regarding errors in the healthcare sector. This report stated, among many other things, that "…studies imply that at least 44,000 and perhaps as many as 98,000 Americans die in hospitals each year as a result of medical errors" and that "Deaths due to preventable adverse events exceed the deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516) (Kohn et al., 2000). The medication management in hospital wards is a complex, multi-stage and multidisciplinary process and involves and concerns physicians, pharmacists, nurses, managers, and patients. By default, it is also a procedure prone to errors. In fact, research has shown that medication errors are very common during the medication process in clinical settings. This is a challenge for hospitals, healthcare organizations and systems (World Health Organization, 2019). Each year, in the United States alone, 7,000 to 9,000 people die due to a medication error (European Medicines Agency, 2013; Institute of Medicine, 2007; Patient Safety Network, 2020; Tariq et al., 2020; WHO, 2017d). Approximately one in every five doses administer to inpatients is with an error, and when it comes to injectable drugs, even higher error rates have been reported (Brady et al., 2009; Fahimi et al., 2008; Härkänen et al., 2015; Keers, et al., 2013; Taxis & Barber, 2003). More than 100,000 cases associated with a suspected medication error are reported to the U.S. Food and Drug Administration (FDA) each year (FDA, 2019). The problem is also recognized in European countries. The European Medicines Agency (EMA) stated that 18.7 - 56% of all adverse events that occur among hospitalized patients result from medication errors that could be preventable. Medication safety is a concern at all stages of health care delivery in European health care systems (EMA, 2015).

World Health Organization (WHO) defines patient safety as "the absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum" (WHO, 2019). One of the worst

enemies of patient safety is the medication errors problem. Unfortunately, medication errors, when not detected, reported and treated, create a suboptimal level of patient safety. The most negative impact of medication errors is that they put patient at risk, and the quality and safety of the care provided is negatively affected (Härkänen et al., 2019; Zhou et al., 2015). Medication administration errors can prolong hospitalization of patients, increase healthcare costs and of course put the service provider and/or the healthcare professionals in an extremely difficult position, like the risk of being legally prosecuted, or being ethically harmed (Gharekhani et al., 2014; Walsh et al., 2017).

The medication process is a multistage process and involves different healthcare professionals, and patients. Each stage of this complex process carries the risk of being executed in an inaccurate or an erroneous manner. The occurrence of errors during the medication process has several negative implications for patients and medication related-errors have been associated with negative clinical outcomes (Basil et al., 2019). Even though errors have been detected at all stages of the medication process, including the prescribing and the dispensing stage, the administration stage of the process is the most prone to error stage of the medication process (Härkänen et al., 2019). In particular, previous research suggests that medication administration errors only (excluding prescription, preparation or dispensing) occur in 5% of non-intravenous and 35% of intravenous doses (McLeod et al., 2014) or up to 20% of all doses given (Härkänen et al., 2015; Keers, et al., 2013). However, studies have reported even higher error rates detected during the medication administration stage. Some studies have reported medication administration errors levels from 20% to 85% of the doses administered to patients (Fahimi et al., 2008; Feleke, Mulatu, Yesmaw, et al., 2015). This variability in the reported levels of errors in previous studies seems to be attributed to the different methodologies, different definitions and different rate calculations used in previous studies (Feleke, Mulatu, & Yesmaw, 2015; Keers et al., 2013b). Also, the variability maybe related to the different healthcare system level factors, like the use of different health information technologies among hospitals and long care settings for detecting, preventing and reporting errors (Pierson et al., 2007). Common errors detected during the medication administration process include, but not limited to, the administration of a wrong drug, a wrong dose, timing errors, omissions (Feleke, Mulatu, Yesmaw, et al.,

2015; Härkänen et al., 2019; Kim & Bates, 2013). These findings suggest that the prevention of errors made during the medication administration process should be a priority for hospital and health organizations as they count for the vast majority of all medication errors made in hospitals. Thus, medication safety research should particularly be focusing on the errors made during the administration of medicines to patients as there is still, an unmet need in this area (Härkänen, Luokkamäki, et al., 2020).

In Cyprus, the medication errors issue is an unexplored area, as, to the best of our knowledge, there are no studies investigating this problematic phenomenon. However, according to the relevant European Commission survey (Special Eurobarometer 411, 2014), the perceived likelihood of being harmed by healthcare services among citizens in Cyprus is very high. In fact, in this specific survey, approximately 82% of the responders from Cyprus stated that is totally likely for patients in Cyprus to be harmed by hospital care while the EU28 average rate was 53%. Also, 25% of the responders stated that "*healthcare that keeps you safe from harm*" was among the three most important criteria when they think of high-quality healthcare in Cyprus (well-trained medical staff and effective treatment were the two most important criteria) (European Commission Directorate, 2014). These reports may warrant further investigations to understand the magnitude of the safety level during healthcare provision in Cyprus and develop programs promoting patient safety, including medication safety. According to the available data published by the Republic of Cyprus (e.g., official offices, Ministry of Health etc.) and from the findings of this study, no plans, strategies, mechanisms, or prevention programs seem to be in place for preventing and/or reporting errors. A purely national patient safety agency, overseeing the effective operation of preventing mechanisms and programs is established in several countries, but not in Cyprus. However, Special Eurobarometer 411 (2014), revealed that 35% of the responders in Cyprus (EU28 average 27%) admitted experiencing an adverse event while receiving healthcare and only 61% (EU28 average 51%) of them had reported this event. Most of them (71%) stated that they would seek help from the Ministry of Health, if they were harmed during healthcare provision (European Commission Directorate, 2014).

This study aimed to assess the medication administration safety during hospitalization, as this issue had not been explored, until now. In particular, the aim was to record the type of errors and omissions during the medication administration process and explore medication errors associated factors. In addition, it aimed to collect and explore the perceptions of nurses, who are involved in the preparation and administration of medicines to inpatients, regarding the factors associated with errors. The findings of this study can contribute to the prevention of medication administration errors in different ways. First, the study findings can serve as a diagnostic tool. It will provide an indication, a first depiction of the potential magnitude and dimensions of the problem in Cypriot state hospitals. In addition, the reform in the healthcare sector in Cyprus is currently an ongoing national project, and this peculiar conjuncture highlights the need for promoting medication safety, as one of the main goals of the Cypriot healthcare reform is the provision of high-quality health services. Therefore, the results of this study may contribute to raising awareness about the risk of drug errors during the provision of tertiary healthcare services, identify main risk factors and draw attention to the medication errors problem. Medication safety is of utmost importance considering the fact that the National Health Care scheme has just been established, hospitals are functioning now as autonomous entities and patient safety, as well as the quality of care, are (or should be) high in the political agenda. Secondly, the findings of this study will raise awareness of the medication errors problem and of course it could be used as suggestive piece of evidence for developing appropriate interventions to tackle the problem and increase medication safety.

The study consisted of two phases and for each of these two phases a separate sequential methodological approach has been employed for conducting the study; the observation phase (quantitative design) and the focus groups phase (qualitative design). Thus, this PhD thesis is comprised of two studies; an observational study (for assessing the numbers and types of errors) and a focus groups study (to explain and supplement the findings of the observational phase). Furthermore, this dissertation is organized in two parts; the general part and the specific part and it is comprised of eight chapters. The general part (chapters 1-2) is an introduction to the medication errors problem. It highlights the magnitude of the problem and refers to the efforts made globally for addressing it. The specific part (chapters 3-8) presents the methodology of the present study and the material and methods used for collecting and

analyzing the data, the results, including the interpretation of the findings and finally, conclusions and recommendations. Chapter 1 is providing a brief background, an overview of the research topic, starting from a more general description of the medication errors problem, a description of the objectives of the study, and the approach and the framework followed for the conduct of the study. The discussion included in chapter 1 also refers to the prevalence of the problem, the types of medication errors, the definitions, some implication of the medication errors problem and collective efforts to tackle the problem. The importance of reducing errors in healthcare, medication errors in particular, and the need to promote medication safety and patient safety is highlighted and the efforts taken by national and international organizations for achieving this goal is presented. In addition, Chapter 1 also includes a discussion and a comparison of errors of omission and errors of commission. Chapter 2 is in fact a scoping review which was conducted in order to provide an overview of the available research evidence regarding medication administration errors. It includes a detailed description of the problem, presents the different definitions, the different research methodologies employed for exploring the phenomenon, the factors causing or inhibiting the problem, and the prevalence and types of medication administration errors. Chapter 2 includes evidence from literature regarding the methods used in previous research for detecting medication errors, the frequency and the type of medications errors detected. The scoping review will inform about the current status of the problem by mapping the available scientific evidence regarding medication administration errors and will provide guidance for the design and conduct of the research. All chapter thereafter are more specific to this study and are focused on the details of the design and conduct of the present study. Chapter 3 provides a detailed discussion on the conceptualization and the significance of the study, on the research questions and on the objectives and aims of the study. Chapter 4 refers to the study methodology and the material and methods employed to address the study's research objectives. Since two different methodological approaches were employed for conducting the study, both of them are presented in chapter 4. Chapter 4 includes information about the methods used to collect the data, about the settings, the participants and the sample used, as well as the statistical methods used for managing and analyzing the data. Ethical aspects of the study are also discussed in Chapter 4. Chapter 5 is dedicated to the presentation of the results of the observational phase of the study. Chapter 5 presents the findings from

Observational study that was conducted to detect and explore Medication Administration Errors (MAEs) during hospitalization and associated factors where the study was conducted. It includes all relevant details, the challenges faced for initiating the observation and the methods employed for collecting and analyzing the data. Chapter 5 presents information about the setting, the participants and the working environment as well as the prevalence and the types of the errors detected. Chapter 5 also presents the prevalence and types of errors and the associations between different factors and medication errors. Chapter 6 presents the results of the second phase of the study. Apart from the direct observation study, the focus group discussion method was employed for collecting additional data about the problem. Two focus group discussion have been carried out in order to obtain the perceptions of nurses involved in the medication process regarding the causes of medication administration errors. Chapter 7 includes a discussion on the overall findings which were obtained from the two phases of the study (i.e., observational study and focus groups discussion study). Chapter 8 is the last chapter of this study and includes the conclusions, the strengths and limitations of the study as well as suggestions for future research and implications for policy.

Importance of the present study

Medication errors is an important problem in healthcare because it affects many people and organizations (i.e., patients, healthcare professionals, researchers, healthcare associations and organizations). It is an important problem because is a "high volume" problem, it is a common problem in healthcare sector and it is frequently detected or reported, it constitutes a risk factor for patient safety and because it has a significantly negative impact on health economics (The Joint Commission, 2020; World Health Organization, 2019).

Patient safety is a fundamental parameter of the quality of the care provided and medication errors are threatening patient safety (National Coordinating Council for Medication Error Reporting and Prevention, 2020; Singh et al., 2006). No healthcare organization can argue that they provide quality healthcare service when that service is unsafe. Medication errors constitute a threat for patients. Therefore, healthcare organizations aiming to provide quality services should address the medication errors problem in order to be able to be competitive,

successful and to avoid the risk of being held ethically or legally responsible for harming patients (Gleeson et al., 2020; Zhou et al., 2015).

Despite many efforts and interventions for improving medication safety, medication errors are still a common problem in hospitals around the world (Härkänen et al., 2015; Elizabeth Manias et al., 2019; Morimoto et al., 2011; National Coordinating Council for Medication Error Reporting and Prevention, 2020). There is no reason to believe that in hospitals in Cyprus the situation is different. However, no study has been conducted to date to investigate the problem of medication errors in any hospital in Cyprus. To our knowledge, there is an incidence reporting system, but it is for general incidents, not specifically focusing on medication errors. Also, if there are such internal hospital reviews regarding medication errors, then it can be argued that there is no transparency in review process and results as these pieces of information (if any) are not published or available anywhere. The occurrence and the magnitude of this problematic phenomenon are unknown. Therefore, no intervention plan can be developed or proposed, since the problem remains underdiagnosed (WHO, 2017d). With this study it will be possible to quantify and understand the problem of medication errors and thus be able to inform and propose appropriate interventions for preventing medications errors and enhancing patient safety.

At international level, there is ample evidence regarding medication administration errors, but the important differentiation of this study from previous research and its' contribution to the international scientific knowledge, is that it gives an emphasis on errors of omission. Omission is one of the most frequent type of error detected during the medication process. Previous studies detected errors during the medication process, particularly during medication administration stage, however, the errors reported from most these studies are focusing on errors of commission. In contrast, when it comes to errors of omissions, these are commonly limited to the omission of a dose or of a drug (Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Härkänen et al., 2015). However, additional omissions and deviations from safe drug administration principles are not always detected or reported. In this study, all procedural errors constituting an omission were considered and included in the

observational form and data analysis. Furthermore, two different methodologies were employed for collecting the data; a qualitative and a quantitative methodology, thus a well-rounded picture of the topic under investigation could be obtained. The findings of the present study can inform about the prevalence and types of errors made in medical wards and capture the perspective of nurses of the factors that can contribute to errors. The study used the direct observation method which is considered optimal for the specific field of research (i.e., assessing MAEs prevalence and types) and also by completing two focus group discussions, elucidated more information than can be obtained by only quantitative research. Therefore, the findings from this study can inform and guide the development of future interventions programs for reducing medication errors. They may serve as a fundamental evidence upon which future research can be collated and may contribute to the prevention of medication errors in Cypriot hospitals as well as to the global effort to decrease medication errors and enhance patient safety. Furthermore, there is a scientific interest in cross-country comparisons of health systems and policies among policy analysts and policy makers (Cacace et al., 2013). Patient safety and drug safety are two parameters that are highly considered when evaluating the quality, safety and efficacy of the provided health services (Mitchell, 2008). Thus, the findings of the present study may contribute in comparing or contrasting the magnitude of the medication administration errors problem between different countries and highlight the need to standardize the approaches, methods and tools for future cross-country comparisons by developing, for example, tools that can be applied elsewhere and facilitate discussions on common problems, prevention programs, interventions and policies.

PART I: General Part

Chapter 1

1.1 Study Topic Overview

When patients are admitted to hospitals, they expect to receive the appropriate medical treatment, and should have the assurance that it will proceed correctly and safely so they have the best possible chance of achieving the desired outcome (Kohn et al., 1999; Lassetter & Warnick, 2003). Healthcare providers must maintain an optimal level of quality in the health service they provide and patient safety is an integral part of the quality of healthcare services (WHO, 2017d). National and international organizations have recognized the importance of patient safety. The World Health Assembly (WHA) in May 2019 adopted a resolution entitled "Global action on patient safety" (WHA72.6) to give priority to patient safety as an essential foundational step in constructing, designing, operating and evaluating the performance of all health. Following this, World Health Organization initiated the Global Patient Safety Action Plan 2021–2030, a plan that aims to provide a strategic direction for concrete actions to be taken by countries, partner organizations, health care facilities and WHO to implement WHA72.6. According to WHA (2019), the overall objective is to strengthen health systems globally to diagnose, treat, cure, and care, whilst striving to: "First, do no harm," the celebrated maxim of the Greek physician, Hippocrates (460–375 BC) (WHO, 2021).

Patient safety gained attention in the late 1990's, upon the publication of the Institute of Medicine (IOM) report, "To Err is Human" which reported that approximately up to 98,000 patients die each year from preventable errors in the US only (Kohn et al., 2000; Lark et al., 2018). However, despite this publication, which had presented alarming statistics for organized patients, a decade later the US Office of Inspector General (OIG) published a report which revealed that the number of Medicare beneficiaries who had experienced an event that contributed to their death had reached 180,000 (The Patient Safety Movement,

2021). This led in forming and activating the Patient Safety Movement, an initiative which aims to reduce medication errors by using a collective approach and by involving different stakeholders in the effort. The Patient Safety Movement Foundation is a non-profit organization with a goal of ZERO preventable deaths by 2020. The movement convened the first annual Patient Safety, Science and Technology Summit in 2013, where clinicians, hospital CEOs, patient advocates and government leaders participate and aimed to identify patient safety challenges and provide tested solutions (The Patient Safety Movement, 2021). Furthermore, in January 2019, the Patient Safety Movement Foundation held its 7th Annual World Patient Safety, Science and Technology Summit and announced over 90,146 lives saved because of commitments made by over 4,710 partnered hospitals across 50 countries. This announcement showcased how far the movement have come, and how much further it must go to reach ZERO preventable deaths (Lark et al., 2018; The Patient Safety Movement, 2021). Many organizations around the world, including European governments, patients' organizations and patient representatives as well as healthcare professionals' organizations, have joined forces with the Patient Safety Movement and aim to develop strategies for the implementation of Actionable Patient Safety Solutions (APSS) all across healthcare (The Patient Safety Movement, 2021).

Medication safety is an integral part of a quality and safe healthcare service. No one can consider care that is unsafe to be quality care. Hospitals should be able to deliver care which will have patient safety at the core of their productive procedure. It can be argued that the number of medication errors made during the medication process, is indicative of the level of safety of the provided care. A higher number of medication errors during the medication process reveals suboptimal levels of safety (Härkänen et al., 2019). But before initiating any efforts to decrease errors and improve medication safety is necessary to first measure the frequency and the extent of the problem, identify and map all factors that contribute to the occurrence of the error, and then, based on these findings, develop appropriate, targeted interventions to effectively deal with the problem. Last but not least, the interventions should be evaluated for their effectiveness and efficacy, and an observable decrease in the monitored error rates should be the primary outcome of such interventions. To this end, the present study is a first step for measuring the medication errors problem in Cypriot hospitals and

explore associated factors. Thus, the findings will provide an indication of the intervention needed for mitigating the problem.

1.2 Patient Safety

Despite the advances of the health sciences in the treatment of many diseases, hospitals, the foremost settings where tertiary healthcare is provided within a healthcare system, do not seem to be the safest places for patients. Hospitals continue to be a place where patients can be harmed or put at risk (Crane & Crane, 2006; Härkänen et al., 2019; Sutherland et al., 2019). Healthcare organizations are endeavoring to provide optimal, safe and high-quality healthcare services and dedicate a significant proportion of their resources for this purpose. Patient safety is fundamental in the delivery of quality essential health services (World Health Organization, 2016). Safety and quality in healthcare are necessary for preventing and reducing the risks, errors and harm that occur to patients during their treatment and stay in a healthcare facility. Nevertheless, despite all the effort made, in some cases, they fail to guarantee the provision of the safe and quality service and sometimes people are inadvertently harmed. Unsafe health care has been recognized as a global challenge and collective efforts should be made to understand the causes, the consequences and the potential solutions to this problem (World Health Organization, 2016).

The World Health Organization states that “Patient Safety is a health care discipline that emerged with the evolving complexity in health care systems and the resulting rise of patient harm in health care facilities” (World Health Organization, 2019). However, the problem with patient safety is not a recent one, but it is in fact a very old one. The risk of being harmed by the medical care provided has been discussed many years ago and in particular, has its roots back in Greek antiquity. In fact, Hippocrates was probably the first who described the concept of medical harm. Thereafter, many notable scientists explored this problematic phenomenon. Just after 1950 published papers used the phrase "iatrogenic disease" which actually referred to adverse outcome or injury caused by the healthcare provided (Patient Safety Network, 2020). For national and international health organizations, patient safety is an important and sensitive issue, and reducing patient harm, particularly harm associated

with medication use is a top priority (McLeod, 2013; WHO, 2017d). Practices, interventions and systems for improving patient safety are vital for achieving high safety standards in healthcare (Elden & Ismail, 2016). In fact, since the Institute of Medicine's well-publicized 1999 report “To Err is Human”, the healthcare patient safety movement has grown at an exponential pace (Kohn et al., 2000).

Errors in the provision of health care are major threads and put patients at risk (Kohn et al., 2000). What is an indisputable fact, is the occurrence of errors during the provision of healthcare services (AHRQ, 2010; Patient Safety Network, 2020). As Prof James Reason, a pioneer in the field of human error, stated in an interview regarding human error in healthcare, “there are only two kinds of professionals in health care: those who have unwittingly harmed a patient and those who will unwittingly harm a patient. And that’s the entire population. You don’t, you can’t escape.” (Peltomaa, 2012). Thus, it can be said that errors, cannot be completely avoided when providing healthcare services because of the complexity of the scientific knowledge, the uncertainty of clinical predictions and prognosis, time pressure and the need to make decisions based on limited or uncertain data (Wu et al., 1991).

Error as a concept was unacceptable in the past for healthcare organizations and healthcare professionals did not easily admit of committing errors (D. W. Bates, 2007; Leape, 2009). Doctors used to believe that after admitting that they have committed an error they would on the one hand have to face criticism and further supervision, and on the other hand, feel disappointed and embarrassed, because their colleagues or patients will consider them careless or incompetent. In addition, every error made by a healthcare professional carries the risk of disciplinary and/or legal prosecution (Bernzweig, 1968; Mira et al., 2017; Winning et al., 2018). Similarly for nurses, there is an ethical and mental burden to cope with after committing an error when performing their clinical duties and this affects their personal lives and professional performance (Papastavrou et al., 2014; Sirriyeh et al., 2010).

1.3 Patient Safety as a Global Objective

Since 1990, several publications related to serious healthcare adverse events and their implications on patients' health outcomes in the United States, made all stakeholders, particularly patients, hospitals and healthcare professionals, to turn their attention to the patient safety concept, and to the safety and quality attributes of the care and service they provided (Bates et al., 1993; Kahn, 1995; Leape et al., 1995). In October 1996, in the US, the American Association for the Advancement in Science, the American Medical Society (AMA) and the Joint Commission on Accreditation for Healthcare Organizations, in collaboration with the Annenberg Center for Health Sciences organized the first interdisciplinary conference on patient injury or death due to medical mistakes. In 1997, the AMA established the National Foundation for their Safety Patient (National Patient Safety Foundation, NPSF), an independent non-profit institution, in order to take action on issues related to errors and risks, during the provision of healthcare services (David W Bates, 2001; Leape, 2009). A second Annenberg conference, "Enhancing Patient Safety and Reducing Errors in Health Care," was held on November 8-10, 1998, where several of the panelists called for greater involvement of state and federal regulators, legislators, and consumers and patients in the dialogue concerning patient safety. They also stated that patient safety deserves more attention as it represents a constitutional part of the quality in health care, there is no health care that is "of high quality, but unsafe" (Anderlik, 1998). In 2000, following the publication of the report of the Institute of Medicine on United States (Kohn et al., 1999), which was particularly caustic and revealing for human errors in healthcare, patient safety gained attention and promptly began to be a priority for healthcare organizations and systems and a demand from patients' side. At the same time, it became clear that safety in healthcare depends on implementing effective and sustainable policies and programs, not only at the local and national level but also at the international level, since patients' safety objectives, methods and results, have a worldwide application (D. W. Bates, 2007; Kohn et al., 1999; Pal et al., 2013; WHO, 2019).

Moreover, in the last two decades, the World Health Organization (WHO) has played an important role in the global promotion of safety in healthcare. Major advances have been

achieved, and all these efforts are still ongoing (WHO, 2017b, 2019). The WHO, after recognizing the importance of providing safe health services to patients, in 2002 issued, via the World Health Assembly, a resolution for the quality and patient safety aspects of the care and health service provided (WHO, 2002). The World Health Assembly encouraged Member States to pay particular attention to patients' safety-related issues. In October 2004, WHO presented the "World Alliance for Patient Safety", with the aim of strengthening international cooperation for patient safety (WHO, 2017b). This Alliance published in 2005 an action plan for promoting patent safety. This plan had been based on six pillars: (a) the Global Patient Safety Challenge which concerned the implementation of basic safety guidelines and infection prevention and control principles, (b) the "Patients for patient safety" initiative, which aimed to invite, stimulate and engage patients and their representatives in working towards the enhancement of safety in healthcare provision, (c) the "Taxonomy for patient safety" which aimed to develop internationally accepted criteria for the collection, and classification of adverse events and errors, (d) the "Research for Patient Safety" which aimed to create a focused to patient safety agenda which included relevant research topics, which in turn, enhanced research in the field of patient safety and improved the tools and methods used for measuring the impact of errors on healthcare outcomes and the harm caused to patients, (e) the "Solutions for patient safety", which aimed to disseminate successful interventions and coordinate the efforts to find future solutions for promoting safety in healthcare, and (f) "Reporting and learning" which aimed to establish adverse events reporting systems, the improvement of existing ones and utilizations of the data collected from incidents reporting for learning and educating purposes (Haw et al., 2014; Procter et al., 2017; WHO, 2017b, 2019).

Furthermore, WHO put an emphasis in the prevention of harm caused from medication use and from medicines adverse events. In 2017, WHO launched a third global patient safety challenge entitled "Medication Without Harm", an initiative which had the objective to improve medication safety, after recognizing the fact that medication errors can cause injury and put patients at risk. The medication errors problem constitutes a serious threat to health care systems as it has a substantial negative economic impact. The global costs attributed to

medication errors has been estimated at 42 billion US dollars annually (WHO, 2017d). In 2019, The WHA resolution entitled "Global action on patient safety" (WHA72.6) gave priority to patient safety as an essential foundational step in constructing, designing, operating and evaluating the performance of all healthcare services. In this resolution WHO stressed the importance of medication safety, highlighted some serious and common drug errors. For example, the unsafe injections practices given in health care settings and the consequent transmission of infections, including HIV and hepatitis B and C were included, as well as the direct danger to patients and health care workers that unsafe medication use carries. These type of errors also account for an estimated 9.2 million disability-adjusted life years lost per year worldwide (WHO, 2019). WHO's Global Patient Safety Action Plan 2021–2030, aims to strengthen health systems globally to diagnose, treat, cure, and care, whilst striving to: "First, do no harm," the celebrated maxim of the Greek physician, Hippocrates (460–375 BC) (WHO, 2021). So, it can be concluded that at international level, the efforts of preventing harm during the provision of healthcare, including harm from unsafe use of medicines, is an ongoing, live and collective effort.

In Europe, protecting patients from being harmed is also a priority and patient safety prevention programs have commenced. In November 2005, a workshop was held in London for patient safety ("Patients for Patient Safety Workshop"), and representatives from different countries participated including patients from Europe and the United States who had suffered an adverse drug event with serious health consequences. The importance of the issue was pointed out during the summit and the activities taking place concerning patient safety by bodies such as World Health Organization, the European Union and other scientific bodies were presented (WHO, 2011). Since then, many initiatives, programs and research regarding patient safety has been made.

The European Council Recommendation of 9 June 2009 on patient safety (2009/C 151/01), including the prevention and control of healthcare associated infections, adopted an all-encompassing approach to patient safety at EU-level and proposed an overarching EU-level strategy to promote patient safety and to address healthcare-associated infections. This

Recommendation has lifted patient safety up the political agenda of Member States, and provided an important catalyst for action at EU and national levels (Commission, 2014). Most Member States have taken a variety of actions in line with the Recommendation and embedded general patient safety as a priority in healthcare policies. In fact, several EU-member states have designated a competent authority with responsibility in this area. In addition, most European countries have implemented at a national level plans and strategies to prevent and control healthcare-associated infections. Furthermore, the European commission regularly conducts several surveys (Eurobarometer surveys) regarding patient safety and quality of care in Europe. These surveys are coordinated by the European Commission, Directorate-General for Communication (DG COMM "Strategy, Corporate Communication Actions and Eurobarometer" Unit) and represent useful tools for assessment of the current situation in regards to patient safety and quality of care provided in each EU country. However, there are still various areas of the Recommendation with considerable room for improvement, mainly with regard to providing patients with information about patient safety measures, including the right to complain about misconduct or report unsafe practices and adverse events. Information on how patients can legally protect themselves from inadequate healthcare practices is also included. In 2014, the European commission reported that just over half (53%) of all EU citizens think it is likely patients could be harmed by hospital care in their country and approximately the same percentage (50%) was reported in 2009 (European Commission Directorate-General for Health and Consumers (DG SANCO), 2014).

At national level, many EU countries have adopted different patient safety programs, but still there is much room from improvement. According to the European Commission's Second Report to the EU Council on the implementation of Council Recommendation 2009/C 151/01 on patient safety (2014), patient safety standards were mandatory in 20 countries (11 in 2012) and recommended in four others. 19 countries use patient safety guidelines, in most cases developed at national level, by the health ministry or other nationally dedicated agency (Commission, 2014). Furthermore, patient safety standards were mandatory in 20 countries and recommended in some others. Some European countries use their own patient safety guidelines, but the understanding of standards and guidelines varies across European

countries. Further progress was also reported on establishing reporting and learning systems (Commission, 2014). In addition, the European Centre for Disease Prevention and Control (ECDC), produced several guidance documents and reports to support European Member States in the area of appropriate use of antibiotics and evidence-based guidance to improve the compliance of healthcare professionals with appropriate administration, timing, dosage and duration of perioperative antibiotic prophylaxis for the prevention of surgical related infections (Commission, 2014).

Many European countries have initiated programs for promoting patient safety. In 2020, the Swedish National Board of Health and Welfare created a National Action Plan for Increased Patient Safety, which aimed to help developing and coordinating work on patient safety in the country (National Board of Health and Welfare, 2020). In Germany, patient safety became a major socio-political and health topic over the past decade and research was conducted with a focus on patient safety. The Institute for Patient Safety (IfPS) was founded in January 2009 and was the first academic institute in Germany explicitly focusing its research and educational activities on patient safety (The Institute for Patient Safety, 2009). In France, implementation of patient safety activities mainly developed after the "contaminated blood crisis" in the mid-eighties, when a large number of patients contracted HIV after transfusion of unsafe blood; healthcare professionals and politicians, including the prime minister and the minister of health, were pursued (Mougeot et al., 2017). A French law of 9 August 2004 defined the targets concerning reduction of "iatrogenic events" and the first national patient safety program was launched by the French Ministry of Health in 2013 and in the same year the French national authority for health stated a patient safety mission. Health professionals are now actively involved in the reduction of medical and nursing errors in France (Mougeot et al., 2017). In 2017, Italy enacted a new law on patient safety and health professionals' responsibilities and recognized that "Patient safety is a fundamental right of each individual within any healthcare service and it is a primary goal of the national healthcare service." (Bellandi et al., 2017). However, not all European countries seem to have established national agencies that are purely dedicated in protecting and/or promoting patient safety.

In Cyprus in particular, there is no agency solely focusing on patient safety. There are several departments and offices in the Ministry of Health that their mandates include the promotion of patients' interests, including patient safety, however, as this responsibility is not the pure mission of a dedicated office, probably is not gaining the attention it should. For example, there is the Patients´ Rights Commission, which actually functions as a complaint investigation committee, however, its main general, formal goal is to become a participant and contributor in rebuilding the health system and to upgrade the quality of service provided to the citizens (MINISTRY OF HEALTH, 2021). Also, after the introduction of the new national health scheme in Cyprus (i.e., 2019), the government in 2019 established a new independent, autonomous office called 'Commissioner of the supervision of national health system'. However, the role of this office seems to be mainly limited to exploring the report of complaints regarding any action or omission of the healthcare providers, and overseeing the implementation of the new health system. It can be assumed that its mission also includes the investigation of complaints regarding errors and omission during the provision of healthcare. However, according to the information uploaded in the respective office's website, the commissioner role seems to be focusing (and limited) to reporting problems and making suggestions than taking active prevention action. If a case or a complaint is brought to justice (i.e., court of law) the commissioner cannot interfere or being involved further. Also, after almost three years of the establishment of this office, its website is still under development and there is no evidence or other information on the work or on the output of this office (Επίτροπος Εποπτίας του ΓεΣΥ, 2021).

On the contrary, in the US, patient safety has gained the attention of all stakeholders and several advances have been accomplished in this field. In 2005, the federal Patient Safety and Quality Improvement Act of 2005 (PSQIA) was developed in response to the Institute of Medicine report, To Err Is Human. The Agency for Healthcare Research and Quality (AHRQ) oversees the Patient Safety Rule. The Agency for Healthcare Research and Quality (AHRQ) is the lead Federal agency and has the responsibility of improving the safety and quality of America's health care system. AHRQ develops the knowledge, tools, and data

needed to improve the health care system and help Americans, health care professionals, and policymakers make informed health decisions. AHRQ aims to help health systems and healthcare professionals to deliver quality and safe healthcare service. Additionally, it promotes research in patient safety area and produce evidence about how to deliver a high-quality, safe and high-value healthcare. AHRQ has initiated the Patient Safety Network (PSNet) which is a web-based resource featuring the latest news and essential resources on patient safety. The PSNet provides a variety of formats, including literature, research, tools, and Web sites. (AHRQ, 2010; Patient Safety Network, 2020).

1.4 Drug safety and medication errors

In healthcare provision there is a huge dependence on drug therapy since is the primary intervention for most illnesses, therefore patients receiving medication treatment are exposed not only to the respective benefits, but also to potential harm due to unsafe medication practices (Hughes & Blegen, 2008). Medication safety can be defined as the freedom from accidental injury during the provision of healthcare, particularly during the medication process (American Society of Hospital Pharmacists, 2018). Patients may get seriously injured or their stay in hospital can be prolonged as a result of a medication error (Bates et al., 1993; D. W. Bates, 2007; Härkänen et al., 2019; Keers et al., 2013). They also may experience psychological, mental and physical pain and disturbance as a result of medication errors (Tariq et al., 2020).

Medication errors also contribute to a decreased patients' satisfaction and, as a result, people's trust in the healthcare system may be inevitably broken. Aside from the negative impact on the quality of the care provided, medication errors have also economic implications. In fact, medication errors constitute a substantial economic burden (Choi et al., 2016; Hernández Martínez et al., 2015). Globally, the annual cost associated with medication errors has been estimated by World Health Organization (WHO) at $42 billion USD (WHO, 2017d). Improving patient safety is intertwined with improving medication safety and therefore is also related to the reduction of medication adverse events. The economic benefits of improving patient safety are well recognized by healthcare providers (Blignaut, 2015;

Walsh et al., 2017). There is evidence that additional hospitalization, litigation costs, and medical expenses have cost some countries between US$ 6 billion and US$ 29 billion a year (Blignaut, 2015; Walsh et al., 2017; WHO, 2017d). In Europe, the annual cost of medication errors is estimated between €4.5 billion and €21.8 billion (European Medicines Agency, 2013). In UK only, it is estimated that 237 million medication errors occur at some point in the medication process annually (Elliott et al., 2021). Adverse drug events are estimated to cost the NHS £98 462 582 per year, consuming and causing/contributing to 1708 deaths (Elliott et al., 2021).

Thus, when considering the frequency of errors during the medication process and their contribution to the cost of the provided health service, healthcare organizations and systems should be alarmed and of course take appropriate action to face this problem. Medication safety deserves more attention, given the scope of medication use in patient care and the frequency and severity of potential harm (Cohen et al., 2018).

1.5 The theoretical background of Human Error in Healthcare

It is not easy to define error despite the several efforts made by researchers, national and international organizations (Yu et al., 2005). There is no single definition that can be used to perfectly define the word error (Aronson, 2009; Ferner & Aronson, 2006; Gold et al., 2010; M. Lisby et al., 2012; Runciman et al., 2009). Errors, mistakes, lapses, slips, failures, deviations, faults, misses and near misses, omissions, misconducts, malfunctions, slights, glitches, dysfunctions and many other terms have been used to describe or refer to an erroneous action or a problematic situation, but each word has slightly different meaning and comes with its own shortcomings. The term “accident” is nonetheless not used and should be avoided when the discussion concerns injury during healthcare provision (Davis & Pless, 2001). Actually, in healthcare it is discouraged to use of the term “accident” when refer to injuries or the events that produce them. This is because an accident is often perceived by people as an unpredictable event (i.e., "act of God") and therefore, unavoidable. However, most adverse events and the harm they cause, as well their precipitating events, are predictable and in most cases are also preventable (Davis & Pless, 2001).

The error definition stated by James Reason, a pioneer in the research of human error, is one of the most popular, endorsed, adopted by many organizations and industries and widely used in many error-related studies, papers and reports. It is extensively employed in healthcare research as well. Reason (2000) defined error as a failure of a planned action to be completed as intended (i.e., error during the execution phase) or the use of a wrong plan to achieve an aim (i.e., error during planning phase). According to Reason (1990), error is the failure of a predesigned sequence of mental and physical activities in achieving the desired result, since these failures cannot be attributed to the interventions of some random events (J. Reason, 1990). Therefore, it can be concluded that error is any deviation from an agreed plan or from the desirable outcome.

The last three decades, along with the advances achieved in the treatment of many diseases, the safety and quality of the health care provided foregrounded and gained attention. There was a need to develop an approach, a tool aiming to understand the hazards and threads jeopardizing patients' safety and promote safety in healthcare by supporting healthcare professionals and health organizations to achieve this target. Healthcare is a high risk, complex, and sensitive sector. To this end, it seems that several theories of error (or for preventing errors) have been developed and described in the literature.

For example, there is the Eindhoven Classification Model which aims to help, among other business sectors, healthcare organizations develop strategies to decrease errors. The Eindhoven Classification Model concerns incident causation and identifies three main causes of error: human operator, organizational and technical failure (Vuuren, van, W., Shea, C. E., & Schaaf, van der, 1997). In addition, there is the Charles Vincent's framework for the analysis of clinical incidents, which is also known as the London Protocol, which actually builds on Reason's organizational accidents model to provide practical examples of the various failure types relevant to a healthcare context. Charles Vincent's framework provides a broader view of the information needed to create and sustain safer care (Vincent et al., 2014).

Emphasis, however, is placed on Reason's theory, which is widely acceptable, and is relevant for different high-risk industries and disciplines, including the healthcare sector. Reason's theory suggests that the human error has two constitutional dimensions, and can be explored in two ways: the person approach and the system approach. The person approach focuses on the errors of individuals, and suggests that people may forget, maybe not engaged in the work and may demonstrate unprofessional behavior or moral weakness, and hence, fall into erroneous actions. According to the human approach, errors, lapses and mistakes are attributed to deviant mental processes such as negligence, inattention, carelessness, or recklessness. Based on the person approach, when an error occurs, the person who committed the error may face disciplinary and legal charges. Usually, errors are treated as ethical issues and it is often argued that "bad things happen to bad people ". Thus, it is the person that is blamed, not the system. The system approach focuses on the conditions under which individuals work and tries to create barriers for preventing errors and failures (Reason, 2000). Reason's theory argues that the good practices and systematic mistakes are two sides of the same coin. A broad analysis of the recurring mistakes that occur during daily activities, tasks, is essential in order to understand the hidden processes that affect human thought, cognitive processes and actions.

The system approach focuses on system attributes and errors are to be expected, even in the best organizations. Errors are viewed as consequences rather than as causes which are due to systemic factors. The basic principle of the system approach is that since we cannot change human nature, we can change the conditions under which people work. To this end, when an adverse event occurs, the important thing is not identifying the individual who caused it and punishing him/her, but how and why the system failed and allowed the mistake to happen. The choice of punishment of individuals for their mistake leads to hiding the errors (and accidents) due to the fear of punishment. On the contrary, the prerequisite must be the recognition of the error, the understanding about its causes and developing strategies to tackle the system failures that cause the error. Of course the human and system approach are efficient only if they are viewed and improved together as integral parts of an organization (James Reason, 2000; Veazie et al., 2019). In fact, Reason likened the efforts addressing the

“person approach” to the effort that one makes to kill the mosquito that bit him and the efforts addressing the “system approach” with the effort to drain the swamp which is the mosquitoes natural reproductive environment (J. Reason, 1990; James Reason, 2000).

Erroneous actions and malfunctions that potentially take place in routine tasks, are many in numbers and can be detected in different stages of the productive process. However, although many mistakes can occur in any stage of even simple processes, in fact only few of these mistakes will eventually penetrate the various defense mechanisms and barriers set by the system, so only few of these mistakes will cause an adverse event. Since the errors passing through the preventing walls are neither so many nor so varied, then they maybe predictable. Therefore, taking the right steps, errors can be prevented. However, to achieve a satisfactory reduction of errors, according to Reason’s theory, one should build appropriate preventing mechanism which will address both; the human factor and the system factor (James Reason, 2000).

The High Reliability Organization Theory shares common elements with Reason’s theory of error. According to High Reliability Organization Theory, accidents can be prevented through the proper management and motivation of the staff of all levels and through the efficient and correct use of equipment and technology (Veazie et al., 2019). In addition, organizational planning and efficacious management can achieve satisfactory levels of safety even when conducting hazardous activities. Although accidents cannot be completely limited, high reliability organizations must be judged on a risk-benefit basis, implying that the benefits deriving from their operation must significantly overweight the risk of an accident (Veazie et al., 2019).

High reliability organizations, such as nuclear power stations, armies and aviation control authorities, which are considered and expected to have much less incidents, errors or deviation from their safety principles (and of course near to zero accidents), are always focused on the possibility of failure (James Reason, 2000). They put substantial proportion of their resources on building error preventing mechanisms. Healthcare systems and some

healthcare settings in particular (e.g. intensive care units) should be considered to act as a high reliability organization and should recognize that human variability is a tool that should be utilized in any error preventing effort (James Reason, 2000). It is preferable by organizations and in some cases by different groups of people, to blame individuals for an error or an accident than targeting institutions and systems. It is also economically more efficient and emotionally more satisfying as well (James Reason, 2000). But is wrong and maybe unethical. High reliability organizations are the prime examples of the system approach. They expect the worst and prepare themselves to deal with it, they put safety measures in place, at all levels of the organization, in an effort to prevent future failures (James Reason, 2000; Veazie et al., 2019).

1.6 Conceptual and operational definitions of medication errors

It seems that there is some difficulty in finding a generally accepted definition for medication errors. A preliminary search in the published literature indicates that it is challenging to establish a widely accepted definition of medication errors. While several definitions were proposed for medication errors by previous studies, there is still lack of an internationally standardized term that clearly defines what constitutes an error, error cause, or contributing factor (Escrivá Gracia, Brage Serrano and Fernández Garrido, 2019).

A medication administration error can be defined as “a deviation from the prescriber's medication order as written on the patient's chart, manufacturers' preparation/administration instructions, or relevant institutional policies” (Keers et al., 2013). Medication errors are defined by the United States National Coordinating Council for Medication Error Reporting and Prevention 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” (National Coordinating Council for Medication Error Reporting and Prevention, 2020). Finding a globally standardized and acceptable term for errors seems to be a great challenge. It is difficult to define “error”. To define something (Latin definire) is to determine its boundaries (Latin fines), and hence to state exactly what the thing is or to

explain its essential nature; this is what Aristotle called “το τι ην ειναι” which literally means, that which is (Aronson, 2009). Interestingly, Aristotle believed that the opposite meaning of error is truth.

Aronson (2009) states that an “error” is an action done incorrectly due to ignorance or inadvertence; a mistake, or a failure to complete a planned action as intended, or the use of an incorrect plan of action to achieve a given aim (Aronson, 2009). Reason (1990) defines "error" as a general term that included all of the cases where a predesigned sequence of mental and physical activity fails to achieve the desired result, since these failures cannot be attributed to the interventions of some other random events (Reason, 1990). Leape (1994), defines as "error" any pointless action (performed or even omitted) or action which does not lead to the expected result. A similar definition is given by Kohn et al. (2000), who defined error as the failure of a planned operation to be completed as was designed or use the wrong design to achieve a goal. Senders (1993) defines as "error" the failure to execute a deliberate task which was the most appropriate, given the specific conditions. Essentially, it combines the concept of error with respect to consequences, however, clarifies that a mistake does not always lead to an undesirable or serious result. Interestingly, minor inconsistencies in the definition of “error” may be observed even between dictionaries. According to the second edition of the dictionary of the Modern Greek Language by Babiniotis (2005), "error" is defined as anything that deviates from the rule, something that is not done or said in the right way. The Collins English Dictionary defines “error” as something you have done which is considered to be incorrect or wrong, or which should not have been done (Collins English Dictionary, 2020).

As with the term error, the term “medication error” is also not yet precisely or catholically defined. Until now, there has been significant variability among the terms used for defining medication errors and classifying consequences e.g., error, failure, near miss, rule violation, deviation, preventable adverse event. While other phenomena in health care are adequately defined with widely standardized definitions, on the contrary, no single definition is currently being used to define medication errors. A systematic literature review identified 26 different

terminologies employed for a medication error and confirmed the inconsistent use of definitions (Lisby et al., 2010). However, despite the inconsistency among the terms used in the literature, still it would be useful to be aware of these different definitions.

Medication administration errors can be defined as “a deviation from the prescriber's medication order as written on the patient's chart, drug manufacturers' preparation/administration instructions, or relevant institutional protocols, guidelines or policies” (Keers et al., 2013). This is a comprehensive definition; it covers different types of errors that can potentially be made during the medication process and this definition was adopted for the conduct of this study.

1.7 Errors of omission and errors of commission

An error of omission is “a failure to carry out the necessary steps in the performance of a task” (J. Reason, 2002). Reason (2002) explains that there are four distinct stages in the performance and completion of a task or action; planning, intention storage, execution, and monitoring (Figure 1). Any malfunction, misconduct or issue in any of these steps can lead to an omission, however, it is not easy to identify the precise cognitive processes that were involved in omitting one or more of these four steps when performing a task and even the person who made the error cannot easily discover the cause of the failure (J. Reason, 2002).

Summary of the possible processes involved in omitting a necessary item		
Level of Failure	**Nature of failure**	**Failure type**
Planning and intention formation	A necessary item is unwittingly overlooked	Mistake
	The item is deliberately left out of the action plan	Violation
Intention storage in prospective memory	The intention to carry out the action(s) is not recalled at the appropriate time	Lapse
Action execution	The actions do not proceed as intended and a necessary item is unwittingly omitted from the sequence	Slip
Monitoring	The actor neither detects nor corrects the prior omission	Slip or violation

Figure 1: Summary of the possible processes involved in omitting a necessary item (Adapted from Reason, 2002)

It seems, at least from a legal point of view, that there is a gap, a difference, between acting in a wrong way and omitting to act in the right way. For example, is letting someone die as bad as killing? Sometimes, omissions are not considered, perceived or approached in the same way as with commissions, as these actions are different in many ways (Spranca et al., 1991). More specifically, omissions may result from ignorance or lack of knowledge, but commissions usually require effort, or they may even involve hostile or more vicious motives. In addition, omissions can refer to missed actions, unexecuted tasks, on the other hand, commissions usually concern erroneously or inappropriately executed actions or task, so require effort to be made. Errors of commission are considered more serious by people, and there is a perceived understanding among stakeholders that injury caused by acts of commission, is often more critical or serious, in comparison with injury caused by acts of omission (Hayward et al., 2005). This is a phenomenon often referred to as ‘‘omission bias” (Hayward et al., 2005; Spranca et al., 1991). For example, people have the perception that a death resulting from the administration of a drug is much worse than a death resulting from not getting the drug. However, omissions are unlawful acts, as they often represent cases of professional negligence (Hayward et al., 2005; Kalisch & Xie, 2014; Spranca et al., 1991). While errors of omission represent the failure of making the correct action, like omitting to disinfect the site of injection when administering an injectable drug, commission errors, on

the other hand, are mistakes that consist of doing something wrong, such as administering a wrong drug, or administering the right drug but at the wrong time.

In the healthcare sector, omissions seem to be much more common than commission errors. The risk of iatrogenic harm resulting from errors of commission when using the huge number of healthcare treatments and services has increased, and so has the potential of causing serious injury and death from inadequate, incomplete, omitted or missed care. In fact, when it comes to medication safety, there is some evidence suggesting that omissions are the most common type of medication error (Härkänen et al., 2015; Keers, et al., 2013; Kim & Bates, 2013). Therefore, they represent a bigger problem particularly when it comes to medication errors. Healthcare professionals, when they make an error of omission, they may be accused of professional negligence particularly when patients are in anyway harmed by that omission during their hospitalization (Giannetta et al., 2020; James Reason, 2000; Wu et al., 1991). Omissions have been associated with poor healthcare outcomes and they increase the risk of putting patients at risk (Kalisch & Xie, 2014; Spranca et al., 1991). There is evidence for example, suggesting that a large proportion of all hospitalized patients are being placed in jeopardy because of errors of omission (Brady et al., 2009; Kalisch & Xie, 2014; Keers et al., 2013).

In many previous studies investigating medication errors, the omission of administering a prescribed dose without a valid clinical reason, was defined as an error of omission. In fact, this type of omission was the only type of omission error recorded and this type of error was either the first or second most frequently recorded type of error in these studies (Haw et al., 2007; Lisby et al., 2005; Truter et al., 2017). Also, different types of errors of omission are described in the literature. Omissions have been detected in all stages of the medication process and even within each stage of the medication process different subtypes of omissions have been found (Hughes & Blegen, 2008; Shawahna et al., 2019). For example, omissions have been detected in the prescription stage, like omitting to describe one drug even though indicated or omitting to correctly complete the prescription (e.g., omitting to state the starting date of the treatment on omitting to specifying the formulation or the route when needed).

Also, one study reported other type of omissions that were detected during the administration stage, such as omission in the "five rights" principles of medication administration (right patient, drug, dose, route, time), or omission in the basic infection control principles (Kim & Bates, 2013).

During the medication administration process, it is difficult to understand the real causes of errors of omission because omissions may be attributed to many different causal factors. For example, omissions may occur due to lack of knowledge or due to the huge workload and the stress that is put on staff (Bisht et al., 2014; J. Choo et al., 2014; Härkänen et al., 2015; Tenhunen et al., 2014). Omission errors are also caused by the availability of non-stock drugs and through difficulty in locating stock drugs prescribed generically but supplied in brand name packaging (Bavle & Andrade, 2016; Miljković et al., 2019; Salmasi et al., 2015; Tranchard et al., 2016). Additionally omission of a medicine or a dose could be the result of a problematic or insufficient communication between the prescribers or between changes after medical and surgical consults or due to prescriptions of bad quality (Brady et al., 2009; Keers et al., 2013).

1.8 The medication process: An error-prone process

Pharmacotherapy is an important part of the healthcare provided to inpatients, is also a resource-demanding process (Choi et al., 2016; Härkänen et al., 2019) and there is an obvious correlation between medication errors, patient safety and quality of the care provided (Hughes & Blegen, 2008; Zhou et al., 2015). Medication errors are common in clinical settings and patients face the risk of being harmed as a result of involuntary actions during drug treatment (Giannetta et al., 2020; Härkänen et al., 2015). Reports of coroners in the United Kingdom (UK), have led to wider publicity for rare but potentially fatal drug errors (Ferner, 2014; Ferner, Easton and Cox, 2018). Previous research suggests that medication administration errors only (i.e. excluding prescription, preparation or dispensing) occur in 5% of non-intravenous and 35% of intravenous doses (McLeod et al., 2014) or up to 20% of all doses given (Härkänen et al., 2015; Keers et al., 2013). However, significantly higher

rates of errors were reported in other similar studies, particularly with parenteral medicines (Cousins et al., 2005; Fahimi et al., 2008; Keers et al., 2013; Taxis & Barber, 2003).

The medication process, particularly in hospital wards is a multistage, multidisciplinary process involving physicians, pharmacists, nurses and patients. In healthcare settings like hospitals or community and primary healthcare centers, different healthcare professionals are involved in the medication process, like nurses, physicians and pharmacists. For physicians and nurses, the medication process is an integral part of their work, while for pharmacists, the medication process and drug management are the main core of their work. This multidisciplinary process has many stages until being concluded, but there are five different procedures, five distinct steps in this process, and all of these steps are prone to errors. The five stages of the medication process include: (a) ordering and/or prescribing, (b) transcribing and verifying, (c) dispensing and delivering, (d) preparing and administering, and (e) monitoring and reporting (Institute of Medicine, 2007). However, the rates of error in the stages of the medication process vary and are associated with many and different contributing factors (Härkänen et al., 2015; Hughes & Blegen, 2008).

Prescribing/ordering:

Prescription errors are a common and a hazardous problem as it may cause patient harm. In this stage, the wrong drug, dose, or route can be ordered, or even drugs to which the patient has known allergies. Prescription errors also include (but not limited to) prescriptions with a wrong identification, poor quality (particularly when hand written) and incomplete prescriptions. Prescriptions in which a drug or dose or other required piece of information was omitted, were found in 72.1% in at least one study (Murphy et al., 2014). Other studies exploring prescription errors, also emphasized the importance of other healthcare professionals' contribution, like pharmacists, in the identification and correction or resolution of potential prescribing errors. In fact, pharmacists can have an important role in intercepting and preventing prescribing/ordering errors (Anderson et al., 2016; Hughes & Blegen, 2008; Institute of Medicine, 2007; Khalili et al., 2011; Leone et al., 2013; Murphy et al., 2014; Olsen et al., 2007).

Transcribing and verifying, Dispensing and Delivering:

In some settings, both nurses and pharmacists are involved in transcribing, verifying, dispensing, and delivering medications. Transcription and verification of orders and prescription is not a common practice in all healthcare settings, but it is very common practice in hospitals and tertiary healthcare settings (Hughes & Blegen, 2008). However, with the extensive use of information technology, the problem with hand-written prescription or records has been reduced (Akiyama et al., 2010; Marini & Hasman, 2009). For example, the use of electronic records and prescriptions, the use of automated drug cabinets or bar-code assisted administration of drugs in hospital wards has helped in reducing medication errors (B.D. Franklin et al., 2008). Physicians prescribe medications and then nurses (or ward pharmacists, if any) transcribe the medications prescribed by physicians, on specific order transcripts, or via an electronic system where applicable, to obtain these medications from the ward pharmacy (if any) or in many cases, from the central hospital pharmacy. Upon arrival of these transcripts to the pharmacy, pharmacists dispense the respective prescribed medication, corresponding volumes and doses. Medications are then distributed and administered to the patients, usually by the ward nurses (Hughes & Blegen, 2008; Shawahna et al., 2019). Pharmacy dispensing errors also common and have been found to range from 4 percent to 42 percent of all adverse drug events (Håkonsen et al., 2010; Tariq et al., 2020; Walsh et al., 2006; Weingart et al., 2010). In these two stages (transcribing/verifying, and dispensing/delivering) errors mostly concern failures in the correct transcription and verification of the prescription, incorrectly filling the order, and failure to deliver the correct medication for the correct patient (Hughes & Blegen, 2008; Shawahna et al., 2019).

Medication administration:

This stage is usually performed by nurses, particularly in tertiary centers and hospitals. In hospital wards, in which there is an absence of a pharmacist (i.e., clinical or ward pharmacist), nurses are, in addition to administering the drugs, responsible for transcribing and verifying prescriptions/orders and charts, preparing the medicines of their ward, as well as for the storage and handling in the ward's medication room. This is of course a challenge for them as it is not their only task in a ward. In addition, the administration of medicines is

the most prone to error stage of the medication process. As research showed, most medication errors are medication administration errors (Härkänen et al., 2019; Hughes & Blegen, 2008; Shawahna et al., 2016). Medication administration error rates considerably high, in several studies more than 60 percent of all administered doses have been reported to be with one or more errors, including wrong time, wrong rate, or wrong dose or wrong patient (Basil et al., 2019; Fahimi et al., 2008). In other studies, approximately one out of every three ADEs were attributable to nurses administering medications to patients (Hughes & Blegen, 2008; Wondmieneh et al., 2020). Furthermore, research indicated that in the administration stage of the medication process omissions are among the most commonly detected types of error (Brady et al., 2009; Cousins et al., 2012; Härkänen et al., 2015; Haw et al., 2014; Keers et al., 2013).

Monitoring and reporting:

In the effort to safeguard and promote patients' safety, monitoring, reporting and preventing medication errors is crucial. Monitoring and reporting programs encourage adverse drug reactions surveillance, facilitate the documentation of such events, errors in particular, promote the reporting of medication errors, and enhance the safety of medication use in healthcare settings and nursing homes (American Society of Hospital Pharmacists, 2018; Goldspiel et al., 2015). Last but not least, monitoring and reporting of adverse drug events stimulate and promote research on the field, development and evaluation of relevant interventions and also stimulate the education of health professionals regarding potential adverse drug events, including medication errors (Giannetta et al., 2020; Kunac & Tatley, 2011; B. J. Wakefield et al., 2015; Johanna I Westbrook et al., 2015). Unfortunately, while the contribution of a medication errors monitoring and reporting program or service is recognized by most researchers and healthcare organizations, still such programs or interventions are not available in all healthcare settings (Golder et al., 2016; Raschi et al., 2016; Tanti et al., 2015).

However, for nurses, the medication process is a substantial part of their daily nursing duties. It is also a demanding and challenging part of nurses' work and they are expected, by other

healthcare staff and by patients, to be able to detect and prevent errors and protect patients. It can be said, therefore, that nurses are the final stage of defense in the medication process (Marja Härkänen, 2014). Since nurses have an important role in the medication process, it is crucial to explore their perceptions of medication error associated factors, before drafting plans to limit drug errors in a ward and improve patient safety (Cooper, 1998). Clinical nurses spend much of their working time in preparing and administering medicines (Härkänen et al., 2015). Medication administration in hospital wards is a complex process, involves different healthcare staff and is a live procedure where anything at any time may need to change (Brady et al., 2009). Nurses along with other healthcare professionals, therefore, are involved in a prone to error procedure (Giannetta et al., 2020; Härkänen et al., 2015). The occurrence of medication errors made by nurses in clinical wards may be related to different factors, such as professional practice environment and related factors, including leadership and management, monitoring, staffing, work allocation, detractions and/or interruptions, drug related factors, procedures, and systems, including prescribing, communication and managing procedures; and nurse related factors such as experience, knowledge and physical or mental status, and patient related factors such as health condition, age and polypharmacy (Brady et al., 2009; Härkänen et al., 2015).

Medications errors can be detected in all stages of the medication process (i.e. prescribing, dispensing or administration), however errors during the administration process are the most commonly detected type of medication errors (Cousins et al., 2012; Härkänen et al., 2019) and the medication administration stage of the medication process considers to be susceptible to errors (Härkänen et al., 2017a, 2019). In addition, the majority of medication incidents are medication administration errors (Härkänen et al., 2019). In the United Kingdom, medication administration errors (MAEs) in hospitals account for the majority of patient harm and deaths (Cousins et al., 2015; Rodney W. Hicks et al., 2004).

Common types of medication administration errors include omitted doses, timing errors, documentation errors and handling errors (Härkänen et al., 2015; Keers et al., 2013b). Omissions are among the most frequently detected MAEs (Härkänen et al., 2015; Keers et

al., 2013b). In many previous studies, omission was defined as the failure to give an ordered dose or a prescribed drug, and that was the only type of omission recorded (K N Barker et al., 2002; Haw et al., 2007; Marianne Lisby et al., 2005). However, additional errors of omission may exist, like deviations from the basic infections and safety regulations (Kim & Bates, 2013). According to the literature, factors associated with the occurrence of medication administration errors varied and differentiate among different environments and different studies. These include factors associated with health care professionals (e.g. inadequate drug knowledge or experience, physical or emotional fatigue), factors associated with patient characteristics (e.g. clinical condition, age, polypharmacy), factors associated with the work environment (e.g. staffing, distractions and interruptions, communication between health care professional and patients), and factors associated with the medicines administered (e.g. form and type of medicines) (Bates et al., 1999; Härkänen et al., 2015; Hellström et al., 2012). In addition, other organizational factors, like the patient safety climate and/or safety culture of the organization, are relevant with the prevalence of errors (Gleeson et al., 2020).

Moreover, several prevention plans were employed to decrease errors according to previous studies. Some of the interventions implemented to limit MAEs include quality improvements (Zhou et al., 2015), health information technologies, such as bar code medication administration systems (Bryony Dean Franklin et al., 2007; Helmons et al., 2009; Jheeta & Franklin, 2017; Warrick et al., 2011), and training or education the personnel (Nguyen et al., 2014). However, research in the field indicates that the problem is still present and more effort is needed to be further decreased (Härkänen et al., 2019; Keers et al., 2013b; Safholm et al., 2019).

1.9 Medication safety and nurses

For nurses, the medication errors problem is an important issue. As mentioned above, the medication process is a substantial and integral part of nurses' daily work. It is also a demanding and challenging part of nurses' work and they are expected, by other healthcare staff and even more by patients, to be able to detect and prevent errors and protect patients.

Clinical nurses spend much of their working time in preparing and administering medicines (Brady et al., 2009; Härkänen et al., 2015; Martyn et al., 2019). Therefore, they are involved and exposed to a process where errors can be easily made.

It is the nurses' responsibility to understand the medication orders correctly, prepare the medication doses correctly and correctly administer the medication in order to ensure that the right patient received the right drug in the right dose, at the right time, via the right route and in line with the approved administration method of each medicine administered (Härkänen et al., 2015). Nurses receive training during their undergraduate studies as well as during their clinical practice of the importance of adhering to the five rights of the safe medication administration. These "rights" of medication administration include right patient, right drug, right time, right route, and right dose. These "five rights" are critical for nurses, they consist basic nursing knowledge and nurses are expected not only to be aware of them but also be adhere to these principles (Hughes & Blegen, 2008; Kim & Bates, 2013). Nurses are expected to possess a comprehensive medication competence in order to be able to conduct their duties safely and effectively. Upon graduation, nurses are expected to be able to administer medications correctly and safely (Blignaut, 2015; Kim et al., 2016). However, in several cases, problems in the knowledge and skills of healthcare professionals have been noted. For example, in Finland, the Ministry of Social Affairs and Health, raises awareness about the knowledge regarding safety in pharmacotherapy and had previously noted that nurses' know-how of pharmacotherapy was somehow incomplete (Finnish Ministry of Social Affairs and Health, 2009; Samsiah et al., 2016; Sneck et al., 2016). Of course, similar reports have been issued by different authorities around the world. In UK, the National Institute for Health and Care Excellence (NICE) recommends an annual review of staff knowledge, skills and competency. Also, the Nursing and Midwifery Council (NMC) in the UK sets standards for administering medicines and to that end, in order to be eligible for inclusion in the NMC register, nurses must keep their knowledge and skills up-to-date and ensure that their practice satisfies the NMC's standards (Care Quality Commission, 2020). For maintaining a high level of medication competency among nurses involved in the medication process, regular training programs should be considered for the nursing staff. Training and education play an important role for stimulating and helping the staff to be engaged to the medication safety

principles. However, training should be incorporated with other medication safety efforts, like reporting errors, introduction of appropriate electronic systems and/or records for error reporting and monitoring and enhancing the working environment and related working conditions (Elnour et al., 2008; Richard N. Keers et al., 2014; Niemann, Bertsche, Meyrath, Koepf, Traiser, Seebald, Schmitt, Hoffmann, Haefeli, Bertsche, et al., 2015; Sneck et al., 2016). It is important to ensure adequate medication competence to guarantee the safe and effective administration of medicines by nurses to inpatients. Nurses should consider the medication process as a part of the patient care process. This includes understanding why, how and what kind of medication is administered to each patient. Involvement in the medication process requires pharmacological, physio-pathological and ethical knowledge and skills (Blignaut, 2015; Finnish Ministry of Social Affairs and Health, 2009; Härkänen, Vehviläinen-Julkunen, et al., 2020). In some cases, additional skills are required, like the preparation of injectable drugs or the preparation extemporaneous forms or handling hazardous medications (e.g., anticancer or diagnostic agents). All this different knowledge should be integrated into undergraduate courses in nursing schools or into training programs or other professional development programs for nurses.

In addition, the professional development program of nurses should contain training courses relevant with medication administration process. In Cyprus, the national law for Nursing and Midwifery foresees the continuous training and development of nurses and requires, among other things, the participation of nurses in different training programs or seminars in order to maintain an active practice nursing license in Cyprus.

Moreover, nurses should be able to work in an appropriate working environment and optimum working conditions. This means that healthcare organizations should be able to provide optimum working environment. Optimum conditions mean error-preventing conditions. However, in many cases healthcare organizations fail to create the conditions needed for nurses and other staff, to work in a safer and efficient manner. Not only they fail, but as previous research suggested, in some cases there are problematic working conditions, failures in the standard procedures, weak leadership, lack of basic equipment or technological applications and other systemic problems create a prone to errors environment (Aldawood et

al., 2020; Härkänen, Vehviläinen-Julkunen, et al., 2020; Kiwanuka et al., 2020; Schneider et al., 2019).

1.12 Importance, originality, and contribution of this study

According to the Joint Commission (2020), the importance of a problem is determined by its effect size (high volume), its frequency (problem prone), the risk it carries (high risk) and /or its cost (high costs). Based on this approach, medication errors are an extremely important problem in healthcare because it affects many people and organizations (i.e. patients, healthcare professionals, researchers, healthcare associations and organizations), therefore is a "high volume" problem, it is also a common problem in healthcare sector, therefore is frequent, it constitutes a risk factor for patient safety and because it has a significantly negative economic impact on health economics (The Joint Commission, 2020; World Health Organization, 2019). In addition, the fact that in the last two decades many studies exploring the different aspects of the medication errors problem have been published, is at least indicative of the importance of the medication safety issue for healthcare stakeholders and for the research community as well. It is also noted that despite the different studies conducted in the field of medication errors, the problems still exist and is a major handicap for the quality of the healthcare provided.

It is crucial to prevent adverse outcomes and avoid placing patients at the risk of being harmed. Patient safety is a fundamental parameter of the quality of the care provided and medication errors are threatening patient safety (National Coordinating Council for Medication Error Reporting and Prevention, 2020; Singh et al., 2006). Therefore, healthcare organizations aiming to provide quality healthcare services should address the medication errors problem in order to be able to be competitive, patient-centered and successful (Gleeson et al., 2020; Zhou et al., 2015). In the literature there is a plethora of studies investigating medication errors, factors associated with drug errors or interventions and preventions plans, yet, medication errors are still a common problem in hospitals around the world (Härkänen et al., 2015; Elizabeth Manias et al., 2019; Morimoto et al., 2011; National Coordinating Council for Medication Error Reporting and Prevention, 2020).

There is no reason to believe that in hospitals in Cyprus things are different. However, to the best of our knowledge, no study has been conducted to investigate the problem of medication errors in any hospital in Cyprus. The occurrence and the magnitude of this problematic phenomenon is unknown. The frequency, the types, and the numbers of medication errors as well as any associated factors have not been described. Hence, no intervention plan can be developed or proposed, since the problem remains underdiagnosed (WHO, 2017d). Therefore, this study will potentially constitute a starting point for developing and implementing appropriate interventions in the future to prevent medications errors and enhance patient safety. It will provide an indication about the magnitude and extent of the problem as the findings (i.e., frequency and types of errors). Furthermore, the tools developed for this study can be used to develop a preliminary database since currently there is no other available data collected in Cyprus that concerns this specific field of research. It will provide a depiction of the medication administration process failures and latent conditions as the errors related factors that will be detected would bring out these problematic situations and would suggest the need for specific improvements. The findings will help raise awareness among healthcare professionals about the problem and can potentially be integrated in professional development training programs and/or workshops on medication safety. Also, the time of completion of this study is concurring with the still ongoing implementation of the new national health scheme in Cyprus which, in addition to improving the access to healthcare services, aims to provide high quality healthcare services, meaning that the provision of safe healthcare services is crucial, as there are no quality healthcare services that are unsafe for patients. Therefore, the outcome of the study could also be flagged or brought to the attention of the decision or policy makers for information or even for further consideration and actions, particularly when it comes to the development of preventing actions or programs aiming to promote patient safety.

An important differentiation of this study from previous research on medication errors, is that this study gives an emphasis on errors of omission. Omission is one of the most frequent type of error detected during the medication process. Apart from being the first attempt to study this important issue in Cyprus, the study is an important addition to the international literature

because it focuses on an aspect of the medication errors problem that is often left unexplored by other studies; that of potentially extremely high number of omissions during the medication process which, of course, create an environment prone to drug related adverse events with a negative impact on patient safety. Previous studies detected errors during the medication process, particularly during medication administration stage, however, the errors reported from most studies are focusing on errors of commission and when it comes to omissions, these are limited to the omission of a dose or of a drug (Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Härkänen et al., 2015). Also, the omission of executing tasks and following guidelines that should be followed when administering drugs, for example the disinfection of the site of injection when administering a drug subcutaneously, and other kind of deviation from safe drug administration principles that may be present in a healthcare setting are not always detected or observed in several previous studies and thus, neither reported. In this study, all procedural errors constituting an omission were considered and included in the analysis. Furthermore, two different methodologies were employed for collecting the data, which means a well-rounded picture of the under-investigation topic could be obtained. Moreover, the perspectives of nurses were also collected in order to obtain an insight from their point of view about the problem. For collecting the perspectives of nurses involved in the medication process regarding the factors associated with errors, a qualitative approach was followed, and two focus groups were completed. This led to having the perceptions of nurses, who in fact, have a central role in the medication administration to inpatients and therefore their perception of error risk factors may provide an insight into the medication errors problem. Based on the analysis of the data collected from the direct observation of the medication administration process and from the focus-groups discussions, the findings from these studies may contribute to the prevention of medication errors in Cypriot hospitals as well as to the global effort to decrease MAE and enhance patient safety.

Identifying and analyzing the omissions and related factors will allow future studies to design appropriate research-informed and targeted interventions to address the medication errors problem and reduce the error rates. The present study will contribute to the understanding of the above problem and to the design of future mechanisms for dealing with it. This is the best and possibly the only way, for healthcare organizations to protect and promote the quality

and safety level of any healthcare services provided for the benefit of patients (M. R. Cohen, 2007; WHO, 2017d). Therefore, a rational approach for addressing a problem is by first measuring the magnitude of the problem, then identifying the real causes that create the problematic situation, and then drafting appropriate actions and treatments for tackling the problem. Finally, the effectiveness and efficacy of the interventions that have been implemented and integrated into daily practice is evaluated. The first three steps (measuring the problem, identifying causes, identifying solutions) are critical for the next two steps (evaluating interventions and translating evidence into safer care) to be implemented. Hence the evaluation of the intervention will involve measuring errors to judge its success, something for which the findings of this study will function both as the force for change and the baseline for the assessment of change. This is of course a repetitive cyclical process (Figure 3), the patient safety research cycle, which begins by measuring harm, understanding causes, identifying solutions, evaluating impact, and translating evidence into safer care (Härkänen et al., 2015; Kim & Bates, 2013; WHO, 2017b), it will be possible to investigate and suggest appropriate future intervention programs that could be implemented in order to reduce errors during the medication process.

Based on the findings of this study it will be possible to expand the research on medication errors to other settings (i.e., different type of wards or hospitals) and compare the findings among these different settings.

Figure 3: Research cycle: strengthening capacity for patient safety research (WHO, 2020)

The findings of this study can be utilized in clinical practice in an effort to improve patient safety in hospitals, particularly when developing interventions to tackle this problematic phenomenon, and could also constitute a fundamental basis for future research on medication errors.

Chapter 2

Prevalence, types of medication administration errors and associated factors: A Scoping Review

2.1 Introduction

In order to obtain a comprehensive picture of the medication safety issue and collect available research evidence regarding medication errors in hospital settings, a scoping review was conducted. A scoping review would be useful to obtain an insight into the different aspects of the medication errors problem, including the definitions, the available methodologies for collecting the data, the frequency of the phenomenon, the factors and causes generating the problem, its impact on organizations, healthcare professionals and patients and the interventions for preventing errors. Scoping review is a useful tool as it can be employed for the synthesis of evidence on a research topic, before the initiation of the main study (Munn et al., 2018; Pham et al., 2014). Scoping reviews have many common characteristics with systematic reviews, for example, they both follow a structured process, nonetheless, they represent two distinct methods as they are performed for different reasons and have some key methodological differences (Munn et al., 2018). More specifically, a scoping review will have a broader scope than a systematic review and sometimes has broader inclusion criteria, as it aims to provide an overview of a large and a multifaceted available literature concerning a broad research topic, such as the medication safety topic which is under investigation in this study (Munn et al., 2018; Pham et al., 2014). Scoping reviews may examine the extent, the variety, and nature of the available evidence on a research question and thus, summarize findings from a large and maybe heterogeneous body of knowledge in methods or discipline (Tricco et al., 2015, 2018).

In this PhD thesis, the scoping reviewed was chosen as an exploratory mean for helping the researchers obtaining a comprehensive and up to date understanding on the medication administration errors problem. After a first look at the available literature it seems that there is an abundance of studies exploring the medication safety issue. However, there was a need to map this vast amount of data and in particular, specify on the aspects of the medication administration errors problem that were most of interest and most relevant with the objectives of this study.

Aim of the review:

The aim of the review is to gather and collate scientific knowledge and available evidence regarding the prevalence and types of errors and omissions made during the administration of medicines to adult inpatients in hospital wards and to explore the range of associated factors. Thus, by undertaking a scoping review it will be possible to collect specific evidence on errors made during the administration phase of the medication process, by nurses, in clinical wards, and to adult inpatients. Other type of errors, such as prescribing or dispensing errors, medication errors in different settings, such as nursing homes or primary healthcare centers, or drug errors in pediatric populations, were out of the scope of this study and out of the scope of this literature review.

2.2 Method

As mentioned above, this scoping review aimed to map and assess available evidence regarding the medication errors made during the medication administration process in hospital wards and the related risk factors. A protocol had been developed a priori for undertaking the scoping review. The scoping review protocol (Appendix I) pre-defined the objectives, methods, and reporting of the review and enhance the transparency of the process. The protocol and the scoping review were undertaken based on the recently updated JBI scoping review guide (2020). The protocol included the criteria that the reviewers used to include and exclude sources of evidence and to identify what data is relevant, and how the data were extracted and presented (Arnott et al., 2013; Hutton et al., 2015; JBI, 2020; Khalil

et al., 2016; Munn et al., 2018; Peters et al., 2015, 2020; Tricco et al., 2018). As this scoping review was undertaken only for informing the preparation of the present study, the protocol and the review itself have not been registered in any relevant database (e.g., to Open Science Framework or Figshare).

2.3 Scoping review questions

The specific review questions were:

(1) Which are the functional definitions of medication administration errors adopted in the relevant studies?
(2) What are the methodologies used for investigating the medication administration errors problem in hospital wards? Which methods are used for collecting the respective data?
(3) What is the prevalence and types of errors made during the administration of medicines to inpatients in hospital wards?
(4) What are the medication errors associated factors?
(5) What are the perceptions of nurses of the medication errors associated factors?

The answers to the above review questions would provide useful information for the planning of this study, and clearer understanding of the phenomenon and thus guidance for developing an appropriate and efficient research methodology design for the needs of this study. Also, the review questions were in line with the study objectives i.e., detecting medication errors in medical wards as well as the associated risk factors.

2.4 Inclusion and exclusion criteria

The inclusion criteria of the protocol are actually the basis upon which sources were screened for inclusion in the scoping review and included information about the participants, the concept, and the context and highlighted relevant exclusions. Inclusion and exclusion criteria are summarized in Table 1.

Inclusion criteria:

Published peer-reviewed research in English language, investigating the medication administration errors in hospital adult wards with any type of study design and methodological approach, such as qualitative and quantitative designs, were eligible for inclusion. Studies that collected the views or the perspectives or perceptions of the staff involved in the medication process by using interviews, focus group discussions or questionnaires were also considered to be eligible because staff's perceptions of the medication administration error problem, particularly staff' perception of the medication errors contributing factors, may provide information of the real medication administration errors associated factors. Although there is evidence that in many cases there is a gap between a perceived situation and the reality (King et al., 2018; Visscher et al., 2017), asking from people who are involved in the medication administration procedure to give relevant information and express their perception of the problem, could facilitate the better understanding of how they experience the problem, what they feel and what they believe about errors and the error-related causes. Perceptions and beliefs are highly subjective, based on one's culture, education, experience, gender, or age, and are subject to constant change and also, maybe inaccurate, but still the contribution of qualitative data can complement and explain to a large extend the data collected through other methods (Glasser, 1998). However, the review aimed to also focus on studies collecting data by using the direct observation method, medication records review, incident reports analysis and secondary to review the nurses' perceptions on the factors that are associated with this type of errors. We included studies undertaken in different hospital wards using different types of medication and different methods for collecting data. We also considered and reviewed papers presenting systematic review studies (Appendix V), mostly for collecting information regarding the available published data and for contrasting the papers included in the scoping review with the findings of the systematic literature review papers. Studies exploring definitions and methodological approaches for investigating medication errors were included in the scoping review, so to address all review questions described above and have a well-rounded picture of the respective research topic. We also focused on nurses as they have a leading role within

medication process, particularly at the administration phase of the medication process. No chronological limitation was set in order to allow the gathering of a higher number of eligible papers, regardless of their publication date, since the medication errors problem is not a new one, but still common and in focus.

Exclusion criteria:

Studies in pediatric populations or studies conducted in other settings than hospitals, like nursing homes or primary health centers were excluded as they were not in line with the scoping review objectives; nor to the present study objectives. In addition, studies concerning medication errors during the prescription or dispensing phase of the medication process were not eligible for consideration as the focus of this thesis is the errors occurring during the administration phase of the medication process. Other published material, such as grey literature, conference abstracts, commentaries, correspondences, opinions, editorials, and not peer reviewed articles or articles not published in English, were excluded not only because there was a vast amount of peered reviewed papers in English, but also for obtaining studies that implemented a more solid methodological design and thus produced a more solid scientific evidence. Studies investigating or reporting exclusively interventions or programs for reducing or preventing errors were also excluded. Furthermore, studies investigating the economic impact of medication errors, or their implication on health outcomes were also excluded. Due to the general nature and many different aspects of the medication errors problem, it was expected that a rather high number of papers will be elicited, thus we used specific terms which were highly relevant with MAEs when searching the literature and applied a filter in the field options when searching the literature in order to restrict the extraction of papers that did not include any of the preset keywords in their title and/or abstract (Table 1).

Table 1. Inclusion and exclusion criteria

Inclusion criteria: 1. Adult patients (>18 years of age) 2. Nurses involved in the medication administration process. 3. Hospital wards (for adults) 4. Only the administration stage of the medication process 5. Observational studies, Medication records review, Incident reports 6. Peer-reviewed articles 7. Key terms in title or abstract: "medication administration errors" or "medication administration safety"
Exclusion criteria: 1. Pediatric patients (<18 years of age) 2. Staff other than nurses involved in the administration process (e.g., physicians) 3. Settings other that hospitals (e.g., primary health centers or nursing homes) 4. Dispensing or prescribing medication errors 5. Opinions, reports, grey literature, or unpublished material 6. Interventional studies (when the focus is only on the intervention's particularities)

2.5 Search strategy

The primary source of literature derived from the structured search of the following electronic databases: PubMed, CINALH, Cochrane and Scopus. The search in these databases was made by using keywords specifically attached to the medication administration errors problem, in particular the following key terms were used: "Medication administration errors" and "medication administration safety" (Figure 2). There is a vast number of studies exploring medication errors, but the aim was to put an emphasis on medication administration errors specifically. By keeping the term "administration" it was possible to avoid the collection of studies exploring medication errors not relevant with the aim of our study, such as dispensing or prescribing errors. To identify all possible studies exploring medication administration errors in hospitals, the search was not restricted to MeSH terms.

2.6 Source of evidence selection

The study selection process was conducted independently by two researchers (GS, EP). The first-stage was based on the title and abstract of the studies that were collected from first search. Reviewing the titles and abstracts against the preset eligibility criteria it was possible to conclude on the relevance of each paper and disregard or accept a paper for further reading and probably use in the study thereafter. The second stage of the selection of articles concerned the reviewing and assessing the full text of the article in order to determine whether it met the agreed inclusion criteria. Moreover, the references of studies that fulfilled the inclusion criteria were used to find additional relevant studies that could probably missed in the first search.

2.7 Data extraction

Studies that met the inclusion criteria were abstracted by using a customized form based on a recommendation template by the Joanna Briggs Institute (JBI, 2020) (Appendix II). In particular, the "charting" of the data included information regarding the Author(s), the year of publication, the country, the objectives of the study concerned, the methodology used and the results. The data were organized and presented in a tabular form (Table 3, Appendix V), and includes information about the studies selected during the review for further analysis (i.e., objectives, methodologies followed, data analysis, study results)

2.8 Results

Table 2 presents the main findings of the literature review and Figure 2 summarizes the search and screening process followed. By using the two specific key terms described above, the initial search identified 602 articles. 8 articles which were identified through other sources were added, resulting in 610 articles. However, after removing duplicates, 398 studies remained. After reviewing the titles and the abstracts of these 398 articles, 108 studies remained which underwent through a full text review in order to check whether they met all the inclusion/exclusion criteria. After full-text review, 48 articles satisfied the inclusion criteria and a synopsis of the aims, methods, errors, and factors found is presented in Table

2. A more detailed presentation of the studies identified and selected during the review is presented in Table 3 (Appendix V). The 48 articles met all the inclusion criteria and adequately covered the scoping review aims and queries. The steps followed for the review and selection process are reflected below in Figure 2.

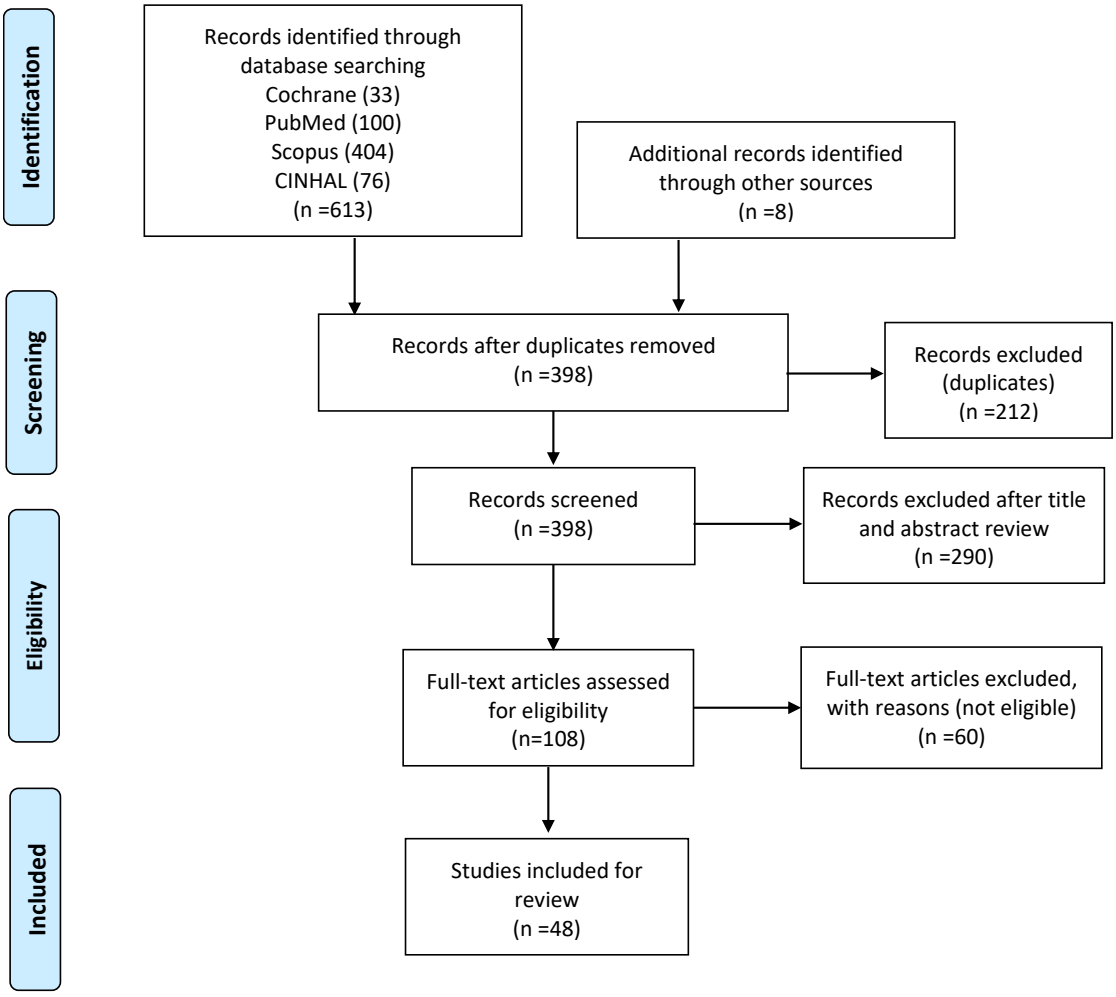

Figure 2: Flow diagram of literature search of impact of electronic health records. (as depicted by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.)

2.8.1 General information on the studies included in the review.

From the 48 studies selected for review, 8 were reporting the prevalence, types of medication administration errors, 9 studies were reporting medication administration error associated

factors, and 21 studies reported the prevalence, types and associated factors of medication administration errors. Also, 3 studies were assessing and/or comparing methods for detecting medication administration errors. Finally, 7 studies were presenting nurses' perception of MAEs and contributing factors. All studies concerned nurses, adult patients, hospital settings and only the medication administration phase of the medication process, as these were the eligibility criteria set in advance by the research team, in an effort to identify studies that specifically address the scoping review research questions. Moreover, as far as the methodological design is concerned, 7 studies were reporting medication errors by reviewing and analyzing data from incident reports. Incident reports provide useful information which is relatively easier to be obtained as it is gathered at one place (e.g. a database, or records) and can retrospectively be accessed, assessed and reported and therefore provide useful information regarding medication adverse events, including medication administration errors (Härkänen et al., 2015). 28 studies were reporting medication administration errors that were collecting by using the direct observation method. In particular, the medication administration process was directly observed by one, two or more observers. The direct observation method provides the possibility to record the whole process, identify different error related factors, and clearly state the specific type of each error made (McLeod, Barber, Dean Franklin, et al., 2013). Moreover, 7 studies were literature reviews. Literature reviews gave very useful information, not only on prevalence and types of medication administration errors, but also on the associated factors and the methods used in previous research on the same topic (i.e., medication administration errors). Also 5 studies concerned surveys where a self-administered questionnaire was used and 1 study used focus group discussions.

From the 48 studies included in the review, 3 have been undertaken in Australia, 1 in Brazil, 2 in Canada, 7 in Africa (South Africa, Egypt, Ethiopia and Ghana), 18 in Europe (UK, France, Spain and Finland), 1 in Jordan, 1 in Malaysia, 1 in Canada, 11 in the US, 1 in New Zealand and 2 in South Korea. Studies cover different types of hospital wards (e.g., surgical, medical wards, ICUs, emergency departments, psychiatric wards) and all medication attributes (e.g., route of administration, oral drugs, topicals and injectables and different therapeutic classes). In addition, different medication administration error factors were

assessed or reported in the selected papers (e.g., working conditions related factors, nurses' or medication's attributes, procedural failures, technological applications etc.).

Regarding the observational studies, all studies specified the background of the observer(s) carrying out the observation, and it seems that in the majority of the observational studies, the observations were undertaken by pharmacists or nurses, or physicians. One study reported and compared the efficiency of the observations made by nurses, pharmacy technicians and other auxiliary staff. Studies that reported errors and/or associated factors by analyzing incident reports that concerned medication administration errors, used incident reports records, or respective electronic records and databases, to extract the information needed (e.g., the Global Trigger Tool, National Reporting and Learning System for England and Wales, or MEDMARX).

2.8.2 Operational definitions of medication administration errors

As discussed in the previous chapter, the adoption of a universally accepted and precise definition of medication error is quite challenging. However, in the 48 papers we gathered to examine the medication administration errors issue, we found that more or less, a relatively common operational definition has been adopted in the selected studies. However, none of them use exactly and precisely the same term to define medication administration errors. This is just indicative of what has been mentioned in chapter 1 where a preliminary search focusing on "medication error" definitions showed that there is a lack of a globally accepted and standardized term. However, in this case, the focus is not on "medication errors" but rather on "medication administration errors" as the term "medication error" in several cases concerned also prescription or dispensing errors.

In all studies reviewed medication administration error is described as a deviation from a prescriber's valid prescription or the hospital's policy in relation to drug administration, including failure to correctly record the administration of a medication (Haw et al., 2007; Keers et al., 2013c). In addition to this definition, medication administration errors were defined as procedural failures, such as failure to read medication label, failure to check

patient identification, temporary storage of medication in unsecured environment (i.e., nurses' station), failure to record medication administration on medication chart, using incorrect administration technique, or non-adherence to basic safety guidelines, such as the infection prevention guidelines (Kim & Bates, 2013; J.I. Westbrook et al., 2010). Apart from communication errors, deviations from the five rights principles (i.e., Wright drug, Wright dose, Wright formulation, Wright route, Wright strength, Wright timing) were also recorded as errors (Härkänen et al., 2015; Keers et al., 2013c). A medication administration error was also defined as a deviation from the prescriber's medication order as written on the patient's chart, manufacturers' preparation or administration instructions, or relevant institutional policies (Keers et al., 2013b) or as deviation from the conventional method of administration of a particular drug as ordered by the prescribing physician (Agalu et al., 2012). Other definitions identified in the selected articles include: '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" (which is adopted by the US AHRQ) or as an incorrect dose, drug, delivery route, documentation, preparation, time, administration technique, administration of defunct drug, or omission of a prescribed drug (Härkänen et al., 2015). It is highlighted here that in many studies we noted that omission is defined as the omission of a prescribed drug or dose. However, additional procedural omissions do exist but are not always recorded in observational studies and thus not reported. Furthermore, the term "opportunity for error" seems to be present in many studies. Any dose given plus any dose ordered but omitted represents an Opportunity for Error (OE). In many studies each dose represents an OE. However, this term is not used with consistency among studies as in many studies more than one OE per dose is reported, implying that more than one errors maybe detected within one administration while in others one dose is an OE, implying that an administration maybe only correct or incorrect (Härkänen, Luokkamäki, et al., 2020; Härkänen, Turunen, et al., 2020; Haw et al., 2007; Keers et al., 2013b). Furthermore, while referring to the use of different definitions of the term "medication administration errors", among published studies, it should be noted that the methods used for calculating and analyzing errors is even more diverse. In fact, a high degree of heterogeneity is found among studies regarding this issue and different methods and formulars are used to determine the number of error or the error rates (Keers et al., 2013b). For example, the total number of

doses given, whether correct or incorrect, plus omitted doses was the rate denominator used in many studies and numerator data were presented as the number of doses considered to have 1 or more errors, which means that each dose can be only correct or incorrect, or the total number of errors, which means that more than 1 error per dose could be counted, which could result in error rates above 100% (Blignaut et al., 2017; Härkänen et al., 2015; Keers et al., 2013b).

2.8.3 Methods used for investigating medication administration errors in hospital wards.

As mentioned above, from the 48 articles included for review, 7 studies were reporting medication errors by reviewing and analyzing data from incident reports and 28 studies were reporting medication administration errors that were collecting by using the direct observation method. The studies we included in the scoping review built their methodology based on five different methods of collecting the data: (1) analyzing incident reports, (“) directly observing the medication administration process, (3) systematically reviewing the relevant literature and by collecting the perceptions of nurses regarding errors and related factors (e.g., by sending questionnaires to participants or conducting focus grouped discussions). We also included in the scoping review methodological designs that aimed solely to collect the views or the experiences or beliefs and/or perspectives of the staff, as this could help in better understanding the research problem. However, we primarily aimed to find methodological approaches that would be most useful in detecting the real factors that could contribute to errors and more importantly, detect errors while are happening during the medication administration process. It is acknowledged, that personnel’s perspectives can provide additional useful information about the errors made during the medication process or even provide some explanation of why some attitudes or behaviors that deviate from safety guidelines are expressed. A preliminary review of the literature indicated that the perceived medication administration risk factors may not be identical with the real risk factors for errors. In addition, when the medication administration errors made by the staff is reported by the staff themselves, then these reports may not include all errors made during the medication process for different reasons, such as fear, guilt, or just because some of the errors

made are not perceived by the staff as errors. Misperceptions of medication errors among healthcare professionals have been noted in the literature. However, we included studies that used data exclusively derived from staff's views or perceptions (i.e., studies collecting and analyzing staff perceptions of medication administration errors or related factors, by administering questionnaires to the staff or by conducting focus grouped discussions or interviews) as we wanted to also see what were the perceived by the staff error related factors. Similarly, there are concerns with regards to the incident reports review as well (Härkänen et al., 2017b). For instance, there is some evidence suggesting that not all incidents or events are always reported. Therefore, the main limitation in this method concerns underreporting and bias (Ramírez et al., 2018).

Incident reports and/or chart review:

Exploring medication administration errors by analyzing the data obtained by incident reports provide useful information which can easily be extracted or collected from respective database or other similar records. The search of the literature showed that this is a method commonly used for detecting medication administration errors in clinical settings (Dean & Barber, 2001; Härkänen, Turunen, et al., 2020). The data included in incident reports records or similar electronic databases and reporting systems can be accessed retrospectively, statistically processed and presented without directly involving healthcare professionals or patients. Similarly, by reviewing drug chart reviews it is possible to collect data that maybe the outcome of a medication adverse event, such us a side effect (e.g., form overdosing, or dose omission). Therefore, incident reports and charts review provide useful information regarding medication adverse events, including medication administration errors (M. Härkänen, Saano and Vehviläinen-Julkunen, 2017). In our review 7 studies used this method for detecting medication administration errors and 2 studies used and compared the direct observation and incident reports method and charts review.

Direct Observation:

In contrast to collecting data from incident reports, the direct observation method involves patients and healthcare professionals as well. The direct observation method provides the possibility to record the whole medication process, identify different error related factors, and clearly state the frequency and type of each error made (McLeod, Barber, Dean Franklin, et al., 2013). In particular, the medication administration process can be directly observed by one, two or more observers with different academic backgrounds (i.e., pharmacist or nurses). Direct observation of the medication administration process provides the possibility to collect comprehensive data for errors made during the process. It is a relatively easy method, and is also the preferred method that is used in many studies exploring medication errors and omissions as it proved to be the most, accurate, valid and efficient, when compared with all other methods for collecting this kind of data (Kenneth N Barker et al., 2002; Dean & Barber, 2001; Härkänen, Turunen, et al., 2020). In one study the validity and cost-effectiveness of three methods for detecting medication errors were examined: incident report review, chart review, and direct observation (Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002). This study showed that direct observation was more efficient and accurate than reviewing charts and incident reports in detecting medication errors (Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002).

In some studies, covered (disguised) observation method is implemented while other studies employed an overt (undisguised) observation method, meaning that the staff is aware of the fact of being observed. There is evidence suggesting that the observation method maybe the preferred method for recording and investigating MAEs. Research showed however that there is no difference between the observation and non-observation periods in the percentage of errors observed during the medication process. Also, there is evidence that there is no change in the error rate with repeated observations and no change with increasing duration of observation (Dean & Barber, 2001). A study in a UK hospital suggested that observation of nurses during drug administration did not significantly affect the medication error rates and concerns about the validity and reliability of observational methods for identifying MAEs are unfounded (Dean & Barber, 2001). In this study by Dean & Barber, (2001), error rates for each drug administration round were analyzed according to whether they were for

the nurse's first, second, third (and so on) observed round. There was no difference in error rates before and after the first observation for each nurse. There was also no difference in error detection between the two observers and no change with increasing duration of observation (Dean & Barber, 2001), and these results are enforcing the argument that the observation method is perhaps the preferable method for assessing MAEs. In fact, without neglecting the usefulness of other methodological designs, the review of the available literature suggests that the direct observation method seems to be the golden standard when it comes to recording and studying medication errors. The observation method, which allows the observation of clinical practice, could reveal additional and undetected information regarding problems in the medication process, as well as information about the factors that are associated with errors (Härkänen et al., 2015).

Almost all observational studies exploring medication errors employed a non-participant observation method. Some of the studies implement the disguised observation method (Berdot et al., 2012; Bruce & Wong, 2001; Khawaldeh & Wazaify, 2018) but many choose to employ the undisguised technique (Blignaut et al., 2017; Härkänen et al., 2015; Kim & Bates, 2013). Studies suggested that the undisguised technique has no impact on the overall clinical performance of staff being observed neither on the numbers of error observed regardless of the duration of the observation and in addition, staff seems to accept to participate in observational studies where a non-interfering, non-participant, discreet observation method is used (Dean & Barber, 2001; Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Haw et al., 2007). However, this is also a limitation for the observation method; the fear that participants may alter their behavior or their standard practice and performance just because they know they are observed (Hawthorn effect). Still, there is evidence, as described above, suggesting that Hawthorn effect may not be a major disadvantage as it has been found that staff performance and actions and the number of errors between observation and non-observation periods had no differences, regardless of the duration of the observation (Dean & Barber, 2001). Also, several techniques have been proposed to prevent or mitigate the Hawthorn effect. Like prolonging the observation, thus the stuff get used with the presence of observers in the wards, or by providing adequate information to participants

about the study and confirming and assuring their anonymity (Dean & Barber, 2001; Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Haw et al., 2007).

Finally, it is noted that most observational studies use a checklist (observation form) for the recording of the medication process. However, not all studies provide detailed information regarding the format and content of these observation forms (Blignaut et al., 2017; Härkänen et al., 2015; Kim & Bates, 2013). It seems that these tools are adapted and constructed on the needs of each study and in accordance to the respective research objectives. Most observation forms used in previous studies include coded items that reflect the medication administration process and record the behavior and other characteristics of the administrator during the process. Also, they collect information about the working environment, and about the drug administered. Based on the requirements of each study these forms need to be adjusted and adapted accordingly. Some forms are just checklists where tasks to be performed are listed and checked by the observers during the observation process. Some studies discuss the development and the validity testing of these forms, however, not all studies provide information regarding the format and content of these forms (Härkänen et al., 2015; Kim & Bates, 2013).

Surveys, interviews or focus group discussions:

The medication administration errors problem is examined by some studies with the use of surveys which are usually send to survey respondents. With this type of research, the researchers actually collect the views, the perceptions and the perspectives of the responders regarding the frequency and types of medication errors as well as the error associated factors conduct self-administered questionnaires (Wakefield et al., 1998; You et al., 2015). In addition to surveys, some studies have used other types of qualitative approaches such as interviews or focus group discussions (Table 2) (McBride-Henry & Foureur, 2007; Schroers et al., 2020). It is important to be aware of the staff perceptions of the medication administration errors problem. People involved in the medication process, nurses in particular, who are primarily involved in the drug administration process, could report some factors contributing to the problem and their reports, views or perceptions may reveal

information about the problem which may not be possible to be collected via other methods (i.e., observation method). For example, we may observe a nurse omitting to disinfect the site of injection before administering an injectable drug but we cannot understand the real reason for this omission. However, via qualitative design research, such as focus group discussions, this piece of information may come to light (Härkänen et al., 2015).

Using more than one method:

Furthermore, it should be highlighted that many studies exploring the medication administration errors problem employ more than one method to collect their primary data. Indeed, many studies use the direct observation and the chart review simultaneously (Basil et al., 2019; Feleke, Mulatu, Yesmaw, et al., 2015). Or they combine the direct observation with an additional quantitative or even qualitative method in order to supplement the data derived from the observational studies with additional information that cannot be obtained just by observing the medication process (Härkänen, Turunen, et al., 2020). Also, some studies for instance may combine an observational study and a self-administered questionnaire or conduct interviews with the staff (Feleke, Mulatu, Yesmaw, et al., 2015; Haw et al., 2007; Popescu et al., 2011). The use of a mixed methods approach may have the advantage of collecting diverse data as the information collected by using one method, such as observation, maybe further enriched by the use of additional methods, such as interviews and focus groups that collect supplementary information (Härkänen et al., 2015; Härkänen, Turunen, et al., 2020).

2.8.4 Medication administration errors prevalence and types

Direct observations of the inpatient medication process produce the most rigorous data on the prevalence of medication errors (Dean & Barber, 2001; Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Härkänen, Turunen, et al., 2020). Data from such observational studies suggest that MAEs occur from approximately 5% to an up to 80% of all doses administered depending on the study methods, definitions, and error calculation particularities (Berdot et al., 2016; Härkänen et al., 2015; Keers et al., 2013b). However, the literature review revealed that there is a variability in the reported magnitude of the medication administration error

problem (Feleke, Mulatu, Yesmaw, et al., 2015; Keers et al., 2013b). This is not a surprise as different methods and different definitions are used in the published studies, thus they observe, record and therefore report different numbers of medication errors (al Tehewy et al., 2016; Blignaut et al., 2017; Calabrese et al., 2001; Härkänen et al., 2015). Particularly with studies focusing on intravenous medication or including some frequently observed deviations and omissions in the definition of error, a higher number or rate of medication administration errors is reported (Agalu et al., 2012; Al Khawaldeh & Wazaify, 2018; al Tehewy et al., 2016; Kim & Bates, 2013). This conclusion is reflected in the findings of this scoping review. As shown in Table 3 (Appendix V), error rates reported form different studies varied largely, form as little as 0.3% to up to 86% of the administered doses. However, higher or lower error numbers should be read with caution as the methods and definitions used in the respective studies maybe correlated with the higher or lower rates of errors reported. This also makes comparisons between studies difficult, if not impossible.

For example studies that report error rate below 20% of the administered doses do not include omissions or non-adherence to basic safety guidelines or other procedural errors in their definition of "error", consequently they do not observed or detect these types of errors and thus do not report them, which results in reporting of a lower number of errors (Alaíde Francisca de Castro et al., 2019; Härkänen et al., 2015; Haw et al., 2007; Kim & Bates, 2013). In addition, some studies exploring medication errors, consider additional deviations from safe drug administration guidelines, resulting in the reporting of even higher number of errors. For example, Rodriguez-Gonzalez et al. (2012), in their observational study they reported a rather high rate of administration errors (86% of all doses administered) but they have considered several errors regarding the correct (or incorrect) administration techniques. In fact, errors in the administration method were the most frequently observed type of errors in this study were use of wrong administration techniques, wrong reconstitution/dilution, omission, and wrong infusion speed (Rodriguez-Gonzalez et al., 2012). Similarly, Kim and Bates (2013), in their observational study, focused on the non-adherence of nurses in basic safety guidelines, such as the infection control and safety guidelines and the five rights principles of medication administration, and they also reported a rather higher number of errors. For instance, they found that, only 45.6% of nurses verified the amount of medication

indicated on the vial for at least once or for at least one-second. In addition, administering the medication at the correct time was observed only 41.0% of the time. The guideline regarding hand washing before external and oral medications was followed only 4.5% of the time (Kim & Bates, 2013). Likewise, Westbrook et al. (2010), reported that of total drug administrations, 74.4% had at least 1 procedural failure and similarly Basil et al. (2019) found that medication administration errors were detected in 85% of the doses observed. The same is noted with Feleke et al. (2015) study where medication administration errors were detected in 56.4% of the observed administrations. All these studies used a more "comprehensive" and "inclusive" definition of error meaning that they could observed a higher number of deviations and thus reported a rather higher number of errors.

On the other hand, other studies have reported a lower number of errors (i.e., below 40% of all doses). In addition to this finding, there is solid evidence suggesting that clinical errors in general are often not reported and from the errors occurring in clinical practice, only a small proportion is noticed. Based on estimations, only 10–20% of these errors are reported (Härkänen et al., 2015). Therefore, studies that did not include the omission of hand washing before administering a medication or the omission of confirming patient's name (Kim & Bates, 2013), for instance, seem to have reported a comparatively lower number of errors (i.e. <25%) (Härkänen et al., 2015). Also, in some studies, the term omission reflects only the omission of a prescribed drug or dose (i.e., Haw 2007, Barker & Flynn 2002.) Some other observational studies also revealed error rates from 18-30% of administered dosed observed (Berdot et al., 2012; Donaldson et al., 2014; Han et al., 2005; Härkänen et al., 2015) but they used different definitions of errors and consequently some errors have been left outside the observation procedure and this could, at least partially, explain the lower error rates. Systematic literature studies have shown that observational studies suggested more than 1 error could be counted per dose was 25.6% and 20.7%, excluding wrong-time errors. A higher rate was observed for the intravenous route (53.3%) excluding timing errors, where each dose could accumulate more than one error (Hassink et al., 2012; Keers et al., 2013b). On the other hand, it seems that studies analyzing the data from incident reports reported a lower error rate (R W Hicks & Becker, 2006).

Studies consistently reported wrong time, omission, and wrong dosage among the 3 most common medication administration subtypes. Interestingly, omission is reported in most studies as one of the most common types of error, regardless of the methodology used for collecting and analyzing the data. In fact, errors of omission seem to be among the three most frequently reported types of error (Blignaut et al., 2017; Härkänen et al., 2015; Haw et al., 2007; R W Hicks & Becker, 2006; Keers et al., 2013b; Kim & Bates, 2013). Moreover, as shown in Table 3 (Appendix V), administration method errors seem to be a very common finding and are reported by 13 studies included just in this one review. Administration method errors concern a range of subtypes of errors such as wrong reconstitution technique or wrong rate of infusion or other deviations from the approved method/instructions of administration. A study that explored the differences between methods of detecting medication errors (incident reports, the Global Trigger Tool Method, and Observations) indicated that the incident reports and the Global Trigger Tool (electronic reporting database) method, mainly revealed wrong doses, whereas most medication administration errors in the observational data were errors involving the use of the incorrect technique (Härkänen, Turunen, et al., 2020). Wrong time of administration is reported in 10 studies included in the review and is also among the most commonly detected types errors. Wrong dose or dosage form and wrong drug are also included in the errors detected in the studies reviewed (Blignaut et al., 2017; Donaldson et al., 2014; Härkänen, Turunen, et al., 2020; Hassink et al., 2012). Procedure failures and deviations from safe drug administration guidelines have also been reported but not in all studies as some studies did not observed these procedural errors. For example, only few studies have reported deviations from infection prevention guidelines or other deviations from safety and best practice guidelines (Kim & Bates, 2013; Popescu et al., 2011). Additionally, documentation errors were another error type commonly detected in many studies (al Tehewy et al., 2016; Blignaut et al., 2017; Härkänen et al., 2015), one study, for example, reported that 87.5% of the medication administrations observed had a documentation error (Feleke, Mulatu, Yesmaw, et al., 2015).

2.8.5 Medication administration errors associated factors

The scoping review revealed that several factors seem to be associated with the occurrence of medication administration errors, indicating that this is a multifactorial and complex phenomenon. A first analysis of the articles included in this review shows that the vast majority of the reported error-associated factors seem to be related with the working environment and working conditions, to the nurses' and patients' characteristics and to the drug attributes. However, this may be a generalized classification and a more detailed exploration is warranted.

Working conditions and related factors are the most frequently reported error-related factors. In fact, in 22 studies it was noted that different factors and conditions of the working environment are the main determinants for medication administration errors. In particular, busy environment, distractions and/or interruptions, workload, number of patients in ward, number of shifts taken by nurse per month (i.e., work organization), night shifts, weekends, ward design and wards type, staffing, technological applications or equipment (i.e., Bar Code Medication Administration System, electronic records/prescriptions), and similar system failures like communication problems, incomplete or illegible prescriptions are reported by several studies (Acheampong et al., 2016; Blignaut et al., 2017; Härkänen et al., 2015; Rodríguez Vargas et al., 2016). However, not all these factors were found to be significantly related to medication administration errors. Some of the associations are not clearly established since in same studies they are reported as error contributing factors while, in other studies, they are either not reported at all (i.e., not explored) or a non-significant relationship is reported. For example, staffing and workload are two factors that are not always reported as significantly associated risk factors and interestingly, only seven studies reported an association between staffing, workload and errors (Blignaut et al., 2017; Härkänen et al., 2015). These studies seem to present understaffing as a latent condition which, when combined with other failures or deviations, it poses a risk factor for errors (Rodríguez Vargas et al., 2016). Interruption and/or distractions are also reported as an error associated by five studies (Feleke, Mulatu, Yesmaw, et al., 2015; Trbovich et al., 2010; J.I. Westbrook et al., 2020), but still, there are inconsistencies among studies as some studies have reported no

significant association between errors and interruptions or distractions (Thomas et al., 2017). Ward design and ward type may also be related with an increased number of errors, in fact two studies clearly associate ward design and type with errors (Popescu et al., 2011; Schutijser et al., 2018).

Nurses' attributes such as experience, educational background, skills and/or training, age, feeling fatigue or under pressure were also mentioned as error associated factors in four studies (Blignaut et al., 2017; Carlton & Blegen, 2006; Thomas et al., 2017). Patient related factors concerns polypharmacy, age and acuity (four studies). Moreover, drug factors that found be associated with medication administration errors include drug availability issues or drug shortages, route of administration or form (injectables, oral etc.) and therapeutic class (Berdot et al., 2016; Calabrese et al., 2001; Alaíde Francisca de Castro et al., 2019; Rodríguez Vargas et al., 2016). Cardiovascular drugs, injectables and "when needed" medication was associated with higher number of errors (Khawaldeh & Wazaify, 2018; Schutijser et al., 2018).

2.8.6 Nurses' perceptions of medication administration errors and of errors-related factors

Studies exploring nurses' perceptions of medication administration errors and of error related factors suggested that nurses have good understanding and perception of medication administration errors (Ayorinde & Alabi, 2019). During their clinical career nurses experience medication errors and this is not a surprise as they spent much of their time administering drugs to inpatients (You et al., 2015). Also, many nurses, when asked, admitted the commission of medication administration errors in the previous 12 months and they acknowledged that not all systems work well, and offered a variety of ways to improve current medication practices. (McBride-Henry & Foureur, 2007; Wondmieneh et al., 2020). Nurses' perceptions of the medication administration errors associated factors have also been reported by several studies. The lack of medication knowledge and personal factors including fatigue and complacency were reported as error contributing factors (Schroers et al., 2020). Furthermore, heavy workloads and interruptions were reported in many studies and were often interconnected with personal and knowledge-based factors (Schroers et al., 2020).

Other significant predictors of medication administration errors reported in previous studies include the lack of adequate training, unavailability of a guideline for medication administration, inadequate work experience, interruption during medication administration, night duty shift, prescriptions not legible, not clear, wrong doses are delivered by pharmacy, non-adherence to guidelines, inadequate number of nurses in each working shift and administering drugs with similar names or labels or administering drugs intravenously (Hemingway et al., 2015; Wakefield et al., 1998; Wondmieneh et al., 2020; You et al., 2015).

Table 2: Synopsis of aims, methods, errors and factors		No. of Studies
Study Objective/Aim	Errors	8
	Factors	13
	Errors and Factors	24
	Comparing Methods	3
Methods	Incident reports / Chart reviews	7
	Direct Observation	28
	Literature Review	7
	Survey	5
	Focus Group Discussion	1
Error Type	Administration method error	13
	Documentation error	4
	Wrong patient	3
	Drug unavailability	2
	Wrong dose	6
	Procedural failures/deviations	3
	Omissions	9
	Wrong time	10
	Wrong drug	3
Associated factors	Drug Related Factor	11
	Nurse Related Factors	8
	Patient Related Factors	7
	Professional practice environment related factors	22

2.9 Discussion of the scoping review

This scoping review aimed to guide the drafting of the present study and explored available evidence regarding medication administration safety, medication administration errors and associated factors, as well as the methods employed by previous research for exploring errors and their contributing factors. The definition of medication errors used, and the methods employed for collecting the data in the studies included in the scoping review, were also considered. This scoping review, revealed that medication administration errors constitute a major problem for healthcare organizations, particularly for hospitals. Errors during the administration of medicines to inpatients are very common and concerns deviations from the safe drug administration principles such as the 5 rights of medication administration safety or the infection preventions protocols. Also, in most cases, errors do reach the patient, nevertheless, in most cases the risk of causing serious harm is rather limited. Still, errors during the medication process in hospital wards increase the risk of negative clinical outcomes, like prolonging hospitalizations and breaching cross infection barriers and threating patient safety.

Regarding the definitions of MAEs it is noted that there is no single term that is used with consistency among the different studies. The variability between the terms used to define medication administration errors should not be a surprise to reviewers because each study focuses on different types of errors or, on just one specific type of error, for instance de Castro, Oliveira and Rodrigues, (2019), explored only the error of dose omission while Härkänen et al, (2015) explored different types of medication administration errors, including dose omissions. Nevertheless, most studies define error as a deviation from the medical prescription/instruction and/or any deviation from safe drug administration principles. Furthermore, the term “opportunity for error” seems to be stated in many studies. Any dose given plus any dose ordered but omitted represents an Opportunity for Error (OE). In many studies each dose represents an OE. However, this term is also not used with consistency among studies as in many studies more than one OE per dose is reported, implying that more than one errors maybe detected within one administration while in others one dose is an OE,

implying that an administration maybe only correct or incorrect (Härkänen et al., 2015; Härkänen, Vehviläinen-Julkunen, et al., 2020; Haw et al., 2007; Keers et al., 2013b).

There are different methodologies that can be employed to explore medication administration errors, depending on the research questions, or on the concerned population's or on the concerned setting's characteristics. However, we filtered out studies that collected their primary data from pediatric populations or from settings other than hospitals (i.e., neonatal wards or nursing homes). Literature suggests that the preferable (i.e., most efficient, accurate and valid) method for investigating medication administration errors is the direct observation (Dean & Barber, 2001; Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002). In this review we collected studies that used one of the following research designs: direct observation, incident reports or chart report analysis, qualitative design and literature reviews. Even though staff perceptions of errors and errors risk factors may deviate from the real error rates and associated factors (Glasser, 1998), we also included studies that used this type of methods (e.g., focus groups, questionnaires) as additional information may be obtained when the staff perceptions or views on the MAEs problem are considered and assessed. However, when reviewing the different methods for detecting MAEs or for collecting data or relevant information, special attention was given to the direct observation as it seems to be one of the most valid and efficient methods used for the specific type of research and for detecting and recording MAEs (Dean and Barber, 2001; Flynn et al., 2002).

Some studies used mixed methods (i.e., questionnaire and direct observation) however, at least one of the above-mentioned methods should have been used in order for an article to be eligible for inclusion. However, it is acknowledged that the perception of the personnel of the medication errors and of the associated factors may also provide supplemental information, complete the findings of an observational study or of an incident review studies, thus to provide a clearer and more comprehensive picture of the problem in any hospital ward. However, in order to prepare this PhD study, we aimed to explore all available options, not only by collecting nurses' perceptions, but primarily by either assessing incident reports or by observing the medication process. Combining methods would be of course an important

methodological enhancement for the study because the data derived from different methodologies give the possibility to the researchers to compose a better, clearer picture of the problem, as different information may derive by using different methodological designs (Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Härkänen, Vehviläinen-Julkunen, et al., 2020). For example, direct observation may be the optimal approach to collect the data as it provides a realistic picture, a "snap shot" of what is happening during a process, however, additional data may be needed in order to better understand why something happened or explain behaviors or attitudes. Therefore, by combining two methods (i.e., observation and interviews with staff), particularly if one of these is the direct observation method, the data may be enriched and able to provide a more integrated information and more solid conclusions. In this scoping review some of the studies included used different methods for collecting data (i.e., questionnaire or knowledge testing and direct observation) and these studies did collect additional information that could help in the better understanding of the problem (Blignaut et al., 2017; Feleke, Mulatu, Yesmaw, et al., 2015; Haw et al., 2007).

The prevalence of errors varies largely among studies (from 0.3% to 90% of all dose administrations), however, this is also not a surprise considering that different definitions and different methods are used in these studies. For example, in most studies error of omission refers to omitting the administration of a dose or a drug, however, other studies explore additional types of omission like omitting to follow all the steps foreseen in a safety principle.

In studies where procedural errors and deviations from safe drug administration guidelines are considered (i.e. defined as errors), a higher number of errors is reported (Feleke, Mulatu, Yesmaw, et al., 2015; Kim & Bates, 2013). For example, omitting to wash hands or disinfect the site of injection, and in general not following the infection control and safety regulations was among the major findings of several studies that raises concerns of possible cross infection (Kim & Bates, 2013; Schutijser et al., 2018). Errors of omission in the basic five right principles of medication safety is also an important outcome of many studies. This may indicate that clinical nurses are prone to deviate from safe practice regardless of their experience in the field.

The error of not administering a drug in line with the correct administration method, could have been caused by a lack of knowledge, time pressure, or because of a lower risk perception. Some studies that did perform knowledge testing (Blignaut et al., 2017; Feleke, Mulatu, Yesmaw, et al., 2015; Haw et al., 2007) have revealed some knowledge deficits, while other studies have shown that there is a significant variability among healthcare professionals concerning safety attitudes and behaviors (Blignaut et al., 2017; Parry et al., 2015). Administration method errors have also been reported by many studies (Härkänen et al., 2015; Keers et al., 2013b). Non-adherence to the drug administration record protocol (i.e. documentation errors) was commonly recorded, as well (al Tehewy et al., 2016; Keers et al., 2013b).

Omissions constituted deviations from safe drug practice and seemed to be the most frequent type of error during the medication administration process (Blignaut et al., 2017; Härkänen et al., 2015; Keers et al., 2013b). Omissions lead to deviations from safe clinical practice, but probably also reveal a hidden risk factor, like a low drug safety perception among healthcare professionals (Nichols et al., 2009a; Pelzang & Hutchinson, 2020). It is crucial to explore the personnel perspectives regarding drug administration safety in order to obtain a better understanding of why these deviations from safe practice are observed. Along with contributing factors, personnel's perceptions on medication safety should be considered in order to provide a more solid explanation of why errors happen. This point was taken into account when preparing the methodological design of the present study.

Regarding associated factors, interruptions and/or distractions, medication type, and number of medicines administered to the patient were all associated with higher error numbers. In particular, the administration of injectable forms was associated with a higher number of errors compared to administering oral or other forms. Factors that could predict the occurrence of higher error rates were the medication class, the pharmaceutical form and the number of medicines administered per patient. When administering a higher number of medicines to a patient or when specific drug therapeutic class was administered (i.e.

cardiovascular medicines) the risk of a higher number of errors made (in total or within an administration) was increased (Calabrese et al., 2001; Härkänen et al., 2015; Keers et al., 2013c). Additional error contributing factors are reported by different studies but there is inconsistency among findings from different studies as some factors are highlighted as error-contributing factors but in other studies are not reported as risk factors (i.e., staffing, shifts, electronic records, procedure failures). The routes however of most factors reported are found in the working environment domain, patients' and nurses' attributes and medication particularities (Table 2.3).

2.10 Limitations

Scoping reviews are subject to the limitations of any review, meaning that relevant sources of information may had been omitted and the information extracted from the review is depended on the eligibility criteria set. This means that additional information that could be relevant and useful for the purposes of this study may have been missed. No rating of the quality of evidence is provided either because of the methodological heterogeneity across studies, and since the main purpose of the review was to gain some insights into the methods, definitions, range of errors studies use, therefore implications for practice or policy cannot be graded (JBI, 2020).

2.11 Conclusions

Medication administration errors are still a common problem in healthcare services, with omissions and deviations from safety protocols being one of the most common types of error. It is a complex and multifactorial problem and has its roots in system failure and in person related factors. Exploring the causes of this phenomenon is crucial in the effort to address it. However, each case and each setting have their own particularities and conditions (i.e., working conditions/environment, staff, patients, medication) which may differently contribute to errors. Factors associated with medication errors need to be identified, explored and taken into account in an attempt to develop targeted interventions and therefore prevent and limit errors. An efficient, valid and accurate method for detecting and assessing

medication administration errors is the direct observation method which has been used for this purpose for several decades now. However, additional methods do exist such as exploring the data contained in records or databases concerning incident records, adverse event reports, medication records, staff interviews and questionnaires. In fact, different methods may reveal different types of error (Härkänen, Turunen, et al., 2020). Combining these methods can gain an insight and a clearer picture than using just one method, thus obtaining a better understanding of the problem.

PART II: SPECIFIC PART

Chapter 3

Conceptualization and Study Objectives

3.1. Introduction

As described in previous chapters, the medication errors problem concerns both; the persons and the system under discussion and is a multifactorial and multidimensional phenomenon that needs collective efforts to be minimized and decrease the possibility of placing patients at risk (Keers et al., 2013c; Kuitunen et al., 2008; James Reason, 2000). Errors contributing factors may have their roots in working environment conditions, and people involved in the medication process attributes. Error contributing factors must be identified and addressed when implementing medication safety interventions. They are important pieces of the safety culture puzzle of an organization. Cultivating a safety culture within a ward begins from the management team and affect members' attitudes, values and behaviors and can inhibit most of the medication error contributing factors and promote medication safety and consequently improve patient safety. The problem with patient safety is not a new one, it is in fact very old one. The risk of being harmed by the medical care provided has been discussed many years ago and in particular, has its roots in Greek antiquity. In fact, Hippocrates was probably the first who described the concept of medical harm and thereafter other notable physicians also explored this problematic phenomenon. Just after 1950 published papers used the phrase "iatrogenic disease" which actually refers to adverse outcome or injury caused by the healthcare management (Patient Safety Network, 2020)

3.2 Objectives of the study

The objective was to record the type and frequency of errors, with an emphasis on omissions, during administration of medicines to inpatients and to investigate associated error factors, as well as to collect the perception of nurses regarding the factors associated with errors and omissions. A more detailed description of the objectives of the study is provided below.

The research questions were:

1. What is the prevalence of medication errors and omissions during the medication administration process in hospital wards?

2. What are the types of errors made during the medication administration process in hospital wards? (e.g., omissions, errors of execution, deviations from the "5 rights" or from the basic infection prevention and safety regulations, documentation errors, administration method errors)

3. Which factors could be associated with the occurrence of errors during the medication administration process and what is the association between medication errors and these associated factors?

4. What are the perceptions of nurses involved in the medication administration process in hospital wards regarding the medication errors associated factors?

3.3 Background information about the purpose, aims and objectives.

The general aim of the study was the investigation of medication safety in hospital wards. The goal was to capture the medication errors during the administration of drugs to inpatients and to explore the factors associated with the occurrence of errors. Additionally, the study focuses on investigating and exploring errors of commission and errors of omission. The

National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), when categorizing medication errors, specifically refers to omissions, and states that an error of omission does reach the patient (National Coordinating Council for Medication Error Reporting and Prevention, 2020). Previous research has shown that the frequency of errors among the different stages of the medication process vary significantly and that a higher number of errors is reported during the administration of medicines and omissions are among the most commonly detected type of error (Härkänen et al., 2019; Rodney W. Hicks et al., 2004; Kim & Bates, 2013). Therefore, exploring the types and causes of omissions in drug administration is important for improving patient safety. In addition, the study aims to investigate the perceptions of nurses towards safe drug administration, particularly their views on medication errors associated factors. Nurses spend much of their time in preparing and administering medicines and therefore their perceptions on the causes and factors contributing to medication errors is crucial for drafting and implementing interventions to enhance medication safety.

This study aimed in presenting a comprehensive and a representative picture of the medication safety problems that arise during the medication process in hospital wards. So, the objective was to detect medication errors made during the medication administration to inpatients and explore error related factors. In particular, recording the number and specifying the types of errors occurring were the primary objectives of the study and are presented in detailed below in this chapter. Also, exploring associations between errors and some associated factors was also an objective of this study. Finally, the study aimed to explore nurses' perceptions of MAEs associated factors. By achieving these objectives, the study results may provide a clear picture of the problematic phenomenon's magnitude and of some related contributing factors.

This study also highlights important methodological information regarding the differences between the methods used for detecting medication errors by comparing the information obtained from two different methods that were utilized in this study; the direct observation method and the focus group discussions method. By using two different methods for

collecting data, it was possible to obtain real life data, on the one hand by direct observation of the medication process and, on the other hand by mapping the perceptions of the professionals that have the responsibility to administer the medicines to inpatients, that is the nurses who are involved in the medication process in the hospital wards.

Medication errors is a major constituent of the medication-related outcomes and threatens patient safety, therefore the purpose of the study, which is the detection of the medication errors and the investigation of associated factors, and the collection of the nurses' perceptions regarding medication errors contributing factors, is relevant with the important issue of patient safety. It composes a key parameter of the quality of the care provided and a crucial performance measurement that is used to estimate, analyze and improve all relevant healthcare processes to increase patient safety.

Furthermore, this study aimed to give an emphasis on omissions during the medication process. Omissions are the most common type of error during the medication administration process. Omissions may constitute a deeper problem because it concerns attitudes and behaviors of the personnel and are relevant to the general safety climate and culture of the team and of the organization(Gleeson et al., 2020; Pelzang & Hutchinson, 2020). Omissions lead to deviations from safe clinical practice, but probably also reveal a hidden risk factor, like a low drug safety perception among healthcare professionals (Nichols et al., 2009a; Pelzang & Hutchinson, 2020). However, it seems that there is a lack of knowledge as regards to omissions since most of the studies on medication errors are focusing on performing wrong actions and less attention is given on omissions. It is therefore crucial to record omissions, in addition to the errors of commission, as they constitute the most frequent and often under-reported type of medication error, and this study aims to address this gap.

3.4 Research Framework

To describe the prevalence of errors made during the medication administration process in hospital wards.

The primary aim of this study was to detect and report the prevalence of the errors made during the medication administration process in the tow wards where the study was conducted. There are, to the best of our knowledge, no other studies conducted in Cyprus which explored or investigated this issue. Even though we know from previous research that MAEs are common in hospital wards, specifically in medical wards, for hospital wards in Cyprus this is an unexplored area. It could be assumed that in accordance with the literature, approximately (or at least) in 20% of all doses administered in these wards there is an error (Härkänen et al., 2015; Keers et al., 2013b). However, this is just an assumption and, we know from the literature that the prevalence of errors during the medication process and the patterns of the reported error rates largely vary among different studies, not only because of the different definitions and methods used but also because of the specific characteristics and particularities of each setting where the data had been collected (Haw et al., 2007; Kim & Bates, 2013). Also, for drafting targeted interventions for treating a problem, it is required first to diagnose the problem, measure it and then implement the appropriate interventions (Bates et al., 1999; Drach-Zahavy & Pud, 2010; Härkänen, Luokkamäki, et al., 2020). Thus, as a first step, we aimed to describe prevalence of MAEs and present the frequency, the numbers of MAEs made during the administration of medicines to patients in two medical wards of a state tertiary hospital in Cyprus and assess related risk factors. After studying the methods used in previous studies assessing MAEs, we concluded that to achieve this research objectives it was necessary to record the whole medication process in the wards (i.e., observing the nurses administering drugs to inpatients) and also to record other working or environmental parameters, such as the medication records, the drugs and the people involved in the process (e.g., nurses or patients) in order to be able to assess related factors and other aspects relevant with the medication process.

To describe the types of errors made during the medication administration process in hospital wards

In addition to capturing the prevalence of MAEs, the aim was to identify the types of errors during the medication administration process in two different wards of a state hospital in Cyprus and under all possible working conditions. The objective was to record the medication errors made during the drug administration process during weekdays and weekends, during all shifts (morning, evening and night) and under different types of work allocation system in ward (patient and task allocation), in an effort to obtain a comprehensive and representative sample of administrations under all possible working conditions. As the aim of the study was to detect and describe the types of the possible errors made during the medication process in the two wards where the study took place, the particularities of the working environment and the people and procedures concerned by or involved in the medication process had to be considered in order to be able to understand and therefore detecting all possible errors made during the medication process. This need was captured in advance by the research team before initiating the study and also after reviewing previous studies on this research topic. Thus, the medication records, the therapy sheets, and the whole medication documentation process had to be considered and taken into account, as well as other specific environmental parameters, such as the shifts, the organization of the nursing work in the ward, even the atmosphere or the interruptions during the process. Moreover, because it was also aimed to put an emphasis on omissions during the medication process, the observational study considered this type of error as well. Therefore, it would be possible to make a comparison between errors of omission and errors of commission from the results of the study. After reviewing the available literature, it was noted that many previous studies left unexplored several procedural errors and deviations from safe drug practice. However, studies which addressed the issue, did report the high occurrence of omissions during medication administration. The majority of these omissions, concern procedural errors and deviations which constitute a threat for safe drug administration and for patients' safety. For example, omitting to hand wash before administering a medicine, particularly when administering an injectable drug, or omitting to confirm the patient's name, are some of the errors that often left unexplored and hence unreported by previous studies in the field. In addition, errors of omission are underdiagnosed in many studies or omissions are just are

limited to the omitted doses (Keers et al., 2013b). In this study, omissions during the medication administration process were put under investigation. Furthermore, errors in the administration methods of different types of medicines were also explored. Documentation errors were also investigated.

To explore medication errors related factors and assess associations between medication errors and contributing factors.

The other objective of this study was the assessment of potential associations between different contributing factors and medications errors. In particular, different factors, that potentially may constitute error risk factors, were under investigation and associations between these factors and errors were assessed. Factors like working conditions and working environment related factors, patients' or nurses' attributes, medication type, were explored in order to assess their association with errors. The factors associated with medication errors in previous studies were classified using the classification of error producing conditions and included work environment, person-specific, patient-specific and medication-related factors (Härkänen et al., 2015). Distractions during the medication process caused by other co-workers, patients, or events in the unit have been found to be related to an increase of medication errors. Additionally, perceived staffing or resource inadequacy, nurses' stress, heavy workload, or increased patient load affect medication errors (Härkänen et al., 2015; Keers et al., 2013c). It is known from previous research that different factors are assessed for associations among different studies, and include work environment related factors (e.g., staffing, interruptions), medication related factors (e.g., therapeutic class, form), patient related factors (e.g., patient age), and the nurse related factors (e.g., experience of the person administering the medicines).

To explore the perceptions of nurses involved in the medication administration process in hospital wards regarding the medication errors contributing factors.

Based on the above-mentioned aims of the study, the first three primary objectives were to describe the prevalence, the type of MAEs and to explore for associations between different

factors and errors. The fourth study objective was to explore nurses' perceptions regarding the factors contributing to errors. Nurses spent much of their working time in the medication process and they have the leading role and the responsibility to curry out the medication administration process. Therefore, it was crucial to take into account nurses' perceptions of medication error related factors. By collecting the perceptions of clinical nurses involved in the medication process it was possible to supplement the information resulted from the observational study with qualitative data. This gave the opportunity to the research team to explore the problem by using a different research approaches and thus gaining a well-rounded picture and an insight to the causes of medication errors as perceived by nurses.

3.5 Selection of methods for addressing the research questions

It was decided to employ a dual methodological approach; a qualitative and a quantitative approach in order to adequately address the research objectives. The decision for combining two different methodological approaches was also based on the findings of the scoping review which is presented in Chapter 2. The use of two different methods for collecting the data would help in the collection of additional, enhanced information which may not be possible to be collected just by using a single method and, thus, helped in obtaining a clearer picture of the problem. Using the observation method for recording errors maybe more appropriate compared to both; surveys and focus groups for the same purpose. However, the use of more than one method maybe the optimal approach as the results obtained by each method are not identical and may produce findings different findings. Different methods can supplement each other and hence compose a comprehensive picture of the phenomenon. In fact, it was understood from the literature, and after discussing with experienced researchers in the field, that one of the best methods for collecting information about the MAEs in hospital wards was the direct observation method. However, it was also noted, after reviewing the literature, that the collection of the perceptions of nurses about the errors made during the medication process and about error causes, would supplement the information collected from the observational study. Specifically, the first three research objectives (i.e., prevalence, type of MAEs and associated factors) were addressed by the direct observation method and the fourth objective was addressed by employing a qualitative approach where

two focus groups were completed. With the conduct of focus group discussions, nurses would provide their own input regarding errors and enrich the information collected from the observation. As nurses have a central role in the medication administration process and spend much of their time administering drugs to inpatients, they are in position to give valuable input concerning the factors contributing to MAEs. A detailed description of the research methods and the tools used for data collection is provided in Chapter 4 Methodology.

Chapter 4

Methodology

This chapter describes the study design and the study methods used for collecting the data needed to investigate the research objectives. In particular it describes the design and preparation of the focus group phase and the observational phase of the study. Information regarding important attributes of the methodological strategy followed, including the design, the sampling approach, the recruitment process, the participants and the inclusion/exclusion criteria, is provided in this chapter. A description of the processes used for collecting the data is also included. Moreover, this chapter includes the ethical aspects concerning the study including information about approvals granted by ethical and research committees (i.e., Cyprus National Bioethics Committee, the Research Promotion Committee of the Cyprus Ministry of Health).

4.1 Research setting, environment and participants

Observational study:

The study took place from August to September 2018 in two adult medical wards of a tertiary state hospital in Cyprus offering healthcare services to more than 200000 habitants. Medication errors can be detected in different hospital wards and different settings (Grasso, 2007; Pepper, 2008; I. C. K. Wong et al., 2009). However, it was preferred to carry out the observation in medical wards as they commonly have a heavy workload, different types of medicines are administered, they accommodate patients of different age range and in different health conditions, therefore they constitute a good setting to obtain data capable of producing a representative picture of medication errors or error prone conditions (Alghamdi et al., 2019; Blignaut, 2015; Härkänen et al., 2015). Also, despite the fact that medication errors are detected in different settings, there is some evidence from the literature that medications errors are very common in medical wards, perhaps for the reasons mentioned

above (i.e. heavy workload, patients with different health conditions, different types of drugs administered) (Blignaut, 2015; Härkänen et al., 2015; Lawton et al., 2012; Tang et al., 2007).

In this study, each medical ward had 30 beds and 25 nurses employed during the period the study was conducted. Furthermore, in order to efficiently prepare the observation phase, and to ensure the smooth conduct of the study, information regarding the medication process in the wards was collected by the researchers prior to commencing the observational study. It was noted that in both wards the nurses were responsible for medication preparation and administration, as there were no ward pharmacists or other staff involved in these procedures. Drug orders and medication records were on paper, as there was no electronic prescription or electronic medication records system used in the wards during the conduct of the study. There were three scheduled routine medication rounds in the two medical wards (i.e., morning, evening and night). The medication rounds in the two wards lasted from thirty minutes to approximately two hours, depending on the type of work organization system in the ward and on staffing. In particular, when nurses were allocated to tasks rather than to patients, drug administration rounds were prolonged, approximately up two hours, because one or two nurses had to prepare and administer medication to all ward inpatients. When nurses were allocated to patients, time per drug administration round was decreased and approximately took thirty minutes to be finalized because one nurse had to prepare and administer medication for three or four inpatients.

Two observers, one in each ward, recorded the medication administration process with a simultaneous review of medication charts. Observers had great expertise in medication administration but had no relationship with the two wards where the observation took place. It was important to avoid any kind of familiarity between the observers and the nurses who participated in the study in order to avoid any possible impact on the participant's behavior or performance (i.e., Hawthorne effect). Observers had a theoretical and practical information regarding the observation method. They were also involved in the drafting of the observation form and tested the method and the form during a pilot study. The observers employed a non-judgmental and a non-interfering observation approach in order to decrease

the Hawthorne effect. However, it was agreed in advance by the research team that observers will not interfere with the medication process unless a potentially harmful error was about to happen. Observers reviewed medication records and prescriptions and recorded the medication process using the observation form. This was an undisguised study. The ward manager and nurses were informed in person about the study. In order to further limit the Hawthorne effect, the presence of observers in the wards was prolonged by implementing a pilot phase, therefore the staff got familiar with the observers following the medication process. Also, the word error was strictly avoided so that nurses' performance would not have altered under the pressure of committing an error which will be reported.

In total, 25 nurses worked in each ward and a convenience sample of 24 nurses from both wards (48%) agreed to participate in the study. This level of participation considered to be acceptable because it was equivalent with others used in previous studies (Härkänen et al., 2015) and because in this study it represented almost half of the personnel worked in the two wards (48%). All nurses involved in the medication process in the medical wards were eligible to participate. Nurses and ward management were informed in advance about the study. A detailed oral explanation had been provided where the researchers explained that the study which were invited to participate concerned the investigation of medication administration safety, however, the use of the word "error" was avoided. Recruitment was not easy because when nurses were informed about the study were reluctant to participate. As mentioned above, nurses may not feel at ease or comfortable to be observed during their work as the research question (i.e., medication errors by nurses) concerns a sensitive issue because it concerns errors, mistakes in the professional practice of the participants and therefore this poses a challenge in the recruitment of nurses. Nevertheless, after informing participants and hospital administration about the study and ensuring the anonymity of the participants, an adequate level of enrollment by nurses had been achieved. It is noted here that the study size was determined by the required number of the observed doses administered and not by the number of nurses who participated in the study. The sample and sample size calculation are described below. Participant's characteristics (i.e., nurses' and patients' attributes) and relevant information, as well as a comprehensive summary of the observed administrations attributes, are presented in chapter 5 (i.e., Results).

Focus group study:

Nurses involved in the medication process in the two medical wards of a tertiary hospital in Cyprus were invited to participate in two focus group discussions, 5 nurses were participated in the first group and 7 nurses in the second one. More details about the participants and recruitment process for the focus group discussions is presented below in this chapter and in chapter 6. Therefore, the setting of this focus group study is the same as the one where the observational study was carried out and is described above. As mentioned previously in the description of the setting of the observational study, in the two wards that the focus group study was conducted, nurses had the responsibility of preparing and administering the prescribed drugs to all inpatients. Because the aim was to collect the perceptions of nurses on causes of medication errors, other healthcare professionals were not invited to participate. Recruiting was not easy because medication errors is a sensitive topic (Kim et al., 2016; Papastavrou & Andreou, 2012) and nurses, despite being informed about the study and protection of their anonymity, hesitated to participate in the discussions.

4.2 Ethical considerations

The study protocol was approved by the National Cyprus Bioethics Committee and by the research committee of the Ministry of Health, which grant permit of access to state hospitals (Appendix IV). Access to the field was also given by the hospital and ward management. The research team organized separated meetings in both wards where the study was conducted and inform the management and the staff about the study. These information meetings included open discussions that aimed to explain to the participants the aims of the study and the design. It was made clear to all that this study concerns the medication administration safety and nothing else. Nurses and administration were also informed that the study was granted a positive opinion form the National Cyprus Bioethics Committee and by the research committee of the Ministry of Health (Appendix IV). It was also made clear that the aim was to explore drug administration safety and any results would be used for understanding and improving, if needed, the current situation in the wards. Most importantly

these meetings aimed to provide assurance to the staff that all information will be used solely for the purposes of the research and no personal or other sensitive information will be disclosed to anyone. Clinical nurses and ward management were assured that no connection or association could be possible to be made between the study results and the ward or between the study results and the staff. This was a verbal confirmation that was given to the staff by the research team to facilitate recruitment, limit the level of skepticism about the study and reduce reluctance for participation. After explaining all these issues to the staff, a positive opinion was provided at the end of these meetings from both; staff and management. During the study, high ethical quality was maintained. Ethical principles for medical research including human subjects and the Declaration of Helsinki 1964 (WMA) were followed to the extent suitable and/or relevant for the study. The analysis conducted in this study was based on the information collected during the direct observation method and from the data collected during the focus groups discussions. This means that the data collected are case sensitive as they concern information derived from the medication process (e.g., medical prescriptions, patients' records, ward records etc.) and it was made sure that any kind of connection with the patients or healthcare professionals during or after the study would not be possible. This was an important consideration for the study as it concerns research on a sensitive issue; medication errors during clinical practice. The research team took all necessary measures to eliminate the risk of connecting the data with the participants in both sub-studies (i.e., observational study and focus groups study). In particular, during the collection and analysis of the data it was confirmed that there was no personal information or identifiers concerning patients or healthcare professionals. Therefore, a high level of confidentiality was kept during the whole study and the anonymity of the participants was guaranteed. For example, during the collection of the data, participants' names were replaced by a code number and in the focus groups study, for instance, the interviews that were recorded, were destroyed after the transcriptions, coding and analysis was finalized. In addition, the observation forms used in the observational study, did not contain any confidential or personal identifier that could be related to any of the participants. Despite the fact that the observation was carried out in the two medical wards and in patients' rooms, any kind of connection or interaction with the patients was strictly avoided. The observation was undisguised and all nurses and ward management were informed about the study. Nurses who agreed to participate were invited

to join a group information session where they were presented in detail the practical aspects of the study. Confirmation and assurance that the anonymity of the participants is guaranteed were given to participants, in order to comply with the ethical permissions granted by the relevant bodies mentioned above, to maintain a high ethical quality and in an effort to make participants feel more comfortable and therefore enhance enrollment in the study. The observers had no relationship with wards or with the ward staff where the study was conducted and did not know the nurses worked in the wards beforehand. This was important as any previous relationship between observes and nurses could influence the ratings during the observation. Additionally, during the observation the observers tried to be discreet, unconstructive and non-interfering and they were informed about these important principles of the naturalistic observation method as they minimize the risk of affecting the normal, routine performance of the nurses who were enrolled in the observation phase. Therefore, any kind of distractions made by the observers were avoided. Still, it could be assumed that the observations had an impact on the clinical performance of the nurses. However, this issue is addressed by the specific observation method used. As described above in this chapter, the Hawthorne effect refers to a type of reactivity in which individuals modify an aspect of their behavior in response to their awareness of being observed. In this study, Hawthorne effect was addressed in this study by the use of the above-mentioned observation method (i.e., naturalistic approach) and assurance is also gained by the fact that it is already known from previous research that the direct observation is not affecting the performance of the participants. In particular, there is evidence in the literature supporting the fact that the implementation of a non-interfering, non-obstructive and discreet approach during the observation (i.e., naturalistic approach) the behavior of the subjects observed is not affected or altered. Also there is evidence from previous research (Dean & Barber, 2001) that there is no difference in the numbers of medication errors and omissions during observation and non-observation periods, which means that observers did not affect the clinical performance or the normal routine practice of the nurses who were enrolled in the study.

For ethical reasons, it was agreed in advance, that any potentially harmful errors detected during the observation will be prevented by discreetly notifying the nurse that an error is about to be made. This was in line with previous observational studies as well and it was a

measure that could protect the patient of being harmed and the nurse from committing an error during his/her work. It is noted here that according to there is a substantial ethical burden of falling into errors for nurses

4.3 Study Design

A qualitative and a quantitative research design was followed for the conduct of this study. In particular, a descriptive observational study and a focus group study were planned for the purposes of the present research. The research design was drafted by the research team in order to answer the research questions validly, objectively, accurately and economically. Relevant variables (i.e., medication errors, associated factors) were operationalized in such a way that they could be measured, and appropriate sampling approaches were considered, as well as appropriate methods for collecting and analyzing the data. Therefore, the development of the study design was based on the need to effectively and efficiently addressing the research objectives as set by the research team and described in the previous chapter. A design that would produce valid evidence and would ascertain the validity and reliability of the study was sought. After considering the available, feasible options, and taking into account the methodological strategies implemented by previous similar research, the research team decided to implement a mixed method approach; a qualitative and a quantitative approach. In the case of the current study, the two different methods were combined in such a way as to enhance and inform the findings resulted from of each other. The direct observation phase has preceded in terms of timing the focus groups; thus, it was very helpful in drafting the interview guide used later in the focus groups study. Similarly, the focus group study results informed, supplement and in some cases explained the findings of the observational phase.

In particular, based on the available literature and after several exploratory literature reviews, this study consisted of two stages: an observational and a focus groups stage. The final picture of the under-investigation issue (i.e., medication errors) would be the outcome of the evidence derived from both studies. It is reminded however that the focus group study only

focused on the related factors, not frequency and types. In fact, the latter phase of the study would complete the data collected by the former approach (i.e., observation). These two stages had a different design, different timeframes, different samples, different data collection method and different method of analysis. It is clarified at this point that not all nurses who participated in the observational study have participated later in the focus groups. Few of the participants however did participate in both phases. Therefore, this study contained both; a quantitative design (i.e., observational study) and a qualitative design (i.e., focus groups). The methodological characteristics of these studies are provided below, with a detailed and in-depth description of the methods employed for collecting and analyzing the data.

4.3.1 Quantitative approach

The first part of this research was a descriptive observational study where the direct, undisguised, non-participant observation method was used in order to address the first two of the previously described research objectives (i.e., number and type of errors and associated factors). Medication errors and associated factors were identified via direct observation of the medication administration process with parallel review of patients' medication records. More specifically, the whole medication process was considered, and its operational characteristics and details were captured by the researchers before initiating the study. The observation covered and recorded, as appropriate, all relevant parameters needed for the purpose of this study including the preparation of medicines for administration, the work organization system employed, the staffing, the shifts in each medication round observed, the environmental conditions (e.g., visitors in the wards, interruptions) nurses experience and patients' age and number of medicines taken, as well as the medication attributes (i.e. pharmaceutical form and therapeutic class). In order to collect all this information, apart from directly observing the medication process and the nurse administering the drugs, in parallel the medication records were reviewed for collecting additional information, like the drug, the dose and the instructions prescribed, in order to compare the prescriptions and records with the actual administration and to check whether the administration was properly documented in the records.

4.3.2. Qualitative approach

The second phase of this research consisted of a qualitative descriptive study where two focus group discussions took place in order to explain the findings of the first stage and obtain a picture of nurses' perceptions regarding the factors contributing to medication errors in medical wards. In this study, focus group interviews aimed at exploring the determinants constituting risk factors for medication errors, based on perceptions of nurses involved in the medication process in medical wards. The rationale for selecting a quantitative design, focus group discussions particularly, gave the possibility to go deeper and investigate several aspects of the medication errors problem from the participants' statements and narratives. This qualitative design gave the opportunity to the research team to obtain relevant useful information on the under-research topic, information that probably could not have been collected only from a quantitative research approach.

4.4 Functional Definitions used for the purpose of the study: Errors and Associated Factors

Errors:

As already mentioned in previous chapters, there are many definitions of medication errors in the published literature. Many studies use different terms for defying medication errors. The selection of a specific term is important for every study because it predetermines the results and their interpretation. For example, in some studies, as noted in the discussion on definitions in the scoping review chapter above, omission was defined as the doses omitted, thus any other types of omission were excluded from and not reported in these studies. In this study we aimed to explore and report all possible types of errors made during the medication process in the two medical wards where the study took place. Therefore, a more inclusive and comprehensive definition was sought in this study. To this end, in this study any deviation from safe drug administration was recorded as an error. Deviations have been described as outliers, exceptions, or aberrations and represent actions that deviate from protocols intended to uphold patient safety during medication administration (Visweswaran et al., 2010). Omissions in drug administration are considered preventable events that do reach the patient and have the capacity to cause or lead to inappropriate drug use or even

patient harm (National Coordinating Council for Medication Error Reporting and Prevention, 2020). Therefore, exploring the different types and causes of omissions in drug administration is important for improving patient safety. Medication administration errors were defined as a deviation from the doctor's order as written on the patient's therapy charts, a deviation from the manufacturers' preparation/administration instructions, or deviations from the relevant organization's guidelines or policies (Keers et al., 2013b).

In fact, in this direct observation study, each dose administered or omitted represented an Opportunity for Error (Allan & Barker, 1990), and each opportunity for error could result in more than one type of error. This was one of the major differentiations of this study from previous ones where omission represented only an omitted dose or drug. In this observational study actions or procedures omitted, missed or left unfinished were recorded as omissions while actions executed wrongly, inaccurately or inappropriately were recorded as errors of commission. More specifically medication errors were grouped in eight different categories based on their characteristics and resulted eventually in 17 different items to be observed during the observation phase of the study (Table 4). These were selected based on previous observational studies that used such forms, and on relevant information from the literature. They were adapted in the needs of the present study and agreed by a panel of experts which was comprised of different healthcare professionals with different academic and scientific backgrounds. These were the "adherence to the five rights of medication safety" as they are taught in pharmacology practice of almost all nursing schools (Kim & Bates, 2013; Martyn et al., 2019), "adherence to basic infection and safety regulation" (Kim & Bates, 2013; Rao et al., 2013), "adherence to drug administration record protocol" (i.e. documentation errors) (Hartel et al., 2011; Kim & Bates, 2013) and "adherence to administration methods and guidelines" (Härkänen et al., 2015; Kim & Bates, 2013).

Table 4: Types of medication administration errors considered in the study

Error Category		Item
Adherence to basic infection and safety regulation		Wash hands before administering medication
		IV equipment placed only in disinfected areas
		Disinfect site of injection
Adherence to the 5 rights of medication Safety	Right Medicine	Read medicine's name on label for at least one second
		Medication is prepared by the nurse who will administer it
	Right Dose	Confirm the strength indicated on label for at least 1 sec
		Confirm the dose from prescription for at least 1 sec
		Confirm the dosage at eye level for syringes
	Right Patient	Read patient name from medication record
		Ask patient to confirm his/her name
	Right Route	Read administration route on label at least one second
	Right Time	Medicine administered at the right time
Adherence to administration methods and guidelines		Infusion rate is in accordance to manufacturer instructions
		Prepare the medication right before the administration
		The medicine is injected at the correct site and/or angle
Adherence to drug administration record protocol		The nurse who administered the drug records the event
		The time of the administration is accurately recorded

Factors:

The selection of the factors to be assessed for association with the occurrence of error was based mostly in the literature and based on previous observational studies that used such forms. They were adapted in the needs of the present study and agreed by a panel of experts as already described above. Studies that explored errors related with MAEs were considered and based on previous evidence it was decided to include specific factors. In particular, factors assessed for associations with errors, and detected during the observation stage of this

study, were staffing, work system in ward (i.e. number of patients assigned per nurse for medication administration), distractions and/or interruptions (by staff, patients or visitors), shifts (morning, evening, or night shift), days (weekdays or weekends), pharmaceutical form (oral, injectable or other forms), drug therapeutic class (e.g. cardiovascular, antibiotics, anticoagulants, nervous system drugs, or other class), patient's age, number of medicines taken per patient and nurse experience (Table 5).

Regarding the focus group study, the same definition for associated factors was used however, since this was a study where the perceptions of nurses were sought via an open group discussion about the error related factors, these factors definitions were not put on the table for discussion but were embedded in the questions raised during the discussion by the moderator in a discreet manner in order to guide the interviews but at the same time not be leading or confusing for participants. This issue is discussed further under the focus group study description. It is noted for clarification that these factors guided the development of the focus group interview guide, but they did not provide a framework for the analysis, in fact the analysis was rather based on an inductive approach. It is noted that errors were classified in order to create the appropriate variables (e.g., nominal variables) and to facilitate statistical analysis and calculations which are presented in chapter 5.

Table 5: Medication errors related factors

Associated Factors	
Professional practice environment and related factors	**Shift**
	Morning
	Evening
	Night
	Days
	Weekdays
	Weekends
	Interruptions or distractions
	Yes
	No
Drug related factors	**Number of patients for medication administration per nurse**
	above five patients
	below five patients
	Pharmaceutical Form
	Oral
	Injectable
	Other
	Drug Therapeutic Class
	Cardiovascular drugs
	Antibiotics
	Antithrombotic
	Nervous System drugs
	Other drug class
Nurse related factors	**Nurse Experience**
	Mean number in years
Patient related factors	**Patient Age**
	Mean age in years
	Number of medicines taken by patient
	Mean number

4.5 Sample and Sample size

Observational study:

A “sample” consists of a small collection drawn from a larger “population” for which the desired information is sought. It is the sample that is observed, but it is the population that is studied. The “study population” is a subset of the target population from which the sample is actually selected (Hu, 2014; Korstjens & Moser, 2018). The number of observations in the sample is referred to as “sample size”, while the physical composition and magnitude of a single sample is called the “sample unit” (Ruesink, 1980). In this study, all doses administered in the two medical wards during the study is the study population from which the sample will be derived. Each dose administered to a patient in this study is the basic sample unit which is actually the issue under investigation, thus, each dose administered represents an element of the study population.

Although there is no generally accepted view on sample size, it is recommended for researchers dealing with quantitative measurements to use samples as large as possible (J. Cohen, 1988). The larger the sample of a survey, the smaller the potential type II error, i.e., probability of not rejecting the null hypothesis when it is false. On the other hand, it has been argued that the choice of larger from the required sample leads to a waste of time and resources (J. Cohen, 1988). Furthermore, the power of a statistical test is the probability that it will yield statistically significant results. A power analysis can be used to estimate the minimum sample size required for an experiment, given a desired significance level, effect size, and statistical power (J. Cohen, 1988).

In this study the power analysis was used to find the appropriate sample size and for this purpose the statistical program G*Power 3.1 (Faul et al., 2007) was utilized. G*Power was designed as a general stand-alone power analysis program for statistical tests commonly used in social and behavioral research. It covers many different statistical tests of the t, F, and x^2 test families. In addition, it includes power analyses for z tests and some exact tests. G*Power 3 provides improved effect size calculators, supports both distribution-based and design-

based input modes, and offers different types of power analyses and is free (Erdfelder et al., 1996; Faul et al., 2007).

The estimation of the study size (i.e., number of administrations) was based on the principle that an intervention would be made. The rationale behind it was that this estimate would function as a baseline rate in a future interventional study. Having said that, the research team reviewed the determination of sample sizes in previous observational studies investigating medication errors and the impact of different interventions for reducing medication errors (before and after studies), and concluded that the sample size in this study should be capable of detecting a reduction in medication errors from 7% (before implementing the intervention) to 3.5% (after the intervention) with an alpha of 0.05 and a power of 80% (Campbell et al., 1995; B. Dean, Schachter, Vincent, & Barber, 2002; Bryony Dean & Barber, 2000; Franklin, O'Grady, Donyai, Jacklin, & Barber, 2007; M. McLeod, 2013). Even though it was anticipated that a higher proportion would be recorded in our study, a lower figure was used (i.e., 7%) to ensure that the sample size would be adequate for smaller proportions as a smaller sample would be needed to detect. The rationale of estimating sample sizes based on the assumption that an intervention capable of reducing errors to half, would be made, is adopted from several previous research (Campbell et al., 1995; B. Dean, Schachter, Vincent, & Barber, 2002; Bryony Dean & Barber, 2000; Franklin, O'Grady, Donyai, Jacklin, & Barber, 2007; M. McLeod, 2013). Therefore, by using the z test for the difference between two proportions (i.e., proportion of errors pre and post intervention) as described by Cohen (1988), which is supported by G*Power, it was possible to calculate the sample size for this study. The z score test for two population proportions aims to estimate if two populations or two groups differ significantly on a single categorical characteristic (Campbell et al., 1995; J. Cohen, 1988). It is acknowledged that the estimation of the sample size is possible to be made by using other options. For instance, similar estimates can be yielded by using simpler modified formulas appropriate for binary data (e.g. the Lehr's modified equation) (Campbell et al., 1995; Kirkwood & Sterne, 2003; Lehr, 1992). The aim here was to observe enough administrations under all possible working conditions. In an effort to collect information under all possible conditions, observations took place in all days, including weekends, all shifts and during all possible work organization systems in the wards. As mentioned above,

the estimation of the study size (i.e., number of administrations) was based on the assumption that an intervention would be made. It was calculated that a sample of 637 administrations before and 637 after an intervention would be needed to detect a reduction in MAEs from 7% to 3.5%, based on a two-sided test with an alpha of 0.05 and a power of 80% (Campbell et al., 1995; B. Dean et al., 2002; Bryony Dean & Barber, 2000; Bryony Dean Franklin et al., 2007; McLeod, 2013). A total of 665 administrations were observed.

Focus group study:

Nurses involved in the medication process in the two medical wards of the tertiary hospital where the study was conducted, were invited to participate in the focus group discussions. It is reminded that some of the nurses participated in the observational study, also participated in the focus group study, but not all participants participated in both phases. In order to achieve a comprehensive representation of nurses involved in the medication process in the medical wards, a purposive sampling approach was implemented. Eligible nurses were identified and approached by the researchers, after consulting with the ward management, and a face-to-face detailed oral explanation about the study was provided. Inclusion criteria for nurses' participation were the involvement in the medication process and currently working in one of the two medical wards. In the two wards that the study was conducted, nurses had the responsibility of preparing and administering the prescribed drugs to all inpatients. Because the aim was to collect the perceptions of nurses on the causes of MAEs, other healthcare professionals were not invited to participate, as they were not directly involved in this drug administration process. Recruitment aimed to create two groups with homogeneity in respect of educational level and job rank in order to ensure an open discussion among participants without being cautious in expressing their personal perceptions in the presence of their senior colleagues (Papastavrou & Andreou, 2012). Heterogeneity however, was sought for work experience in order to obtain the perceptions of both; fresh and experienced nurses (McLafferty, 2004; Papastavrou & Andreou, 2012). Therefore, nurses with a difference in the years of work experience and with a bachelor and a master's degree were invited. In total, 13 nurses, that met the above criteria, agreed to be enrolled. None of the nurses revoked his/her participation and two focus groups were

conducted (Group A=5 nurses, Group B=7 nurses). All of the participants were registered nurses while five of them had additionally a master's degree. In addition, their work experience, including experience in the medication process, ranged from two to eighteen years, none of them had a managerial position and they were all working in one of the two medical wards of the same tertiary hospital where recruitment took place.

4.6 Data Analysis Methods

Observational study:

Descriptive statistics were used to calculate the numbers and types of errors and for presenting the demographic data, working environment conditions and the characteristics of the participants. Each administration observed was considered as a whole and the count of errors per administration reflects the number of errors out of the 17 items recorded. Observed administration were then dichotomized at two cut-off points: administrations with more than three errors (≥ 3) and administrations with more than five errors (≥ 5). By dichotomizing the administrations based on the number of errors observed in each one gave the possibility to treat these two variables as categorical variables and therefore assess associations between different factors and occurrence of a higher number of medication errors. In particular, Chi square and logistic regression test were used to assess relationships between categorical or continuous variables respectively and number of errors (i.e., administrations with ≥ 3 and administrations with ≥ 5 errors). Furthermore, two stepwise binary logistic regression models have then been completed, one for each dichotomized response (≥ 3 and ≥ 5 errors) in order to explore which factors could predict the occurrence of a higher number of errors. Risk factors were included in the regression models and factors without a statistically significant contribution to the model were removed by using a stepwise (backwards) approach. When the observation of the targeted number of administrations was finalized, data were processed using IBM SPSS Statistics v23 for Windows. All the statistical analysis results, including respective tables, are described, and presented in detail in the following Chapter 5. It is highlighted here that data analysis that specifically concerns the pilot study (the study preceded the main study) is provided below in the pilot's study dedicated section (4.8.3 Pilot study).

Focus Groups study:

Analysis of data collected during focus groups discussions included the transcription of the discussions, data coding and analysis based on the thematic analysis method. The details of the thematic analysis method used in this study are described below.

4.7 Methods used for data collection

Different methods can be used to collect primary data. The choice of a method largely depends upon the purpose of the study and the resources available. Additionally, when selecting a method of data collection, the socioeconomic and demographic characteristics of the population involved play an important role, particularly the attitudes towards the participation in the study. Participants may not feel comfortable or willing to participate in a study because of the specific method of data collection used (Kumar, 2005). For example, in this study, nurses may not feel at ease to be observed during their work or comfortable to express their opinion when being interviewed. In this study the research question (i.e., medication errors made by nurses) is a sensitive issue because it concerns errors, mistakes in the daily professional practice of the participants and therefore this pose a challenge in the smooth conduct of the study and was taken into account by the research team when drafting the methods for collecting the data. After considering all possible options, it was decided to use the direct observation method to record the number and types of medication errors and explore associated factors and the focus group interviews to explore nurses' perceptions of medication errors associated factors. The use of both of these methods as well as the rationale for the reasons for selecting these two specific methods is described below.

4.8 Collection of data through Direct Observation

The observation is a purposeful, systematic and selective way of watching and listening to an action or a phenomenon as it takes place (Kumar, 2005). There are many situations in which observation is the most appropriate method of data collection; for example, when the

aim is to study the functions performed by a worker or the behavior of an individual. It is also appropriate in situations where full and/or accurate information cannot be elicited by questioning because responders either are not co-operative or unaware of the answers because is difficult for them to detach themselves form the interaction. When individuals are so involved in the problem under investigation they are unable to provide objective information about it, therefore, the observation is the best approach to collect the required information (Kumar, 2005). The direct observation method is one of the oldest methods and remains one of the most commonly used methods for collecting data in scientific research, including MAEs (Dean & Barber, 2001; Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Härkänen, Vehviläinen-Julkunen, et al., 2020; Jersild & Meigs, 1939).

Observational studies could be divided into non-participant or naturalistic, participant and contrived observation (Gravetter & Forzano, 2012; Kumar, 2005). Naturalistic or non-participant observation is when the researcher does not get involved or interfere in the activities of the group or of the individual being observed but remain a passive observer, watching, listening and recording the activities of the group or of the individual being observed (Blignaut, 2015; Kumar, 2005). The observational method implemented in this study was naturalistic, non-participant observation, as the observers tried to be as inconspicuous and discreet as possibly, passively recording what occurred in order to have the minimum impact possible on the behavior of the participants.

As already described in Chapter 2 (Scoping Review), despite the fact that different methods may be employed to detect medication errors, the direct observation method is considered to be the golden standard. In fact, there are many and different methods for detecting medication administration errors (Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002). These methods include the direct observation of the medication administration process, reviewing patients' charts, reviewing incident reports involving medication errors, interviewing health care personnel to stimulate self-report, analyzing doses returned to the pharmacy, testing urine for evidence of omitted drugs and unauthorized drug administration, examining death certificates, reviewing nursing shift report, comparing medication administration record with

physicians' orders, performing computerized analysis to identify patients receiving target drugs that may be used to treat a medication error or to search for serum drug concentration orders that may indicate an overdose, comparing drugs removed from an automated drug-dispensing device for patients with physicians' orders and using trigger tools for measuring adverse drug events or using automated error-reporting tools (Dean & Barber, 2001; Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002). However, the direct observation is considered to be more efficient and accurate than other methods (McLeod, Barber, Dean Franklin, et al., 2013). Direct observation provides many advantages for detecting medication errors. Moreover, the validity of the results of the direct observation is clearly superior and have a direct clinical interpretation. Data are collected with objectivity and can be conducted under normal working conditions (Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Härkänen et al., 2015). There is also evidence suggesting that MAE rates were not affected when a non-judgmental, non-interfering observation method is employed (Dean & Barber, 2001; Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Flynn & Pepper, 2003).

4.8.1 Validity and reliability of the observation method

It is suggested by previous research that the direct observation method, particularly naturalistic observation, has a higher level of validity than most other research methods because a discreet, non-judgmental, non-interfering approach is employed and therefore true and natural behaviors are observed (Blignaut, 2015; Dean & Barber, 2001; Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Jersild & Meigs, 1939). However, it has disadvantages too. One of the disadvantages of the observation method is that the observer may pay more attention to behaviors that are expected to be observed or behaviors that support the research hypotheses and ignore behaviors that might not support the study expectations (Kumar, 2005). In addition, if an observer is biased then she/he can easily introduce bias in the study and there is no easy way to verify the observations and the inferences drawn from them. A subjective and idiosyncratic nature of the observer who carries out the observation may jeopardize the external validity of the study (i.e., the results of the research may not be applicable to different settings). Similarly, if the observer is too attached to the participants or to the group then his/her ratings will be affected, thus internal validity can be affected as

well (i.e. the results of the research may not represent the real situation) (Cohen et al., 2007; Kumar, 2005). Also, the interpretations or the ratings drawn from observations may vary between different observers. Moreover, participant's behavior or performance may be impacted or altered when they know they are being observed (i.e., Hawthorne effect). These risks can be mediated by the way the observation is recorded. There are different types of mechanisms of recording an observation and the selection of a method of recording depends upon the purpose of the observation (Blignaut, 2015; Jersild & Meigs, 1939; Kumar, 2005).

In this study, in order to mitigate all these risks carried by the chosen method, the following strategies were implemented; first, it was decided to use a structured checklist, an observational form, where the observers recorded the administration based on the items listed in the observational form. This way objectivity was enhanced because the observers had to record all actions observed during the administration of medications by completing the form and not by using their personal judgement. The recording was done on this observation form therefore the risk of observer bias was prevented. Hence a structured study was conducted, with the use of a measuring instrument, i.e., observational form, which offered a high level of precision in recording relevant behavior or acts and included exclusive and exhaustive categories. There is evidence in the literature that by using checklists and observational forms in an observational study, a more structured and objective method of data collection is achieved, allowing the researchers to focus on a limited, and relevant to the study objectives, behaviors or acts (Blignaut, 2015; Dean & Barber, 2001; Härkänen et al., 2015; Jersild & Meigs, 1939; Kumar, 2005). Furthermore, with the use of an observational form the data were quantified much easier than would have done in a narrative type of recording (Blignaut, 2015; Kumar, 2005). Measures were also taken in order to ensure that observers entered the data into the appropriate categories in a consistent and accurate manner. In other words, in order to ensure the validity of the study, the risk of having a variability between the ratings of the two observes who carried out the observation with the use of the observational form, had to be assess and establish that the tool had acceptable inter-observer reliability. To that end, the research team decided to carry out a pilot study to ensure that the observational form and the items included in the form are appropriate, discrete, and effectively operationalize the purposes of the research. This pilot study had a multiple role; it helped testing the

observational form, observers had the chance to test the form and the method, the personnel in the wards got used to the presence of the observers in the ward during the medication process, therefore mitigating the Hawthorn effect. There is also evidence suggesting that MAE rates are not affected when a non-judgmental, non-interfering observation method is employed (Kenneth N Barker et al., 2002; Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Flynn & Pepper, 2003). Also, the data derived from the pilot study was used to confirm agreement between observers (i.e., inter-rater agreement and Cohen's kappa). The pilot study is described below.

4.8.2 Observation Form and Data collection

A structured observation form was used for data collection (Appendix III). The form was developed based on forms used in previous observational studies (Bertsche et al., 2008; Härkänen et al., 2015; Kim & Bates, 2013) but adapted to the needs of this study. Each item included in the form had a logical and direct link with the objective of the observational study, and cover the full range of the medication errors issue. Hence, the form reflected all possible errors and omissions that could occur during medication administration. When the initial observation form was designed, a multidisciplinary team of experts reviewed, discussed and revised the components of the form and confirmed the face validity of the final version of the form. In particular, the team developed the form comprised from two professors of the nursing school, two clinical nurses with expertise in medication administration to inpatients and one pharmacist. The team discussed the selected items in the first drafts of the form, adapted the content in such a way that it would be easy to be observed and thus completed by the observers and also confirmed the validity of the form. After removing eight items and rewording four other items, the final version of the form was ready. The observation form constituted of two sections (Appendix III). The first section covered working environment related factors, patients age and number of medicines taken per patient, nurse's age, shift, the day, and additional information about the drug administered. The second part focused more on the actual administration process and collected information about the possible deviations from basic safety administration (e.g., infection control

principles, 5 rights of the drug administration guidelines) including documentation of administration in the medication records.

In the first section of the form, in particular, the observer could record general information like the date, the observation number and the ward identifying code. Professional practice environment and related information was also included and could be recorded in this section (day, shift, staffing, work organization system, number of patients in ward). In this section observers could also record information about the nurse (e.g., experience, relevant training, educational level), about the patient (e.g., age, sex, number of medicines taken), about the medicine administered (type, form and route of administration, administration method, infusion rate). With the exception of the information concerning the administration method details (i.e., time between preparation and administration, infusion rate etc.), most of the first part of the form could be completed by the observer before the medicine reached the patient for administration because the first part of the form contained information that could be found mostly form the medication records or other information like ward code or nurse's information. The second part of the form was related with the actual drug administration by nurses and consisted of information relevant with the non-adherence to the five right principles of safe medication administration, with the non-adherence to the basic infection and safety regulation, non-adherence to administration methods and guidelines, and non-adherence to drug administration record protocol. Furthermore, in order to be easily completed, the second part of the form constituted from check-points with the option of YES, NO or N/A (i.e., not applicable) and the observer checked the relevant tick-box as appropriate. The observation form had a small space for writing comments or notes, in case the observer needed to note something.

The observation was carried out by the two observers in parallel, one in each ward. Observers arrived at the ward before the medication administration began and informed the nurse, who had already agreed to participate, that the medication process will be recorded. Observers recorded the administration process by following the nurses carrying out the medication round and reviewed drug orders and records in order to be able to cross check the medicine

administered with the medicine prescribed. Drug orders and medication records were on paper, as there was no electronic prescription or medication system used in the wards. There were three scheduled routine medication rounds in the wards (i.e., morning, evening and night). Medication rounds in the two wards lasted from thirty minutes to approximately two hours, depending on the type of work organization system in the ward and on staffing. In particular, when nurses were allocated to tasks rather than to patients, drug administration rounds were prolonged (approximately two hours) because one or two nurses had to prepare and administer medication to all ward inpatients. When nurses were allocated to patients, time per drug administration round was decreased (approximately thirty minutes) because one nurse had to prepare and administer medication for three or four inpatients. Observers were registered nurses, and both were experienced in the medication process in hospital wards. However, as mentioned above, they did not have any relationship with the wards where the study was conducted. Observers were informed about the study and had theoretical and practical training in the direct observation method before the study was initiated. They were involved in helping to draft the observation form and were able to test the method and the form during the pretest phase (pilot study). The study was undisguised; hence the nurses and ward managers were informed about the study beforehand. If there was a risk for an error during observation (e.g., giving a wrong dose), observers intervened and politely asked the nurse to check again before administration in order to protect patients from being harmed. This was in line with previous studies (Dean & Barber, 2001; Härkänen et al., 2015; Westbrook et al., 2011) and such doses were considered as MAEs. In both wards the nurses were responsible for medication preparation and administration, as there were no ward pharmacists or other staff involved in these procedures.

4.8.3 Pilot study

A pilot study took place before initiating the main study. The pilot study had been conducted in order to test the form and to evaluate the inter-rater agreement. Inter-rater agreement analysis was needed in this study in order to demonstrate consistency among observational ratings provided by multiple coders (Hallgren, 2012). It is noted that intra-rater agreement does not apply in this case as it refers to the consistency in ratings given by the same person

across multiple instances, which is not the case in our study. Thus, only inter-rater agreement is assessed. Inter-rater agreement analysis aimed to determine how much of the variance in the observed scores is due to variance in the true scores after the variance due to measurement error between coders has been removed (Hallgren, 2012). Cohen's (1960) kappa and related kappa variants are commonly used for assessing inter-rater agreement for nominal variables. Kappa statistics measure the observed level of agreement between coders for a set of nominal ratings and corrects for agreement that would be expected by chance, providing a standardized index of IRR that can be generalized across studies. The degree of observed agreement is determined by cross-tabulating ratings for two coders, and the agreement expected by chance is determined by the marginal frequencies of each coder's ratings (Hallgren, 2012). The values for kappa statistics range from −1 to 1, with 1 indicating perfect agreement, 0 indicating completely random agreement, and −1 indicating "perfect" disagreement. It suggested that conclusions should be discounted for variables with values less than 0.67, conclusions tentatively be made for values between 0.67 and 0.80, and definite conclusions be made for values above 0.80 (Hallgren, 2012). In this testing phase the two raters observed simultaneously and independently the same nurse administering the same medicine to the same patient and each one recorded the administrations using the observation form which was drafted for serving this specific purpose. During the pilot phase 85 administrations were recorded by using the observation form and Cohen's Kappa coefficient was used to confirm agreement between observers (Hallgren, 2012; Härkänen et al., 2015). A very high level of agreement between the observers was noted in all cases. The lowest level of agreement between observers calculated at 92.9% and the lowest Cohen's kappa coefficient found was $k=0.81$, $p<0.001$, which confirmed almost perfect agreement between the observers' ratings. The results of the inter-rater agreement test are provided in a tabular form in Appendix VII for all items (error types) recorded. No items were removed from the observation form after the pilot study. The calculations of the raters' agreement and Cohen's kappa coefficient were made with IBM SPSS v23 for Windows.

Additionally, the pilot study gave the opportunity to the observers and staff to get used to each other's presence during medication administration, by prolonging the presence of the observers in the wards, therefore mitigating the Hawthorne effect. When individuals or

groups become aware of the fact that they are being observed, they may change their behavior and this change could be either negative or positive or may alter their performance for a number of reasons. When the change in the behavior of persons or groups is attributed to their being observed is known as “Hawthorn effect” (Kumar, 2005). The Hawthorne Effect was first reported following a research program investigating methods of increasing productivity in the Western Electrical Company's Hawthorne Works in Chicago during the 1920s and 30s, but although first reported in industrial research, the Hawthorne Effect have its implications in clinical research as well (McCarney et al., 2007). The 'Hawthorne Effect' may be an important factor affecting the generalizability of clinical research to routine practice (Campino et al., 2008; McCarney et al., 2007) and should be taken into account when implementing observational studies. Therefore, in this study by having this pilot phase we informed the staff about the study in a friendly manner, we prolonged the presence of the observers in the wards therefore staff got used to their presence during medication administration, we avoided talking about errors during the observation and we explained to the staff that the study is to detect systemic flaws in order to improve the system and not to accuse individuals. Moreover, assurance was given that any information obtained in connection with the study that could identify the subject will be not disclosed and will remain strictly confidential.

4.8.4 Data analysis

In this study any deviation from safe drug administration was recorded as an error. In addition, each dose administered or omitted represented an opportunity for error (Allan & Barker, 1990), and each opportunity for error could result in more than one type of error. Deviations are considered as outliers, exceptions, or aberrations and constitute actions that deviate from protocols intended to uphold patient safety during medication administration (Visweswaran et al., 2010). Omissions in drug administration are considered preventable events that do reach the patient and have the capacity to cause or lead to inappropriate drug use or even patient harm (National Coordinating Council for Medication Error Reporting and Prevention, 2020). In this study, actions or procedures omitted, missed, or left unfinished

were recorded as omissions while actions executed wrongly, inaccurately, or inappropriately were recorded as errors of commission.

The primary end point here was to explore errors of omission and error of commission, as well as to classify the errors based on the type and nature. Hence, in accordance with the psychological error-classification approach, medication errors were categorized in two groups; errors of omission and errors of commission. Furthermore, to further classify errors, an additional categorization was made based on the type and nature of the deviation from safety basic principles in which medication errors were observed. To that end, medication errors were categorized as follow: non-adherence to basic infection and safety regulation (3 items), non-adherence to the five rights of medication safety (9 items), non-adherence to administration methods and guidelines (3 items), Adherence to drug administration record protocol (2 items). In total, 17 different types of errors and omissions were put down for observation (Table 4). So apart from presenting the number of errors recorded during the observational study, a detailed description of the errors, based on their type and category, is also provided below.

The prevalence and types of errors are presented and described in two ways, as a percentage of the number of administrations observed and as a percentage of the total number of errors recorded. Also, they are classified, presented, and described based on their type and on the "omission-commission" classification in chapter 5 Results (Tables 16 and 17). The associations were investigating with chi-square test and logistic regression analysis.

4.8.5 Normality testing of the distribution of medication errors detected per administration

The number of errors per administration was the numerical dependent variable under investigation here and apart from finding the minimum, maximum and mean number, it was necessary to determine whether the data were normally distributed, and if they were normally distributed, the appropriate parametric statistical analysis of the data could be employed.

Otherwise, if the distribution of errors per administration was not normally distributed nonparametric tests would be appropriate for statistical analysis. IBM SPSS, Statistics version 23 was employed to test for normality and all statistical test thereafter. In particular, the following numerical and visual outputs were investigated to test for normality: skewness and kurtosis z values, the Shapiro-Wilk test p value and Histograms, and Normal Q-Q plots. Both tests, Kolmogorov-Smirnov test and Shapiro-Wilk test were statistically significant, therefore the null hypothesis (i.e., the variable is normally distributed) was rejected and can be said that the number of medication errors per administration is not normally distributed. In addition, kurtosis and skewness departure from zero (Table 14). When kurtosis and skewness measures are as close to zero as possible in SPSS, it can be suggested that the data is morally distributed. Small departures from zero are acceptable, if the measures are not too large compared to their standard error. As it can be seen from the below Table 14, in this case kurtosis and skewness measures are not close to zero enough and they are large in comparison with their standard error. In addition, the z-value of kurtosis and skewness measures should be somewhere between -1.96 and +1.96 in order to be able to assume that the variable under investigation is normally distributed. Still this condition is not met in this case (Table 14), therefore, it can be concluded that the medication error number per administration is not normally distributed. This was an important aspect for the statistical analysis of the data hereafter. Moreover, the assumption that the data is not normally distributed was also supported by the Histogram and Normal Q-Q plots.

Table 6: Normality test for medication errors distribution

errors per administration	Statistic	Std. Error
Mean	3,5	0,0761
Std. Deviation	1,9	
Minimum	1,00	
Maximum	11,00	
Skewness	1,4	0,095
Kurtosis	2,5	0,189
Skewness z value	15,1	
Kurtosis z value	13,3	
Kolmogorov-Smirnov test p value	<0.001	
Shapiro-Wilk test p value	<0.001	

4.9 Collection of Data through Focus Groups

The second phase of this research was a qualitative study where two focus group discussions took place in order to obtain a picture of nurses' perceptions regarding the factors contributing to medication errors in medical wards. Qualitative data deriving from focus group discussions allow an in depth comprehension of participant's perceptions on the discussion topic concerned, and have been used extensively in previous research aimed to gain insights of participants' perceptions (Escrivá Gracia et al., 2019; Papastavrou & Andreou, 2012). In a focus group interview, the perceptions, experiences and understandings of a group of people who have some experience in common with regard to a situation or an event can be explored (Kumar, 2005; Papastavrou et al., 2014). In this study, focus group interviews aimed at exploring the determinants constituting risk factors for medication errors, based on perceptions of nurses involved in the medication process in medical wards. In comparison with other methods, focus group discussions have several advantages (Freeman, 2006). The sense of freedom and security among participants and the dynamic of a focus group is motivating for participants and creates a suitable environment to elicit the opinions of the group (McLafferty, 2004; Wilkinson & Birmingham, 2003). Furthermore, because

"errors" is a sensitive issue, this method gives the opportunity to the participants to express their perceptions in a safe environment (McLafferty, 2004; Papastavrou et al., 2014). The study was conducted and reported in accordance with the Consolidated Criteria for Reporting Qualitative Studies (COREQ) (Tong et al., 2007).

4.9.1 Data collection

Focus group interviews were conducted from January to February 2020 in one of the hospital's meeting rooms. The first interview lasted 75 minutes and the second 90 minutes. Focus groups were led by a moderator in the presence of an observer. The moderator guided the discussion based on a semi-structured interview guide, while the observer took notes of the conversation. The moderator had previous experience in conducting focus group interviews and with the medication process in clinical wards but had no relationship with the medical wards or the participants. The interviews went on up to the saturation point of the data where no additional statements or views were expressed (McLafferty, 2004; Papastavrou & Andreou, 2012). Two audio recording devices was used at each focus group to record the discussions for later transcription and analysis. The observer distinctively helped to avoid issues relevant with medication error but irrelevant with the aim of the study (e.g., legal or ethical aspects of medication errors), informed the moderator if more details are needed to elaborate on a participant's comment and took notes of participants' reactions and behaviors relevant to the issues raised during discussions. Transcripts and notes taken during the collection or during the analysis of the data were strictly confidential and were not disclosed to anybody.

4.9.2 Development of the interview guide

It was agreed by the research team to develop a semi-structured guide (Appendix . A semi-structure guide is considered to be suitable when there are issues that participants are not used to talking about, such as errors in this case, and is possible to focus on the issues that are meaningful for the participants, allowing diverse perceptions to be expressed (Kallio et al., 2016). The development of the interview guide was based on a literature review that led

in mapping the most common causes of medication errors in clinical settings and created a conceptual basis for the interview (Kallio et al., 2016). After this step, medication error risk factors, as described in literature, were embedded into an initial set of questions and a preliminary semi-structured interview guide was drafted. Then the researchers, who in addition had expertise in medication administration, reviewed the preliminary version and formulated the questions in order to be participant-oriented, non-leading, and clearly worded (Kallio et al., 2016; Papastavrou & Andreou, 2012). The research team then discussed and made additional modifications including an introductory section for smooth induction of participants to the subject and included short, conversational, open-ended, and one-dimensional questions (i.e., "In your opinion, what factors may be related to the appearance of errors?"). The questions followed a rational flow guiding the discussion from general to more specific issues and promoted dialogue during the interview.

4.9.3 Data analysis

Data analysis included several steps like transcription of the discussions, data coding and analysis based on the thematic analysis method (Table 7). Interviews were transcribed verbatim by the moderator in order to produce an accurate record of everything said in each of the focus-group interviews (Wilkinson & Birmingham, 2003). Transcripts were organized and coded by two researchers separately (SV and GS). Data analysis was based on the inductive method and the thematic analysis approach was employed. There are various techniques used for data analysis in the inductive method, however thematic analysis is among the most common ones (Papastavrou et al., 2014; Ritchie & Lewis, 2004). The aim of thematic analysis is to archive in a detailed and systematic manner the coding and themes resulted from the interviews or observations of the participants (Ritchie & Lewis, 2004; Wilkinson & Birmingham, 2003). Researchers discovered topics that emerge from the discussions, and then verified and expanded these topics through the data. The process was repeated for finding any additional topics that could emerge from the transcribed discussions (Papastavrou et al., 2014; Papastavrou & Andreou, 2012; Ritchie & Lewis, 2004). Then the researchers compared their coding, discussed and interpreted the content of several statements and reviewed the differences between their coding. Codes along with the

respective wording were grouped based on their content and similarity. Researchers repeatedly performed this task until consensus was reached (Table 7). In particular, this task was repeated until researchers agreed that data saturation has been achieved (Korstjens & Moser, 2018). In fact, the availability of enough and an in-depth data showing the patterns, the categories and the variety of the medication errors issue was the main criterion used to decide whether saturation has been reached. Codes with similar content were grouped together forming separated thematic categories. The objective of this effort was the continuous analysis and synthesis of categories into themes that were directly linked to the interview data.

Table 7. Summary of the steps followed for the collection and analysis of data

Steps	Phase
1	Drafting the interview guide
2	Recording and transcribing the focus group discussions
3	Familiarizing, organizing and reviewing the raw data
4	Data coding
5	Clustering data relevant to each code
6	Grouping similar codes
7	Creating thematic categories
8	Synthesis of categories into themes
9	Defining and naming the themes
10	Selection of quotes illustrating the data analysis and the synthesis of the themes

Chapter 5

Results: Prevalence and types of medication errors and related factors as recorded in the observational study

This chapter and the following chapter will present the results of the study. The results are organized and presented in line with the main study objectives. In this chapter the detailed results and information regarding the type of medicines administered (i.e., pharmaceutical form, therapeutic class etc.), the professional practice environment and the working conditions related factors (i.e., staffing, work allocation system, interruptions and/or distractions) will be provided. In addition, the demographic characteristics of the participants (i.e., clinical nurses and patients) and relevant information will also be presented. The results of the pilot study concerning the establishment of an acceptable level of agreement between the ratings of the two observers, are also mentioned in this chapter. Last but not least, in this chapter, the number, frequency and types of medication errors, as detected during the direct observation of the medication administration process, will be presented. The next chapter (Chapter 6) will present the findings from the focus group study.

5.1 General Information from the Observational study

As mentioned in chapter 4, the sample in this study was the medication administrations observed and different attributes relevant with the observations mentioned are presented hereafter. In total, 665 administrations were observed and recorded during the observational study and 85 administrations were recorded during the pilot study. Below the results derived from the observational study are provided, also the results of the pilot study that confirmed the agreement between the observers are presented. In addition, the medication error related factors, such as the professional practice environment and related factors, the medicinal product attributes and the nurses' and patients' characteristics are provided. Relevant with the study information regarding the wards, such as work allocation system, shifts and medication rounds, is also described here. During the observational study, apart from

recording the errors, it was possible to collect information about the factors that could possibly have (or not), some association with the occurrence of errors. This was made possible by the design of the observation form. As described in previous chapters the form contained items that were relevant to other information (i.e., related factors), such as working environment parameters, information about the medication type, about the nurses and patients. In this Chapter, the findings concerning the medication errors related factors are presented.

5.1.1 Information about the wards and the medication administration process

In total, 665 administrations were observed and recorded during the observational study in both medical wards where the study was conducted. From these, 364 (54.7%) were observed in medical ward A and 301 (45.3%) were observed in the medical ward B (Table 8). In an effort to collect information under all possible working conditions, observations took place in all days, including weekends, all shifts and during all possible work organization systems in the wards. There were three scheduled routine medication rounds in the two medical wards (i.e., morning, evening and night). The medication rounds in the two wards lasted from thirty minutes to approximately two hours, depending on the type of work organization system in the ward and on staffing.

It was noted that there were two different types of nursing organizational practice system in the wards. The first type of organization of nursing care was task-oriented meaning that patient care was conceived as being a series of distinctive tasks, and one of these tasks was the administration of medicines. When this type of work system was in place, one nurse was responsible of carrying out the task of administering the medicines to all patients in the ward, meaning that one nurse had to carry out the whole medication round. Also, it was noted that in most cases, the allocation of the tasks in the first type of work system, was based on the level of difficulty of the task, and medical or technical tasks with some degree of complexity was left to more experience nurses or nurses with an acceptable among ward nurses' grade or status. Medication administration process was one of these more complex tasks. The absence of allocating specific nurses to patients implied that many different nurses provided

care to any one patient over the course of a stay in one ward. The second type of organization of nursing care was patient oriented, meaning that nurses were allocated to patients rather than tasks. Therefore, when this type of work system was in place in the wards, a nurse had to provide all the care the patient needed, including medication administration. It was noted that when this type of system was operationalized, each nurse was allocated to 3 to 4 patients for care. In contrast, when the first type of work system was in place (i.e., task oriented), usually one, or in some cases two nurses, had to administered all medicines to all patients in ward who in most cases were above 27 up to 30 patients. In addition, it was noted that, when nurses were allocated to tasks rather than to patients, drug administration rounds were prolonged, approximately up two hours, because one or two nurses had to prepare and administer medication to all ward inpatients. When nurses were allocated to patients, time per drug administration round was decreased and approximately took thirty minutes to be finalized because one nurse had to prepare and administer medication for three or four inpatients. We also found that in the night shift in particular, the work system was almost always task oriented, meaning that one nurse had to carry out the whole medication round. The task-oriented allocation system was more commonly employed in the two wards where the study took place (63.8%), while the patient-oriented system was recorded in a lower frequency (36.2%) (Table 8).

The above parameters of the working environment and of the working conditions were considered when the observational study was conducted in order to obtain a good representation of the medication process. From the 665 observations the 243 (36.5%) were made during weekends and 422 (63.5%) were made during weekdays. Most of the observations were made on Sunday (23.5%) and Tuesday (20.8), however, observations were recorded during all days of the week (Table 8). Observations were conducted during the three shifts in both medical wards; the morning, evening and night shift. In particular, 353 (53.1%) administrations during the morning shift were observed, 141 (21.2%) during the evening shifts and 171 (25.7%) during the night shift (Table 8). The number of nurses in the ward ranged from 3 to 9 and 252 (37.9%) of the observations were made when 6 nurses were working in the ward where only 27 (4.1%) of the observations were made when 7 nurses were working in the ward. From the 665 administrations observed, in 171 (25.7%) only 3

nurses were working in the ward and in 59 (8.9%) 9 nurses were working in the ward. On the other hand, patients' number ranged from 27 (3.9%) to 30 (51.3%), meaning that in approximately half of the observations made the wards' beds were fully occupied by patients, as both wards had only 30 beds available (Table 8). When it comes to work system at ward, in most observations (63.8%) the task allocation system, as described above, was in place, meaning that in 63.8% of the observation made one nurse had to administered all medicines to all ward patients. In 36.2% of the administrations observed, nurses were allocated to patients, meaning that in 36.2% of the observations one nurses was administering medicines to 3 to 4 patients only (Table 8). Similarly, in both wards, in more than 60% of the observed administrations nurses were responsible for administering the medicines to more than five patients, which is relevant with the work system most commonly used in both wards, that is nurses allocated to tasks, also implying that in more than 60% of the observed administrations, the medication round was conducted by one nurse only. Finally, in approximately 25% of the administrations recorded there was some kind of distraction or interruption during the administration process while in the majority of the observation no distractions or interruptions were noted. Any kind of interruptions or distractions (i.e., from phone calls, staff, patients or visitors) were recorded.

It was noted that only during the morning shifts the patient-oriented system was employed, meaning that nurses were allocated to patients in the morning shift only. This meant that only during morning shifts nurse had under their responsibility less than 5 patients to care and to administered medicines. In particular, it was most common to see an allocation of below 5 patients per nurse in the morning shift (63.8%) and in the evening and night shifts nurses were always allocated to above 5 patients (Table 8). In the night shift in particular, the work system was almost always task oriented, meaning that one nurse had to carry out the whole medication round. In the morning shifts, a work system where allocation of above 5 patients per nurse was implemented was recorded in a lower frequency (36.2%) (Table 8).

Table 8: Information regarding the Professional practice environment and related factors during the observational study

			Observed Administrations		
			Ward A (%)	Ward B (%)	Total (%)
		No. of Observations	364 (54.7)	301 (45.3)	665 (100)
Professional practice environment and related factors	Week Days	Monday	20 (5.5)	65 (21.6)	85 (12.8)
		Tuesday	86 (23.6)	52 (17.3)	138 (20.8)
		Wednesday	0	35 (11.6)	35 (5.3)
		Thursday	87 (23.9)	1 (0.3)	88 (13.2)
		Friday	47 (12.9)	29 (9.6)	76 (11.4)
		Saturday	32 (4.8)	55 (18.3)	87 (13.1)
		Sunday	92 (25.3)	64 (21.3)	156 (23.5)
	Days	Weekdays	240 (65.9)	182 (60.5)	422 (63.5)
		Weekends	124 (34.1)	119 (39.5)	243 (36.5)
	Shifts	Morning	222 (61.0)	131 (43.5)	353 (53.1)
		Evening	83 (22.8)	58 (19.3)	141 (21.2)
		Night	59 (16.2)	112 (37.2)	171 (25.7)
	Nurses in Ward	3	59 (16.2)	112 (37.2)	171 (25.7)
		6	176 (48.4)	76 (25.2)	252 (37.9)
		7	0	27 (9.0)	27 (4.1)
		8	129 (35.4)	27 (9.0)	156 (23.5)
		9	0	59 (19.6)	59 (8.9)
	Patients in Ward	27	0	2 (8.6)	26 (3.9)
		28	102 (28.0)	26 (8.6)	128 (19.2)
		29	86 (23.6)	84 (27.9)	170 (25.6)
		30	176 (48.4)	165 (54.8)	341 (51.3)
	Work System at ward	task oriented	236 (64.8)	188 (62.5)	424 (63.8)
		patient oriented	128 (35.2)	113 (37.5)	241 (36.2)
	Interruptions and/ or distractions	Yes	87 (23.9)	78 (25.9)	165 (24.8)
		No	277 (76.1)	223 (74.1)	500 (75.2)
	Number of patients for medication administration per nurse	above five patients	236 (64.8)	188 (62.5)	424 (63.8)
		below five patients	128 (35.2)	113 (37.5)	241 (36.2)

Table 9: Work organizational system in wards (work allocation system) during shifts

Patients Per Nurse (Work allocation system)	Shifts			
	Morning	Evening	Night	Total
above 5 patients	112 (31.7)	141 (100)	171 (100)	424 (63.8)
below 5 patients	241 (68.3)	0	0	241 (36.2)
Total	353 (53.1)	141 (21.2)	171 (25.7)	665 (100)

5.1.2 Nurses' and Patients' characteristics

All nurses involved in the medication process were eligible to be enrolled and were invited to participate. Overall, 25 nurses worked in each ward and a convenience sample of 11-13 nurses per ward (48%) agreed to participate in the study, meaning that 24 nurses from both wards participated in the observational study; 13 nurses from ward A and 11 nurses from ward B. All of them were registered nurses and 5 (20.8%) of them had a Master's Degree (Table 10). However, none of the nurses had participated in any kind of training regarding medication safety after their graduation. Although nurses are receiving training regularly as a part of the renewal of their license to practice, no official program on medication if offered by the responsible department of the Ministry of Health. Nurses' experience ranged from 6 to 24 years with a mean of 13.1 years of working experience. The minimum number of patients under care for nurses was 4 (15%) and maximum 30 (37.7%), meaning that in 37.7% of the observations one nurse had to administered medicines to 30 patients.

During the observational study 128 patients received medication by nurses and 73 (57%) were men and 55 (43%) were females. Patients' age ranges from 21 to 102 years of age. The median age in years was 80 (IQR 12) years of age. It was noted that general health conditions were used to describe patients' condition and therefore the etiology for admission. In fact, different types of disorders were stated at admission however, the most common diagnosis at admission was infection (20.6%) followed by gastroenterological disorders (16.7%). Interestingly, the number of medicines prescribed and therefore administered to a patient

ranged from 1 to 16 different medicines, with a mean number of 8.7 drugs per patient, which can be considered as a rather high number of medicines taken by a patient (i.e., polypharmacy) (Table 10).

Table 10: Information regarding participants' characteristics

			Ward A (%)	Ward B (%)	Total
Nurses' Characteristics	Nurses participated in the study		13	11	24
	Educational level (%)	University Degree	11 (84.6)	8 (72.7)	19 (79.2)
		Master Degree	2 (15.4)	3 (27.3)	5 (20.8)
	Work Experience (years)	Minimum	6	10	6
		Maximum	24	18	24
		Mean	14.3	13.2	13.1
	Patients under care (%)	4	100 (27.5)	0	100 (15.0)
		5	28 (7.7)	113 (37.5)	141 (21.2)
		27	0	26 (8.6)	26 (3.9)
		28	88 (24.2)	16 (5.3)	104 (15.6)
		29	0	43 (14.3)	43 (6.5)
		30	148 (40.7)	103 (34.2)	251 (37.7)
Patients' Characteristics	Number of patients received medication during study		66 (51.6)	62 (48.4)	128 (100)
	Sex	Male	36 (54.5)	37 (59.7)	73 (57.0)
		Female	30 (45.5)	25 (40.3)	55 (43.0)
	Age	Minimum	21	22	21
		Maximum	93	102	102
		Mean	77.9	75.8	76.9
	Diagnosis at admission	infection	54 (14.8)	83 (27.6)	137 (20.6)
		cardiovascular	55 (15.1)	35 (11.6)	90 (13.5)
		Gastroenterology-hepatology	47 (12.9)	64 (21.3)	111 (16.7)
		fever	74 (20.3)	24 (8.0)	98 (14.7)
		Neurology/Psychiatric	23 (6.3)	19 (6.3)	42 (6.3)
		anemia	21 (5.8)	42 (14.0)	63 (9.5)
		shock (septic/anaphylactic)	54 (14.8)	16 (5.3)	70 (10.5)
		Other (respiratory/pulmonary, renal failure, pleural infusion)	36 (9.9)	18 (6.0)	54 (8.1)
	Number of medicines taken per patient	Minimum	3	1	1
		Maximum	16	13	16
		Mean	9.2	8.1	8.7

Concerning polypharmacy, it seems that there are controversial approaches concerning its definition. Polypharmacy has been correlated with negative clinical outcomes, including medication errors and in a relatively small number of studies was correlated with MAEs (Härkänen et al., 2015). For these reasons we completed an additional table which shows that polypharmacy was very common in these two medical wards (Table 10). Polypharmacy is usually defined as the routine concurrent prescription and intake of five or more drugs, and this seems to be the most common definition of polypharmacy in the literature (Pazan & Wehling, 2021). However, some researchers exclude PRN drugs (i.e., "as needed" drugs) from the numerical definition for polypharmacy while others consider the prescription of above 9 drugs per patient as a more suitable definition for polypharmacy. Also overprescribing and polypharmacy are intertwined and also in many cases considered to be a as a 'necessary evil', as the use of multiple drugs for the treatment of different conditions is in line with respective therapeutic guidelines and additionally there is a vast number of safe and effective medicines in the prescribers' arsenal (Pazan & Wehling, 2021; Salvi et al., 2016). Having discussed polypharmacy, in our study we found that only a small proportion of the patients was prescribed and received below 5 drugs per patient during the study (7.4%) and almost half (45.1%) received above 9 drugs while some received above 12 (22.6%) (Table 10).

Table 11. Description of polypharmacy in the two wards

Number of medicines prescribed per inpatient		**N (%)**
Polypharmacy (Number of drugs prescribed per patient)	Min	1
	Max	16
	Mean	8.7
	< 5 drugs per patient	49 (7.4)
	> 5 drugs per patient	616 (92.6)
	< 9 drugs per patient	365 (54.9)
	> 9 drugs per patient	300 (45.1)
	< 12 drugs per patient	515 (77.4)
	> 12 drugs per patient	150 (22.6)

5.1.3 Medication attributes

During the observational study of this study, 665 administrations of different medicinal products were recorded and many different types and categories of medicines were administered. The different medicines administered during the study were categorized based on their therapeutic class (Table 10). The fact that different types of medicines were prescribed and administered was not an unexpected finding given that the study took place in two medical wards of tertiary hospitals where elderly patients with different types of diseases and in a variety of health condition were treated.

In these two medical wards, during the observation, the most commonly used medicine was paracetamol (7.7%), in both; injectable and oral forms (Table 10). Medicines for inhalation and drugs for respiratory, salbutamol and/or ipratropium in particular, were also commonly administered to inpatients (7.1%). Antibiotic medicines were also commonly administered with ceftriaxone (3.0%), piperacillin/tazobactam (4.5%) and amoxicillin/clavulanic acid (2.4%) being the most frequently used antibiotics (Table 10), and they were administered mostly in an injectable form. Cardiovascular drugs were the most frequently administered type of medication with Alpha and/or beta blockers (7.1%) being the most common type of cardiovascular drug administered followed by diuretics (3.0%), such as hydrochlorothiazide and furosemide and antihypertensive medicines (3.0%), such as angiotensin II receptor blockers and angiotensin converting enzyme (ACE) inhibitors (Table 10). Among antithrombotic and anticoagulants medicines, enoxaparin (6.0%) and aspirin (3.2%) were the most commonly recorded medicines during the study. Some drugs were much less frequently administered (i.e., <2%) and were initially grouped together into one category (Table 10).

Table 12: Medicines administered during the observational study (active substance)

Medicine administered (active substance)	**Total (%)**
metronidazole	14 (2.1)
enoxaparin	40 (6.0)
paracetamol	51 (7.7)
antihypertensive (sartans, ACE inhibitors, clonidine)	20 (3.0)
salbutamol and/or ipratropium	48 (7.2)
insulin	25 (3.8)
diuretics (hydrochlorothiazide, furosemide or spironolactone)	20 (3.0)
KCl	18 (2.7)
ceftriaxone	20 (3.0)
piperacillin/tazobactam	30 (4.5)
proton pump inhibitors (omeprazole/pantoprazole)	27 (4.1)
amoxicillin/clavulanic	16 (2.4)
Antipsychotics (quetiapine, olanzapine, clozapine)	14 (2.1)
Lactulose solution	14 (2.1)
Alpha and/or beta blockers	47 (7.1)
antiepileptic (Fosphenytoin, Phenytoin, Lamotrigine, Gabapentin, acetazolamide)	18 (2.7)
aspirin	21 (3.2)
Other Drugs (drugs administered less frequently i.e., <2.0%)	222 (33.4)
Total	665 (100)

In order to facilitate calculations and for the practical evaluation of the medications' attributes of the observational study, administered drugs recorded during the observation were categorized based on their therapeutic class (Table 12 and Table 13). Medicines belonging to therapeutic categories which were not frequently administered (i.e., <3%), such as non-steroid anti-inflammatory agents, antifungals, or medicines for topical use (e.g., ointments, immunosuppressant drugs) were grouped together under category "Other Class" and therefore formed a bigger category which represented 7.5% of all administrations observed

(Table 12). The findings revealed that cardiovascular drugs were most commonly administered drugs (22.4%) during the study followed by antibiotics (16.4%) and antithrombotic/anticoagulants drugs (9.9%). Drugs belonging to other therapeutic classes, such as the nervous system and psychiatric drugs (8.3%), analgesics and fever medication (8.1%), respiratory drugs (7.5%), corticosteroids (5.0%) or medicines for the gastrointestinal system (7.7%), non-steroid anti-inflammatory agents, fluids/saline, antihistamines, antifungal drugs, and vitamins were less frequently administered (Table 12).

Table 13: Medication therapeutic classes observed during the observational study

Medicine Therapeutic Class	**Ward A (%)**	**Ward B (%)**	**Total (%)**
analgesic/fever	29 (8.0)	25 (8.3)	54 (8.1)
antibiotics	57 (15.7)	52 (17.3)	109 (16.4)
antithrombotic/anticoagulants	43 (11.8)	23 (7.6)	66 (9.9)
antidiabetics	17 (4.7)	8 (2.7)	25 (3.8)
Cardiovascular drugs	88 (24.2)	61 (20.3)	149 (22.4)
neurology-psychiatric drugs	33 (9.1)	22 (7.3)	55 (8.3)
asthma/respiratory drugs	23 (6.3)	27 (9.0)	50 (7.5)
corticosteroids	19 (5.2)	14 (4.7)	33 (5.0)
Gastroenterology drugs	29 (8.0)	22 (7.3)	51 (7.7)
Vitamins, supplements and Minerals	10 (2.7)	13 (4.3)	23 (3.5)
Other drug products*	16 (4.4)	34 (11.3)	50 (7.5)

*Medicines belonging to therapeutic categories which were less frequently administered (i.e., <3%), such as non-steroid anti-inflammatory agents, antifungals, or medicines for topical use (e.g., ointments, immunosuppressant drugs) were grouped together under category “Other Class”

After the above initial grouping of drugs administered during the observational study, it was observed that still some drug classes were rather small in numbers (i.e., Vitamins, supplements and Minerals 3.5% or diabetes drugs 3.8%) and could probably not be practical when running the statistical analysis (i.e., testing for associations or completing regression models). To this end, administered drugs recorded during the observational study were then further re-categorized and organized in five therapeutic classes based on their frequency of administration during the observation study (Table 13). In addition, drugs belonging to therapeutic categories which were not frequently administered (i.e., <8%), were grouped again together under category “Other Class” and therefore formed a bigger category which

represented 45.1% of all administrations observed (Table 12). The grouping of these medicines under one category was made in order to be able to handle the data regarding the medicines administered, particular when evaluating associations when running the logistic regressions needed (chapter 6) or for making comparisons among medication therapeutic classes. In particular, the "Other class" category was the largest group of medicines administered because contained all other medicines administered that belonged to other classes which were much less frequently administered (i.e., <8%), and therefore, afterwards during the statistical analysis of the data and when completing the regression models, the rest of the drug classes was possible to be contrasted against this bigger group, thus, it was practically made statistical analysis more feasible.

In fact, the following therapeutic groups were formed and also were used for statistical analysis; Cardiovascular, Antibiotics, Antithrombotic, Nervous System drugs, Other class (Table 13) with cardiovascular drugs being the most frequently observed doses (22.4%).

Table 14: Categorization of medicines into Drug Therapeutic Classes

Drug Therapeutic Class	Ward A (%)	Ward B (%)	Total (%)
Other classes*	148 (40.7)	138 (45.8)	286 (43.0)
Cardiovascular drugs	119 (32.7)	30 (10.0)	149 (22.4)
Antibiotics	28 (7.7)	81 (26.9)	109 (16.4)
Antithrombotic/anticoagulants drugs	36 (9.9)	30 (10.0)	66 (9.9)
Nervous system / Psychiatric drugs	33 (9.1)	22 (7.3)	55 (8.3)
Total	364 (100)	301 (100)	665 (100)

*Medicines belonging to therapeutic categories which were less frequently administered (i.e., <3%), such as non-steroid anti-inflammatory agents, antifungals, or medicines for topical use (e.g., ointments, immunosuppressant drugs) were grouped together under category "Other Class"

Moreover, based on the above rationale for grouping medicines based on their therapeutic class and their frequency of administration, and in order to assess the relationship between

pharmaceutical form and medication errors, similarly, drugs administered during the observational study were categorized in three groups based on their formulation; oral forms, injectable products (i.e., IV, IM or SC forms) and other forms (Table 13). The group "other forms" contained several pharmaceutical forms, that were less frequently administered, such as medicinal products for topical use administered via different routes of administration (e.g., dermal route, like creams or ointments, patches, or eye or nasal route like eye drops or nasal sprays). The most frequently administered form was the oral form (47.7%), followed by injectable medicines (41.7%) and other forms which were less frequently observed (10.7%). As mentioned above, for completing regression models, during the statistical analysis of the data, pharmaceutical form categories were contrasted against this bigger group (i.e., oral forms), which was practically helpful in statistical analysis and processing of the data. Concerning injectable drugs, the only routes of administration observed and recorded during the study were the intravenous, intramuscular and the subcutaneous route (Table 13). Other injectable routes of administrations were not observed during the observational study (e.g., intraocular, intrathecal).

Table 15: Pharmaceutical forms of medicines administered during the observational study

Pharmaceutical Form		Ward A (%)	Ward B (%)	Total (%)
	Oral forms	168 (46.2)	149 (49.5)	317 (47.7)
Injectable forms	Intravenous	116 (72.0)	94 (81.0)	210 (75.8)
	Intramuscular	0	1 (0.9)	1 (0.4)
	Subcutaneous	45 (28.0)	21 (18.1)	66 (23.8)
	Total injectables	161 (44.2)	116 (38.5)	277 (41.7)
Other forms (Topical & Parenteral) *		35 (9.6)	36 (12.0)	71 (10.7)

* The group "other form" contained several pharmaceutical forms that were less frequently administered, such as medicinal products for topical use administered via different routes of administration (e.g., creams or ointments, patches, eye drops or nasal sprays)

5.2 Results from the pilot study

As mentioned in previous chapters, the pilot study aimed to evaluate the observation form, to confirm a high level of agreement between the two observers by calculating the Cohen's kappa coefficient, to mitigate the Hawthorn effect by prolonging the presence of the observers in the ward and therefore the staff getting used to having an observer in the ward during the medication process, and in addition, to test the observation method on the field. Also, the observes had the chance to gain experience with the observation form, with the setting and with the method.

Inter-rater agreement analysis was needed in this study in order to demonstrate consistency among observational ratings provided by the two coders and determine how much of the variance in the observed scores is due to variance in the true scores after the variance due to measurement error between coders has been removed (Hallgren, 2012). Cohen's (1960) kappa and related kappa variants are commonly used for assessing inter-rater agreement for nominal variables. Kappa statistics measure the observed level of agreement between coders for a set of nominal ratings and corrects for agreement that would be expected by chance, providing a standardized index of inter-rater reliability that can be generalized across studies. So in this study the degree of observed agreement was calculated by cross-tabulating ratings for two coders, and the agreement expected by chance was determined by the marginal frequencies of each coder's ratings (Hallgren, 2012).

In particular, in this pilot phase, which took place in the two medicals wards where the observation was conducted afterwards, the two raters observed simultaneously and independently the same nurse administering the same medicine to the same patient and each one recorded the administrations using the observation form which was drafted for serving this specific purpose. During the pilot phase 85 administrations were recorded by using the observation form. Then, Cohen's Kappa coefficient was used to confirm agreement between observers (Hallgren, 2012; Härkänen et al., 2015). A very high level of agreement between the observers was noted in all cases. The lowest level of agreement between observers calculated at 92.9% and the lowest Cohen's kappa coefficient found was $k=0.81$, $p<0.001$,

which confirmed perfect or almost perfect agreement between the observers' ratings. The results of the inter-rater agreement test are provided in a tabular form in Appendix VII for all items (error types) recorded. No items were removed from the observation form after the pilot study. The calculations of the raters' agreement and Cohen's kappa coefficient were made with SPSS for Windows. This level of agreement is well above acceptable, therefore agreement between the two observers was confirmed in advance. The values for kappa statistics range from −1 to 1, with 1 indicating perfect agreement, 0 indicating completely random agreement, and −1 indicating "perfect" disagreement. It suggested that conclusions should be discounted for variables with values less than 0.67, conclusions tentatively be made for values between 0.67 and 0.80, and definite conclusions be made for values above 0.80 (Hallgren, 2012).

5.3 Prevalence and type of medication errors during drug administration process

Below the findings from the observational study are presented, starting with the prevalence and types of errors and then presents the associations between errors and factors. The prevalence and types of errors are presented and described in two ways; as a percentage of the number of administrations observed and as a percentage of the total number of errors recorded. Also, they are classified, presented and described based on their type and on the "omission-commission" classification (Tables 16 and 17). Table 16 in particular presents the four major categories of errors, their prevalence per category (for example 107 drug administration method errors in 665 administrations) and their percentage of the total number of error (for example 4.5% of all errors recorded concerned errors in the drug administration method). Table 17 it provides additional detailed information as it presents the numbers of errors and percentages per item per category of error type.

Overall, 665 administrations were recorded and in total 2371 errors were detected (Table 16 and Table 17). All administrations observed were with at least one error (Tables 16 and 17). In particular, the minimum number of errors observed within one administration was 1 (6%)

and the maximum 11 (1.2%). The mean number of errors per administration was 3.5 (Table 15).

5.3.1 Non-adherence to basic infection and safety regulation

This category contained three items (i.e., hand washing before administration, equipment for sterile administration kept only in disinfected areas and not disinfecting the site of injection). We recorded 1104 errors in this category. The most commonly detected error in the study was that nurses didn't wash the hands before administering a drug to a patient (98.4%). Also, when an injectable drug was administered the site of injection was not disinfected before administration (37.7%) and the equipment used for injectable drugs, was not kept in disinfected areas only (29.9%) as it should (Table 16 and Table 17). With the exception of five cases where the nurse did wash his/her hand, however, not in line with the relevant guideline (i.e., the duration of hand washing was less than 5 seconds or the level or no antibacterial agent was used, just tap water), all other errors in this category were errors of omission. These five cases were classified as errors of commission as the action/task was not omitted, it was executed, but in a wrong way, thus it was an error of commission. In fact, omissions detected in this category (i.e., adherence to basic infection and safety regulation) represented more than half of all omissions detected in the whole observational study (57.1%) and almost half of all errors detected in the entire study (46.6%) (Tables 16 and 17).

5.3.2 Non-adherence to the five rights of medication safety (Five Rights Errors)

In the category of "five rights" seven items were included for completion by the observers during the observation. The five principles which must be followed during the administration process were Right Medicine, Right Dose, Right Patient, Right Route, and Right Time. The five "R" is the basic principle for medicines administration, that is included in the training of nurses from the very beginning of their studies in the fundamentals of nursing. The most frequently detected error in this category was the omission of asking the patient to confirm his/her name (74.4%) followed by the omission to confirm patient's name from the medication record (11.7%), indicating that the most commonly observed error was the

inadequate confirmation of the basic principle "Right Patient". It is important to note here that in the wards where the research was performed, patients do not wear a bracelet with their identity, and the only way to confirm who the patient is, you need to ask. Therefore, this is an omission related to the hospital management as well. Other errors detected were the omissions within the basic principle "Right Dose", such as not confirming the dose from prescription for at least 1 second (7.4%), not confirming at eye level for medicines administered via a syringe (9.0%), or not confirming the strength indicated on the drug's label for at least 1 second (6.2%). Within the sub-category of "Right Medicine" the error of a medicine being administered by one nurse while it was prepared by another nurse (i.e., reconstitution of a powder to a solution for injection) represented 3.2% of the all errors detected while the omission of confirming medicine's name on label for at least one second represented 2.6% of all errors detected. Errors relevant with the principle "Right Route" were the omission of reading the administration route on label for at least one second (9.8%) and concerning the "Right Time" omitting administering at the right time was also an error detected during the study at percentage of 3.6% of all errors detected (Table 17). In this category, errors detected represented 35.8% of all errors detected during the study and omission represented 41.8% of all omissions detected in the whole observational study and a 10.1% of all errors of commission detected in the entire study (Table 16 and Table 17).

5.3.3 Non-adherence to administration methods and guidelines (Handling Errors)

Errors relevant with non-adherence to the manufacturer's guidelines or to the approved guidelines of the medicinal products regarding the method of administration (i.e., Summary of products characteristics), were also detected during the study. It was possible to record the administration method because the observation form, in its first part, contained a check list where the observer could note this kind of information (e.g., infusion rate for iv drugs, time between drug preparation and administration). After the data were collected the main researcher, which is a pharmacist, double checked the administration method information collected with the approved drug product administration method. Thus, in this way, it was possible to assess the deviations recorded during the observation and concerned the correct or incorrect administration method for each drug administration recorded. In particular, the

infusion times not being in accordance to the approved product's instructions were recorded in 8.6% of the observations and the time between preparation (e.g., reconstitution) and administration were also outside the approved product's specification in 3.3% of all doses administered during the observation. Moreover, not injecting the medicine at the correct site and/or angle for injection (8.7%) was also a deviation from the approved instructions for use (Table 17). Omissions regarding the correct handling of the medication (i.e., preparation and administration method) represent 19.1% of all omissions detected during the observational study, however, only 22 (1.1%) cases were found to be with an error of commission (Table 16 and Table 17).

5.3.4 Non-adherence to drug administration record protocol (Documentation Errors)

Non-adherence to drug administration record protocol was another type of deviation detected during the study. More specifically, the documentation of the administration of a medicine was made by a different nurse from the one who administered the drug (3.0%) and the time of the administration not being accurately recorded (43.6%) were the errors detected in the non-adherence to drug administration record protocol category. Both of these documentation errors were errors of commission (i.e., actions executed in a wrong, erroneous way). In particular, errors detected in the group of "Non-adherence to drug administration record protocol" represented the majority of errors of commission detected in the observational study (69.7%) (Table 16 and Table 17).

Table 16: Frequency of medication errors detected by category.

		Type of error	
	Errors (%)	Omission (%)	Commission (%)
Adherence to basic infection and safety regulation	1104 (46.6)	1099 (57.1)	5 (1.1)
Adherence to the 5 Rights Principles	850 (35.8)	805 (41.8)	45 (10.1)
Adherence to administration methods and guidelines (Handling errors)	107 (4.5)	22 (1.1)	85 (19.1)
Adherence to drug administration record protocol (Documentation errors)	310 (13.1)	0 (0)	310 (69.7)
Total error number	2371 (100)	1926 (100)	445 (100)

Errors were in addition categorized into two groups; errors of omission and errors of commission and based on this classification they are prescribed below (Table 16 and Table 17).

5.3.5 Errors of omission

It was among the aims of this study to explore errors of omissions, in addition to errors of commission. We found that from the 2371 errors, only 455 (18.8%) were errors of commission while 1926 (81.2%) were omissions (Table 16), meaning that omissions were the leading and most frequently observed type of error. Omissions in the basic infection and safety regulations (46.6%) were the most common type of error, followed by deviations from the five right principles (35.8%) (Table 16 and Table 17). Omitting to hand wash was a predominant finding (98.4%). Also not disinfecting the site of injection was a major omission recorded in 37.7% of the administrations observed. Practically, almost no one of the nurse in the two medical wards who administered medicines washed his/her hand before administering a medicine to the inpatient, despite the fact the he/she had been followed by the observer during the process of medication administration (Table 17).

Within the category “adherence to the five rights of medication safety”, omissions were also the most common type of error (41.8%) (Table 16 and 17). In fact, the most common type of error was the omission to adequately confirm that the patient to whom the medicine is about to be administered is indeed the right patient, by either confirming from medication records (11.7%) or by asking the patient to confirm his/her name (74.4%) (Table 17). Nurses omitted to read medicine’s name on label for at least one second (2.6%), or to confirm the strength indicated on label for at least 1 sec (6.2%). They omitted to confirm the dose from prescription for at least 1 sec (7.4%) or to confirm the dosage at eye level for syringes (9.0%). They also omitted to read (i.e., confirm) administration route on label for at least once second (9.8%) and all these omissions, which actually constitute deviations from basic medication administration principles, were made in the presence of the observer. Regarding the adherence to administration methods and guidelines, the omission of preparing the medication right before the administration, in line with manufacturer’s instructions and product’s characteristics and specifications was recorded in 3.3% of the administered drugs observed during the study (Table 17).

5.3.6 Errors of commission

Actions during the medication administration process that were executed wrongly, inaccurately or inappropriately were recorded as errors of commission. As stated, errors of commission represented only a percentage of 18.8% of the errors observed in the administrations. In particular, errors of commission were recorded in the category “Adherence to the five rights of medication Safety”, for example in some administrations the medication was prepared by one same nurse but it was administered by another nurse (3.2%). Non-adherence to administration methods and guidelines for specific medicines (handling errors) was also recorded during the observation and these deviations were errors of commission. For instance, infusion rate for same injectable medicines was not in accordance to manufacturer guidelines for administrations or medicine’s approved specifications and instructions for use (8.6%) or the medicine was injected to an incorrect site of injection or at incorrect angle (8.7%). Documentation errors (adherence to drug administration record protocol) was also an important finding, in particular, most errors of commission observed

were documentation errors (13.1%) (Table 16 and Table 17). More specifically, the error of recording a wrong or inaccurate time of the medication administration was the most frequently observed error of commission (43.6%) while the error of not documenting the time of the administration or the documentation and filing of the administration is completed by a different nurse from the one administered the medicine, was a much less frequently observed error of commission (3.0%) (Table 17).

In conclusion, the rather high number of the omissions detected during the medications process was a predominant finding of the observational study. Omissions in the infection prevention guidelines (46.6%) and in the five rights of medication safety principles (35.8%) were common, as the study revealed. Omissions in the infection prevention guidelines (46.6%) and in the five rights of medication safety principles (35.8%) were a major outcome. In particular, omitting to hand wash before administering a drug (98.4%), omitting to disinfect the site of injection (37.7%), and omitting to confirm the patient's name (74.4%) were the three most frequently observed omissions. Documentation errors (13.1%) and administration method errors (4.5%) were also detected

Table 17: Prevalence and types of medication errors detected

Error Category		Item	Observations with Error, N (%)	Type of error	
				Omissions	Error
Adherence to basic infection and safety regulation		Wash hands before administering medication	654 (98.4)	649	5
		IV equipment placed only in disinfected areas	199 (29.9)	199	0
		Disinfect site of injection	251 (37.7)	251	0
		% of All Errors (Total/Omissions/Commissions)	**1104 (46.6)**	**1099 (57.1)**	**5 (1.1)**
Adherence to the 5 rights of medication Safety	Right Medicine	Read medicine's name on label for at least one second	17 (2.6)	17	0
		Medication is prepared by the nurse who will administer it	21 (3.2)	0	21
	Right Dose	Confirm the strength indicated on label for at least 1 sec	41 (6.2)	41	0
		Confirm the dose from prescription for at least 1 sec	49 (7.4)	49	0
		Confirm the dosage at eye level for syringes	60 (9.0)	60	0
	Right Patient	Read patient name from medication record	78 (11.7)	78	0
		Ask patient to confirm his/her name	495 (74.4)	495	0
	Right Route	Read administration route on label at least once second	65 (9.8)	65	0
	Right Time	Medicine administered at the right time	24 (3.6)	0	24
		% of All Errors (Total/Omissions/Commissions)	**850 (35.8)**	**805 (41.8)**	**45 (10.1)**
Adherence to administration methods and guidelines		Infusion rate is in accordance to manufacturer instructions	27 (8.6)	0	27
		Prepare the medication right before the administration	22 (3.3)	22	0
		The medicine is injected at the correct site and/or angle	58 (8.7)	0	58
		% of All Errors (Total/Omissions/Commissions)	**107 (4.5)**	**22 (1.1)**	**85 (19.1)**
Adherence to drug administration record protocol		The same nurse who administered the drug records the event	20 (3.0)	0	20
		The time of the administration is accurately recorded	290 (43.6)	0	290
		% of All Errors (Total/Omissions/Commissions)	**310 (13.1)**	**0**	**310 (69.7)**
		Total Errors N (%)	**2371 (100)**	**1926 (81.2)**	**445 (18.8)**

5.4 Associations between medication errors and related factors

The results of the associations between errors and related factors are presented below. Associated factors were described in chapter 4, section 4.4 (Definitions: Errors and Associated Factors) and include staffing (number of patients assigned per nurse for

medication administration), distractions and/or interruptions (by staff, patients or visitors), shifts (morning, evening, or night shift), days (weekdays or weekends), pharmaceutical form (oral, injectable or other forms), drug therapeutic class (e.g. cardiovascular, antibiotics, anticoagulants, nervous system drugs, or other class), patient's age, number of medicines taken per patient and nurse experience. In addition, associated factors were presented in detailed above (i.e., frequencies, numbers and percentages of associated factors were provided) but no associations were made. The associations between errors and related factors are presented hereafter.

As mentioned above administrations were classified into two categories; administrations with below or above three errors and administrations with below or above five errors and that resulted into two categorical variables (i.e., two different variables, each of them consisting of two categories): administrations with ≥ 3 and with ≥ 5 errors per administration. The specific classification of administrations was based on the fact that all administrations were with at least one error, and the mean number of errors per administration was 3.5 per administration. Also, the statistical analysis of the data was facilitated by creating these two new variables. These two categorical variables, i.e. administrations with less than or more than 3 errors and administrations with less than or more than 5 errors, were examined for associations with the factors: (1) certain characteristics of the professional practice environment and related factors (i.e. staffing, distractions and/or interruptions, shifts, days of the week), (2) medication attributes (i.e. pharmaceutical form, drug therapeutic class), (3) patients' related factors (i.e. patient's age, number of medicines taken per patient) and (4) and nurses' attributes (i.e. experience). The associations per each group of factors and number of errors are described in detail below. It is highlighted, however, that, at this point, the existence of an association between two variables does not necessarily suggest any causal link or indicate any cause-and-effect relationship, but does suggest that an association exists.

5.4.1 Associations between professional practice environment and related factors and number of errors per administration

For examining associations between administrations with below or above three errors and shift (i.e., morning, evening, night shift) the chi square test and logistic regression was employed (Table 18 and Table 19). A statistically significant association between the professional practice environment related factor "Interruptions or distractions" and administrations with ≥ 3 errors and with ≥ 5 errors was noted. In fact, 72.1% of the administrations with ≥ 3 errors were recorded when there were interactions and/or distractions during the medication process while only 60.4% of the administrations with ≥ 3 errors were recorded when there were no interactions and/or distractions during the medication process (Table 18), and this association was statistically significant (p=0.007). It was also 70% more likely to detect ≥ 3 errors when there were interactions and/or distractions during the medication process than when there were no interactions or distractions (Table 18). Similarly, 32.1% of the administrations with ≥ 5 errors occur when there were interactions and/or distractions during the medication process while only 23.6% of the administrations with ≥ 5 errors were recorded when there were no interactions and/or distractions during the medication process (Table 19), and this association was statistically significant (p=0.03). It was also 53% more likely to detect ≥ 5 errors when there were interactions and/or distractions during the medication process than when there were no interactions or distractions (Table 19). This finding simply suggests that when there are no interruptions or distractions during the medication process less errors are made. As already mentioned in previous chapters, interruptions and distractions were mostly cause by other staff (nurses and doctors), phone calls, visitors or patients asking for help or information. Furthermore, a statistically significant association between the professional practice environment related factor "number of patients per nurse" and administrations with ≥ 5 errors was noted. 31.5% of the administrations with ≥ 5 errors occur when the nurse had less than 5 patients to administered medicines while only 22.4% of the administrations with ≥ 5 errors were recorded when the nurse had more than 5 patients to administered medicines (Table 19), and this association was statistically significant (p=0.01). It was also 60% (p=0.01) more likely to detect ≥ 5 errors when the nurse had less than 5 patients to administered medicines than when the nurse had above 5 patients to administered medicines (Table 19). However,

the risk of having ≥ 3 errors per administration was increased by 23% when had less than 5 patients to administered medicines to, but this association was not statistically significant (Table 18). Finally, the professional practice environment related factor "shift" and "Days" did not seem to be statistically significantly related with the occurrence of a higher number of errors. The percentage of the administrations with ≥ 3 or ≥ 5 errors seems to be similar across the three shifts (morning/evening/night) (p=0.97 and p=0.40 respectively). Similarly, the administrations with ≥ 3 or ≥ 5 errors seems to be similar between days and weekends (p=0.85 and p=0.78, respectively)

5.4.2 Associations between administered medicines' attributes and number of errors per administration

The tests showed that the drug therapeutic class was a factor that was significantly associated with the occurrence of a higher number of errors. In fact, 80.5% (p<0.001) of the administrations with ≥ 3 errors were recorded when a cardiovascular drug was administered (Table 18) and 50.3% (p<0.001) of the administrations with ≥ 5 errors (Table 19). Also, it was 2.59 (p<0.001) times more likely to observe ≥ 3 errors when a cardiovascular drug was administered than a drug from another class (Table 18) or 4.16 (p<0.001) times more likely to observe ≥ 5 errors when a cardiovascular drug was administered than a drug from another class (Table 19). The likelihood of detecting ≥ 3 errors per administrations seemed to be decreased approximately by half when an antibiotic was administered than a drug from another class. Additionally, it was 34% more likely to observe ≥ 3 errors when an antithrombotic drug was administered than a drug from another class, but it was less likely to observe ≥ 5 errors when an antithrombotic drug was administered than a drug from another class. Logistic regression suggested that cardiovascular drugs seemed to be the drug therapeutic class that was most strongly associated with a higher number of errors (Table 19). Concerning the pharmaceutical form, the tests showed that only 18.4% of the administrations with ≥ 5 errors were detected when an injectable drug was administered. On the contrary, when an oral drug or other form were administered approximately 31% of the administrations were with ≥ 5 errors. In addition, the likelihood of detecting ≥ 5 errors per administrations seemed to be decreased by half when an injectable drug was administered than an oral drug

(p=0.001) (Table 19). The association between pharmaceutical form and administrations with 3 or more errors were not found to be statistically significant (p=0.86) (Table 18).

5.4.3 Associations between patients' attributes and number of errors per administration

Two patient-factors were assessed for associations with a higher number of errors: patient age and number of medicines taken (i.e., polypharmacy). Polypharmacy has been described in a previous section in this chapter (5.1.2 Nurses' and Patients 'characteristics). Patient age was classified into two age groups; ≤75 years of age and >75 years of age in order to assess how the percentage of administrations with ≥ 5 or 3 errors varies across the two age groups.

The results of the tests showed that polypharmacy is a factor that is associated with the occurrence of a higher number of errors. In fact, when the number of medicines takes by patient is increased, the percentage and the likelihood of more errors being detected is also increased. Particularly, 67.0% of the administrations with ≥ 3 errors were recorded when the patient was taking above 9 drugs (p=0.07) and 74.7% of administrations with ≥ 3 were recorded when the patient was taking above 12 drugs (p=0.001). Lower percentages of administrations with ≥ 3 errors are noted when the patient was receiving below 9 or below 12 drugs. It was 34% more likely to observe ≥ 3 errors when the patient was receiving above 9 drugs (p=0.07) and approximately 2 times more likely to observe ≥ 3 errors when the patient was receiving above 12 drugs (p=0.001) (Table 18). The same pattern has been noted with administrations with above 5 errors. 29.7% of the administrations with ≥ 5 errors were recorded when the patient was taking above 9 drugs (p=0.03) and 34.7% of administrations with ≥ 5 were recorded when the patient was taking above 12 drugs (p=0.004). Lower percentages of administrations with ≥ 5 errors are noted when the patient was receiving below 9 (22.5%) or below 12 drugs (23.1%). It was 46% more likely to observe ≥ 5 errors when the patient was receiving above 9 drugs (p=0.04) and 77% more likely to observe ≥ 5 errors when the patient was receiving above 12 drugs (p=0.005) (Table 19). There was no statistically significant association between the patient's age and number of errors per administration. In fact, there was no association with statistical significance between patient's age and administrations with more or less than 3 errors (p=0.80). It was 7.75 times less likely to

observe ≥ 5 errors when the patient was below 75 than if the patient was above 75 years of age, however, this association was not statistically significant (p=0.56) (Table 18).

Table 18: Associations between risk factors and administration with ≥ 3 errors per administration

Associated Factors	≥ 3 errors, N (%)	p*	OR (95% CI) #	p#
Shift				
Morning	225 (63.7)		REF	
Evening	89 (63.1)	0.97	0.97 (0.65-1.46)	0.96
Night	107 (62.6)		0.95 (0.65-1.39)	
Days				
Weekdays	266 (63.0)	0.85	REF	0.85
Weekends	155 (63.8)		1.03 (0.74-1.43)	
Interruptions or distractions				
No	302 (60.4)	*0.007*	REF	*0.006*
Yes	119 (72.1)		1.70 (1.16-2.49)	
Number of patients for medication administration per nurse				
above five patients	261 (61.6)	0.21	REF	0.21
below five patients	160 (66.4)		1.23	
Pharmaceutical Form				
Oral	199 (62.8)		REF	
Injectable	175 (63.2)	0.86	1.02 (0.73-1.42)	0.86
Other	47 (66.2)		1.16 (0.68-1.99)	
Drug Therapeutic Class				
Other class	176 (61.5)		REF	
Antibiotics	50 (45.9)		0.53 (0.34-0.83)	
Antithrombotic	45 (68.2)	*<0.001*	1.34 (0.76-2.37)	*<0.001*
Nervous System drugs	30 (54.5)		0.75 (0.42-1.34)	
Cardiovascular	120 (80.5)		2.59 (1.62-4.14)	
Patient Age (years)				
Above 75	275 (63.7)	0.80	0.96	0.78
Below 75	146 (62.7)		0.96 (0.69-1.33)	
Nurse Experience (years)				
Below 12	216 (64.1)	0.67	REF	0.67
Above 12	205 (62.5)		0.93	
Number of medicines taken by patient (polypharmacy)				
≥ 5 per patient	390 (63.3)	0.99	REF	0.99
< 5 per patient	31 (63.3)		0.99 (0.55-1.83)	
< 9 per patient	220 (60.3)	0.07	REF	0.07
≥ 9 per patient	201 (67.0)		1.34 (0.73-1.84)	
< 12 per patient	309 (60.0)	*0.001*	REF	*0.001*
≥ 12 per patient	112 (74.7)		1.97 (1.31-2.96)	

* a p-value from of chi-square test is reported. # a p-value and OR from logistic regression model is reported. Values in *italic* indicate significant association with number of errors.

Table 19: Associations between risk factors and administration with ≥ 5 errors per administration

Associated Factors	≥ 5 errors, N (%)	p*	OR (95% CI) #	p#
Shift				
Morning	95 (26.9)		REF	
Evening	30 (21.3)	0.40	0.73 (0.46-1.12)	0.39
Night	46 (26.9)		0.99 (0.66-1.51)	
Days				
Weekdays	110 (26.1)	0.78	REF	0.78
Weekends	61 (25.1)		0.95 (0.66-1.37)	
Interruptions or distractions				
No	118 (23.6)	*0.03*	REF	*0.03*
Yes	53 (32.1)		1.53 (1.04-2.26)	
Number of patients for medication administration per nurse				
above five patients	95 (22.4)	*0.01*	REF	*0.01*
below five patients	76 (31.5)		1.60 (1.12-2.28)	
Pharmaceutical Form				
Oral	98 (30.9)		REF	
Injectable	51 (18.4)	*0.001*	0.50 (0.34-0.74)	*0.001*
Other	22 (31.0)		1.00 (0.58-1.75)	
Drug Therapeutic Class				
Other class	56 (19.6)		REF	
Antibiotics	22 (20.2)		1.04 (0.60-1.80)	
Antithrombotic	7 (10.6)	*<0.001*	0.49 (0.21-1.12)	*<0.001*
Nervous System drugs	11 (20.0)		1.03 (0.50-2.11)	
Cardiovascular	75 (50.3)		4.16 (2.70-6.43)	
Patient Age (years)				
Above 75	108 (25.0)	0.57	REF	0.56
Below 75	63 (27.0)		0.57	
Nurse Experience (years)				
Below 12	72 (21.4)	*0.009*	*REF*	*0.009*
Above 12	99 (30.2)		1.60 (1.12-2.26)	
Number of medicines taken by patient (polypharmacy)				
≥ 5 per patient	162 (26.3)	0.22	REF	0.21
< 5 per patient	9 (18.4)		0.63 (0.30-1.33)	
< 9 per patient	82 (22.5)	*0.03*	REF	*0.04*
≥ 9 per patient	89 (29.7)		1.46 (1.03-2.06)	
< 12 per patient	119 (23.1)	*0.004*	REF	*0.005*
≥ 12 per patient	52 (34.7)		1.77 (1.19-2.61)	

* a p-value from of chi-square test is reported. # a p-value and OR from logistic regression model is reported. Values in *italic* indicate significant association with number of errors.

5.4.5 Logistic regression analysis results for the investigation of associations between related factors and errors per administration

In addition to Chi square and logistic regression tests for the assessment of relationships between associated factors and number of errors per administration (i.e., administrations with ≥ 3 errors and administrations with ≥ 5 errors), two binary stepwise logistic regression models have then been completed, one for each dichotomized response (≥ 3 and ≥ 5 errors per administration) in order to explore which factors could predict the occurrence of a higher number of errors. Risk factors were included in the regression models and factors without a statistically significant contribution to the model were removed using a stepwise (backwards) approach (Table 20 and Table 22). It is reminded at this point, for clarity to the readers, that the number of errors per dose administered per patient, and the associated factors, is actually the issue under investigation. More specifically, to further investigate the relationship of contributing factors and prevalence of errors, one stepwise (backwards) logistic regression model was completed for administrations with three errors or above (≥ 3) (Table 20) and one stepwise (backwards) logistic regression model was completed for administrations with five errors or above (≥ 5) (Table 22).

Table 20: Stepwise logistic regression model for associations between risk factors and administrations with ≥ 3 errors, OR (95% CI), $p < 0.05$

Associated Factors[#]	Odds Ratio (95% CI)	p value*
Pharmaceutical Form		
Oral	REF	
Injectable	*1.64 (1.08-2.47)*	*0.02*
Other	1.29 (0.73-2.29)	0.38
Medication Therapeutic Group		
Other	REF	
Cardiovascular	*3.26 (1.90-5.62)*	*<0.001*
Antibiotics	0.68 (0.42-1.10)	0.11
Anticoagulants	1.61 (0.88-2.96)	0.12
Nervous system drugs	0.71 (0.39-1.29)	0.26
Number of medicines taken by patient (polypharmacy)		
< 12 per patient	REF	
≥ 12 per patient	2.05 (1.34-3.15)	*0.001*
Interruptions or distractions		
No	REF	
Yes	1.46 (0.97-2.18)	0.07
-2 LL	817.82, x^2=56.38, df=8, p<0.001	
Nagelkerke R^2	11.10%	
Hosmer and Lemeshow Test	p=0.73	
Classification accuracy	66.2%	

*p value of a stepwise (backwards) regression model is reported. Values in *italic* indicate significant association with number of errors. [#]Shift was not included in the model as it was correlated with the factor "number of patients per nurse for medication administration"

The results suggested that drug therapeutic class was also associated with more errors per administration with a statistical significance. In particular, the first regression model was completed with the "administrations ≥3 errors" being the dependent variable and all previously discussed associated factors as the independent variables. The results revealed that factors increasing the risk of ≥ 3 errors being detected per administration were the pharmaceutical form, the medication therapeutic class and the number of medicines administered to each patient (Table 20). Specifically, it was 64% (p=0.02) more likely to detect ≥ 3 errors in an administration when an injectable medicine was administered than

when administering an oral medicine. Similarly, when a cardiovascular medicine was administered it was 3.26 ($p<0.001$) times more likely to detect ≥ 3 errors within an administration, than when a drug from another drug class was used. Also, when the patient was taking above 12 drugs it was 2.05 ($p=0.001$) times more likely for ≥ 3 errors to occur than when the patient was receiving below 12 medicines. It was also 46% more likely to detect ≥ 3 errors per administration, when there were interruptions or distractions during the medication administration process than when there were not any interruptions or distractions, however, this association was not statistically significant ($p=0.07$) (Table 20).

Based on the results of the regression model and as the chi square revealed as well, it was noticed that drug therapeutic class had a strong association with errors. Thus, it was decided to re-run the logistic regression model but this time excluding the factor "drug therapeutic class" from the analysis. By not entering this factor in the model it would be possible to see how the associations between the remaining factors and the number of errors will change and how the whole statistical model would be affected. After re-running the model and by leaving the factor "drug therapeutic class" outside the model, it seemed that the only factors that were associated with a statistical significance with the occurrence of ≥ 3 errors per administration were the number of medicines taken by patient (polypharmacy) and the interruptions or distractions during the medication administration process (Table 21). In fact, it was also 74% more likely to detect ≥ 3 errors per administration, when there were interruptions or distractions during the medication administration process than when there were not any interruptions or distractions, and this association was now statistically significant ($p=0.05$). Also, polypharmacy remained a statistically significantly associated factor. When the patient was taking above 12 drugs it was 2.01 ($p=0.001$) times more likely for ≥ 3 errors to occur than when the patient was receiving below 12 medicines. Furthermore, by looking at the model diagnostics and comparing the respective tests between the two models (Table 20 and Table 21), it seems that when "drug therapeutic class" is removed there is an increase in the deviance (-2LL) and a significant decrease in Nagelkerke R^2, also the classification accuracy is slightly decreased. All these suggests that by entering the factor "drug therapeutic class" in the model, the model is improved and can explain the data better than the model without

the concerned factor entered. It also reinforced the indication that drug class and cardiovascular drugs in particular, can be associated with a higher number of errors.

Table 21: Stepwise logistic regression model for associations between risk factors and administrations with ≥ 3 errors, and with "Medication Therapeutic Group" excluded from the model, OR (95% CI), $p < 0.05$

Associated Factors[#]	**Odds Ratio (95% CI)**	**p value***
Number of medicines taken by patient (polypharmacy)		
< 12 per patient	REF	
≥ 12 per patient	2.01 (1.33-3.03)	*0.001*
Interruptions or distractions		
No	REF	
Yes	1.74 (1.18-2.56)	*0.05*
-2 LL	854,83 x^2=19.37, df=2, p<0.001	
Nagelkerke R^2	3.90%	
Hosmer and Lemeshow Test	p=0.99	
Classification accuracy	63.3%	

*p value of a stepwise (backwards) regression model is reported. Values in *italic* indicate significant association with number of errors. [#]Shift was not included in the model as it was correlated with the factor "number of patients per nurse for medication administration". Factor "Medication Therapeutic Group" excluded from the model.

Following the above tests, a logistic regression model was run again but this time with the "administrations ≥ 5 errors" as the dependent variable, where things were a slightly different. The new model showed that the factors increasing the risk of detecting ≥ 5 errors within an administration were only the medication therapeutic class and the number of medicines taken by each patient and nurse experience. Particularly, the association between the detection of ≥ 5 errors per administration and the patient taking above 12 drugs has been attenuated in the second regression model but still remained statistically significant (Table 20 and Table 22). In fact, when the patient was taking above 12 drugs it was 57% (p=0.04) more likely for ≥ 3 errors to occur than when the patient was receiving less than 12 medicines. Drug therapeutic class could predict the occurrence of ≥ 5 errors per administration with a statistical significance. When a cardiovascular medicine was administered it was 4.11 (p<0.001) times more likely to detect ≥ 5 errors within an administration, than when a drug from another drug

class was used. When an antithrombotic medicine was administered it was approximately 2 times less likely (p=0.09) to detect ≥ 5 errors within an administration, than when a drug from another drug class was used, however, this was not a statistically significant finding. Based on the analysis up to this point, no association was revealed with this factor and ≥ 3 errors per administration. However, interestingly, nurse experience found to be a factor that was related with the occurrence of ≥ 5 errors per administration with a statistical significance. It was 48% (p=0.05) more likely for ≥ 5 errors to occur when the nurse had above 12 years of experience than when the nurse had less than 12 years of experience (Table 22).

Table 22: Stepwise logistic regression model for associations between risk factors and administrations with ≥ 5 errors, OR (95% CI), $p < 0.05$

Associated Factors[#]	**Odds Ratio (95% CI)**	**p value***
Medication Therapeutic Group		
Other	REF	
Cardiovascular	*4.11 (2.65-6.38)*	*<0.001*
Antibiotics	0.97 (0.55-1.67)	0.91
Anticoagulants	0.48 (0.21-1.11)	0.09
Nervous system drugs	0.99 (0.48-2.05)	0.97
Number of medicines taken by patient (polypharmacy)		
< 12 per patient	REF	
≥ 12 per patient	1.57 (1.08-2.27)	*0.04*
Nurse Experience (years)		
Below 12	REF	
Above 12	1.48 (1.02-2.15)	*0.05*
-2 LL	688.48, x^2=69.69, df=6, p<0.001	
Nagelkerke R^2	14.60%	
Hosmer and Lemeshow Test	p=0.80	
Classification accuracy	76.8%	

*p value of a stepwise (backwards) regression model is reported. Values in *italic* indicate significant association with number of errors. [#]Shift was not included in the model as it was correlated with the factor "number of patients per nurse for medication administration"

Finally, an additional regression model was completed, this time with "≥ 5 errors per administration" being the depended variable and all the risk factors the independent but with excluding the factor "drug therapeutic class" from the analysis. As mentioned above, by not entering this factor in the model it would be possible to see how the associations between the remaining factors and the occurrence of ≥ 5 errors per administration will change and how the whole statistical model would be affected. This model, without "drug therapeutic class" included, showed that interruptions or distractions, number of patients per nurse (workload organization), polypharmacy, nurse experience and pharmaceutical form, were associated with the occurrence of ≥ 5 errors per administration (Table 23). It was 57% more likely to detect ≥ 5 errors per administration, when there were interruptions or distractions during the medication administration process than when there were not any interruptions or distractions, however, this association was not statistically significant (p=0.03). Also, when the nurse had less than 5 patients to administer medicines, it was 61% (p=0.01) more likely to detect ≥ 5 errors per administration than when the nurse had above 5 patients to administer medicines. It was 66% (p=0.007) more likely for ≥ 5 errors to occur when the nurse had above 12 years of experience than when the nurse had less than 12 years of experience. Furthermore, polypharmacy still remains a significant predictor for ≥ 5 errors per administration being detected. When the patient was taking above 12 drugs it was 61% (p=0.02) more likely for ≥ 5 errors to occur than when the patient was receiving less than 12 medicines. Also, when an injectable drug was administered it was 1.82% (p=0.03) times less likely for ≥ 5 errors to occur than when an oral drug was administered. This finding was in line with the chi square analysis (Table 19).

Finally, by comparing at the model diagnostics (Table 22 and Table 23), it seems that when "drug therapeutic class" is removed there is an increase in the deviance (-2LL) and a significant decrease in Nagelkerke R^2, also the classification accuracy is slightly decreased. All these, as mentioned in the previous similar comparison made for administrations with ≥ 3 errors, suggests that by entering the factor "drug therapeutic class" in the model, there is an improvement in the model. It can explain the data better than the model without the

concerned factor entered and reinforced the indication that drug class and cardiovascular drugs in particular, can be significantly associated with a higher number of errors.

Table 23: Stepwise logistic regression model for associations between risk factors and administrations with ≥ 5 errors, and with "Medication Therapeutic Group" excluded from the model OR (95% CI), $p < 0.05$

Associated Factors[#]	**Odds Ratio (95% CI)**	**p value***
Interruptions or distractions		
No	REF	
Yes	1.57 (1.06-2.34)	*0.03*
Number of patients for medication administration per nurse		
Above 5	REF	
Below 5	1.61 (1.10-2.34)	*0.01*
Number of medicines taken by patient (polypharmacy)		
< 12 per patient	REF	
≥ 12 per patient	1.61 (1.07-2.41)	*0.02*
Nurse Experience (years)		
Below 12	REF	
Above 12	1.66 (1.15-2.41)	*0.007*
Pharmaceutical Form		
Oral	REF	
Injectable	0.55 (0.37-0.82)	*0.03*
Other	1.06 (0.60-1.88)	0.85
-2 LL	721.22, x^2=36.94, df=6, p<0.001	
Nagelkerke R^2	7.9%	
Hosmer and Lemeshow Test	p=0.08	
Classification accuracy	75.2%	

*p value of a stepwise (backwards) regression model is reported. Values in *italic* indicate significant association with number of errors. [#]Shift was not included in the model as it was correlated with the factor "number of patients per nurse for medication administration". Factor "Medication Therapeutic Group" excluded from the model.

Chapter 6

Results: Nurses' Perceptions of the medication errors associated factors

This chapter is dedicated to the qualitative stage of this doctoral thesis and particularly, it presents the findings of the focus group study. As previously discussed in chapter 3 (Conceptualization and Significance of the Study) and chapter 4 (Methodology), the focus group study concerns two focus group discussions which were conducted in order to explore nurses' perceptions regarding the factors contributing to medication errors in medical wards. Qualitative data deriving from focus group discussions allow an in depth comprehension of participant's perceptions on the discussion topic concerned, and have been used extensively in previous research aimed to gain insights of participants' perceptions (Escrivá Gracia et al., 2019; Papastavrou & Andreou, 2012). In this study, focus group interviews aimed at exploring the determinants constituting risk factors for medication errors, based on perceptions of nurses involved in the medication process in medical wards and is considered complementary to the first stage of the study. In comparison with other methods, focus group discussions have several advantages (Freeman, 2006). The sense of freedom and security among participants and the dynamic of a focus group is motivating for participants and creates a suitable environment to elicit the opinions of the group (McLafferty, 2004; Wilkinson & Birmingham, 2003). Additionally, and perhaps most importantly, this qualitative study gave the opportunity to the research team to obtain relevant useful information on the medication errors problem, information that probably could not have been collected only from a quantitative research approach. Therefore, this study was a valuable supplement of the observational study as it enriched the data obtained from the direct observation phase with purely qualitative information, thus providing a more complete and real picture of the medication problem in the two medical wards where the study was conducted.

6.1 Focus group data collection and analysis

Focus group interviews were conducted from January to February 2020 in one of the hospital's meeting rooms. The first interview lasted 75 minutes and the second 90 minutes. Focus groups were led by a moderator in the presence of an observer. The moderator guided the discussion based on a semi-structured interview guide, while the observer took notes of the conversation. The interviews went on up to the saturation point of the data where no additional statements or views were expressed (McLafferty, 2004; Papastavrou & Andreou, 2012). Two audio recording devices was used at each focus group to record the conversation for later transcription and analysis. More details regarding the methodological aspects and the participants and setting information for the focus group study, as well as the method used for data analysis, are provided in previous chapters (i.e., chapter 4, Methodology).

6.2 Main outcome from the two focus group discussions

As mentioned in chapter 4 (methodology), analysis of the data derived from the two focus groups interviews, was made by using the thematic analysis method. From the analysis of data collected from the two focus groups, initially thirty-three different thematic categories have been formed from the codes. Nonetheless, further analysis was made by the researchers and these initial categories were substantially reduced because some of the categories were indistinct, not clear, or not relevant enough with the topic and thus were discarded, while other categories were combined into one as they actually captured the same meaning. This was a cycling process, and it was repeated until the researchers who analyzed the data agreed that only the thematic categories that are useful and accurate representations of the data remain on the table. However, after further analyzing and refining the data and discussing the potential themes, researchers concluded in only four themes which they named based on the concept captured within each theme (Table 24). These were (a) Professional practice environment and related factors; (b) Person related factors; (c) Drug related factors; (d) Processes and Procedures (Table 20). However, Professional practice environment and related factors was the dominant theme as it captured an important group of parameters relevant with the research question (i.e., reasons and factors that can be associated with

medication errors) and represented a rather frequently observed patterned responses and meaning within the data set.

Table 24. The four themes with codes formed after data analysis

Theme	Example Codes
Professional practice environment and related factors	Staffing, type of the Ward, Days (weekdays/weekends), Work load, Busy atmosphere in ward, Shift (morning/evening/night), Interruptions and/or Destructions, Visitors, Control over practice, supervision, motivation, staff engagement, organization of work
Person related factors	Nurses' experience, knowledge, conscientiousness, mental and/or physical fatigue, patients' health condition, age, polypharmacy
Drug related factors	Availability of medicines/shortages, type of medicine (form and route of administration), preparation and administration method/technique
Processes and Procedures	Medication processes (storage, preparing, administering, documentation), Safety and Infection control procedures, Communication procedures

6.3 Medication errors related factors according to clinical nurses.

According to nurses involved in the medication process and who participated in the group interviews, and based on their narratives during the discussions, the reasons and factors that can be associated with the occurrence of medication errors, are embedded in each of the four themes listed in Table 24. Each theme is described below.

6.3.1 Professional practice environment and related factors

Nurses raised several issues regarding their professional practice environment and working conditions. Many aspects of their work environment were pointed out as major medication error contributing factors. Additionally, specific work conditions constitute factors that in their view were significantly contributing to errors. For example, the presence of family members and relatives visiting the patients during medication rounds, and the interruptions and/or destructions or a busy atmosphere in ward during medication administration created a prone to errors working environment. Interruptions and/or destructions were caused by relatives or visitors or from other reasons like personnel, phone calls, and patients:

"*We have noticed that when there are no patients' relatives in the ward, all work is completed on time. The staff is more focused and calmed and can do their job better. There are no interruptions or destructions in our work outside visiting hours*" (Nurse 2)

"When we are interrupted during the medication process the chance of making mistakes increases significantly. Common causes of interruptions are relatives, doctors, telephones or when new test results for a patient are sent to the ward, we have to interrupt to go find them before administering his/her medicines." (Nurse 7)

"Wrong dose or even the wrong medicine may be administered when the nurse is interrupted during administration. Interruptions by colleagues or doctors are often during the afternoon shift." (Nurse 1)

Staffing level was also an important factor that contributes to errors according to nurses. They claimed that with lower staff numbers is more likely to omit several tasks that shouldn't be omitted in order to finish the tasks on time:

"Staffing is too low and does not allow us to wash our hands before administering medicines, not only the oral but the parenteral drugs as well to each patient. There is just not enough time". (Nurse 5)

"*Actually, we are far less from the numbers we should have in terms of staffing and this force us to omit some tasks during medication rounds"* (Nurse 11)

"All shifts are understaffed. This means that some tasks may left unfinished in order to manage to administer medicines on time" (Nurse 9)

It was made clear by the participants that shift (morning, evening and night shift) was also a factor associated with medication errors. They emphasized that the night shift is usually understaffed and that nurses feel physically fatigue at night:

"*For me there is a big problem in the administration of medicines at the night shift. It takes much longer to finalize medication administration at night shift"* (Nurse 6)

"Early morning in particular, where you may feel more tired, the likelihood of mistakes increases" (Nurse 10)

"At the end of the night shift, nurses are often more exhausted. This can make them prone to errors. You get tired at night." (Nurse 3)

"In comparison with the morning shift, at the night shift, there is a heavier workload for nurses" (Nurse 2)

When participants were asked to discuss if there was a difference in the errors made between weekends and weekdays, they stated they do not believe that there is any difference. However, some of them expressed the view that maybe less errors are made in weekends because of a less busy atmosphere in the ward. They stated that medical wards, in comparison with other wards, are more demanding when it comes to medication rounds, indicating that the type of ward may also has a role in errors:

"In our ward the work is not affected much if it is weekend or holiday. In surgical wards, for example, there are no planned surgeries during weekends, so in surgical wards there is maybe less workload during weekends. But not in this ward". (Nurse 7)

"There is less noise or destructions in weekends because there are less people in the ward. There is a calm atmosphere. So maybe less medication errors are made during weekend because of these better working conditions". (Nurse 8)

"I do not think there is much difference. The atmosphere in the ward can be less noisy or busy, but visitors and interruptions are still there and on the top of that, often the staff is reduced during weekends". (Nurse 11)

As derived from the discussions, communication problems varied from communication lapses between ward staff, between staff and patients or between the ward and other hospital departments. Prescriptions that cannot be read and the absence of an electronic prescription system seemed to be an error contributing factor according to nurses:

"When a drug therapy needs to change or discontinued, is not always reported on time or not at all, and the nurse administering medicines may not be informed on time". (Nurse 4)

"If everything were computerized or if there was an electronic prescription system many problems would have been solved. We would not need to look for the treatment charts and doctors would be able to timely change the treatment; there should be an electronic system in place." (Nurse 3)

"I think communication is problematic. Even if we contact the doctor, practically the problem cannot be solved because the doctor has to be present to change a drug treatment by signing the treatment charts. So, whenever we have to administer a different therapy and the doctor is not available, we have to delay the administration until the problem is solved." (Nurse 12)

Regarding leadership and ward management, participants agreed that leadership could have an important role. They stated that when the management of the ward does not take into consideration the problems that may lead to errors, then the occurrence of errors increases:

"When we report the problems to the management they seem not to be listening. And it is in the good conscience of each nurse how we will carry out a task." (Nurse 13)

"*I think the leader has a decisive role. For example, if the leader does not emphasize on safety or errors, then the rest of the staff will do the same. Basically, the leader set the lines. Staff will follow*." (Nurse 2)

"*Omissions during the medication process maybe increased when staff is aware of the fact that the manager doesn't supervise or doesn't control that things are done in the right way.*" (Nurse 5)

Moreover, the organization of work has an impact on medication errors according to nurses. For example, it seemed that there are two basic types of work allocation in the wards. One is when the nurse is assigned a number of patients, so the nurse has to provide all the care needed solely for these patients only. Another type is when nurses are assigned specific tasks, so one nurse for example is responsible for administering the medicines to all inpatients. Nurses supported those organizational aspects of nursing work and allocation of tasks to the available shift staff, affects the occurrence of errors:

"In night shifts medication rounds are carried out by only one nurse, usually the most experienced one. In morning shift things may be different." (Nurse 2)

"In night shifts one nurse is usually allocated to all 30 patients of the ward meaning that he/she has to prepare and administer all medicines to all patients, and this is very challenging for the nurse." (Nurse 13)

"There are two ways to administer drugs. One way, which is mostly applied in the morning shift, each nurse is assigned a number patients and is responsible for their nursing care including administering their medication. But at night shifts, only one administers medicines to all patients in ward, and this is problematic." (Nurse 6)

6.3.2 Person related factors

Some attributes of the nurse administering the medicines or some characteristics of the patient, may have an impact on the number of errors made, according to participants. In particular, for nurses, person related factors included work experience, lack of knowledge, work conscientiousness, mental and/or physical fatigue. However, experience was a controversial issue as participants did not agree whether it has an impact on errors. Experience and knowledge considered intertwined by nurses, however, being conscientious, seemed to be more important factor according to nurses from just been experienced:

"I don't think it has to do with experience. I think it has to do with the individual. If you are conscientious and careful in your work you will make fewer errors, no matter how experienced you are" (Nurse 7)

"The experience and knowledge you gain when you administer many drugs for many years is important. I think an experienced person can avoid many mistakes." (Nurse 9)

"At the end of the night shift, nurses are often more exhausted. This can make them more prone to errors". (Nurse 3)

For patients, health condition and age are factors that may influence the occurrence of errors. These factors were mentioned during focus group discussions:

"It has to do with the patient's condition, take for example a patient who cannot swallow tablets and we have to crash them for administration, it's easy to make a mistake in such circumstances. It can be very difficult to administer medicines to these patients" (Nurse 9)

"In some cases, patients cannot communicate or confirm their name, and in such cases, errors are easier to happen" (Nurse 6)

"Some patients are in difficult health condition and in these cases, it is easier for an omission or an error to happen" (Nurse 4)

"When a patient is very old, towards the end of his life sometimes is very difficult for the nurse to provide care to such patients, because they usually are in a bad condition. I remember an elderly patient with dysphagia that he was choking not only on his medication but on his food and fluids as well" (Nurse 3)

In addition, it was stressed out by nurses that when a patient is prescribed a high number of medicines the possibility of error may increase, indicating that polypharmacy is a serious risk factor:

"…our patients are usually in a difficult health condition and they take many and different type of medicines and they often need catheterization…" (Nurse 1)

"When a patient takes a lot of medication, in addition to making a mistake in the administration, other problems can be caused, like side effects". (Nurse 7)

"Patients often take 2or 3 different antibiotics simultaneously plus the other medicines the routinely take. I remember I had to administer five different antibiotics to one patient, imagine how difficult is to prepare an administer 5 different antibiotics to one patient only". (Nurse 8)

"A lot of medicines are prescribed to patients, so the nurse often has to administer many different drugs to a patient. Some patients may be taking 7-8 medicines at a time. This is a problem; it needs attention, and the nurse must be very careful in order to avoid errors or even adverse events" (Nurse 1).

6.3.3 Drug related factors

During the discussions, the following medication related factors have been emerged: type of medicine, availability of medicines/shortages, preparation and administration method/technique, route and time of administration. In fact, availability of medicines seemed to be an important medication error contributing factor according to nurses:

"A drug that is not available at the time of administration, then it will not be administered. This is an omission." (Nurse 3)

"With injectable medicines administration sometimes can be tricky. Several things may go wrong, like a vein rapture, or some injectable drugs must be reconstituted in a specific way before administration, administered at a certain rate, etc." (Nurse 1)

"Some injections must be prepared in a specific way, in the right liquid and volume, the right infusion rate, in these cases extra care is needed." (Nurse 6)

6.3.4 Processes and Procedures

Another medication error risk factor that came to light from the discussions was the absence of standard and written operation procedures. For example, it seemed that there was no standard procedure to handle problems with medication shortages or availability issues. There was no written standard procedure on medication preparation and administration. Many processes were completed based on the nurses' experience, knowledge, and goodwill:

"Another issue is when the drug to be administered is in short supply or not available. There is a problem in this case because the patient may not eventually get the medicine." (Nurse 10)

"When I give a medicine via gastrostomy or nasogastric tube, or to a patient with infection, I wash and disinfect my hands afterwards. If I administer a drug intravenously, however, I will not wash or change gloves." (Nurse 8)

"We prepare the medicines for administration before the medication round begins, we place them on the trolley and the administration begins later, sometimes up to approximately two hours later, it depends on the workload" (Nurse 9)

All the above participants' narratives are indicative of the main themes composed from data analysis and they provide nurses' perception of the factors related to the occurrence of medication administration errors. Most of them have been described in the literature, however, some may deserve further investigation (e.g., exploring the association of leadership, professional consciousness, patient acuity and errors). The findings from the two phases of the study (observation and focus groups) are discussed in the following chapter.

Chapter 7

Discussion

This chapter contains a comprehensive discussion on the findings presented in previous chapters 5, and 6. The discussion is focused on the findings of both phases of the study (i.e., observational and focus group) but also discuss some differences and similarities of the findings of this research with findings from previous similar studies. In addition, the discussion also covers other parameters relevant with the medication errors problem such as reflecting possible reasons or explanation for the medication errors detected in this study. A comparison between the findings of the two sub-studies is also discussed in this chapter. Moreover, a discussion on relevant interventions for reducing medication errors is made in this chapter. In addition, the discussion is expanded to cover also other relevant aspects of the study such as the challenges faced during recruiting or during data collection and some ethical aspects regarding the conduct of the study. The originality, contribution and importance of the study, for the scientific community but also for patients' safety and quality of healthcare provided, is discussed here. Furthermore, a section where the limitations of the study are discussed is included in this chapter, as well as a section with some suggestions for further research and recommendations for nursing education, practice and policy.

7.1 Summary of main findings

The main findings are summarized and discussed below in line with the specific objectives set out in the study. In particular, the prevalence of medication errors as well as the medication errors associated factors as derived from the observational study and the perceived associated factors as derived from the focus groups study are discussed hereafter.

7.1.1 Frequency and types of medication errors

Omitting to hand wash or disinfect the site of injection, and in general not following the infection control and safety regulations was among the major findings that raises concerns of possible cross infection (Table 16 and Table 17). The omission of hand washing has previously been reported by other researchers (Kim & Bates, 2013), however, in many observational studies which investigated medication errors, is not observed as it was not included in the errors that these previous study aimed to observed. While hygiene is the simplest obstacle to transmission of an infectious disease, in this study hand washing was omitted and disinfecting the site of parenteral medication administration was omitted in almost 100% and 40% of medication administrations, respectively raising serious concerns as regards patient safety in hospital settings. While there is also other important information in the observational study's results, the omission of handwashing and the non-adherence to the basic infection and safety principles, is an alarming evidence of lack of a basic safety culture in the wards where the study was conducted.

In fact, this study highlights the importance of the adherence and compliance with the infection preventions protocols. One major finding from this study were the deviation in these guidelines during the medication process. Hand hygiene is the single most important and yet so simple measure of prevention and control of nosocomial infection which can significantly reduce the burden of disease. Nonetheless, insufficient compliance levels with the recommended hand hygiene procedures has been reported by many studies and agencies, with mean baseline rates of 5% to 81% (Ferreira De Almeida E Borges et al., 2012). The healthcare environment contains a diverse population of microorganisms, and few of them are significant pathogens for susceptible humans, and can be transmitted from source to host through indirect means such as via hand transferal (CDC, 2019). Furthermore, more patients are now becoming immunocompromised in the course of treatment and are therefore at increased risk for acquiring health-care associated opportunistic infections. Trends in healthcare delivery (e.g., early discharge of patients from acute care facilities) also are changing and increasing the number of immunocompromised persons in nonacute-care hospitals (CDC, 2019). The Centers for Disease Control and Prevention full discussion of

hand hygiene is available as the Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the Hand Hygiene Task Force (CDC, 2019). This guideline stressed the need to be adherent with the infection prevention regulations. Strict adherence to hand hygiene/handwashing and the proper use of barrier precautions help to minimize the potential for spread of these pathogens (CDC, 2019). Thus, this study contributes in raising awareness on an issue that constitute a risk for patient safety, and even being known to hospital staff and hospital administrations, still left untreated and with a remarkably poor compliance with relevant safety protocols.

Moreover, errors of omission in the basic five right principles of medication safety were also an important outcome of this study. This may indicate that clinical nurses are prone to deviate from safe practice regardless of their experience in the field. In particular, the omission of not confirming the patient's identity was a major finding. The error of not administering a drug in line with the correct administration method, could have been caused by a lack of knowledge, time pressure, or because of a lower risk perception. However, as assessing the knowledge of nurses did not form part of this study nor exploring risk perceptions, the explanation of this specific omission remains unknown. Some studies that did perform an assessment of the knowledge of nurses (Bertsche et al., 2008; Niemann, Bertsche, Meyrath, Koepf, Traiser, Seebald, Schmitt, Hoffmann, Haefeli, Bertsche, et al., 2015) have revealed some knowledge deficits, while other studies have shown that there is a significant variability between risk perceptions among healthcare professionals (Bourne et al., 2017; Nichols et al., 2009b). Administration method errors have also been reported by previous studies (Härkänen et al., 2015; Keers et al., 2013b; McLeod et al., 2014). In some previous studies the errors in the administration method detected, when reported, are attributed either to the lack of knowledge (i.e., dose calculation errors or lack of pharmacological knowledge) or to heavy workload and low staffing levels (Blignaut et al., 2017; Niemann, Bertsche, Meyrath, Koepf, Traiser, Seebald, Schmitt, Hoffmann, Haefeli, Bertsche, et al., 2015; Schroers et al., 2020; D. S. Wakefield et al., 1999). Whatever the reason for these erroneous behaviors, hospital administrations carry a huge amount of responsibility when it comes to the tackling this problematic conditions. Hospital administrators are responsible for organizing, overseeing

and assuring the provision of safe and quality healthcare services. To achieve this goal, they must develop and implement efficient quality systems and safety programs, introduce new technologies (i.e., bar-coded assisted drug administration or patient identification system), train their personnel and provide all necessary means in order to prevent latent conditions and system failures from creating a hospital environment that is unfriendly for patients and staff.

Also, non-adherence to the drug administration record protocol (i.e. documentation errors) was commonly recorded, and this is in line with findings from previous studies (Härkänen et al., 2015; Keers et al., 2013b; Safholm et al., 2019). In fact, documentation errors were the most common type of error of commission recorded with the inaccurate time of documentation being the most frequently detected documentation error. It is noted that in the two medical wards where the study was conducted there was no electronic prescription system and no electronic mediation records, therefore prescriptions and records were actually handwritten. There is some evidence in the literature to suggest that there is a high incidence of documentation errors in the traditional handwritten prescription process (Bryony Dean Franklin et al., 2007; Hartel et al., 2011). A number of previous studies have found that most errors occurred when prescriptions are transcribed into the patients 'charts. The readability of the handwritten prescriptions can be problematic while by replacing the traditional handwritten documentation process with information technology could potentially improve the safety in the medication process (Allison et al., 2015; Bryony Dean Franklin et al., 2007; Hartel et al., 2011; Schiff et al., 2015). Since in this study all documentation relevant with the medication process was made by hand, it could be assumed that documentation errors maybe attributed, at least partially, to the fact that no information technology or any kind of electronic system has been used for the documentation of the medication process. However further research is warranted to explore the impact of using electronic medication records on documentation errors.

One very important finding from this study was the high number of omissions. Omissions constitute deviations from safe drug practice and seemed to be the most frequent type of error

during the medication administration process. This is an important finding because errors of omission are often underestimated or not reported by staff (Pelzang & Hutchinson, 2020) but at the same time are one of the most common types of error detected in observational studies (Härkänen et al., 2015, 2019; Sears & Goodman, 2012). Errors of commission were also recorded in this study but were much less frequently observed. In comparison with previous studies (Härkänen et al., 2015; Keers et al., 2013b), a rather higher number of errors were detected in this study. However, this was not a surprise because this study aimed, apart from recording errors of commission, to detect as many errors of omission as possible. Many of the omissions detected in our study were not considered and therefore not recorded in previous similar observational studies (K N Barker et al., 2002; Härkänen et al., 2015; Haw et al., 2007). Specifically, in previous studies omission was defined as the failure to give an ordered dose, and that was the only type of omission recorded in several studies, thus a lower number or rate of errors were reported (K N Barker et al., 2002; Haw et al., 2007; Lisby et al., 2005). However, in this study more types of omission were considered, therefore a higher number of errors were recorded overall. One important difference between this study and previous ones is that within each Opportunity for Error (OE) different types of omission were observed; therefore, one administration could have more than one errors.

Previous studies have operationalized medication errors in terms of a rate which is calculated as the number of medication administration errors divided by the total number of OEs, multiplied by 100 (Allan & Barker, 1990; Bryony Dean Franklin et al., 2007). This rate is useful for comparing study results, however, is not always feasible to compare findings from different studies because of the different settings, definitions and methods used in each study (Keers et al., 2013b; McLeod, Barber, Dean Franklin, et al., 2013). Additionally, different approaches when calculating error rates are noted among different studies (Keers et al., 2013b; McLeod, Barber, Dean Franklin, et al., 2013). However, when contacting an experimental study or a before and after study, calculating OEs and error rates could be useful for evaluating the impact of the intervention on the reduction of MAEs rate.

Some studies suggested that medication administration errors occur in 5.6% of non-intravenous, or in 35% of intravenous doses (McLeod, Barber, Dean Franklin, et al., 2013) or up to 20% of all doses given;(K N Barker et al., 2002; Härkänen et al., 2015). However, other studies suggest higher rates of error (from 19.6% up to 85.9%), particularly for intravenous administrations (Fahimi et al., 2008; Keers et al., 2013c; Lisby et al., 2005). This is particularly relevant for medical wards, as many patients in these wards take drugs intravenously or in an injectable form (SC or IM), and may leave hospital as soon as they can take their medication orally. So, the fact the administration of injectable drugs in this study was conducted in a manner that may decrease safety of cross-contamination and transmission of diseases, e.g., due to poor hand hygiene practices during drug administration, is at least worrying considering the administration of a rather high number of injectable drugs (approximately 42% of all doses administered) and high number of omissions in the respective safety protocols. All these omissions, procedural errors and deviations has additionally a legal implication for hospitals and for healthcare professionals as well and minimizing the transmission of infectious diseases is a core function of public health law (WHO, 2017a).

In this study, the medication error rate is considerably higher in comparison with other studies. If the total number of doses given, plus omitted doses, is used as denominator and the number of doses with one or more errors as a numerator, multiplied by 100, the medication error rate will be 100% since all observed doses had at least one error. If the total number of errors is used as numerator, error rate will be above 100% (i.e., 356.5%). This was not an unexpected outcome since in this study we included additional types of procedural errors that were not commonly reported in previous studies. As mentioned above, the aim was to put an emphasis on omissions since they are among the most commonly reported errors (Härkänen et al., 2015; Keers et al., 2013b; Kim & Bates, 2013). Omissions of a drug or a dose are reported by previous studies (K N Barker et al., 2002; Härkänen et al., 2015; Lisby et al., 2005). However, procedural errors, like omitting to hand wash before administrating medicines intravenously, omitting to confirm the patient's name, omitting to check that the correct strength is about to be administered or omitting to disinfect the site of injection, are not always considered and therefore not recorded when investigating

medication administration errors. These omissions increase the possibility of additional adverse event to occur and also the risk of inpatients being harmed (National Coordinating Council for Medication Error Reporting and Prevention, 2020). Furthermore, findings from this study revealed that basic medication safety and prevention guidelines are not always followed by staff. The omissions detected in this study, highlighted failings in the medication administration process, and non-adherence to safety guidelines, which composes a prone to errors environment. These problematic conditions cultivate a suboptimal safety level, and are associated with poor health outcomes for patients (Härkänen et al., 2019). The findings also highlight the need to identify procedural errors in order to prevent medication adverse events. Further research will be needed to explore causes of procedural failures and identify potential barriers for staff to adhere to safety guidelines.

7.1.2 Medication errors associated factors.

Regarding associated factors, interruptions and/or distractions, medication type (i.e., form and therapeutic class), and number of medicines administered to the patient were all associated with a statistical significance to a higher number of errors (Table 18 and 19). In particular, the administration of injectable forms was associated with a higher number of errors than administering oral or other forms. Factors that could predict the occurrence more than three errors (≥3) with a statistical significance were medication class, pharmaceutical form and the number of medicines administered per patient. The association between pharmaceutical form and a higher number of errors is reported elsewhere, however, results from previous research on medication errors and pharmaceutical form are often contradictive as some studies report a significant association between medication errors and intravenously administered medicines (i.e. injectable drugs) while others report a significant association with orally administered drugs (i.e. oral formulations) (Fahimi et al., 2008; Härkänen et al., 2015; Elizabeth Manias et al., 2014; Westbrook et al., 2011).

It should be highlighted that after completing the two regression models, none of the professional practice environment factors found to be statistically significantly associated with medication errors. Chi square tests however and simple logistic regression did show a

significant association with interruptions or distractions, number of patients per nurse and a higher number of errors. For instance, the shift or the day had no statistically significant association with errors. However, other studies have reported an association between errors and shift, but still, findings among studies vary on this point (i.e. association between shift and errors) or are even contradictive as some studies report a statistically significant association between medication errors and morning shift (Fahimi et al., 2008; Härkänen et al., 2015) while other studies suggest a statistically significant association between medication errors and night shift (Brady et al., 2009; Di Muzio et al., 2019). However, in this observational study, shift was not found to be a statistically important error contributing factor. Concerning distractions and/or interruptions, despite of being known that distractions and interruptions disrupt concentration and attention, which can lead to loss in patient focus and subsequently incorrect actions or omissions that result in errors (Keers et al., 2013c), in this study interruptions or distractions were not found to be statistically significantly associated with errors when completing the two stepwise regression models. However, the chi square test did reveal a statistically significant association however, this association had been attenuated when the regression models were completed. On the contrary, it is known that previous similar studies do support a statistically significant association between errors and interruptions/ distractions (Brady et al., 2009; Härkänen et al., 2015; Keers et al., 2013c). Furthermore, there were no statistically significant differences in the occurrence of errors between weekdays and weekends, however there is some evidence in the literature suggesting that weekends maybe associated with an increase number of medication errors in comparison with weekdays, but still no definite conclusions can be made as findings from different observational studies are sometimes controversial on this issue (Härkänen et al., 2015; Keers et al., 2013c; Miller et al., 2010). Moreover, previous observational studies suggest that inadequate staffing is associated with an increased number of errors (Brady et al., 2009; Härkänen et al., 2015; Keers et al., 2013c; Mark & Belyea, 2009). In this study, staffing (i.e., number of patients for medication administration per nurse) had a statistically significant association with administrations with a higher number of errors (≥5 errors per administration), however, when running the regression model, the relation between number of errors and number of patients assigned per nurse (staffing), had attenuated.

Old age brings many challenges for safe use of medication (Metsälä & Vaherkoski, 2014). Nevertheless, patient age was not associated with a higher number of errors per administration in this study. However, in this study the vast majority of inpatients were above 65 years of age (85%), few were between 40 and 64 (12.2%) and very few inpatients were below 40 years of age (2.8%), so it could be assumed that age would not be a factor here as almost all participants were elderly patients (i.e., above 65), in fact 65% of all participants were above 75 years of age. However, we cannot predict what the outcome would be if in the study population we included pediatric patients. There are some studies in the literature indicating that age could be a factor that increase the risk of medication error, including medication reconciliation errors. However, these studies were not exploring errors during the medication process in hospital wards. For example, a study exploring the percentage of patients admitted urgently to the emergency department of a tertiary hospital, as a result of adverse drug reactions, reported that age (75% of patients were ≥ 65 years old), comorbidities and polypharmacy were the main risk factors for urgent hospital admissions (Mejía et al., 2020). However, previous observational studies which were conducted in similar settings (i.e. medical and/or surgical wards) are in line with the findings with this study as far as the patients' age is concerned, meaning that this factor (i.e. patient age) was not associated with a higher number of errors (Blignaut et al., 2017; Härkänen et al., 2015). Furthermore, it is already known that medication errors in pediatric populations are also detected with a similar frequency as in adult populations, which also supports the fact that other factors, besides age, (like type of medication or polypharmacy) may be significant contributing factors to errors (Jain et al., 2009; Krzyzaniak & Bajorek, 2016; Walsh et al., 2009). Finally, and in contrast to previous studies, there is at least one study were an inverse relationship between patient age and medication errors has been reported (Frith et al., 2012).

Moreover, a statistically significant association between nursing experience and ≥5 errors per administration being detected was noted in our study. This finding is in line with some other similar studies conducted in the past (Härkänen et al., 2015; Westbrook et al., 2011; Wilkins & Shields, 2008). In fact, there is some evidence that nurse's experience in a ward (i.e. longer experience in a specific ward) maybe associated with an increased number of errors (Sears et al., 2016).

Some studies do suggest that nursing experience may contribute to the decrease of medication errors, however these are not observational studies and most of them use a different methodology (i.e. qualitative designs or questionnaires), instead of the direct observation method, meaning they usually present the perceived error related factors (Fasolino, 2009). Another interesting point regarding nursing experience, and that must be brought in light, as it deserves further investigation, is separating nursing experience in two or more different types. More specifically, a nurse maybe experienced in treating trauma or wounds in specific group of patients (i.e., in the elderly), while another nurse maybe has an expertise in preparing and/or administering a specific type of medication, like oncological and cancer medication. In an ethnographic disguised observational study, Taxis and Barber (2003) suggested that nurses who are no longer used to preparing intravenous drugs, may make serious errors if they have to prepare drugs in an emergency (Taxis & Barber, 2003). So, if the association between medication errors and nursing experience and/or education relevant with medication process is put under investigation, perhaps the outcome will be different. Nevertheless, in this study experience of the administrator was not associated with a statistical significance to a higher number of errors per administration.

An important finding of this study is that the factors that statistically significantly predicted the occurrence of a higher number of errors (≥3 or 5 errors per administration) were the medication therapeutic class and the number of medicines administered per patient. When administering a higher number of medicines to a patient or when cardiovascular medicines were administered the risk of ≥ 5 errors made per administration was increased. Studies conducted in similar settings, including patients with similar characteristics, have also reported associations between medication errors and polypharmacy or medication errors and cardiovascular drugs (Härkänen et al., 2019; Keers et al., 2013c; WHO, 2017c). However, as mentioned before, different studies use different definitions, methods and assess different factors, hence, making comparisons across studies challenging. Additional investigation may be warranted to further understand factors unexplored in this study (e.g., safety culture, professional engagement) and how they are associated with MAE. Previous observational studies which were conducted in similar settings (i.e. medical, surgical, geriatric wards or

ICUs) and included patients with similar characteristics (i.e. elderly or with polypharmacy), also reported associations between medication errors and polypharmacy (Koper et al., 2013; Pérula de Torres et al., 2014; Saedder et al., 2014; WHO, 2017c) or medication errors and cardiovascular drugs (Brady et al., 2009; Härkänen et al., 2015; Keers et al., 2013c; Kohn et al., 1999). However, different outcomes and different types of associations between factors and errors cannot be precluded if the study was conducted in a different setting. For example, in an orthopedic ward or in a psychiatric hospital, probably different type and classes of medicines are described (i.e., other that cardiovascular) and patients' or nurses' attributes may also be different in comparison with a medical ward, therefore, in different settings and with different participant's characteristics, significant associations between medication errors and related factors could also be different than those detected in this study. Nevertheless, WHO also states that polypharmacy has harmful implications for patients including an increased risk of medication errors (WHO, 2017c). The association of cardiovascular drugs with an increased error risk could also be attributed, at least partially, to the fact that cardiovascular drugs contain many different medications that are frequently administer and require time-sensitive administration. The association of therapeutic class and/or polypharmacy with medication errors may constitute a target for future research as previous studies who had reported this association as well, don does not seem to provide an explanation for this finding.

7.1.3 Nurses' perceptions of medication errors associated factors.

Nurses have a central role in the medication process in clinical wards, and their perceptions of medication errors risk factors are important for enhancing medication safety and protecting patients from the inappropriate use of medicines during their stay in the ward. Different factors contribute to errors (Brady et al., 2009), however, the perception of medication error associated factors among nurses working in different healthcare settings may vary; because of the different working conditions (Sears et al., 2013b), different organization of work, ward management and different nurse or patients characteristics (Härkänen et al., 2013; Jasemi et al., 2019). Whenever an intervention for reducing medication errors in a clinical ward is

under consideration, the perceptions of staff working in the concerned ward should be explored in order for it to be successful (Cooper, 1998).

The focus groups study aimed to explore the perceptions of nurses in two medical wards, regarding the factors associated with medication errors. The focus groups' method and thematic analysis were used for collecting and analyzing the data. After organizing and analyzing the data collected from the discussions, the findings revealed that the "Professional practice environment and related factors" was the dominant theme. Participants emphasized that problems such as communication lapses, leadership and management, staffing, interruptions and/or distractions, busy atmosphere in the ward, have an impact on medication errors. Many of these findings were reported by previous research (Fahimi et al., 2008; Keers et al., 2013c).

Nurses stated that understaffing is an important factor contributing to errors and can lead to substandard health outcomes. Omissions are also increased when staffing level was low and tasks were skipped (i.e., hand washing before drug administration and especially intravenous) in order to have finalized medication rounds on time. Researchers have examined this relationship specifically (staffing and error rate), and results lack consistency because of different units of analysis used among different studies (hospital vs. nursing unit), different measures of nurse staffing (proportion of registered nurses vs. nursing hours per patient day), different approaches for defining medication errors, and different methodological approaches for collecting and analyzing the data (Mark & Belyea, 2009). However, there is evidence in the literature supporting the view that inadequate staffing may contribute to heavy workload as the daily routine tasks and jobs of the ward is distributed to fewer people who is currently available in the ward, and this specific issue has been associated with a higher number of medication errors (Brady et al., 2009; Härkänen, Vehviläinen-Julkunen, et al., 2020; Keers et al., 2013c; You et al., 2015). Actually, the burden on the remaining staff increases when the ward is understaffed and the cycle continues, with many posts left unfilled, particularly amongst registered nurses. When the ward is understaffed, nursing work can be demanding and stressful (Di Muzio et al., 2019; Frith et al., 2012; Härkänen et al., 2019). Inevitably, this

increases stress, lowers job satisfaction, has consequences for healthcare workers' mental and physical health, and precipitates burnout and job turnover (Härkänen, Vehviläinen-Julkunen, et al., 2020; Mark & Belyea, 2009). Previous studies indicate that nurse staffing is an important human resource to keep patients safe from medication errors. In particular is supported that as the nurses number increases, the medication errors number decreases; conversely, as the staffing level decreases, the medication error numbers increases (Frith et al., 2012).

Furthermore, more errors may occur at the night shift in comparison with morning shifts, particularly when the night shift is understaffed, according to nurses. This was explained by the fact that at the night shift they may feel physically fatigued and this may lead to errors. Previous studies indicated that the number of errors on night shift was consistently higher than the day shift and this phenomenon was attributed to physical and mental fatigue (Brady et al., 2009; Reinke et al., 2015). Nurses who were in night shift duty were five times more likely to commit a medication error than those nurses working in daytime shift. Nurses during night shift may feel the need to have a nap, or experience exhaustion or a failure in their effort to be concentrate on their tasks (Wondmieneh et al., 2020). In an effort to tackle the risk of a higher number of medication error at night shifts, nurses may use different strategies like moderate exercise for 30 min, take drinks with caffeine before or during the night shift or even take a nap to decrease sleep disturbance and increase attention during the night shift (Wondmieneh et al., 2020).

Regarding interruption or distractions, many studies revealed that indeed these are error contributing factors (Brady et al., 2009; Härkänen, Luokkamäki, et al., 2020; Zhao et al., 2019). Nurses are often interrupted during their shift by people, pagers, telephone, and this constitutes a risk factor for errors (Kavanagh & Donnelly, 2020). In addition, findings from previous studies are in line with the view expressed by nurses in this study. Nurses have cited interruptions and distractions as a top cause of errors during medication administration and interruptions are associated with different types of medication administration errors, such as administering wrong medication, wrong dose, or at a wrong infusion rate (Prakash et al.,

2014). Thus, the findings of this focus group study are in agreement with previous studies, as far as the factor “interruption or distractions” is concerned.

Nurses expressed the view that communication issues, such as not being able to communicate with the doctor when needed, for a change in the drug therapy or a dosage change for instance, can lead to medication errors or delays in the administration or even omissions of a dose. Communication lapses were found to be a risk factor for medication errors in similar studies (Keers et al., 2013c; Elizabeth Manias et al., 2019; Pandya et al., 2019). Current research indicates that ineffective communication among health care professionals is one of the leading causes of medical errors and patient harm(Leonard et al., 2004). Other researchers have found associations between better nurse-physician communication and collaboration and more positive patient outcomes, i.e., lower mortality, higher satisfaction, and lower readmission rates (Baggs et al., 1999). Hence, in consistency with the findings from previous studies, the findings of this focus group study also support the view that by improving communication between ward staff (i.e., between nurses and nurses and other healthcare professionals) or between different hospital departments or units, may significantly contribute in the enhancement of medication safety and promote patient safety.

An association between nursing leadership with error rates was previously reported (Cooper, 1998; Squires et al., 2010; C. A. Wong et al., 2013). In this study, participants mentioned that leadership is a substantial parameter when it comes to errors. Effective leadership fully integrates safety strategic objectives into all of an organization’s systems (Cooper, 1998), while ineffective leadership is associated with system failures and a negative safety culture (Cooper, 1998; Squires et al., 2010). Open communication canals must be maintained widely open between leadership and frontline staff at the unit level in order to promote medication safety (Aldawood et al., 2020). Ward managers should be responsive to all problems raised by ward nurses. As stated during the discussions by participants in our study: “When we report the problems to the management, they seem not to be listening...”, indicating that this lack of responsiveness form managers when problems are reported may lead to a suboptimal safety climate within the department and jeopardize patient safety. This indicate a

problematic relationship and an insufficient communication between managers and frontline staff, which is indicative of a low safety climate (Aldawood et al., 2020).

For nurses, attributes such as experience, knowledge, professional consciousness, mental and/or physical fatigue, seemed to have a role in medication errors numbers and this finding is in accordance to previous studies (Härkänen et al., 2015; Keers et al., 2013c; Elizabeth Manias et al., 2019). Studies have shown that some medication errors could be attributed to either a lack of knowledge about the medication or a lack of knowledge about the patient (Escrivá Gracia et al., 2019; Härkänen et al., 2015). In this study, nurses did not fully support the view that work experience is a substantial factor when it comes to medication errors. However, there is evidence that the severity of errors does reduce as clinical experience increases (Kim et al., 2016; Westbrook et al., 2011). However, other studies have suggested that experience is not always associated with fewer errors (Chang & Mark, 2009; Koren et al., 1983). As mentioned above in previous section, some studies do suggest that nursing experience may contribute to the decrease of medication errors (Fasolino, 2009). In an ethnographic disguised observational study, Taxis and Barber (2003) suggested that nurses who are no longer used to preparing intravenous drugs, may make serious errors if they have to prepare drugs in an emergency (Taxis & Barber, 2003). So, if the association between medication error and nursing experience and/or education relevant with medication process is put under investigation, perhaps the association between nurse experience and number of errors would be different. Nevertheless, in this study nurses did not support, at least not strongly, that experience of the administrator is associated with a higher number of errors per administration.

Instead, professional engagement, conscientiousness or good mental and/or physical condition were nurses' key attributes for enhancing medication safety (McDowell et al., 2009; Mohammadi et al., 2020; Petrenko, 2014). Professional conscientiousness was a term that came out from the discussions and from participants' narratives. Nurses explained during discussions, that due to different personal aspects and characteristics among nurses, each individual nurse values and understands differently professional ideals, commitment to

professional standards, and may have different motives when carrying out their nursing tasks. They may have different job satisfaction levels, different perceptions of their profession or of the important role that their work has for patients. This could explain why some nurses are more conscientious than others, thus careful and sensitive when providing nursing care to patients and therefore less likely to fall into erroneous actions, including medication errors. Studies exploring the development of professional conscientiousness among professionals, nurses included, seem to support these statements made by nurses (Enns & Shapovalova, 2015; Jasemi et al., 2019; Mohammadi et al., 2020; Petrenko, 2014).

Additionally, work engagement (staff engagement) which also had been mentioned by participants in the discussions, is an important parameter. Work engagement is defined as a constructive, positive and mindful conduct at work which results to a positive work-related outcome (Seligman & Csikszentmihalyi, 2000). Research has proved that healthcare professionals with high levels of work engagement demonstrate a positive behavior during their work, get more satisfaction from there are work, may be more effective, efficient and productive (Seligman & Csikszentmihalyi, 2000). Healthcare professional, when engaged to their work, have a considerable lower chance to suffer from burnout and are more dedicated and energetic in their work (Scheepers, 2017; Seligman & Csikszentmihalyi, 2000). It worth mentioning that the level of work engagement seems to be correlated with professional/work consciousness of each employ and also with some professional practice environment related factors, such as stuffing, work organization and leadership and management (Beck et al., 2020; Mohammadi et al., 2020; Petrenko, 2014; Scheepers, 2017). To this end, it should be highlighted here that all this evidence, easily, and most probably correctly, lead to the conclusion that the medication errors problem is a multifactorial phenomenon, concerns persons and systems and thus, it cannot be approached from only one pathway for understanding the underlying "pathology" causing the problem and for developing appropriate interventions for tackling it.

Regarding patients' characteristics, health condition and age were the two factors that are associated with errors, according to nurses. This finding is in agreement with previous

research, where bad patient's condition found to be related with medication errors (Bates et al., 1999; Härkänen et al., 2015; Keers et al., 2013c). Nurses also emphasized that it is more likely to make a medication error when caring for an elderly patient. However, research shows that medication errors are detected in pediatric wards as well (S. Choo et al., 2017; Sears et al., 2013a). Research suggests that indeed several patient attributes may contribute to adverse drug events. In particular, patient risk factors for drug related adverse reactions include age, number of medicines received by a patient, and factors that modify the bioavailability of a drug (i.e. distribution or metabolism), for example alcoholism or liver or renal failure (Bates et al., 1999; Blignaut et al., 2017; Joosten et al., 2013). The findings of this study are in agreement with these findings. However, in our observational study we did not include the patients' condition as a parameter (i.e., related risk factor) and therefore we did not assess such associations there, however, this factor has been obtained here in the focus group interviews.

Nurses emphasized that the availability of medicines was an important factor that could contribute to errors. In particular, when some medicines that had to be administered were not available or there was a shortage from the hospital pharmacy, the risk of error was increased. This finding has also been reported in previous research (Miljković et al., 2019). In addition, the number of medicines taken by the patients was also a significant error risk factor. There is evidence that the frequency of medication errors is high in patients with polypharmacy (Koper et al., 2013; WHO, 2017c). According to nurses some patients are prescribed different types of medicines simultaneously, a phenomenon associated with medication errors. Drug related factors, such as the pharmaceutical form or the administration route, were not considered to be important error contributing factors by nurses in this study, instead they pointed out that is rather the patient's condition that will increase the risk of an error and not the type of medicine. Previous research indicates that there is an increased risk for medication errors with injectable drugs (Fahimi et al., 2008; Härkänen et al., 2015). Furthermore, some drug therapeutic classes have been accused to be associated with an increased risk of medication error. For example, cardiovascular drugs, antibiotics, anticoagulants and antithrombotic medicines have been associated with a higher rate of medication errors (Brady et al., 2009; Härkänen et al., 2015; Keers et al., 2013c; WHO, 2017c).

Moreover, nurses admitted that occasionally they have to omit certain tasks which they consider less necessary or time consuming (e.g., not confirming patient's name) in order to administer medicines on time. These omissions constitute medication errors (Härkänen et al., 2015; Kalisch & Xie, 2014) and the fact that nurses are used to operating under these conditions in their daily practice is indicative of the negative safety culture in the ward.

It was obvious that even though nurses considered medication safety as an important parameter of the care provided, the discussions revealed a suboptimal level of safety. Participants' narratives have shown that working environment conditions, communication procedures, standard practices regarding the medication process, ward management and leadership are not supporting the development of a positive safety culture in the ward. A good safety culture is believed to positively impact upon an organization's competitiveness, quality and reliability (Cooper, 1998). Nurses' attitudes and behaviors that determine an adequate level of commitment to safety were absent. For example, several infection prevention principles or even the five right principles when administering medication to patients, were not always followed. In some cases, according to nurses, it should be expected that under these problematic conditions some actions needed to be omitted or performed in an inferior way in order to manage to carry out medication rounds on time. It was obvious that the general safety culture in both wards was problematic. Nurses' narratives indicated the absence of a total quality management system in the wards. Systems and processes, including medication prescription, preparation and administration were not carried out according to a written protocol but rather on experience and on the notion "this is the way we do things here". The importance of leadership and the commitment of managers toward safety is crucial for facing these safety obstacles (Cooper, 1998; Squires et al., 2010; C. A. Wong et al., 2013). Relevant training programs or motivation plans for staff are also necessary for enhancing safety attitudes (Cooper, 1998). Focus group discussions in this study revealed that many of these parameters were problematic.

7.2 Assembling and discussing the findings of the direct observation study and of the focus groups study.

As stated in chapter 4 (Methodology), the findings of the focus group study would be a valuable addition to the findings of the observational study as some factors explored via the focus groups study were left unexplored in the observational study, mostly because of feasibility or practical reasons, on the one hand, and on the other hand, the perceptions of nurses of medication errors could only be gathered via a questionnaire or via oral interviews. For example, during the observational study, it would be difficult to observe or explore specific factors such as professional engagement or leadership during the observation.

When reviewing the findings of both sub-studies (i.e., observational and focus groups study), it can be suggested that there is an agreement, to some extent, between them. Also, the data collected from the focus groups discussions seem to complete and supplement the picture composed by the observational study as some factors emerged during the focus groups discussions were not investigated during the observational study. For example, the health condition of each patient or the relationship of leadership and errors were not explored during the observational study but were derived from the focus groups discussions. Therefore, the valuable contribution of the second study is confirmed, as not only the perceptions of nurse on medication errors were obtained, but also additional associated factors have been emerged or some behaviors could be explained in more than one way. For example, several omissions detected during the observation, like the omission of placing the iv equipment in disinfected surfaces only, could be attributed to the workload pressure or to the work allocation system in the ward and not due to lack of knowledge.

One strong agreement between the findings from the two stages of the study was polypharmacy. During focus groups discussions it was noted that the administration of a high number of medicines to each patient poses an additional risk for errors during the medication process. Even more importantly, the observational stage of the study indicated that one factor which was statistically significantly associated to the likelihood of a higher number of errors was the number of medicines administered per patient. Several previous similar studies, and

studies conducted in similar settings (i.e., medical, surgical, geriatric wards or ICUs) and included patients with similar characteristics (i.e., elderly or with polypharmacy), also reported associations between medication errors and polypharmacy. We don't know what would be the outcome if the study was conducted in a different setting (i.e., orthopedic or psychiatric clinic) or with different participants' attributes (i.e., patients' or nurses' characteristics). WHO also states that polypharmacy has harmful implications for patients including an increased risk of medication errors (Keers et al., 2013c; Salazar et al., 2007).

Beside of the obvious concord between the findings derived from both phases of the study, at the same time there is some disagreement between the findings as well. For instance, staffing was one of them. While nurses emphasized the association of medication errors and understaffing, the observational study did not reveal any statistically significant association. Understaffing was perceived as one of the major error- contributing factors. Nurses stated that because of understaffing they omit certain tasks, despite the fact they are aware of the importance of these omitted tasks, such as disinfecting site of injection or washing their hands before administering a medicine, or even confirming patient's name. However, the regression analysis which was completed by using the results of the observational study did not support this nurses' perception. Nevertheless, this finding needs to be interpreted with caution as an association between the number of patients per nurse and ≥5 errors per administration was noted when investigating associations with chi square and simple logistic regression. A possible explanation for this disagreement among findings concerning association among staffing and errors, is that understaffing leads to a disappointment and a decreased job satisfaction which consequently leads to a suboptimal performance which could, at least partially, explains the omission of certain tasks, such as hand washing for instance. The association of understaffing and insufficient work engagement or work performance and satisfaction has been reported in previous research (Nedvědová et al., 2017; Sasso et al., 2019; Schneider et al., 2019) and probably may contribute to a negative behavior or performance during work by nurse. Furthermore, nurses reported that patients' condition in an important a parameter (i.e., related risk factor) when it comes to medication errors, however, the observational study did not assess this possibly error contributing factor. Another point of disagreement was the patient's age. Nurses reported that patient's age is

associated with errors. They emphasized that it is more likely to make a medication error when caring for an elderly patient. However, research shows that medication errors are detected in pediatric wards as well (S. Choo et al., 2017; Sears et al., 2013a) and also the observational study did not indicate any statistically significant association between errors and patient's age. In addition, there is some evidence suggesting that it is not the elderly or the advanced age of patients that may lead to less job satisfaction for nurses, but it is the problematic nursing practice environment that may lead to a lower job satisfaction level (Wang et al., 2015). And as mentioned above, a decreased job satisfaction can consequently lead to a suboptimal performance which could, at least partially, explain the omissions and other errors made during the observation of the administration process. Anyway, the focus group discussions had prompted the problematic nursing practice environment issue and the problematic procedures and processes. Suboptimal working environment and working conditions or problematic procedures and processes negatively affect medication safety (McLeod et al., 2014; Square, 2013). In this study, nurses did not fully support the view that work experience is a substantial factor when it comes to medication errors. This was a controversial point as shown during discussions. The analysis made from the results obtained from the observation study suggest that nurse experience is statistically significantly associated with the occurrence of a higher number of errors (≥5 per administration). Thus, there is an alignment between the findings from the two studies. There is evidence that the severity of errors does reduce as clinical experience increases (Kim et al., 2016; Westbrook et al., 2011). However, other studies have suggested that experience is not always associated with fewer errors (Chang & Mark, 2009; Koren et al., 1983), on the contrary they may be related with a higher number of errors in some cases (Rishoej et al., 2018; Sears et al., 2016).

7.3 Safety culture

James Reason states that "the human error problem can be viewed in two ways: the person approach and the system approach. Each has its model of error causation, and each model gives rise to quite different philosophies of error management. Understanding these differences has important practical implications for coping with the ever present risk of mishaps in clinical practice" (James Reason, 2000). However, it is not always easy to

understand the causes of errors, and for this reason is often difficult to be proactive. Errors can lead to disastrous events. When the roots, the real causes of certain catastrophic events, crisis events, or events that could irreversibly damage the image and status or the name of an organization, could not be explained be system failures or by individuals' behaviors alone, the safety culture approach emerges (Besnard et al., 2018; Cooper, 1998). The French Institute for an Industrial Safety Culture (2003) defines safety culture as a set of practices (ways of doing) and a mindset (ways of thinking) that is widely shared by the members of an organization when it comes to controlling the most significant risks associated with its activities. It is forged gradually by the interactions between people and it continues to evolve (Besnard et al., 2018). This definition applies to many organizations, including hospitals.

Organizational culture is the set of believes, behaviors, perceptions., understandings and standard practices shared and adopted by that the people of an organization. When the members of an organization constantly behave and act in certain ways which for them are considered to be natural, obvious and unquestionable (i.e. the way we do things around here), the more dominant the culture becomes (Cooper, 1998). Safety should be a profound characteristic, a main determinant of the organizational culture of high-risk industries. Thus, organizational culture has a substantial impact on safety. Safety culture is considered to be a major component of organizational culture and is reflected on individuals, on teams and on organizational procedures and systems (Cooper, 1998; James Reason, 2000).

The findings of this study indicate that the safety culture in the two wards where the study was conducted was suboptimal. In fact, there was a strong culture in both wards from which safety was absent. Medication safety and patient safety even though considered to be important by nurses, still in their daily practice both were neglected. Nurses put all their effort into carrying out their task and completing their nursing or other clinical duties rather than doing so more carefully and in line with the relevant basic safety protocols. So it was the important was to finalized their work timely, rather than doing so by adhering to all relevant basic safety protocols. The high numbers of errors, omissions in particular is a strong evidence indicating the absence of a strong safety culture. However, nurses' behavior is just

the one side of the coin. The professional practice environment and problematic working conditions, insufficient procedures and systems, is the other side of the coin, which includes all the conditions under which individuals work. The absence of a strong leadership with a sensitivity on safety, the lack of resources (i.e., electronic systems, understaffing, medication availability issues etc.), problematic procedures (medication orders, storage and preparation, visiting hours etc.) can only lead to a negative safety culture. There is no reason to believe that the problem is not isolated in the two medical wards where the study was conducted, but we may assume that the hospital suffers from a poor safety culture, which inevitably can lead to pour patient outcomes. However, this is only a speculation as, to the best of our knowledge, no medication or patient safety related study have been conducted in this hospital.

7.4 Limitations and strengths of the study

This study had several limitations which should be kept in mind before interpreting the findings or drafting any relevant conclusions. Limitations of this research derived from the methodological characteristics of the study and may influence the interpretation of the findings. In fact, the study bears the limitations of the observation method and it might be susceptible to several disadvantages such as observer bias and hawthorn effect. (Dean & Barber, 2001; Härkänen, Turunen, et al., 2020; McLeod, 2013). However, several measures were put in place to avoid or decrease these limitations. First, the agreement between observers' ratings was confirmed before initiating the study. In addition, the presence of the observers in the wards had been prolonged by conducting a pilot study which gave thw opportunity to the participants to get used to the observers being in the ward during the medication process. Thus, it is not anticipated that these two limitations have influenced the outcome of the study. Additionally, the qualitative designed implemented in the second study (i.e. focus groups interviews), also has a number of disadvantages like subjectivity and a degree of difficulty in collecting the data and interpreting the results and thus may not allow generalization of the results to other settings and/or populations, which is a limitation in terms of external validity of the findings (Freeman, 2006; Kallio et al., 2016; Papastavrou & Andreou, 2012; Sale et al., 2002). However, these issues are part of or related with the design

and the purpose of the study, i.e., to capture the subjective perceptions of nurse in relation to factors that influence the likelihood for error.

It was also mentioned that during the observational study, some factors that may be related with medications errors (i.e., severity of patient's health condition), were not observed and thus not explored for association. In particular, due to the complexity of the medication process, additional factors contributing to errors (i.e., patient's conditions, availability of medicines) may exist but probably were missed and therefore not included in our analysis. Moreover, even though observers tried to be discreet, their presence in the wards may had an impact on nurses' performance, and this is related to the Hawthorne effect mentioned above. Finally, this study conducted in two medical wards of a tertiary hospital and only the administration phase was observed. Expanding the observation in different wards and including different populations (i.e., psychiatric, or pediatric patients) or different stages of the medication process (e.g., prescription stage), could provide a more comprehensive picture of the medication errors problem in Cyprus. As far as the second stage of the study is concerned, the qualitative design, the focus groups discussions and the purpose sampling approach followed, in the two medical wards, means that the findings cannot be generalized to other nurses or other wards (Papastavrou & Andreou, 2012; Papastavrou et al., 2014). Nurses working in different settings may have different perceptions regarding the causes of medication errors. In addition, considering the sensitivity of the research topic, and despite the encouraging environment within the focus groups, some participants may have been reluctant to express their views if it would diverge from the rest of the group (Papastavrou et al., 2014; Ritchie & Lewis, 2004). In addition, a purpose sampling approach was followed in this focus group study which may decreases the validity of the study. Also, we did not approach the medication errors problem from a multi-professional perspective. This means that additional errors that do exist in clinical settings, such as prescribing errors, documentation errors, and dispensing errors (Alanazi et al., 2016; Ben-Yehuda et al., 2011; Glanzmann et al., 2015; Tariq et al., 2020), which were not explored by this study.

Nevertheless, despite these limitations, this study collected nurses' perceptions of medication errors in two medical wards and in addition, collected, by using the direct observation method, which is perhaps the best method for investigating medication errors according to the literature, detailed information regarding the medication preparation and administration process and related factors. The data collected and the analysis data underwent revealed useful information that can be used to capture the magnitude of the medication safety problem in at least the two medical wards where the study was conducted. All the findings here can also be used as baseline data for developing programs for preventing medication errors in similar hospital wards.

An important differentiation of this study from previous research on medication errors, is that this study gives an emphasis on errors of omission. Omission is one of the most frequent type of error detected during the medication process. Apart from being the first attempt to study this important issue in Cyprus, the study also contributes to the literature because it focuses on an aspect of the medication errors problem that is often left unexplored by other studies. That is the extremely high number of omissions during the medication process which of course create an environment prone to drug related adverse events with a negative impact on patient safety. Previous study detected errors during the medication process, particularly during medication administration stage, however, the errors reported from most studies are focusing on errors of commission and when it comes to omissions, these are limited to the omission of a dose or of a drug (Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Härkänen et al., 2015). However, additional omissions and deviations from safe drug administration principles do exist but not always detected and neither reported. In this study, all procedural errors constituting an omission, were detected and included in the analysis. Furthermore, two different methodologies were employed for collecting the data, which means a well-rounded picture of the under-investigation topic could be obtained. In particular, the direct observation method was used for detecting the frequency and types of medication administration errors, as well as the associated factors. Moreover, the perspectives of nurses were also collected in order to obtain an insight from their point of view about the problem. For collecting the perspectives of nurses involved in the medication process regarding the factors associated with errors, a qualitative approach was followed, and two focus groups were completed. This

led to having the perceptions of nurses, who in fact, have a central role in the medication administration to inpatients and therefore their perception of error risk factors may provide an insight into the medication errors problem. Based on the analysis of the data collected from the direct observation of the medication administration process and from the focus-groups discussions, the findings from these studies may contribute to the prevention of medication errors in Cypriot hospitals as well as to the global effort to decrease medication errors and enhance patient safety.

Chapter 8

Conclusions and Recommendations

The focus of this study was on medication safety in two medical wards of a tertiary hospital in Cyprus. In particular, the study, which was performed in fulfillment of the requirements for a PhD degree, aimed to detect the medication errors made during the medication administration process and explore the medication errors associated factors. The findings indicated that medication errors are common in these two wards, and in particular omissions. Omissions lead to deviations from safe clinical practice, but probably also reveal a hidden risk factor, like a low drug safety perception among healthcare professionals. Exploring the causes of this problematic phenomenon is crucial in the effort to address it. Factors associated with medication errors need to be further explored and taken into account in an attempt to limit errors. Moreover, according to nurses' perceptions, medication errors is a multifactorial, multifunctional, and multidimensional phenomenon that needs collective efforts to be minimized and decrease the possibility of placing patients at risk. Error contributing factors may have their roots in the working environment conditions, and in the attributes of those involved in the medication process. Error contributing factors must be identified and addressed when implementing medication safety interventions. They are important pieces of the safety culture puzzle of an organization. Cultivating a safety culture within a ward begins from the management team and affect members' attitudes, values and behaviors. A strong safety culture can inhibit most of the medication error contributing factors and therefore promotes medication safety.

8.1. Summary of major conclusions

Based on the findings of this study, several conclusions can be reached. Firstly, it is restated that medication errors are common during the medication preparation and administration process in medical wards. Medication errors can be observed in every dose administered to a patient. Errors of omission is the most common type of errors. Approximately 80% of all

errors made were errors of omission. Omissions constitute procedural errors and deviations from safe drug administration that do reach the patient and could put patients at risk. However, omissions can be prevented because they concern attitudes and behaviors of the personnel and are relevant to the general safety climate and culture of the team and of the organization. Previous studies exploring medication errors did not assess many of the omissions explored in this study. Approximately 20% of all errors observed were errors of commission (i.e., execution errors).

Moreover, there are many factors contributing to errors. Polypharmacy and cardiovascular drugs were associated with an increased number of errors. Additionally, other factors like interruptions and/or distractions during the medication process, communication failures, the staffing, leadership and management, and the shift as well as the patient's condition could associated with a higher error rate. The type of medication (e.g., pharmaceutical form) may also be associated with errors.

Nurses consider medication safety and patient safety as an important aspect of their work and have their one perception about medication errors. For instance, problematic working environment, insufficient working organization, problematic procedures and processes, lead to negative safety attitudes among staff and negatively affect medication safety. Leadership is also crucial when it comes to medication safety. Ward managers may either guide and influence employees to achieve safety objectives and adhere to safety standards and protocols when performing clinical tasks (i.e., adhering to the basic infection and safety regulations) or by not being focus on safety, managers may promote negative attitude towards safety, which further affects the improvement of safety behaviors among the personnel. Nurses spend much of their time in preparing and administering medicines and therefore their perceptions of the factors contributing to medication errors is crucial for drafting and implementing interventions to enhance medication safety.

Implementing targeted interventions that have the potential to cure the factors that are associated with medication errors should be a priority for each hospital and each ward.

Medication errors risk minimization goals include efficient work allocation systems, reduction of distractions or interruptions during medication administration, use of informative technology and training and educating programs for the personnel. Reporting medication errors is also an important safety parameter that can improve medication safety within a ward or within a hospital and medication error reporting tools (i.e. Global Triger Tool) should be employed in clinical wards (Härkänen, Turunen, et al., 2020; Pal et al., 2013).

8.2. Recommendations for further research

This study provided evidence indicating that medication errors are frequently occurring in clinical wards. Therefore, there is a need for initiatives and actions for facing the problem and further study on the medication errors problem should focus on this direction, developing and maintaining appropriate interventions in order to increase medication safety in hospitals. The most important suggestion is perhaps the need for developing, implementing, evaluating and improving interventions and medication errors preventing programs in all hospitals in Cyprus. This would be necessary for improving medication safety in Cypriot hospitals. Therefore, future research should be focus on interventions, as this study is providing only the base, a starting point and a fundamental evidence, upon new research can be constructed for promoting drug safety and thus patient safety as well.

However, before drafting and implementing any type of intervention, it is necessary first, to identify the real causes that create the problem. This is needed so the intervention will be more integrated and targeted, meaning that it will be formulated for a specific setting to cure specific problematic conditions that contribute to errors. It is necessary, as a first step to accurately detect the roots of the problem, the contributing factors, and the underlying problematic conditions that built up in a ward or in a hospital and altogether compose this problematic phenomenon (Noguchi et al., 2016; WHO, 2017d). To that end, and because of the limitations of each method used to explore errors (i.e. observational studies, incident reports, or focus groups studies), it is recommended to use a diverse methodological approach (i.e. implementing simultaneously more than one method) for detecting the factors and the

real causes of the problem (Härkänen, Turunen, et al., 2020; Noguchi et al., 2016). This will help in developing more targeted and effective interventions for decreasing error rates in hospital settings.

In this study it was found from nurses' narratives that the health condition of the patient (i.e., poor health condition) is a potential error contributing factor. In addition, they pointed out several other medication errors associated factors, such as problematic leadership, communication lapses, availability of medicines. In the observational study of this research, these factors were not explored nor included in the assessment of associations between error and related risk factor. Thus, further research will be needed to better understand the interactions and associations between these factors and medication errors. In addition, our observational study, in line with previous studies, reported an association between medication errors and cardiovascular drugs, and medication errors and polypharmacy (Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Härkänen et al., 2015, 2019; Keers et al., 2013c; Kim & Bates, 2013; WHO, 2017c). The association of these specific factors with medication errors may constitute a target for future research as more evidence maybe needed to understand the actual impact of these factors on errors.

This study has provided clear evidence that omissions are more than common, as they were detected in all of the recorded administrations of a drug to inpatients. Omissions constitute failures in the medication process and deviations from medication safety guidelines, which threaten patient safety. They should be identified and addressed by healthcare organizations, hospitals in particular. Procedural errors and omissions during the medication process are intertwined with non-adherence to safety guidelines which inevitably cultivate an error prone environment. This study highlights the magnitude of the non-adherence to these guidelines which warrants further investigation to understand why and how to resolve this. Nurses' beliefs regarding patient safety, and safety attitudes and behaviors should be explored depth to understand why some actions are left unexecuted and frequently omitted. Qualitative and quantitative research may be warranted to answer these questions, such as surveys, questionnaires, or observational studies. The performance, the safety attitudes and the skills

and knowledge of all healthcare professionals involved in the medication process should be explored and of course be cultivated and maintained oriented towards patient safety. This study, however, was focused on the medication process within a medical ward. More specifically, it focused on medication administration process. This means that additional errors that do exist in clinical settings, and particularly within the medication process, such as prescribing errors, transcribing errors, and dispensing errors (Alanazi et al., 2016; Ben-Yehuda et al., 2011; Glanzmann et al., 2015; Tariq et al., 2020), were not covered by this study. Investigating errors across the entire medication process is highly suggested and should be the aim of future research. In addition, future research should focus on the development and implementation of appropriate interventions for reducing errors.

8.3 Recommendations for clinical practice

The medication process in hospitals is a multidisciplinary clinical task and involves different healthcare professionals, such as physicians, pharmacists, nurses and other staff that facilitate patient care (e.g., pharmacy technicians, nursing assistances). Nurses are involved in the medication process and spend much of their working time in preparing and administering medicines to patients. This means they have a key role in the medication process as they actually perform the last, but not least, stage of the medication process (i.e., administration). Hence, they must be able to work in an environment with as much as possible less distractions and interruptions, with an effective workload allocation system and always kept educated and motivated regarding the adherence to safety principles, including medication administration.

Hospitals and healthcare providers should be able to have in place effective and efficient processes and procedures within their wards or other units. For example, in a ward, the whole medication process, the work allocation and organization process, or the communication or documentation procedures, maybe ineffective and problematic (Pandya et al., 2019; Westbrook et al., 2011; Zhou et al., 2015). Nonetheless, in front of the vast clinical workload of a busy ward, such as medical wards in tertiary hospitals, a problematic process or procedure may have left uncured, and this will lead to additional failures, including omissions

and errors in the medication process. These problematic conditions, if left unresolved, will create a negative safety climate and will drive the concerned unit away from being able to keep an acceptable patient safety perspective. Therefore, it is important to be able to keep effective and robust standard operation procures within a ward or within a hospital in order to make complex procedures more manageable and in line with patient safety standards. Best practices (such as electronic medication records/prescriptions system, access to errors and incident reports system, automated dispensing cabinets, bar-code assisted medication administration etc.) from more experienced and oriented towards patient safety healthcare settings, can be adopted or adapted to current practices in hospitals in Cyprus. Quality management in healthcare is a critical parameter in healthcare organizations (Agency for Healthcare Research and Quality, 2020; World Health Organization, 2019). Hospital wards should implement a quality system management in accordance with International Standardization Organization (ISO) relevant standards. A quality system management is a substantial tool for maintaining high quality standards in the health services provided and maintaining appropriate, understandable, effective and efficient processes and procedures with a focus on patient safety (Aggarwal et al., 2019; Allen, 2013; Herring et al., 2011; Runciman et al., 2009; Zhou et al., 2015). All these interventions assume significant changes in the current clinical practice and their introduction is expected to have a substantially positive impact on patient safety.

8.4. Recommendations for leadership and policy level

The last two years in Cyprus the transformation of the national health system brought many changes for patients and for providers as well. Electronic records are now used extensively, including electronic prescriptions and medication records. However, it remains yet to see how this transformation of the healthcare sector in Cyprus will take on the challenge of maintaining the system not only accessible but also safe for patients as well, after all, patients are actually funding the whole system, so at least the system is expected to be focused on patient safety as well. Patients should be treated according to specific safety standards which can guarantee the quality and safety of the treatment. This is a prerequisite for sustainable,

high-performance, and patient-centered healthcare system. Policy makers should acknowledge the need to develop interventions, test them and then introduce practice-level changes which would need to be tested again in terms of their effectiveness to impact real-life change.

Medication errors can harm patients and prolonged their stay in hospitals. According to the relevant European Commission survey (Special Eurobarometer 411, 2014), the perceived likelihood of being harmed by healthcare services among citizens in Cyprus is very high. In fact, approximately half of the responders (53%) stated that is totally likely for patients in Cyprus to be harmed by hospital care. Also, 25% of responders stated that the three most important criteria when they think of high-quality healthcare in Cyprus is "a healthcare that keeps you safe from harm. Moreover 27% reported that they have experienced an adverse event when receiving healthcare in Cyprus (European Commission Directorate-General for Health and Consumers (DG SANCO), 2014). These findings, among other findings from relevant research, should be an alarming issue for health sector policy makers.

There should be locally, within each hospital a patient safety unit, or at least a responsible officer, for the coordination of patient safety issues, and for managing safety systems and programs within the organization. Similarly, at a national level, there should be a coordination group or a committee for medication safety and patient safety matters that will not only oversee the measures taken for promoting patient safety within healthcare providers, but also guarantee equal opportunities for development in all hospitals and healthcare centers, for the sake of patients. Other countries around the world, including Europe and US, who have already captured the importance of providing their patients access to a safe and quality health care, and realize the costs of not having patient safety programs in place, have already devoted some resources for implementing patient safety initiatives and actions (Agency for Healthcare Research and Quality, 2020; Celikkayalar et al., 2016; World Health Organization, 2019). The same practice should be followed by policy makers in Cyprus as well.

Moreover, reporting medication errors is also crucial in the effort to minimize errors. The reporting of medication errors provides valuable information concerning the problems occurring during the medication process. By having a reporting system in place is feasible to receive information about medication adverse events from different hospital wards. Incidents reported by such systems should be analyzed, and feedback should be provided to stakeholders. An open-minded management of reports may motivate healthcare professionals towards medication safety and patient safety. Motivation is not limited to economic motives. It includes the recognition of workers' work and of their contribution towards achieving the organizations' goals, to leads to the need of establishing clear and easy to understand by the staff goals. Also, as a first step for a good motivation, it is important to hear what staff wants, believes, or expect from the management and capture its motivational needs. This requires an active and responding leadership. Active and responding leadership at a local and at national level is crucial for achieving patient safety goals (Kiwanuka et al., 2020; Squires et al., 2010; C. A. Wong et al., 2013). It is important for the leadership to be focus on safety culture and patient safety in particular. The implementation of a targeted and continuous motivational plan can influence a cultural shift towards the formation of values, attitudes and perceptions, that determine the commitment to the organization's safety values and goals.

8.5 Recommendations for education of healthcare professionals

As previously mentioned, different healthcare professionals are involved in the medication process. They all may fall into a medication error; however, they are capable of preventing errors as well. That is way they should be kept engaged, motivated and committed to adhering to basic safety principles and guidelines. To achieve an optimal level of this kind of commitment among healthcare professionals is not an easy task. The skills and knowledge of clinicians should be maintained sharp and updated, and for this purpose a continue professional development program, integrating medication training, educational seminars and other events, can contribute towards achieving this goal. Dose calculation skills, correct administration techniques or storage and preparation methods, drug-drug or drug-food interactions and other aspects of pharmacotherapy could be part of educating programs for healthcare professionals. Particularly for nurses, who spend much of their time in preparing

and administering medicines, their participation to this training events which are relevant to the last stage of medication process (i.e., administration) should be regular. Also, for nurses, double checking that the correct medicine is administered to the correct patient via the correct route, at the correct dosage and at the right time, is important for preventing medication administration errors. During basic education and undergraduate studies, healthcare professionals should get readiness for seeking and learning the most up-to-date evidence-based practices in medication administration. Medication administration techniques should be practiced in basic and advance level of nursing education programs and medication administration safety programs should be included regularly in continuous nursing education.

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Appendix I. Scoping Review Protocol

Prevalence, nature and associated factors of medication administration errors in adult hospital wards: A Scoping Review Protocol

Abstract

Background: Medication administration errors (MAEs) is a very common problem in hospital wards as it negatively impacts the quality of the provided care, increase healthcare costs and poses a threat for patients. Despite the different interventions implemented, still errors are detected during the medication process, particularly during the administration phase of the process. In order to develop targeted and effective measures to prevent errors and promote patient safety, first the magnitude of the problem must be estimated and the underlying conditions contributing to errors must be identified and addressed. In addition, the conditions associated with MAEs maybe varied among different healthcare settings, thus, interventions must be formulated appropriately so to specifically address the particularities of each setting.

Objectives: To map the available evidence regarding the MAEs prevalence, nature and associated factors in adult hospital wards. The scoping review will also help to identify the different methods and definitions used in previous research on MAEs. Thus, it will constitute a useful tool for informing and guiding future research concerning the investigation of the MAEs problem in hospitals.

Methods and analysis: The relevant studies will be identified and examined using the Joanna Briggs Institute methodological framework for scoping studies. A comprehensive search in 4 electronic databases will be performed. The reference list of included studies will be screened for additional studies. Two reviewers will independently review the extracted studies and after removing duplicates, exclude those that do not meet the eligibility criteria identified in this protocol. Data extraction will be done in parallel by the two review authors. Disagreements about study eligibility of the selected articles will be discussed between the two reviewers until consensus is reached or by arbitration of a third reviewer, if required. A data extraction form has been developed based on the Joanna Briggs Institute recommendation template. The extracted data will be presented in a tabular form in line with PRISMA-ScR reporting guidelines.

Ethics and dissemination: This study does not require ethical approval since all data will be collected from published literature. Findings will be submitted for publication to a scientific journal, and disseminated as part of future medication safety workshops or conferences.

1. Introduction

Medication administration errors (MAEs) are common during drug administration to inpatients (Härkänen et al., 2019; Keers et al., 2013b). MAEs can be defined as "a deviation from the prescriber's medication order as written on the patient's chart, manufacturers' preparation/administration instructions, or relevant institutional policies" (Keers et al., 2013b). Errors in the medication process can be viewed and classified as errors of omissions and errors of commission. Tasks executed or completed incorrectly are regarded as commission errors (Hayward et al., 2005). Error of omission can be defined as the failure to carry out all necessary steps in the performance of a task and is probably the most common human error (Kennedy & MacLean, 2004; J. Reason, 2002). Previous studies defined omission in drug therapy as the failure to administer an ordered dose or a prescribed drug (K N Barker et al., 2002; Haw et al., 2007; Marianne Lisby et al., 2005). However, additional types of omission do exist, like deviations from the basic infection prevention and safety regulations (Keers et al., 2013b; Kim & Bates, 2012; J. Reason, 2002). Deviations have been described as outliers, exceptions, or aberrations and represent actions that deviate from protocols intended to uphold patient safety during medication administration (Visweswaran et al., 2010). Additionally, classification of MAEs can be based on the stage of the medication process detected (i.e., dispensing or prescribing errors) or based on the type of the error (i.e., wrong time or wrong dose) (Härkänen et al., 2015).

Different factors contribute to the occurrence of MAEs (Härkänen et al., 2015; Keers et al., 2013a). These include factors associated with health care professionals (e.g. inadequate drug knowledge or experience, physical or mental fatigue), factors associated with patient characteristics (e.g. clinical condition, age, polypharmacy), factors associated with the work environment (e.g. staffing, distractions and interruptions, communication gaps), and factors associated with the medicines administered (e.g. form and type of medicines) (Bates et al., 1999; Härkänen et al., 2015; Hellström et al., 2012). Other organisational factors, like the patient safety climate and/or safety culture of the organisation, are also relevant with the prevalence of errors (Gleeson et al., 2020). Interventions implemented to limit MAEs include quality improvements (Zhou et al., 2015), health information

technologies (Bryony Dean Franklin et al., 2007; Helmons et al., 2012; Jheeta & Franklin, 2017; Warrick et al., 2011), and training of the personnel (Nguyen et al., 2014). However, research indicates that the problem still exist and more effort is needed to be further decreased (Härkänen et al., 2019; WHO, 2020).

A scoping review would be useful for obtaining an insight into the different aspects of the medication administration errors problem. While there are previous studies reporting the prevalence and nature of MAEs in hospitals (Keers et al., 2013b), the causes of MAEs in hospitals (Keers et al., 2013a; R.N. Keers et al., 2015), the impact or the effectiveness of specific interventions for reducing MAEs (Keers et al., 2014; Seston et al., 2019), none of them maps and reports these three aspects of the phenomenon (i.e., prevalence, nature and associated factors) simultaneously. Additionally, only few studies specifically discuss and focus on the methodological approaches used for exploring MAEs. This scoping review, by mapping the available information on the prevalence and causes of the problem, and by identifying the definitions and methods used in previous research for collecting the data, will help and guide future researchers draft and implement efficient methodological designs based on previous experiences and findings which this scoping review will present. Thus, the scoping review will be a useful guide for future research focusing on the investigation of MAEs in hospital settings.

Objectives

The objective of this scoping review is to map the available evidence regarding the MAEs prevalence, nature and associated factors in adult hospital wards. This scoping review will also help to identify the different methods and definitions used in previous research on MAEs. Thus, it will constitute a useful tool for informing and guiding future research concerning the investigation of the MAEs problem in hospitals.

Methods

The framework of the proposed scoping review will be drafted in accordance with the JBI methodology for scoping reviews (JBI, 2020). This comprises of six stages: (1) identifying the research question; (2) identifying relevant studies; (3) study selection; (4) charting the data; (5) collating, summarizing and reporting the results; and (6) stakeholder consultation.

Stage 1: Identifying the research question

This scoping review aims to outline the MAEs prevalence, nature and associated factors. A preliminary, exploratory search of the literature helped researches in drafting the research questions. No specific criteria or filters were used and different keywords, relevant with the research topic, were used for this first search. In line with the objectives of this scoping review, the following research questions have been formulated:

(1) Which are the functional definitions of medication administration errors adopted in the relevant studies?
(2) What are the methodologies used for investigating the medication administration errors problem in hospital wards? Which methods are used for collecting the respective data?
(3) What is the prevalence and types of errors made during the administration of medicines to inpatients in hospital wards? What are the medication errors associated factors?

Stage 2: Identifying relevant studies

The primary source of literature will derive from the structured search of the following electronic databases: PubMed, CINALH, Cochrane and Scopus. The search in these databases will be made by using keywords specifically attached to the medication administration errors problem. A scoping review is designed to cover a broad spectrum of literature, however, in order to guide the search and filter for relevant sources, appropriate keywords and criteria will be used for a more focus search. To establish these keywords and criteria, a pilot, preliminary search will be conducted in PubMed only. After establishing the appropriate keywords and eligibility criteria, additional searches in the databases will be conducted to confirm the suitability of the established criteria and search terms. After preliminary searches made for establishing appropriate criteria and key terms, the following key terms were composed: “Medication administration errors” and “medication administration safety”. There is a vast number of studies exploring medication errors, but the aim was to put an emphasis on medication administration errors specifically. By keeping the term “administration” in the search terms we will avoid the collection of studies exploring medication errors in general. These studies are not relevant with the aim of our study, as they explore dispensing or prescribing drug

errors instead of administration errors specifically. To identify all possible studies exploring medication administration errors in hospitals, the search was not restricted to MeSH terms. Preliminary searches using MeSH terms showed that there was no extra benefit for this review as additional studies, not relevant with the objectives of this review, were also gathered. The references from the electronic databases will be imported into a reference manager software (Mendeley).

Stage 3: Study selection

The study selection process will be conducted independently by two researchers. Any disagreements will be discussed, and if no consensus can be reached a third reviewer may be consulted, if required. The first stage of the selection process will be based on the title and abstract of the studies that were collected from literature search. Reviewing the titles and abstracts against the preset eligibility criteria (Table 1) it will be possible to conclude on the relevance of each paper and disregard or accept a paper for further reading and probably use in the study thereafter. The second stage of the selection of articles concerned the reviewing and assessing the full text of the article in order to determine whether it met the agreed inclusion criteria. Moreover, the references of studies that fulfilled the inclusion criteria will be used to find additional relevant studies that could probably missed in the first search. Figure 1 presents the work flow used for the selection of the studies. As mentioned in Stage 2 of the protocol, pilot literature search guided the establishment of the keywords and criteria used thereafter for screening and selection of studies.

Table 1 presents the inclusion and exclusion criteria set. In particular, published peer-reviewed research in English language, investigating the MAEs problem in hospital adult wards with any type of study design and methodological approach, such as qualitative and quantitative designs, were eligible for inclusion. Studies that based their findings solely on the collection of the views or the perspectives or perceptions of the staff involved in the medication process (i.e., interviews, focus group discussions or questionnaires) were also considered to be eligible because staff's perceptions of the MAEs problem may provide additional information about the research problem that other methodological approaches (e.g., direct observation) may not be able to collect. Also, nurses have a crucial role in the medication administration process and spent much of their working time in administering drugs to inpatients, hence their perceptions on MAEs can be useful. However, it is acknowledged that staff's perceptions, might not always be relevant with the real MAEs associated factors and different aspects of the problem. Research shows that there is a gap between a perceived situation and the reality (King et al., 2018; Visscher et al., 2017). Perceptions and beliefs are highly subjective, based on one's culture, education, experience, gender, or age, and are subject to constant

change and can be inaccurate (Glasser, 1998). Therefore, even though we deliberately included studies explored staff's perceptions of the MAEs issue, we mainly aimed in more methodologically robust designs, such as direct observational approaches, incident reports reviews or mixed methods studies.

We included studies undertaken in different hospital wards using different types of medication and different methods for collecting data. We also included systematic reviews and studies exploring definitions and methodological approaches for investigating medication errors, so to address all review questions described above. We also focused on nurses as they have the leading role in the administration phase of the medication process. No chronological limitation was set in order to allow the gathering of a higher number of eligible papers, regardless of their publication date, since the medication errors problem is not a new one, but still in focus. Studies in pediatric populations or studies conducted in other settings than hospitals (i.e., nursing homes) were excluded as they were not in line with the scoping review objectives. We excluded pediatrics also because during the preliminary exploratory search made before running the scoping review, indicated that the pediatric patients have specific particularities that complicated medication administration. For example, pediatric patients need specific pharmaceutical formulations or have acceptability issues when receive medication (e.g., swallowability, palatability, vein raptures during iv administration), probably a dedicated to pediatric population study may be warranted. Thus, we excluded these patient group. In addition, studies concerning medication errors during the prescription or dispensing phase of the medication process were not eligible for consideration as the focus of this review is the errors occurring during the medication administration phase. Other published material, such as grey literature, conference abstracts, commentaries, correspondences, opinions, editorials, and not peer reviewed articles or articles not published in English, were excluded not only because there was a vast amount of peered reviewed papers in English but also for obtaining studies that implemented a more solid methodological design and thus produced a more solid scientific evidence. Studies exclusively investigating or reporting the impact or the effectiveness of interventions for reducing or preventing errors were also excluded. Furthermore, studies investigating the economic impact of medication errors, or their implication on health outcomes were also excluded. Due to the many different aspects of the medication errors problem, to make the search more targeted, we applied a filter in the field options when searching the literature in order to restrict the extraction of papers that did not include any of the preset keywords (i.e., "Medication administration errors" and "medication administration safety") in their title or abstract.

Table 1. Inclusion and exclusion criteria

Inclusion criteria:

1. Adult patients (>18 years of age)
2. Nurses involved in the medication administration process
3. Hospital wards (for adults)
4. Only the administration stage of the medication process
5. Observational studies, Medication records review, Incident reports
6. Peer-reviewed articles
7. Key terms in title or abstract: “medication administration errors” or “medication administration safety”

Exclusion criteria:

1. Pediatric patients (<18 years of age)
2. Staff other than nurses involved in the administration process (e.g., physicians)
3. Settings other that hospitals (e.g., primary health centers or nursing homes)
4. Dispensing or prescribing medication errors
5. Opinions, reports, grey literature, or unpublished material
6. Interventional studies (when the focus is only on the intervention’s particularities)

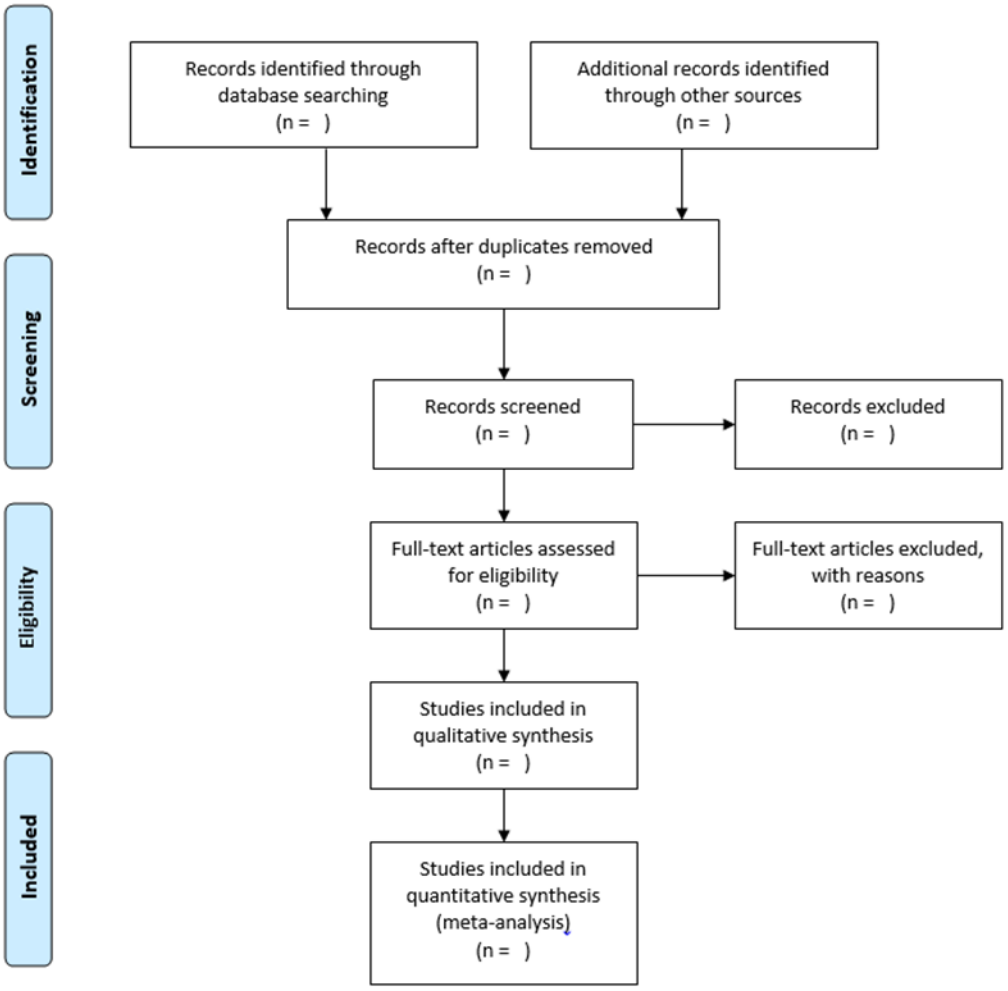

Figure 1. Flow diagram of study selection process, as depicted by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

Stage 4: Charting the data

Studies that met the inclusion criteria will be abstracted by using an extraction tool which will be drafted based on a recommendation template by the Joanna Briggs Institute (JBI, 2020) (Table 2). In particular, the "charting" of the data will include information regarding the Author(s), the year of publication, the country, the objectives of the study concerned, the methodology used and the results. The customized extraction tool will be tested, and if needed revised accordingly, during the process of extracting data from each study. Any disagreement between reviewers will be resolved through discussion and if issue is not resolved then a third reviewer can act as an arbiter. The data will be organized and presented in a tabular form.

Table 2: Data extraction form

Scoping Review Details	
Scoping Review title:	
Review objective/s:	
Review question/s:	
Inclusion/Exclusion Criteria	
Population	
Concept	
Context	
Types of evidence source	
Evidence source Details and Characteristics	
Citation details (author/s, date, title)	
Country	
Aims	
Methods (design, participants, setting etc)	
Results	
Details/Results extracted from source of evidence (in relation to the concept of the scoping review)	
Error prevalence	
Error nature	
Associated factors	
Methodology	

Stage 5: Collating, summarising and reporting the results (results same as data extracted)

The data extracted from the included papers will be presented in a tabular form. In accordance with the objectives of this review, an overview of the MAEs prevalence, nature and related factors as identified in each included study, will be presented. The tabulated results will be presented and discussed in relation with the objectives and aims of this scoping review. The findings will be reported

in line with the “Preferred Reporting Items for Systematic Reviews and Meta-Analysis: extension for Scoping Reviews (PRISMA-ScR)” checklist (Tricco et al., 2018).

Step 6: Stakeholder consultation

The original framework proposed by Arksey and O’Malley suggests an optional consultation practice with stakeholders in order to identify additional studies or to get feedback about the findings of the scoping review. A stakeholder consultation can also help validating and enriching the findings of the review, and even identify unmet research needs that may warrant further research. Stakeholders may help in bringing together researchers and healthcare professionals and work together in order to improve medication safety. For this scoping review, it is anticipated that the findings will be presented to stakeholders and will be collated with their views in an effort to disseminate the outcomes and to facilitated future relevant research.

Discussion

The proposed scoping review aims to outline the available scientific evidence regarding the MAEs prevalence, nature and associated factors. By mapping the available information, a clearer picture of the current status of this problematic phenomenon will be obtained. Moreover, by collecting information form studies which investigated MAEs prevalence or related factors, it will be possible to collect some information about the operational definitions and the methods used from previous studies. In conclusion, the findings from this scoping review will constitute a valuable tool for identifying the current information and will inform and guide future research on MAEs.

Strengths and Limitations of the scoping review

It is acknowledged that the scoping review will be subjected to the limitations of any review, relevant sources of information may be omitted and the review is dependent on information on the review question being available. Grey literature, articles in other than English language were left unexplored. Furthermore, no rating of the quality of evidence is provided, therefore implications for practice or policy cannot be graded (JBI, 2020). However, the present protocol concerns a scoping review of published studies, and is a practical approach to map the vast evidence concerning the prevalence, the nature and the associated factors of MAEs. Thus, it can help and guide the, preparation, the design

and conduct of future research for exploring the prevalence of MAEs and the MAEs associated factors.

Contributors

GS and EP conceived the idea for the review. GS wrote the review protocol. All authors provided methodological guidance and critically review and revised the protocol.

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No funding has been received for the conduct of this protocol or for the scoping review.

Conflicts of Interest

None declared.

Ethics approval

Since the scoping review methodology aims at outlining information from publicly available published papers, ethical approval is not deemed necessary. Future disseminations of the outcomes of this review will include the publication of the results in scientific journal or presentations at scientific conferences.

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Appendix II. Dara extraction form

Scoping Review Details
Scoping Review title: Medication administration errors prevalence, nature and associated factors: A Scoping Review
Review objective/s: to map available evidence regarding the medication administration errors and the related risk factors.
Review question/s: (1) Which are the functional definitions of medication administration errors adopted in the relevant studies? (2) What are the methodologies used for investigating the medication administration errors problem in hospital wards? Which methods are used for collecting the respective data? (3) What is the prevalence and types of errors made during the administration of medicines to inpatients in hospital wards? What are the medication errors associated factors?
Inclusion / Exclusion Criteria
Population: Adults, Nurses
Concept: Errors during the medication administration stage
Setting: Hospital adult wards, hospital setting
Types of evidence source: Observational studies, incidents reports/chart review, English peer-reviewed articles
Evidence source Details and Characteristics
Citation details: Author(s), date, title
Country
Aim
Methods
Results
Details/Results extracted from source of evidence
Error prevelance
Error nature / type
Associated factors
Methodology

Appendix III. Observation Form

Observation Form

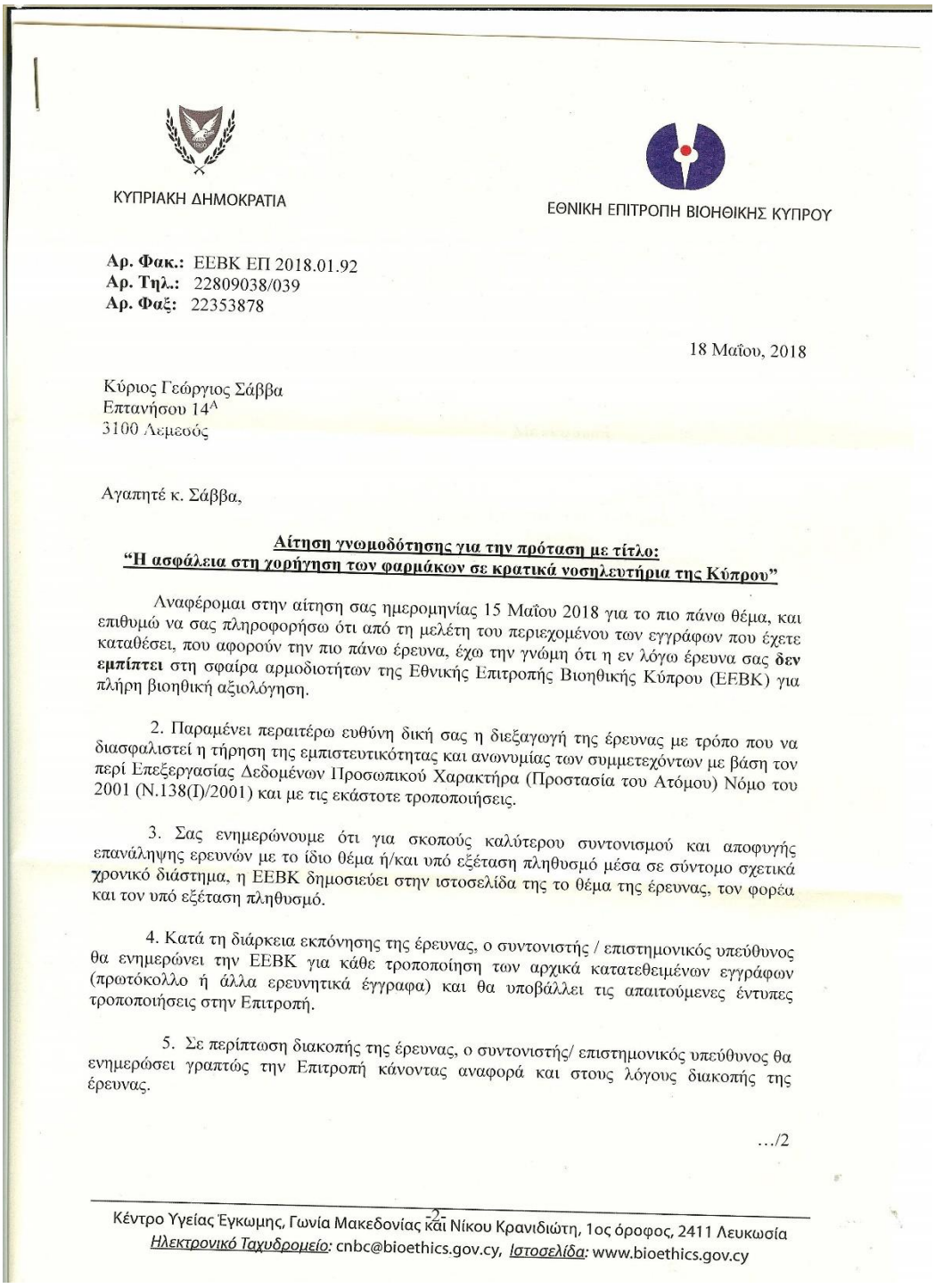
Part A

General Information		
Observation Number:	Unit:	Date:
Working environment informtion		
Day (Monday / Tuesday / Wednesday / Thursday / Friday / Saturday / Sunday)		
Shit (Morning / Evening / Night)		
Number of nurses in ward:		
Number of patients in ward:		
Work organization system in ward during the observation:		
Nurse Information		
Experience (years):		
Education:		
Patients under rensbonsibility:		
Participation in a drug administration safety program (YES/NO):		
Patient Information		
Age:		
Sex (M/F):		
Number of medicines taken:		
Diagnosis for admission:		
Drug Information		
Medicinal product (active substance(s)):		
Pharmaceutical form (tablets, cream, oral iquid, solution for injection, etc):		
The drug is kept in the outer package (YES/NO):		
The drug is immediately administered to the patient after preparation (YES/NO):		
For Injectable drugs		
Administration duration (infusion/injection):	Injection route: IV / IM / SC	Injection Angle:
Instuctions/order for administration duration:	Time between preparation and administration:	
Solution for reconstitution:	Solution for mixing/administrated with:	
Notes Area		

Part B

Adherence to basic infection regulation and safety regulation	**YES**	**NO**	**N/A**
Wash the hands before administering medication			
(The duration of washing (15 to 30 seconds)			
The syringe needles and IV set needles are placed only in areas that are disinfected			
Disinfect the injection site before administering drugs			
Right Medication	**YES**	**NO**	**N/A**
Read the name of the medication indicated on the label at least once for at least one second			
Read the name of the medication indicated on the medication chart at least once for at least 1 sec.			
Medication is prepared by the clinical nurse who will administer it			
The right drug is administered (in accordance with the prescription)			
Right Dose	**YES**	**NO**	**N/A**
Verify the dose on the prescription for at least once for at least one second			
Verify the strenght indicated on the label of the medication at least once for at least one second			
When using a syringe, read the markings at the eye level			
The right dose is administered			
Right Patient	**YES**	**NO**	**N/A**
Read the name of the patient on the drug chart			
Ask from patient to confirm his/her name			
The drug is administered to the right patient			
Right Route	**YES**	**NO**	**N/A**
Read the administration route from the label for at least 1 second			
The drug is administered from the right route			
Right Time	**YES**	**NO**	**N/A**
The drug is administered at the right time in accordance with the prescription (acceptable deviation 1 hr)			
The drug is prepared only just before administration			
The drug is administered before lunch/dinner			
The drug is administered after lunch/dinner			
Working environment	**YES**	**NO**	**N/A**
There are interruptions and/or distractions during drug administration			
There are additional people in the room during drug administration (relatives, visitors, staff)			
Adherence to drug administration record protocol	**YES**	**NO**	**N/A**
The nurse who administered the drug records the event			
The actual time of the administration is accurately recorded			
The event is recorded only after the administration is completed			
Notes Area			

Appendix IV. Ethical approval



ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ

ΕΘΝΙΚΗ ΕΠΙΤΡΟΠΗ ΒΙΟΗΘΙΚΗΣ ΚΥΠΡΟΥ

Αρ. Φακ.: ΕΕΒΚ ΕΠ 2018.01.92
Αρ. Τηλ.: 22809038/039
Αρ. Φαξ: 22353878

18 Μαΐου, 2018

Κύριος Γεώργιος Σάββα
Επτανήσου 14Α
3100 Λεμεσός

Αγαπητέ κ. Σάββα,

Αίτηση γνωμοδότησης για την πρόταση με τίτλο:
"Η ασφάλεια στη χορήγηση των φαρμάκων σε κρατικά νοσηλευτήρια της Κύπρου"

Αναφέρομαι στην αίτηση σας ημερομηνίας 15 Μαΐου 2018 για το πιο πάνω θέμα, και επιθυμώ να σας πληροφορήσω ότι από τη μελέτη του περιεχομένου των εγγράφων που έχετε καταθέσει, που αφορούν την πιο πάνω έρευνα, έχω την γνώμη ότι η εν λόγω έρευνα σας **δεν εμπίπτει** στη σφαίρα αρμοδιοτήτων της Εθνικής Επιτροπής Βιοηθικής Κύπρου (ΕΕΒΚ) για πλήρη βιοηθική αξιολόγηση.

2. Παραμένει περαιτέρω ευθύνη δική σας η διεξαγωγή της έρευνας με τρόπο που να διασφαλιστεί η τήρηση της εμπιστευτικότητας και ανωνυμίας των συμμετεχόντων με βάση τον περί Επεξεργασίας Δεδομένων Προσωπικού Χαρακτήρα (Προστασία του Ατόμου) Νόμο του 2001 (Ν.138(Ι)/2001) και με τις εκάστοτε τροποποιήσεις.

3. Σας ενημερώνουμε ότι για σκοπούς καλύτερου συντονισμού και αποφυγής επανάληψης ερευνών με το ίδιο θέμα ή/και υπό εξέταση πληθυσμό μέσα σε σύντομο σχετικά χρονικό διάστημα, η ΕΕΒΚ δημοσιεύει στην ιστοσελίδα της το θέμα της έρευνας, τον φορέα και τον υπό εξέταση πληθυσμό.

4. Κατά τη διάρκεια εκπόνησης της έρευνας, ο συντονιστής / επιστημονικός υπεύθυνος θα ενημερώνει την ΕΕΒΚ για κάθε τροποποίηση των αρχικά κατατεθειμένων εγγράφων (πρωτόκολλο ή άλλα ερευνητικά έγγραφα) και θα υποβάλλει τις απαιτούμενες έντυπες τροποποιήσεις στην Επιτροπή.

5. Σε περίπτωση διακοπής της έρευνας, ο συντονιστής/ επιστημονικός υπεύθυνος θα ενημερώσει γραπτώς την Επιτροπή κάνοντας αναφορά και στους λόγους διακοπής της έρευνας.

…/2

Κέντρο Υγείας Έγκωμης, Γωνία Μακεδονίας και Νίκου Κρανιδιώτη, 1ος όροφος, 2411 Λευκωσία
Ηλεκτρονικό Ταχυδρομείο: cnbc@bioethics.gov.cy, *Ιστοσελίδα:* www.bioethics.gov.cy

6. Ο συντονιστής/ επιστημονικός υπεύθυνος θα ενημερώσει την Επιτροπή σε περίπτωση αδυναμίας να συνεχίσει ως συντονιστής και θα υποβάλει τα στοιχεία επικοινωνίας του αντικαταστάτη του.

7. Με το πέρας της ερευνητικής πρότασης, ο συντονιστής / επιστημονικός υπεύθυνος θα ενημερώσει εγγράφως την Επιτροπή ότι το υπό αναφορά ερευνητικό πρωτόκολλο ολοκληρώθηκε.

8. Σας ευχόμαστε κάθε επιτυχία στη διεξαγωγή της έρευνάς σας.

Με εκτίμηση,

Κ Ν. Φελλ

Καθ. Κωνσταντίνος Ν. Φελλάς
Πρόεδρος
Εθνικής Επιτροπής Βιοηθικής Κύπρου

Appendix V. Description of the studies included in the Scoping Review.

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
A. Agalu et al., 2012, Ethiopia	Medication administration errors in an intensive care unit in Ethiopia.	To assess medication administration errors in the intensive care unit of Jimma University Specialized Hospital (JUSH), Southwest Ethiopia.	Prospective observation based, cross-sectional study in the ICU of JUSH from February 7 to March 24, 2011. Data were collected by directly observing drug administration by the nurses supplemented with review of medication charts.	Descriptive statistics was used to measure the magnitude and type of the problem under study.	Prevalence of medication administration errors in the ICU of JUSH was 621 (51.8%). Common administration errors were attributed to wrong timing (30.3%), omission due to unavailability (29.0%) and missed doses (18.3%) among others. Errors associated with antibiotics took the lion's share in medication administration errors (36.7%).
A. Blignaut et al., 2017, South Africa	Medication administration errors and related deviations from safe practice: an observational study	To determine the incidence of medication administration errors, and deviations from safe practice as well as factors associated with these errors	Cross-sectional, observational design (according to the authors). The direct observation method, incorporating a checklist based on basic medication guidelines was followed. Knowledge testing on dose calculations was performed. Medication administration to 315 patients was observed in medical and surgical units from eight public hospitals	Statistical significance derived from cross-tabulations and practical significance derived from Cramer's V and correlations of relationships between errors and associated factors	296 medication errors were identified, most were wrong-time errors and omissions. Interruptions and patient acuity were significantly associated with wrong-dose and wrong-route errors, respectively. Most medication administration-related deviations from safe practice were related to patient identification or asepsis. 16 of 50 dosage calculations were answered incorrectly.
A.D. Calabrese et al., 2001, US	Medication administration errors in adult patients in the ICU.	To quantify the incidence and specify the types of medication administration errors from a list of error-prone medications and to determine if patient harm resulted from these errors.	An observational evaluation in five intensive care units (ICUs) in the United States. 851 patients who were at least 18 years of age and admitted to surgical, medical or mixed ICUs during a 3-month period were included.	Descriptive statistics were used to evaluate the data collected and calculated the number of errors detected.	Of 5,744 observations in 851 patients, 187 (3.3%) medication administration errors were detected. the therapeutic classes most commonly associated with errors were vasoactive drugs 61 (32.6%) and sedative/analgesics 48 (25.7%). The most common type of error was wrong infusion rate with 71 (40.1%) errors. Twenty-one errors did not reach the patient and 159 reached the patient but did not result in harm, increased monitoring or intervention. Five errors required increased patient monitoring and two required interventions. None of the errors resulted in patient death.

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
Al Tehewy et al., 2016, Egypt	Medication administration errors in a university hospital	To measure the rates of medication administration errors in medical wards at Ain Shams University Hospital and to identify significant determinants of medication administration errors.	A descriptive direct-observational study of drug administration errors was carried out at medical wards of Ain Shams University hospital for a period of 3 months. A standardized observational checklist was used to observe the nurse during giving medications, and a medical record audit form was used to assess documentation.	The error rates per observation, nurse, and patient were calculated, and the association between error rates and characteristics of each category was tested using linear regression to identify potential risk factors.	The study included 237 patients and 28 nurses. The final number of drug administration observations was 2090 after excluding 310 omissions. A total of 5531 errors were observed with an average number of 2.67 errors per observation. More than 85% of the observations had at least one error, and the overall error rate was 37.68% (per hundred error opportunities). The highest error rate was detected in injections especially the intravenous route. The most frequent errors were wrong documentation and wrong technique, and the least was wrong patient. The significant independent determinants of medication administration errors were high number of shifts taken by nurse per month, night shifts, weekends, elderly patient, and illiteracy.
Ayorinde & Alabi, 2019, Nigeria	Perception and contributing factors to medication administration errors among nurses in Nigeria	The study assessed perception and contributing factors to medication administration errors among nurses	A quantitative descriptive design was adopted. Three hundred nurses participated in the study during. A self-administered questionnaire was used to obtain information on registered nurses characteristics, knowledge and perceived causes of medication admiration errors. Descriptive analysis and inferential statistics were done using Statistical Package for Social Sciences.	Data were analysed using descriptive and inferential statistics. Statistical methods employed included frequency count, percentage and chi square was used for testing associations	Nurses have good knowledge and perception of medication administration errors. Confusion of drugs with different names and increase patient to nurse staffing ratio constitute the major contributing factors for the occurrence of medication administration error among them. Furthermore, majority of the nurses are aware of guidelines and methods to follow to prevent the occurrence of medication administration errors

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
B. Dean and Barber, 2001, UK	Validity and reliability of observational methods for studying medication administration errors	The validity and reliability of observational methods for studying medication administration errors (MAEs) were studied.	Two pharmacists observed consecutive drug administration rounds by nurses on two wards in a U.K. hospital and recorded all MAEs identified. MAE records were audited to determine the percentage of omitted doses for which a corresponding reason was documented for the observation periods and for non-observation periods. Observer reliability was calculated by comparing the rates of errors identified by the two observers.	Separate MAE rates were calculated for each observer and compared by using a chi-square test. MAE rates were analysed according to the number of drug administration rounds observed during each data collection period, and a logistic regression analysis was used to identify any change in the MAE rate over time	There was no difference between the observation and non-observation periods in the percentage of omitted doses for which a reason was documented, and there was no change in the error rate with repeated observations. There was also no difference in error detection between the two observers and no change with increasing duration of observation. Observation of nurses during drug administration at a U.K. hospital did not significantly affect the MAE rate.
B. Schutijser et al., 2018, Netherland	Nurse compliance with a protocol for safe injectable medication administration: Comparison of two multicenter observational studies	The aim of this study was to determine whether nurse compliance to a protocol for safe injectable medication administration had changed over a 4-year period, what factors were associated over time with protocol compliance	Nurses from 16 Dutch hospitals were directly observed during intravenous medication administration. Protocol compliance was compared with results from the first evaluation. Implemented strategies were classified according to the five components of the Systems Engineering Initiative for Patient Safety (SEIPS) model.	Descriptive statistics were used to describe hospital type, ward type, administration time, administration type and medication type. Differences in the protocol compliance were tested with $\chi 2$ statistics.To assess the associations over time between potential explanatory variables and protocol compliance, sepa-rate multilevel logistic regression analyses were conducted	A total of 372 intravenous medication administrations were observed. No significant change was seen in complete protocol compliance (22% in 2016); compliance with the proceedings hand hygiene and check by a second nurse remained low. In contrast to 2012, the majority of the variance was caused by differences between wards rather than between hospitals. Most implemented improvement strategies targeted the organization component of the SEIPS model.

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
Barker et al., 2002, US	Medication Errors Observed in 36 Health Care Facilities	To identify the prevalence of medication errors (doses administered differently than ordered).	Medication errors were witnessed by observation, and verified by a pharmacist. Clinical significance was judged by a panel of physicians.	The overall medication error rates for each site were compared by using an analysis of variance. The Tukey test was used to determine the means between which significant differences existed in the comparison of facility types. The a-level was set at .05.	In the 36 institutions, 19% of the doses (605/3216) were in error. The most frequent errors by category were wrong time (43%), omission (30%), wrong dose (17%), and unauthorized drug (4%). Seven percent of the errors were judged potential adverse drug events.
Berdot et al., 2012, France	Evaluation of drug administration errors in a teaching hospital	We aimed to determine the incidence, type and clinical importance of drug administration errors and to identify risk factors.	Prospective study based on disguised observation technique in four wards in a teaching hospital in Paris, France (800 beds).	We investigated the relationship between the occurrence of errors and potential risk factors, using logistic regression models. The final model was obtained by removing all factors not significant at the 5% level. Results are expressed as odds ratios (OR), with the 95% confidence intervals (CI).	Among 1501 opportunities for error, 415 administrations (430 errors) with one or more errors were detected (27.6%). The highest risks of error in a drug administration were for dermatological drugs. In multivariate analysis, the occurrence of errors was associated with drug administration route, drug classification (ATC) and the number of patients under the nurse's care.
Bruce and Wong, 2001, UK	Parenteral drug administration errors by nursing staff on an acute medical admissions ward during day duty	To determine the error rate during preparation and administration of parenteral medications by nursing staff and to propose strategies to reduce errors.	This was an observational study. A direct, disguised observation technique was used on an admissions ward between 8.00 am and 4.30 pm from Monday to Friday for a 4-week period during December 1998.	Descriptive statistics and regression analysis were used to assess error rates	Drug administration was witnessed for a 4-week period providing 107 opportunities for error. 27 errors were observed which equated to an error rate of 25.2% including wrong time errors. Excluding wrong time errors, the most frequently occurring type of error, reduced the error rate to 10.3% (95% CI 3.8 to 14.9%).

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
C. Haw, Stubbs and Dickens, 2007, UK	An observational study of medication administration errors in old-age psychiatric inpatients	To investigate the frequency and nature of medication administration errors in old-age psychiatry. To assess the acceptability of the observational technique to nurse participants.	Cross-sectional study technique using (i) direct observation, (ii) medication chart review and (iii) incident reports. The study took place in two elderly long-stay wards in an independent UK psychiatric hospital. Nine nurses administering medication at routine medication rounds were recruited.	The x^2 test was used to compare differences between variables and whether or not an error had occurred.	369 errors in 1423 opportunities for errors (25.9%) were detected vs. chart review detected 148 errors and incident reports none. The commonest errors observed were unauthorized tablet crushing or capsule opening, omission without a valid reason and failure to record administration. Of the seven nurses who completed the post-observation questionnaire, all said they would be willing to be observed again.
Cottney and Innes, 2015, UK	Medication-administration errors in an urban mental health hospital: a direct observation study.	To identify the incidence, type, and potential clinical consequence of medication administration errors, and to investigate risk factors.	This was a prospective observational study. The direct observational technique was used to collect data from nurse medication rounds on each of the mental health hospital's 43 inpatient wards.	A Poisson regression was used to determine the best combination of predictors and the relative risk of these predictors, with regards to the occurrence of an administration error.	172 medication rounds were observed, 139 errors were detected in 4177 (3.3%) opportunities. The most common error was dose omission. Other common errors included incorrect dose, incorrect form, and incorrect time. Fifteen (11%) of the errors were of serious clinical severity. Factors that increased the risk of error included the nurse interrupting the medication round to attend to another activity, an increased number of 'when required' doses, a higher number of patients on the ward, and an increased number of doses of medication due.

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
de Castro, Pereira Oliveira and Soares Rodrigues, 2019, Brazil	Anti-infective medication administration errors by dose omission.	To measure anti-infective medication administration errors by dose omission in an adult intensive care unit.	A descriptive, cross-sectional, and prospective study, carried out in October and November 2018 in an adult intensive care unit of a teaching hospital in the Federal District, Brazil. The sample was one of convenience.	The numerator in the fraction of the medication administration error rate indicator was the number of medications prescribed with omission errors (prescribed but not administered), and the denominator is the total number of administered medications. The ratio is multiplied by 100 so as to be expressed as a percentage.	310 dose omissions were identified, which corresponded to a 4.34% error rate in the administration of medications in general. The sample used 711 anti-infective drugs, which were associated with 48 dose omissions, yielding a 6.75% error rate.
Donaldson et al., 2014, US	Improving medication administration safety: using naïve observation to assess practice and guide improvements in process and outcomes	To describe the CALNOC MA accuracy assessment, examine nurse adherence to six safe practices during MA, the prevalence of MA errors and associations between safe practices and MA accuracy.	Using a cross-sectional design (according to the authors), point in time, and convenience sample, direct observation data were collected by 43 hospitals participating in CALNOC's benchmarking registry. Data included 33,425 doses from 333 observation studies on 157 adult acute care units.	The prevalence of both safe practice deviations and MA errors was calculated individually and in aggregate for each safe practice and MA error type. Poisson regression models were used to analyze the data	Results reveal that the most common MA safe practice deviations were distraction/interruption (22.89%), not explaining medication to patients (13.90%), and not checking two forms of ID (12.47%). The most common MA errors were drug not available (0.76%) and wrong dose (0.45%). The overall percentage of safe practice deviations per encounter was 11.40%, whereas the overall percentage of MA errors was 0.32%.
Elizabeth A Flynn et al., 2002, US	Comparison of methods for detecting medication errors in 36 hospitals and skilled-nursing facilities	The validity and cost-effectiveness of three methods for detecting medication errors were examined.	36 hospitals in Colorado and Georgia were selected. Medication administration errors were detected by registered nurses, licensed practical nurses, and pharmacy technicians using three methods: incident report review, chart review, and direct observation.	The number of errors detected by each method was compared by method and site. The rate of agreement between observation and chart review was determined, and the rate of false negatives and false positives was calculated. Kappa values were calculated to assess the accuracy of the data collectors' information.	Observers detected 300 of 457 pharmacist-confirmed errors made on 2556 doses (11.7% error rate) compared with 17 errors detected by chart reviewers (0.7% error rate), and 1 error detected by incident report review (0.04% error rate). Of 457 errors, 35 (8%) were deemed potentially clinically significant; 71% of these were detected by direct observation.

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
Franklin Acheampong, Tetteh and Anto, 2016, Ghana	Medication Administration Errors in an Adult Emergency Department of a Tertiary Health Care Facility in Ghana	To determine the incidence, types, clinical significance, and potential causes of medication administration errors (MAEs).	This study used a cross-sectional nonparticipant observational technique at the emergency department of a tertiary health care facility in Ghana involving 338 patients and 49 nurses.	The x^2 test and regression models were used to compare differences between variables and whether or not an error had occurred.	Of the 1332 observations made, 362 had errors, representing 27.2%. The 2 most frequent error types were omission and wrong time errors. Although only one of the errors was potentially fatal, 26.7% were definitely clinically severe. The probable causes of MAEs were drug unavailability, staff factors, patient factors, prescription, and communication problems.
Härkänen M, Turunen H, 2020, Finland	Differences between Methods of Detecting Medication Errors: A Secondary Analysis of Medication Administration Errors Using Incident Reports, the Global Trigger Tool Method, and Observations	This study aimed to compare medication administration errors detected by 3 different methods in terms of severity, type, and contributing factors.	The study was performed in one university hospital. A convenience sample of medication administration errors (n = 451) reported on incident reports or via the Global Trigger Tool and direct observations of patient record reviews were collected for review	The severity of the medication administration errors, the types thereof, and factors contributing to such errors were reclassified using the National Coordinating Council for Medication Error Reporting and Prevention's taxonomy of medication errors.	The incident reports and the Global Trigger Tool method mainly revealed wrong doses, whereas most medication administration errors in the observational data were errors involving the use of the incorrect technique. In addition, each method produced different information regarding the factors contributing to medication administration errors.
Haw, Dickens and Stubbs, 2005, UK	A review of medication administration errors reported in a large psychiatric hospital in the United Kingdom	To analyse the reports of medication administration errors over a period of three and a half years in a UK psychiatric hospital.	A retrospective analysis of reports of medication administration errors over a period of three and a half years was carried out in a UK psychiatric hospital.	Chi square tests with Yates' correction and Fisher's exact tests were used to compare the frequency of various types of administration errors with the relative frequency of administration.	A total of 112 errors and "near misses" were studied. Psychotropic, intramuscular, and as-needed medications were overrepresented in the error reports. The two most common factors cited by nurses as contributing to error causation were a busy, noisy environment and personal factors, such as feeling tired or unsupported. Physicians were cited as having contributed to some errors.

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
Hemingway et al., 2015, UK	The perceptions of nurses towards barriers to the safe administration of medicines in mental health settings	To investigate perceptions of barriers to safe administration of medicines in mental health settings.	Cross-sectional survey was used, and 70 mental health nurses and 41 students were recruited from a mental health trust and a university in Yorkshire, UK. Respondents completed a questionnaire comprising closed- and open-response questions.	Data were analysed using Statistical Package for Social Sciences. A mainly descriptive analysis of data was undertaken of responses to each sub-question. Statistical significance was taken at below 5%.	Nurse-focused themes included environmental distractions, insufficient pharmacological knowledge, poorly written and incomplete medication documentation, inability to calculate medication dosage correctly, and work-related pressure. Service user-focused themes comprised poor adherence to medication regimens, and cultural and linguistic communication barriers with service users.
J.H. Basil et al., 2019, Malaysia	Intravenous medication errors in Selangor, Malaysia: prevalence, contributing factors and potential clinical outcomes	To determine the prevalence of intravenous medication errors and their potential clinical outcomes. To evaluate associated factors	Direct observation technique and medication record reviews in a secondary hospital in Malaysia. The preparation and administration of intravenous drugs were observed for a total of 213 doses using a checklist supplemented with a review of medication charts.	Descriptive statistics were used to measure the magnitude of the ME. Pearson's Chi-square test was performed to explore the factors associated with errors. The error rate was calculated using the total opportunities for error (TOE), which is the sum of all doses ordered plus all unordered doses administered	Medication administration errors were detected in 85% (181/213) of the doses observed. Overall, 307 errors were identified. More errors were detected during the drug administration stage (62.5%) than in the drug preparation stage (37.5%). Central nervous system drugs recorded the highest error rate at 94.1%. In a bivariate analysis, the occurrence of errors was significantly associated with nurses' experience and level of education.
Karen H Frith et al., 2012, US	Nurse staffing is an important strategy to prevent medication errors in community hospitals	To examine the relationship between nurse staffing and the occurrence of medication errors	Using a retrospective design, researchers analysed secondary data from administrative, databases of one hospital containing 801 weekly staffing intervals and 31,080 patient observations.	Based on the nature of the data and the purpose of the study, we used Hierarchical linear modelling as our statistical method for analysis. Because medication errors are measured dichotomously, we used the Logit model in the tests for medication errors.	The current study shows that increasing the number of RN (registered nurse) hours and decreasing or eliminating (licenced practice nurse) LPN hours can be a strategy to reduce medication errors.

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Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
Kim and Bates, 2012, Korea	Medication administration errors by nurses: Adherence to guidelines	To study the rate using more robust methods for the correct results.	This was an observational study. A checklist using basic medication guidelines, was used. A direct observation using the checklist to evaluate the medication activities of clinical nurses in hospital wards was performed. The study was carried out in a 1700-bed university teaching hospital in Korea.	The observation checklist included 13 items total; 4 for Right Medication, 3 for Right Dose, 3 for Right Patient, 1 for Right Route and 2 for Right Time. To identifying the overall medication error rate, we characterised each error by type	293 cases of medication activities were observed. Only 45·6% of nurses verified the amount of medication indicated on the. Only 6·5% read the name of the patient from the wristband. Administering the medication at the correct time guideline was observed 41·0% of the time. Hand washing before external and oral medications was followed only 4·5% of the time. Among 31 categories regarding drug administration, 17·2 (± 3·6) items per person were followed, whereas 5·7 (± 1·2) items per person were violated.
L. Thomas, Donohue-Porter and Stein Fishbein, 2017, US	Impact of Interruptions, Distractions, and Cognitive Load on Procedure Failures and Medication Administration Errors.	To examine the impact of interruptions, distractions, and cognitive load on procedure failures (PFs) and medication administration errors (MAEs).	The structure of this design is hierarchical. This was an observational study. A structured observation sheet was used for documenting the number and type of medications given, PFs, and the frequency and sources of observed interruptions.	The unit of analysis was an episode of medication administration to 1 patient by a RN working in a medical surgical unit. Linear mixed models were used because they account for the correlation among episodes within a nurse and among nurses within a hospital. Episode-level fixed-effect covariates included presence of a distraction or an interruption, number of interruptions, and number of medications administered.	There were significant relationships between a nurse's age and risk of MAE and between the number of medications being administered within an episode and MAE. Number of medications was also significantly associated with PF. The results suggested that the older the nurse, the greater the risk of an MAE, and as the number of medications being administered in an episode increases, so does the risk of MAE or PF.
M Härkänen et al., 2019, UK	Identifying risks areas related to medication administrations - Text mining analysis using free-text descriptions of incident reports	To extract medication names most commonly reported in medication administration incident reports to identify terms most frequently associated with risk for these medications	Free text descriptions of medication administration incidents (n = 72,390) reported in 2016 to the National Reporting and Learning System for England and Wales were analysed using SAS® Text miner.	Text data (Excel file) was first converted into SAS format for importing into Text Miner where the algorithms would be applied. The SAS® and its Text Miner tool, and descriptive modelling with a 'bag-of-words method' were used to count words in the text and to	The following risk areas related to medications were identified: 1.Allergic reactions to antibacterial drugs, 2.Intravenous administration of antibacterial drugs, 3.Fentanyl patches, 4.Checking and documenting of analgesic doses, 5.Checking doses of anticoagulants,

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
				understand how these words related to each other.	6.Insulin doses and blood glucose, 7.Administration of intravenous infusions.
M. Härkänen, Vehviläinen-Julkunen, Murrells, et al., 2020) UK	The Contribution of Staffing to Medication Administration Errors: A Text Mining Analysis of Incident Report Data	To describe trigger terms that can be used to identify reports of inadequate staffing contributing to medication administration errors, and to examine the association between the most commonly reported inadequate staffing trigger terms and the incidence of omission errors and "no harm" terms.	This was a retrospective study using descriptive statistical analysis, text mining, and manual analysis of free text descriptions of medication administration-related incident reports (N = 72,390) reported to the National Reporting and Learning System for England and Wales in 2016.	Analysis included identifying terms indicating inadequate staffing (manual analysis), followed by text parsing, filtering, and concept linking (SAS Text Miner tool).	The most effective trigger terms for identifying inadequate staffing were "short staffing" (n = 81), "workload" (n = 80), and "extremely busy" (n = 51). There was significant variation in omission errors across inadequate staffing trigger terms, with those related to "workload" most likely to accompany a report of an omission, followed by terms that mention "staffing" and being "busy." Prevalence of "no harm" did not vary statistically between the trigger terms, but the triggers "workload," "staffing level," "busy night," and "busy unit" identified incidents with lower levels of "no harm" than for incidents overall.

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
Marja Härkänen, Ahonen, et al., 2015, Finland	The factors associated with medication errors in adult medical and surgical inpatients: A direct observation approach with medication record reviews	To describe the frequency, types, and severity of medication errors in medical and surgical inpatients as well as to study the relationship between medication errors and associating factors.	A cross-sectional study using direct observations and medication record reviews was conducted to assess how 32 registered nurses administered 1058 medications to 122 inpatients in four medical and surgical wards at a university hospital in Finland between April and May 2012. Observations were recorded using a structured observation form and patients' medication record reviews (n = 122).	Descriptive statistics and logistic regression were used for calculating frequency, types, and severity of medication errors in medical and surgical inpatients the associations	At least one error was found in 22.2% (235/1058) of administered medications, 63.4% of which were medication administration errors and 18.3% of which were documentation errors. Of the medication administration errors, 59.1% involved an incorrect administration technique. 3.4% of errors caused harm to patients. Factors that increased the risk of medication errors included every other weekday, except Sunday; morning shifts; increased rushes; nurses asking for help; and increased number of medications that patients used. Factors that decreased the risk of errors included administering medications through an oral route, double-checking the drugs, and additional people in the medication room at the same time.
McBride-Henry & Foureur, 2007, New Zealand	A secondary care nursing perspective on medication administration safety.	To explore how nurses in a secondary care environment understand medication administration safety and the factors that contribute to, or undermine, safe practice during this process.	This was a qualitative study. Data were collected in using three focus groups of nurses that formed part of a larger study examining organizational safety and medication administration from a nursing perspective.	A narrative approach was employed to analyse the transcripts	Participants had good understandings of organizational culture in relation to medication safety and recognized the importance of effective multi-disciplinary teams in maintaining a safe environment for patients. Despite this, they acknowledged that not all systems work well, and offered a variety of ways to improve current medication practices.
P Trbovich et al., 2010, Canada	Interruptions during the delivery of high-risk medications	To assess the nature and frequency of interruptions during medication administration and the interruptions' effects on task efficiency	A direct observation study was conducted to document the nature, frequency, and timing of interruptions during specific stages of medication administration in a chemotherapy day-care unit.	Descriptive statistics were used to assess the nature, frequency, and timing of interruptions during specific stages of medication administration in a chemotherapy day-care unit.	Nurses were interrupted, on average, 22% of their time and were frequently interrupted while performing safety-critical tasks. Task completion times were greater for interrupted tasks than for uninterrupted tasks.

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
P Y Han, Coombes and Green, 2005, Australia	Factors predictive of intravenous fluid administration errors in Australian surgical care wards	To ascertain the prevalence of medication administration errors for continuous IV infusions and identify the variables that caused them.	A prospective study was conducted on three surgical wards at a teaching hospital in Australia. Medication administration errors and contributing variables were documented using a direct observational approach.	Descriptive statistical tests were performed for calculating errors. Observations were divided into those where an error occurred and those where an error did not occur. Data were compared using either a x^2 test, or Mann-Whitney U test depending on the distribution and nature of the data. The logistic regression analysis was chosen to describe the relationship between the outcome (error or no error) and the variables collected during the study.	Six hundred and eighty-seven observations were made, with 124 (18.0%) having at least one medication administration error. The most common error observed was wrong administration rate. Errors were more likely to occur if an IV infusion control device was not used and as the duration of the infusion increased.
Popescu, Currey and Botti, 2011, Australia	Multifactorial Influences on and Deviations from Medication Administration Safety and Quality in the Acute Medical/Surgical Context	To explore the multifactorial influences on medication quality and safety in the context of a single checking policy for medication administration	An exploratory/descriptive study using non-participant observation and follow-up interview was used to identify factors influencing medication quality and safety in medication administration episodes (n=30) in acute care setting.	Data were analysed using content analysis and thematic analysis. Individual semi-structured interviews were conducted with participants in a private room on the ward following observed medication episodes.	Nurses developed therapeutic relationships with patients in terms of assessing patients before administering medications and educating patients about drugs during medication administration. Nurses experienced more frequent distractions when medications were stored and prepared in a communal drug room according to ward design. Nurses deviated from best-practice guidelines during medication administration.
R.W. Hicks and Becker, 2006, US	An overview of intravenous-related medication administration errors as reported to MEDMARX®, a national medication error-reporting program	To overview the intravenous-related medication administration errors as reported to MEDMARX within a five-year period	A mixed-methodology study using a 5-year review of 73,769 IV-related medication errors from a national medication error reporting program indicates that between 3% and 5% of these errors were harmful.	Data were analyzed using content analysis	The leading type of error was omission, and the leading cause of error involved clinician performance deficit. Using content analysis, three themes-product shortage, calculation errors, and tubing interconnectivity-emerge and appear to predispose patients to harm.

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
Rodriguez-Gonzalez et al., 2012, Spain	Prevalence of medication administration errors in two medical units with automated prescription and dispensing	To identify the frequency of medication administration errors and their potential risk factors in units using a computerized prescription order entry program and profiled automated dispensing cabinets.	Prospective observational study conducted within two clinical units of the Gastroenterology Department in a 1537-bed tertiary teaching hospital in Madrid (Spain). Medication errors were measured using the disguised observation technique. Types of medication errors and their potential severity were described. The correlation between potential risk factors and medication errors was studied to identify potential causes.	The medication error rate was calculated by dividing the number of errors by the total opportunities for error (OEs). OEs were defined as the sum of observed administrations and omitted medications. Univariate and multivariate logistic regression analyses were performed to study the association between potential risk factors and the occurrence of errors. Statistical significance was set at $p<0.05$.	In total, 2314 medication administrations to 73 patients were observed: 509 errors were recorded (22.0%) in preparation and 441 (86.6%) in administration. The most frequent errors were use of wrong administration techniques, wrong reconstitution/dilution, omission, and wrong infusion speed. Potential clinical severity could not be assessed in 1.6% of cases. The potential risk factors morning shift, evening shift, Anatomical Therapeutic Chemical medication class antacids, prokinetics, antibiotics and immunosuppressants, oral administration, and intravenous administration were associated with a higher risk of administration errors. No association was found with variables related to understaffing or nurse's experience.
Sadat-Ali et al., 2010, Saudi Arabia	Medication administration errors in Eastern Saudi Arabia	To assess the prevalence and characteristics of medication errors (ME) in patients admitted to King Fahd University Hospital, Alkhobar, Kingdom of Saudi Arabia.	This is a retrospective study of all patients admitted to the orthopaedic department of the King Fahd Hospital of the University, AlKhobar.	The incident reports were analyzed for age, gender, nationality, nursing unit, and time where ME was reported. The data were analyzed and the statistical significance differences between groups were determined by Student's t-test, and p-values of <0.05 using confidence interval of 95% were considered significant.	The most common error was missed medication, which was seen in 15(39.5%) patients. Over 15 (39.5%) of errors occurred in 2 units (paediatric medicine, and obstetrics and gynaecology). Nineteen (50%) of the errors occurred during the 3-11 pm shift.

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
Senafikish Amsalu Feleke, Mulatu and Yesmaw, 2015, Ethiopia	Medication administration error: Magnitude and associated factors among nurses in Ethiopia	The aim of this study was to assess the magnitude and associated factors of medication administration errors	Prospective, observation-based, cross-sectional study was conducted from March 24–April 7, 2014 at the Felege Hiwot Referral Hospital inpatient department. A total of 82 nurses were interviewed using a pre-tested structured questionnaire, and observed while administering 360 medications by using a checklist supplemented with a review of medication charts.	Multiple logistic regression was used to identify variables independently associated with MAE. The strength of association was interpreted using the adjusted odds ratio with 95 % CI.	The incidence of medication administration error was 199 (56.4%). The majority (87.5%) of the medications have documentation error, followed by technique error 263 (73.1%) and time error 193 (53.6%). Variables which were significantly associated with medication administration error include nurse ages, work experience of less than or equal to 10years, nurse to patient ratio of 7-10 and greater than 10, interruption of the respondent at the time of medication administration, night shift and age of the patient
Thamer Ali Al Khawaldeh and Wazaify, 2018, Jordan	Intravenous cancer chemotherapy administration errors: An observational study at referral hospital in Jordan	To describe types, frequencies and stages of errors during administration of commonly used intravenous cancer chemotherapy medications inclusive of "aseptic technique."	Disguised direct observational study. A checklist consisting of appropriate process of administration was developed and used. The study was conducted at the hematology and oncology wards at King Hussein Medical Centre/Jordanian Royal Medical Services.	MAE rates were analysed based the number of drug administration observed during collection period. Descriptive statistics and regression analysis was used assess MAE	Administration processes of 654 cases, consisting of 15,042 error opportunities, were observed of which 4112 (27.3%) errors were detected. A total of 19.9% (2217/11,118) and 48.3% (1895/3924) of the errors were in the administration process and "aseptic techniques," respectively. Nurses who had finished a cancer chemotherapy medication preparation and administration training course committed significantly ($p > 0.05$) more medication administration errors compared to those who had not completed such course.

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
Tissot et al., 1999, France	Medication errors at the administration stage in an intensive care unit	To assess the type, frequency and potential clinical significance of medication-administration errors.	Prospective study using the observation technique. Pharmacist-performed observation of preparation and administration of medication by nurses, comparison with the original medical order and comparison with the data available in the literature.	For each category, the rate of errors was calculated as the ratio between the number of errors and the number of nurses' specific, observed interventions. Each prescribed dose could be associated with more than one error, but each error was counted once, even if there were multiple consequences. This denominator differs from total opportunities for error as defined by Allan and Barker	132 (6.6% of 2009 observed events) errors were detected. Their distribution is as follows: 41 dose errors, 29 wrong rate, 24 wrong preparation technique, 19 physicochemical incompatibility, 10 wrong administration technique and 9 wrong time errors. No fatal errors were observed, but 26 of 132 errors were potentially life-threatening and 55 potentially significant.
Tissot et al., 2003, France	Observational study of potential risk factors of medication administration errors	To assess the rate and the potential clinical significance of MAEs and to determine the associated risk factors.	In a Geriatric Unit and Cardiovascular-Thoracic Surgery Unit of Besancon University Hospital (France), MAEs were identified using the undisguised observation technique. During a period of 20 days, opportunities for error concerning 56 patients	MAE rate was expressed as the percentage of the total opportunities for error (TOE), which was the sum of all doses ordered plus all the unordered doses given. Univariate and multivariate logistic regression analyses were performed separately foreach unit (GU and CTSU). Data were not pooled while variables analysed as a risk factor were specific to the organization of each unit. Results are presented as odds-ratio (OR) and 95%confidence intervals (95% CI). A p-value <0.05 was considered significant	78 MAEs were observed. The medication administration error rate was 14.9%. Dose errors were the most frequent (41%) errors, followed by wrong time (26%) and wrong rate errors (19%). 8 (10%) were estimated as potentially life-threatening, 20 (26%) potentially significant and 50 (64%) potentially minor. Nurse workload and incomplete or illegible prescriptions were two independent risk factors of MAEs.

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
Wakefield et al., 1998, US	Nurses' perceptions of why medication administration errors occur.	To identify nurses' perceptions of why medication administration errors, occur.	1384 nurses from 24 acute care hospitals in Iowa were invited to participate in the survey. A questionnaire developed for this study containing 18 items was used where responders had to state their agreement with these 18 statements	The unit of analysis is the individual nurse. Descriptive statistics are used to analyse responses to individual items and describe respondent's characteristics. Cronbach's coefficient alpha for testing reliability was used.	Five different group of factors have been identified as the main causes for errors according to nurses: Physicians related factor (e.g., prescriptions not legible, not clear), System related factors (e.g., interruptions) Pharmacy related factors (e.g., wrong doses are delivered), Individuals related factors (e.g., non adherence to guidelines), knowledge related factors (e.g., limited pharmacology knowledge)
Westbrook et al., 2010, Australia	Association of interruptions with an increased risk and severity of medication administration errors	To test the hypothesis that interruptions during medication administration increase errors.	An observational study of nurses preparing and administering medications in 6 wards at 2 major teaching hospitals in Sydney, Australia.	The analyses were per-formed with total interruptions per administration as the primary independent variable and total procedural failures and total clinical errors, respectively, as dependent variables. Logistic regression was used to model binary outcomes for major errors (i.e., the influence of interruptions on the risk of a major error).	Each interruption was associated with a 12.1% increase in procedural failures and a 12.7% increase in clinical errors. The association between interruptions and clinical errors was independent of hospital and nurse characteristics. Interruptions occurred in 53.1% of administrations. Of total drug administrations, 74.4% (n = 3177) had at least 1 procedural failure. Administrations with no interruptions (n = 2005) had a procedural failure rate of 69.6%, which increased to 84.6% with 3 interruptions. Nurse experience provided no protection against making a clinical error and was associated with higher procedural failure rates.

Table 3: Description of the studies included in the analysis

Author(s), Year, Country	Title	Aim	Methods (Design, Setting, Participants)	Data analysis	Results
Wondmieneh et al., 2020, Ethiopia	Medication administration errors and contributing factors among nurses: a cross sectional study in tertiary hospitals, Addis Ababa, Ethiopia	To assess the magnitude and contributing factors of medication administration error among nurses in tertiary care hospitals, Addis Ababa, Ethiopia,	A cross-sectional study in Addis Ababa, Ethiopia. The study involved 298 randomly selected nurses. We used a self-administered survey questionnaire and checklist to collect data via self-reporting and direct observation of nurses while administering medications.	All variables with $P \leq 0.25$ in the bivariable analysis model were included in the final model of multivariable analysis in order to control all possible confounders. Adjusted odds ratio with 95% CI was estimated to identify the factors associated with MAEs using multivariable logistic regression analysis.	2098 nurses (98.3%) completed the survey questionnaire. Of these, 203 (68.1%) reported committing medication administration errors in the previous 12 months. Factors such as the lack of adequate training, unavailability of a guideline for medication administration, inadequate work experience, interruption during medication administration and night duty shift were significant predictors of medication administration errors
You et al., 2015, South Korea	Perceptions regarding medication administration errors among hospital staff nurses of South Korea.	To identify reasons for medication administration errors (MAEs) and why they are unreported, and estimate the percentage of MAEs actually reported among hospital nurses.	Cross-sectional survey design. Conducted in three university hospitals in three South Korean provinces. A total of 312 hospital staff nurses were included in this study. main outcome will be the revision of the Medication administration errors problem.	Data were analysed by using descriptive statistics (frequency, percentages, means and standard deviation)	MAEs were experienced by 217 nurses (69.6%) during their clinical career, whereas 149 nurses (47.8%) perceived that MAEs only occur less than 20% rate. MAEs occurred mostly during intravenous (IV) administrations. Nurses perceived that the most common reasons for MAEs were inadequate number of nurses in each working shift and administering drugs with similar names or labels. Most frequent errors included administering medications to the incorrect patients, incorrect medication doses and drug choices, incorrect infusion rates

Appendix VI. Research Dissemination

Publications / Conferences

1. Omissions and deviations from safe drug administration guidelines in two medical wards and risk factors: Findings from an observational study.

Accepted for publication by the Journal of Patient Safety (Editor-in-Chief: David Westfall Bates, MD, MSc, ISSN: 1549-8417, Online ISSN: 1549-8425, Frequency: 4 issues / year, Ranking: Health Policy & Services: 12/87; Health Care Sciences & Services: 24/102, Impact Factor: 3.031)

Nov 23, 2020

RE: JPS-15-1720R1, entitled "Omissions and deviations from safe drug administration guidelines in two medical wards and risk factors: Findings from an observational study."

Dear Mr Savva,

I am pleased to inform you that your work has now been accepted for publication in Journal of Patient Safety. All manuscript materials will be forwarded to the production staff for placement online ahead of print. Please note that we have a substantial backlog, so it will take some time for your article to appear in print. To accelerate publication in an issue, some articles may be selected for online only publication. Online articles are still listed in the print table of contents for the issue and all papers are indexed the same whether they are in print or online. Should you have any questions about your paper post-acceptance, please do not hesitate to contact the editorial office.

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Title:
Omissions and deviations from safe drug administration guidelines in two medical wards and risk factors: Findings from an observational study.

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Authors have no conflicts of interest to declare.

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Abstract

Objectives: To record the type and frequency of errors, with an emphasis on omissions, during administration of medicines to inpatients and to investigate associated factors.

Methods: This was a descriptive observational study. The medication process in two medical wards was observed by two observers using a structured observation form. Chi Square, Kruskal-Wallis and regression analysis were used to explore associations between factors and errors.

Results: From the 665 administrations observed a total of 2371 errors were detected from which 81.2% were omissions and 18.8% were errors of commission. Omissions in the infection prevention guidelines (46.6%) and in the five rights of medication safety principles (35.8%) were a predominant finding. In particular, omitting to hand wash before administering a drug (98.4%), omitting to disinfect the site of injection (37.7%), and omitting to confirm the patient's name (74.4%) were the three most frequently observed omissions. Documentation errors (13.1%) and administration method errors (4.5%) were also detected. Regression analysis has shown that the therapeutic class of the drug administered and the number of medicines taken per patient, were the two factors with a statistical significance that increased the risk of a higher number of errors being detected.

Conclusions: Errors during drug administration are still common in clinical practice, with omissions being the most common type of error. In particular, omissions in the basic infection and safety regulations seem to be a very common problem. The risk of a higher number of errors being made is increased when a cardiovascular drug is administered and when the number of medicines administered per patient is increased.

1. Introduction

Medication administration errors (MAEs) are common during drug administration to inpatients, with omissions being one of the most common type of errors [(Härkänen et al., 2019; Härkänen, Turunen, et al., 2020; Keers et al., 2013b)]. Any dose given plus any dose ordered but omitted represents an opportunity for error (OE) [(Allan & Barker, 1990; Kim & Bates, 2012)]. MAEs can be defined as "a deviation from the prescriber's medication order as written on the patient's chart, manufacturers' preparation/administration instructions, or relevant institutional policies" [9]. Error of omission can be defined as the failure to carry out all necessary steps in the performance of a task and is probably the most common human error [(Kennedy & MacLean, 2004; J. Reason, 2002)]. Previous studies defined omission in drug therapy as the failure to administer an ordered dose or a prescribed drug [(K N Barker et al., 2002; Haw et al., 2007)]. However, additional types of omission do exist, like deviations from the basic infection prevention and safety regulations [(Keers et al., 2013a; Kim & Bates, 2012; J. Reason, 2002)]. Deviations have been described as outliers, exceptions, or aberrations and represent actions that deviate from protocols intended to uphold patient safety during medication administration [(Visweswaran et al., 2010)]. Omissions in drug administration are considered preventable events that do reach the patient and have the capacity to cause or lead to inappropriate drug use or even patient harm [5,(*Categorizing Medication Errors Algorithm in Color | NCC MERP*, n.d.; National Coordinating Council for Medication Error Reporting and Prevention, 2020)]. Therefore, exploring the nature and causes of omissions in drug administration is important for improving patient safety.

Different factors contribute to the occurrence of MAEs [(Härkänen et al., 2015; Keers et al., 2013a)]. These include factors associated with health care professionals (e.g. knowledge, experience, physical or mental fatigue), factors associated with patient characteristics (e.g. condition, age), factors associated with the work environment (e.g. staffing, distractions and interruptions), and factors associated with the medicines administered (e.g. pharmaceutical form)[(Bates et al., 1999; Härkänen et al., 2015; Hellström et al., 2012)]. Other organisational factors, like the patient safety climate in the unit, are also relevant with the prevalence of errors [(Gleeson et al., 2020)]. Interventions implemented to limit MAEs include quality improvements [(Zhou et al., 2015)], health information technologies [(Bryony Dean Franklin et al., 2007; Helmons et al., 2012; Jheeta & Franklin, 2017; Warrick et al., 2011)], and training of the personnel [(Nguyen et al., 2014)]. However, research indicates that the problem is still present and more effort is needed to be further decreased [(Härkänen et al., 2019; Keers et al., 2013a)].

This study aimed to record the type and frequency of errors, with an emphasis on omissions, during administration of medicines to inpatients in two medical wards of a tertiary hospital in Cyprus. Secondly, to explore factors associated with errors.

2. Methods

2.1 Study Design

This was a descriptive observational study where the direct observation method had been employed in order to address the above-mentioned research objectives. Medication errors and associated factors were identified via direct observation of the medication administration process with parallel review of patients' medication records. There are several techniques for detecting medication errors, however, direct observation is considered to be one of the most efficient and accurate[(Kenneth N Barker et al., 2002; Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Härkänen, Turunen, et al., 2020)]. There is also evidence suggesting that MAE rates were not affected when a non-judgmental, non-interfering observation method is employed[(Kenneth N Barker et al., 2002; Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Härkänen, Turunen, et al., 2020)]. This was an undisguised study and nurses were informed beforehand. Two observers recorded the medication process and a discreet and non-interfering observation approach was followed[(Kenneth N Barker et al., 2002; Härkänen et al., 2015)]. It was agreed that observers will not interfere with the medication process unless a potentially harmful error was about to happen. Observers reviewed medication records and prescriptions and recorded the medication process using a structured observational form.

2.2 Setting and Participants

The study took place in two adult medical wards of a tertiary state hospital in Cyprus offering healthcare services to more than 200,000 habitants. Each medical ward had 30 beds. Two observers recorded the medication administration process with a simultaneous review of medication charts. 25 nurses worked in each ward and a convenience sample of 13 nurses per ward (48%) agreed to participate in the study. All nurses involved in the medication process were eligible to participate.

2.3 Study Size

The estimation of the study size (i.e. number of administrations) was based on the assumption that an intervention would be made. It was calculated that a sample of 637 administrations before and 637 after an intervention, would be needed to detect a reduction in MAEs from 7% to 3.5%, based on a two-sided test with an alpha of 0.05 and a power of 80% [(Campbell et al., 1995; B. Dean et al., 2002; Bryony Dean & Barber, 2000; Bryony Dean Franklin et al., 2007)]. A total of 665 administrations were observed.

2.4 Definitions: Errors and Associated Factors

Any deviation from safe drug administration was recorded as an error. Each dose administered or omitted represented an opportunity for error (OE) [(Allan & Barker, 1990)], and each OE could result in more than one type of error. Actions or procedures omitted, missed or left unfinished were recorded as omissions while actions executed wrongly, inaccurately or inappropriately were recorded as errors of commission. Medication errors were grouped in eight different categories based on their characteristics (Table 1). These were the "adherence to the five rights of medication safety" [(Kim & Bates, 2012; Martyn et al., 2019)], "adherence to basic infection and safety regulation" [(Kim & Bates, 2012; Rao et al., 2013)], "adherence to drug administration record protocol" (i.e. documentation errors) [(Hartel et al., 2011; Kim & Bates, 2012)] and "adherence to administration methods and guidelines" [(Härkänen et al., 2015; Kim & Bates, 2012)]. Factors assessed for associations with errors were staffing (number of patients assigned per nurse for medication administration), distractions and/or interruptions (by staff, patients or visitors), shifts (morning, evening, or night shift), days (weekdays or weekends), pharmaceutical form (oral, injectable or other forms), medication therapeutic class (e.g. cardiovascular, antibiotics, anticoagulants, nervous system drugs, or other class), patient age, number of medicines taken per patient and nurse experience.

2.5 Observation Form and Data collection

A structured observation form was used for data collection. The form was developed based on forms used in previous observational studies[(Bertsche et al., 2008; Härkänen et al., 2015; Kim & Bates, 2012)] but adapted to the needs of this study. The form reflected all possible errors and omissions that could occur during medication administration (Table 1). A multidisciplinary team of experts reviewed the components of the form and confirmed its validity. Data collection took place from August to September 2018. The observation was carried out by two observers, one in each ward. Observers were registered nurses and both were experienced in the medication process in hospital wards. However, they did not have any relationship with the wards where the study was conducted. Observers were informed about the study and had theoretical and practical training in the direct observation method before the study was initiated. They were involved in helping to draft the observation form and were able to test the method and the form during the pretest phase (pilot study). The study was undisguised. The nurses and ward managers were informed about the study beforehand. The Hawthorne effect was reduced by prolonging the presence of observers in the wards when implementing the pilot phase, therefore the staff became familiar with the observers recording the medication process. Also, the word error was avoided by the observers during the observation[(B. Dean & Barber, 2001; Härkänen et al., 2015)]. If there was a risk for an error during observation (e.g. giving a wrong dose), observers intervened and politely asked the nurse to check again before administration in order to protect patients from being harmed. This was in line with previous studies[(B. Dean & Barber, 2001; Härkänen et al., 2015; Westbrook et al., 2011)] and such doses were considered as MAEs. In both wards the nurses were responsible for medication preparation and administration, as there were no ward pharmacists or other staff involved in these procedures. Observers arrived at the ward before the medication administration began and informed the nurse, who had already agreed to participate, that the medication process will be recorded. Observers recorded the administration process by following the nurses carrying out the medication round and reviewed drug orders and records in order to be able to cross check the medicine administered with the medicine prescribed. Drug orders and medication records were on paper, as there was no electronic prescription or

medication system used in the wards. There were three scheduled routine medication rounds in the wards (i.e. morning, evening and night). Medication rounds in the two wards lasted from thirty minutes to approximately two hours, depending on the type of work organization system in the ward and on staffing. In particular, when nurses were allocated to tasks rather than to patients, drug administration rounds were prolonged (approximately two hours) because one or two nurses had to prepare and administer medication to all ward inpatients. When nurses were allocated to patients, time per drug administration round was decreased (approximately thirty minutes) because one nurse had to prepare and administer medication for three or four inpatients. Observations were conducted during weekdays and weekends, during all shifts and under both types of work allocation system (patient and task allocation) in an effort to obtain a comprehensive sample of administrations under all possible working conditions. The study was approved by the National Ethics Committee according to the national law, and by the research committee of the Ministry of Health. Access to the field of research was obtained by the hospital administration and the ward management.

2.6 Pilot study

A pilot study took place before initiating the observation. The pilot study helped test the form and the inter-rater agreement. Additionally, it gave the opportunity to observers and staff to get used to each other's presence during medication administration, by prolonging the presence of the observers in the wards, therefore mitigating the Hawthorne effect. In this testing phase the two raters observed simultaneously the same nurse administering the same medicine to the same patient and recorded the administrations using the observation form. During the pilot phase 85 administrations were recorded and Cohen's Kappa coefficient was used to confirm agreement between observers [(Hallgren, 2012; Härkänen et al., 2015)]. The agreement between observers calculated at 97.8% and the Cohen's kappa coefficient was k=0.971, p=0.005.

2.7 Statistical Analysis

After collection, data were processed using PASW 23 for Windows. Descriptive statistics were used to calculate the numbers and types of errors (Table 1). Observations were dichotomized at two cut-off points: administrations with more than three errors (≥ 3) and administrations with more than five errors (≥ 5). Chi square and Kruskal-Wallis test were used to assess relationships between categorical or continuous variables respectively and number of errors (Table 2). Two binary logistic regression models have then been completed, one for each dichotomized response (≥ 3 and ≥ 5 errors) in order to explore which factors could predict the occurrence of a higher number of errors. Risk factors were included in the regression models and factors without a statistically significant contribution to the model were removed using a stepwise (backwards) approach (Table 3 and Table 4).

3. Results

3.1. Frequency and types of errors

Overall, 31 rounds were observed, 665 administrations were recorded and 2371 errors were detected. The minimum number of errors observed within one administration was 1 (6%) and the maximum 11 (1.2%). The average number of errors per administration was 3.5. From the 2371 errors, only 455 (18.8%) were errors of commission while 1926 (81.2%) were omissions (Table 1). Omissions in the basic infection and safety regulations (46.6%) were the most common type of error, followed by deviations from the five right principles (35.8%). Omitting to hand wash was a predominant finding (98.4%). Also not disinfecting the site of injection was a major omission recorded in 37.7% of the administrations observed. Within the category "adherence to the five rights of medication safety", the most common type of error was the omission to adequately confirm that the patient to whom the medicine is about to be administered is indeed the right patient, by either confirming from medication records (11.7%) or by asking the patient to confirm his/her name (74.4%). Documentation errors (adherence to drug administration record protocol) was also an important finding (13.1%) while errors in the category "adherence to administration methods and guidelines" were a less frequent finding (4.5%) (Table 1).

3.3. Factors associated with medication errors

Interruptions and/or distractions during medication administration were associated with both administrations with more than three errors and administrations with more than five errors (p=0.007 and p=0.03 respectively). The association between the "number of medicines administered to the patient" and the number of errors, was found to be statistically significant and the number of errors increased proportionally to the number of medicines administered to the patient (Table 2). There were no statistically significant associations between the number of errors and patient age, nurse experience, days or shifts (Table 2). There was a statistically significant association between the number of patients assigned per nurse for medication administration and administrations with a higher number of errors (≥ 5) (p=0.01) but not with administrations with ≥ 3 errors (p=0.21).
Similarly, there was a statistically significant association between the pharmaceutical form and ≥ 5 errors per administration (p=0.001) but not with administrations with ≥ 3 errors (p=0.86).

To further investigate the relationship of contributing factors and prevalence of errors, two stepwise logistic regression models were completed: one for administrations with three errors or above (≥ 3) (Table 3) and one for administrations with five errors or above (≥ 5) (Table 4).

Drug therapeutic class was also associated with both ≥ 3 and ≥ 5 errors with a statistical significance (p<0.001). Factors increasing the risk of ≥ 3 errors being detected per administration were the pharmaceutical form, the medication class and the number of medicines administered to each patient (Table 3). Specifically, it was 65% (p=0.01) more likely to detect ≥ 3 errors when an injectable medicine was administered than when administering an oral medicine. Similarly, when a cardiovascular medicine was administered it was 3.35 (p<0.001) times more likely to detect ≥ 3 errors within an administration, than when a drug from another drug class was used. Also, an increased number of medicines taken by the patient increased the risk by 7% (p=0.008) for ≥ 3 errors to occur.

The factors increasing the risk of ≥ 5 errors within an administration were only the medication class and the number of medicines administered to each patient. It was 4.1 (p<0.001) times more likely to observe ≥ 5 errors per administration when administering a cardiovascular drug than a drug from another therapeutic group. An increased number of medicines taken by the patient increased the risk by 6% (p=0.05) for ≥ 5 errors to occur per administration (Table 4).

4. Discussion

Omitting to hand wash or disinfect the site of injection, and in general not following the infection control and safety regulations was among the major findings that raises concerns of possible cross infection (Table 1). The omission of hand washing has previously been reported[(Kim & Bates, 2012)]. Errors of omission in the basic five right principles of medication safety were also an important outcome of this study. This may indicate that clinical nurses are prone to deviate from safe practice regardless of their experience in the field. In particular, the omission of not confirming the patient's identity was a major finding (Table 1). The error of not administering a drug in line with the correct administration method, could have been caused by a lack of knowledge, time pressure, or because of a lower risk perception. However, as we did not perform knowledge testing nor explore risk perceptions, the explanation of this specific omission remains unknown. Some studies that did perform knowledge testing [(Bertsche et al., 2008; Niemann, Bertsche, Meyrath, Koepf, Traiser, Seebald, Schmitt, Hoffmann, Haefeli, & Bertsche, 2015)] have revealed some knowledge deficits, while other studies have shown that there is a significant variability between risk perceptions among healthcare professionals [(Bourne et al., 2017; Nichols et al., 2009b)]. Administration method errors have also been reported by previous studies [(Härkänen et al., 2015; Keers et al., 2013b; McLeod et al., 2014)]. Non-adherence to the drug administration record protocol (i.e. documentation errors) was commonly recorded, and this is in line with findings from previous studies [(Härkänen et al., 2015; Keers et al., 2013b; Safholm et al., 2019)]. In fact, documentation errors were the most common type of error of commission recorded with the inaccurate time of documentation being the most frequently detected documentation error.

Regarding associated factors, interruptions and/or distractions, medication type, and number of medicines administered to the patient were all associated with a statistical significance to a higher number of errors (Table 2). In particular, the administration of injectable forms was associated with a higher number of errors than administering oral or other forms (Table 2 and Table 3). Factors that could predict the occurrence more than three errors (≥3) with a statistical significance were medication class, pharmaceutical form and the number of medicines administered per patient. The only factors that statistically significantly

predict the occurrence of a higher number of errors (≥5) were medication class and number of medicines administered per patient. When administering a higher number of medicines to a patient or when cardiovascular medicines were administered the risk of ≥ 5 errors made per administration was increased. Studies conducted in a similar setting, including patients with similar characteristics, have also reported associations between medication errors and polypharmacy or medication errors and cardiovascular drugs[(Härkänen et al., 2019; Keers et al., 2013b; WHO, 2017c)]. Further investigation may be warranted to understand further factors unexplored in this study (e.g. safety culture, professional engagement) and how they are associated with MAE.

One very important finding from this study was the high number of omissions. Omissions constituted deviations from safe drug practice and seemed to be the most frequent type of error during the medication administration process. This is an important finding because errors of omission are often underestimated or not reported by staff [(Pelzang & Hutchinson, 2020)] but at the same time are one of the most common types of error detected in observational studies [(Härkänen et al., 2015, 2019; Sears & Goodman, 2012)]. Errors of commission were also recorded in this study but were much less frequently observed. In comparison with previous studies [(Härkänen et al., 2015; Keers et al., 2013b)], a rather higher number of errors were detected in this study. However, this was not a surprise because this study aimed, apart from recording errors of commission, to detect as many errors of omission as possible. Many of the omissions detected in our study were not observed and therefore not recorded in previous similar observational studies [(K N Barker et al., 2002; Härkänen et al., 2015; Haw et al., 2007)]. More specifically, in previous studies omission was defined as the failure to give an ordered dose, and that was the only type of omission recorded [(K N Barker et al., 2002; Haw et al., 2007; Lisby et al., 2005)]. However, in this study more types of omission were under observation, therefore a higher number of errors were recorded in total (Table 1). One differentiation of this study from previous ones is that within each OE different types of omission were observed. Previous studies have operationalised medication errors in terms of a rate which is calculated as the number of MAEs divided by the total number of OEs, multiplied by 100[(Allan & Barker, 1990; Bryony Dean Franklin et al., 2007)]. This rate is useful for comparing study results, however, is not always feasible to compare findings from different studies because of the different settings, definitions and methods used in each study[(Keers et al., 2013b; McLeod, Barber, & Dean Franklin, 2013)]. Additionally, different approaches when calculating error rates are noted among different studies[(Keers et al., 2013b; McLeod, Barber, & Dean Franklin, 2013)]. Some studies suggested that MAEs occur in 5.6% of non-intravenous, or in 35% of intravenous doses[(McLeod, Barber, & Dean Franklin, 2013)] or up to 20% of all doses given;[(K N Barker et al., 2002; Härkänen et al., 2015)]. However, other studies suggest higher rates of error (from 19.6% up to 85.9%), particularly for intravenous administrations[(Keers et al., 2013b; Lisby et al., 2005)]. In this study, the medication error rate is considerably higher in comparison with other studies. If the total number of doses given, plus omitted doses, is used as denominator and the number of doses with one or more errors as a numerator, multiplied by 100, the medication error rate will be 100% since all observed doses had at least one error. If the total number of errors is used as numerator, error rate will be above 100% (i.e. 356.5%). This was not an unexpected outcome since in this study we included additional types of procedural errors that were not commonly reported in previous studies. The aim was to put an emphasis on omissions since they are among the most commonly reported errors[(Härkänen et al., 2015; Keers et al., 2013b; Kim & Bates, 2012)]. Omissions of a drug or a dose are reported by previous studies [(K N Barker et al., 2002; Härkänen et al., 2015; Lisby et al., 2005)]. However, procedural errors, like omitting to hand wash before administrating medicines intravenously, omitting to confirm the patient's name, omitting to check that the correct strength is about to be administered or omitting to disinfect the site of injection, are not always considered when investigating MAEs. These omissions increase the possibility of additional adverse event to occur and also the risk of inpatients being harmed[(National Coordinating Council for Medication Error Reporting and Prevention, 2020)]. Furthermore, findings from this study revealed that basic medication safety and prevention guidelines are not always followed by staff. The omissions detected in this study, highlighted failings in the medication administration process, and non-adherence to safety guidelines, which composes a prone to errors environment. These problematic conditions cultivate a suboptimal safety level, and are associated with poor health outcomes for patients[(Härkänen et al., 2019)]. The findings also highlight the need to identify procedural errors in order to prevent medication adverse events. Further research will be needed to explore causes of procedural failures and identify potential barriers for staff to adhere to safety guidelines.

Omissions may constitute a deeper problem because it concerns attitudes and behaviors of the personnel and are relevant to the general safety climate and culture of the team and of the organization [(Gleeson et al., 2020; Pelzang & Hutchinson, 2020)]. Omissions lead to deviations from safe clinical practice, but probably also reveal a hidden risk factor, like a low drug safety perception among healthcare professionals [(Nichols et al., 2009b; Pelzang & Hutchinson, 2020)]. It is crucial to

explore the personnel perspectives regarding drug safety or evaluate the safety climate at organizational level in order to obtain a better understanding of why these deviations from safe practice are observed [(Bourne et al., 2017; Gleeson et al., 2020)]. Along with contributing factors, personnel's perceptions on medication safety should be considered in order to provide a more solid explanation of why errors happen.

5. Suggestions for future research

Based on the findings of this study, it is suggested that failures in the medication process and deviations from medication safety guidelines, which threaten patient safety, should be identified and addressed by healthcare organizations, hospitals in particular. Procedural errors and omissions during the medication process are intertwined with non-adherence to safety guidelines which inevitably cultivate an error prone environment. This study highlights the magnitude of the non-adherence to these guidelines which warrants further investigation to understand why and how to resolve this. This study, in line with previous studies, reported an association between MAEs and cardiovascular drugs and polypharmacy[(Flynn, Barker, Pepper, Bates, Mikeal, et al., 2002; Härkänen et al., 2015, 2019; Keers et al., 2013b; Kim & Bates, 2012; WHO, 2017c)]. The association of specific factors with MAEs may constitute a target for future research as more evidence maybe needed to understand the actual impact of these factors on errors.

6. Limitations

Due to the complexity of the medication process, additional factors contributing to errors may exist but probably were missed and therefore not included in our analysis. Personnel perspectives regarding drug safety for instance, or the organization's safety climate should be considered in order getting a better understanding of why these deviations from safe drug administration principles are observed. Moreover, despite the fact that observers tried to be discreet, their presence in the wards may had an impact on nurses' performance. Finally, this study conducted in two medical wards of a tertiary hospital and only the administration phase was observed. Expanding the observation in different wards and including different stages of the medication process could provide a more comprehensive picture of the medication errors problem.

7. Conclusions

Medication errors are a common problem in healthcare services, with omissions being one of the most common types of error. Exploring the causes of this phenomenon is crucial in the effort to address it. Factors associated with medication errors need to be explored and taken into account in an attempt to limit errors. However, in order to effectively address the problem and improve patient safety, an investigation of the personnel perspectives of drug safety will be needed in order to obtain a better picture of the problem and promote safe drug use in clinical settings.

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Table 1. Frequency and types of medication errors detected

Error Category	Item	Observations with Error, N (%)	Type of error	
			Omissions	Error
Adherence to basic infection and safety regulation	Wash hands before administering medication	654 (98.4)	649	5
	IV equipment placed only in disinfected areas	199 (29.9)	199	0
	Disinfect site of injection	251 (37.7)	251	0
	% of All Errors	**1104 (46.6)**	**1099 (57.1)**	**5 (1.1)**

Adherence to the five rights of medication Safety	Right Medicine	Read medicine's name on label for at least one second	17 (2.6)	17	0
		Medication is prepared by the nurse who will administer it	21 (3.2)	0	21
	Right Dose	Confirm the strength indicated on label for at least 1 sec	41 (6.2)	41	0
		Confirm the dose from prescription for at least 1 sec	49 (7.4)	49	0
		Confirm the dosage at eye level for syringes	60 (9.0)	60	0
	Right Patient	Read patient name from medication record	78 (11.7)	78	0
		Ask patient to confirm his/her name	495 (74.4)	495	0
	Right Route	Read administration route on label at least once second	65 (9.8)	65	0
	Right Time	Medicine administered at the right time	24 (3.6)	0	24
		% of All Errors	**850 (35.8)**	**805 (41.8)**	**45 (10.1)**
	Adherence to administration methods and guidelines	Infusion rate is in accordance to manufacturer instructions	27 (8.6)	0	27
		Prepare the medication right before the administration	22 (3.3)	22	0
		The medicine is injected at the correct site and/or angle	58 (8.7)	0	58
		% of All Errors	**107 (4.5)**	**22 (1.1)**	**85 (19.1)**
	Adherence to drug administration record protocol	The nurse who administered the drug records the event	20 (3.0)	0	20
		The time of the administration is accurately recorded	290 (43.6)	0	290
		% of All Errors	**310 (13.1)**	**0**	**310 (69.7)**
		Total Errors N (%)	**2371 (100)**	**1926 (81.2)**	**445 (18.8)**

Table 2. Associations between risk factors and administration with ≥ 3 and ≥ 5 errors

	Number of errors per administration					
Associated Factors	**< 3 N (%)**	**≥ 3 N (%)**	**p value***	**< 5 N (%)**	**≥ 5 N (%)**	**p value***
Shift						
Morning	128 (52.5)	225 (53.4)		258 (52.2)	95 (55.6)	
Evening	52 (21.3)	89 (21.1)	0.97	111 (22.5)	30 (17.5)	0.40
Night	64 (26.2)	107 (25.4)		125 (25.3)	46 (26.9)	
Days						
Weekdays	156 (63.9)	266 (63.2)	0.85	312 (63.2)	110 (64.3)	0.78
Weekends	88 (36.1)	155 (36.8)		182 (36.8)	61 (35.7)	
Interruptions or distractions						
Yes	46 (18.9)	119 (28.3)	*0.007*	112 (22.7)	53 (31.0)	*0.03*
No	198 (81.1)	302 (71.7)		382 (77.3)	118 (69.0)	
Number of patients for medication administration per nurse						
above five patients	163 (66.8)	261 (62.0)	0.21	329 (66.6)	95 (55.6)	*0.01*
below five patients	81 (33.2)	160 (38.0)		165 (68.5)	76 (44.4)	
Pharmaceutical Form						
Oral	118 (48.4)	199 (47.3)	0.86	219 (44.3)	98 (57.3)	*0.001*

Injectable	102 (41.8)	175 (41.6)		226 (45.7)	51 (29.8)	
Other	24 (9.8)	47 (11.2)		49 (9.9)	22 (12.9)	
Drug Therapeutic Class						
Cardiovascular	29 (11.9)	120 (28.5)		77 (15.0)	75 (43.9)	
Antibiotics	59 (24.2)	50 (11.9)		87 (17.6)	22 (12.9)	
Antithrombotic	21 (8.6)	45 (10.7)	*<0.001*	59 (11.9)	7 (4.1)	*<0.001*
Nervous System drugs	25 (10.2)	30 (7.1)		44 (8.9)	11 (6.4)	
Other class	110 (45.1)	176 (41.8)		230 (46.6)	56 (32.7)	
Patient Age						
Mean Age in Years (SD)	75.91 (12.7)	76.13 (13.0)	0.75	76.02 (13.4)	74.22 (15.6)	0.28
Nurse Experience						
Mean number in years (SD)	13.1 (3.6)	12.8 (3.9)	0.74	12.97 (3.8)	13.38 (3.7)	0.08
Number of medicines taken by patient						
Mean Number (SD)	8.3 (3.1)	8.8 (3.6)	*0.02*	8.6 (3.3)	9.2 (3.3)	*0.01*

*For patient age, nurse experience and number of medicines taken by patient, a p-value from Kruskal-Wallis test is reported, and in all other cases p-value of chi-square test is reported. Values in *italic* indicate significant association with number of errors.

Table 3. Stepwise logistic regression model for administration with ≥ 3 errors including only the statistically significant risk factors, OR (95% CI), p < 0.05

Associated Factors[#]	**Odds Ratio (95% CI)**	**p value***
Pharmaceutical Form		
Oral	Ref	
Injectable	*1.65 (1.10-2.49)*	*0.01*
Other	1.32 (0.74-2.34)	0.34
Medication Therapeutic Group		
Other	Ref	
Cardiovascular	*3.35 (1.95-5.77)*	*<0.001*
Antibiotics	0.68 (0.42-1.10)	0.11
Anticoagulants	1.61 (0.88-2.96)	0.12
Nervous system drugs	0.71 (0.39-1.29)	0.26
Medicines taken by patient	*1.07 (1.02-1.13)*	*0.008*
-2 LL	822.11, x^2=52.09, df=8, p<0.001	
Nagelkerke R^2	10.3%	
Hosmer and Lemeshow Test	p=0.21	
Classification accuracy	64.8%	

*p value of a stepwise (backwards) regression model is reported. Values in *italic* indicate significant association with number of errors.
[#]Shift was not included in the model as it was correlated with the factor "number of patients per nurse for medication administration"

Table 4. Stepwise logistic regression model for administrations with ≥5 errors including only the statistically significant factors, OR (95% CI), p < 0.05

Associated Factors[#]	**Odds Ratio (95% CI)**	**p value***
Medication Therapeutic Class		
Other	Ref	
Cardiovascular	*4.10 (2.65-6.34)*	*<0.001*
Antibiotics	1.04 (0.60-1.80)	0.90
Anticoagulants	0.48 (0.21-1.12)	0.09
Nervous system drugs	0.98 (0.47-2.03)	0.96
Medicines taken by patient	*1.06 (1.00-1.12)*	*0.05*
-2 LL	694.93, x^2=63.23, df=5, p<0.001	
Nagelkerke R^2	13.3%	
Hosmer and Lemeshow Test	p=0.24	
Classification accuracy	76.8%	

*p value of a stepwise (backwards) regression model is reported. Values in *italic* indicate significant association with number of errors.
[#]Shift was not included in the model as it was correlated with the factor "number of patients per nurse for medication administration"

2. Assembling the perceived and the observed medication administration errors associated factors: A case study in two medical wards

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Assembling the perceived and the observed medication administration errors associated factors: A case study in two medical wards

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Abstract

This study presents and discusses nurses' perceptions of medication administration errors (MAEs) related factors in two medical wards of a tertiary hospital. In these two medical wards an observational study investigating the MAEs associated factors had previously been conducted and indicated that the occurrence of a higher number of MAEs was significantly associated with the type of medicine administered and with polypharmacy. To further investigate the problem, a focus group study was conducted to explore nurses' perceptions of MAEs related factors in the same hospital settings, based on the evidence provided from the observational research. Nurses from the two medical wards participated in focus group discussions. Thematic analysis was employed for data analysis and resulted in composing four themes: (a) professional practice environment and related factors, (b) person-related factors, (c) drug-related factors, (d) processes and procedures. For obtaining a clearer picture of the MAEs problem, it is suggested, when feasible, to use more than one method for collecting the data, as different methods may reveal additional risk factors that cannot be obtained only by one method.

Keywords
Medication errors, nurses' perceptions, medical wards, focus groups, thematic analysis

Introduction

Medication administration errors (MAEs) are still common in hospital wards and patients run the risk of suffering harm as a consequence of such errors (Giannetta et al., 2020; M. Härkänen et al., 2019). Medication administration to inpatients is a complex process, individual and system related conditions may change at any point of the process and clinical nurses spend much of their time administering medicines to inpatients (Brady et al., 2009; Härkänen et al., 2015). Nurses, therefore, are involved in a prone to error procedure (Giannetta et al., 2020; Härkänen et al., 2015). Since nurses have an important role in the medication process, it is crucial to explore their perceptions of MAEs associated factors, in order to draft targeted plans to limit drug errors in hospital settings and improve patient safety (Cooper, 1998).

Several definitions have been proposed for medication errors but until now there is a lack of an internationally standardized term that clearly defines what constitutes an error, error cause, or contributing factor (Escrivá Gracia et al., 2019). The United States National Coordinating Council for Medication Error Reporting and Prevention define 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" (NCC MERP, 2021). Medication errors can also be defined as a deviation from the doctor's order as written on the patient's therapy charts, a deviation from the manufacturers' preparation/administration instructions, or deviations from the relevant organization's guidelines or policies (Keers et al., 2013b).

Previous research suggests that MAEs errors only, (excluding prescription, or dispensing errors) occur in 5% of non-intravenous and 35% of intravenous doses or up to 20% of all doses given (M. Härkänen et al., 2019; Keers et al., 2013b; McLeod et al., 2014). Globally, the cost associated with all medication errors has been estimated by the World Health Organization (WHO) at $42 billion USD annually (WHO, 2017d). In Europe, the annual cost of medication errors had been estimated between €4.5 billion and €21.8 billion (European Medicines Agency, 2013).

The occurrence of MAEs may be related to different factors, such as environmental and working conditions, including leadership and management, staffing, work allocation, distractions and/or interruptions, drug related factors, and procedures and systems failures (Brady et al., 2009; Sears et al., 2013b). Additionally, nurse related factors include nurse experience, knowledge, physical or mental status, and patient related factors include health condition, age and polypharmacy (Härkänen et al., 2015; Keers et al., 2013a). However, the perceptions of medication error associated factors among nurses working in different healthcare settings may vary; because of the different working conditions (Sears et al., 2013b), different organization of work, ward management and different nurse or patients characteristics (Härkänen et al., 2015; Jasemi et al., 2019).

Moreover, studies have reported the implementation of different interventions to prevent errors, including technological applications, staff training, improved access to pharmacy services, and improvements in ward systems (European Medicines Agency, 2013; Keers et al., 2014; Manias et al., 2014; E. Manias et al., 2020). However, errors are still commonly detected in healthcare settings, particularly in hospitals (M. Härkänen et al., 2019).

The present study was part of a bigger study investigating the MAEs associated factors and aimed to explore the experience and the perceptions of nurses working in two medical wards, regarding the factors associated with MAEs. An observational study had previously been conducted in these two medical wards which revealed that factors like the type of medicine administered (i.e., injectables or cardiovascular drugs), or some patient's attributes (i.e., polypharmacy) are significantly associated with the occurrence of a higher number of errors. It is important to note that no research has been previously performed on medication errors in the country, therefore at the time of reporting no data were available, rendering this study particularly important for patient safety in Cyprus. In order to get deeper into the existing information and obtain a better understanding of the factors contributing to errors, we aimed to collect nurses' perceptions of these error related factors. The observation method is considered to be one of the most efficient, valid and accurate method for detecting MAEs (Flynn, Barker, Pepper, Bates, & Mikeal, 2002). Nurses' perceptions however, could reveal additional information that could not be collected from

the observational study. More specifically, several errors were detected during the observational study that required further investigation in order to understand why they occurred. For example, we found from the observational study that nurses did not always double checked the medication to be administered, did not disinfect the site of injection before administering an injectable drug, nor they washed their hands, but we could not understand the reasons that led nurses deviated from basic safety drug administration guidelines. In addition, by collecting nurses' perceptions it was possible to examine whether there is a gap between the perceived and the observed MAEs associated factors and in this way the study could contribute to increasing knowledge beyond the national boundaries. The use of more than one method for collecting the data may produce a clearer picture of the problem as the results obtained from different methods may not be identical, even if they were collected from the same setting.

Methods

Design

This was a qualitative study where two focus group discussions took place in order to explore nurses' perceptions regarding the factors contributing to MAEs in medical wards. Qualitative data deriving from focus group discussions allow an in depth comprehension of participant's perceptions on the discussion topic concerned, and have been used extensively in previous research aimed to gain insights of participants' perceptions (Escrivá Gracia et al., 2019; Papastavrou & Andreou, 2012).

In this study, focus group interviews aimed at exploring the perceptions of nurses involved in the medication process in medical wards regarding the risk factors for errors and deviations from the basic medication administration safety guidelines. In comparison with other methods, focus group discussions have several advantages (Freeman, 2006). The sense of freedom and security among participants and the dynamic nature of a focus group discussion is motivating for participants and creates a suitable environment to elicit the opinions of the group (McLafferty, 2004; Wilkinson & Birmingham, 2003). Furthermore, because "errors" is a sensitive issue that cannot easily be discussed freely, this method gives the opportunity to the participants to express their views in a safe environment (McLafferty, 2004; Papastavrou et al., 2014). The study was conducted and reported in accordance with the Consolidated Criteria for Reporting Qualitative Studies (COREQ) (Tong et al., 2007).

Participants and setting

Nurses involved in the medication process in two medical wards of a tertiary hospital in the Republic of Cyprus were invited to participate in the focus group discussions. This hospital provides healthcare services to more than 250000 inhabitants. Each medical ward had 30 beds and a total of 25 nurses were employed at each ward. Access to the field was granted by the hospital administration and the ward management. An observational study was previously conducted in these two medical wards in order to detect the MAEs and to explore the associated factors. In that study nurses were directly observed by two independent observers administering the medication to inpatients. In this study we aimed to explore the perceptions of nurses who participated in the observational study, thus we invited nurses from these two wards to participate in the focus group discussions.

In order to achieve a comprehensive representation of nurses involved in the medication process in the medical wards, a purposive sampling approach was implemented. Eligible nurses were identified and approached by the researchers, after consulting with the ward management, and a face-to-face detailed oral explanation about the study was provided. Inclusion criteria for nurses' participation were the involvement in the medication process and currently working in one of the two medical wards. In the two wards that the study was conducted, nurses had

the responsibility of preparing and administering the prescribed drugs to all inpatients. Because the aim was to collect the perceptions of nurses on the causes of MAEs, other healthcare professionals were not invited to participate, as they were not directly involved in this drug administration process. Recruitment aimed to create two groups with homogeneity in respect of educational level and job rank in order to ensure an open discussion among participants without being cautious in expressing their personal perceptions in the presence of their senior colleagues (Papastavrou & Andreou, 2012). Heterogeneity however, was sought for work experience in order to obtain the perceptions of both; fresh and experienced nurses (McLafferty, 2004; Papastavrou & Andreou, 2012). Therefore, nurses with a difference in the years of work experience and with a bachelor and a master's degree were invited.

In total, 13 nurses, that met the above criteria, agreed to be enrolled. None of the nurses revoked his/her participation and two focus groups were conducted (Group A=5 nurses, Group B=7 nurses). All of the participants were registered nurses while five of them had additionally a master's degree. In addition, their work experience, including experience in the medication process, ranged from two to eighteen years, none of them had a managerial position and they were all working in one of the two medical wards of the same tertiary hospital where recruitment took place.

Data collection

Focus group interviews were conducted from January to February 2020 in one of the hospital's meeting rooms. The first interview lasted 75 minutes and the second 90 minutes. Focus groups were led by a moderator in the presence of an observer. The moderator guided the discussion based on a semi-structured interview guide, while the observer took notes of the conversation as well as the non-verbal signals. The moderator had previous experience in conducting focus group interviews and with the medication process in clinical wards but had no relationship with the medical wards or the participants. The interviews went on up to the saturation point of the data where no additional statements or views were expressed (McLafferty, 2004; Papastavrou & Andreou, 2012). Two audio recording devices were used at each focus group to record the conversation for later transcription and analysis. The observer distinctively helped to avoid issues relevant with medication error but irrelevant with the aim of the study (e.g., legal or ethical aspects of medication errors), informed the moderator if more details are needed to elaborate on a participant's comment and took notes of participants' reactions and behaviors relevant to the issues raised during discussions. Transcripts and notes taken during the collection or during the analysis of the data were strictly confidential and were not disclosed to anybody.

Development of the interview guide

It was agreed by the research team to develop a semi-structured guide. A semi-structure guide is considered to be suitable when there are issues that participants are not used to talking about, such as errors in this case, and is possible to focus on the issues that are meaningful for the participants, allowing diverse perceptions to be expressed (Kallio et al., 2016). The development of the interview guide was based on the findings of the observational study and on a literature review that led in mapping the most common causes of medication errors in clinical settings and created a conceptual basis for the interview (Kallio et al., 2016). After this step, medication error risk factors, as described in literature, were embedded into an initial set of questions and a preliminary semi-structured interview guide was drafted. In this study MAEs were defined as a deviation from the doctor's order as written on the patient's therapy charts, a deviation from the manufacturers' preparation/administration instructions, or deviations from the relevant organization's guidelines (Keers et al., 2013b).

Then the observer and moderator, who had expertise in medication administration, reviewed the preliminary version and formulated the questions in order to be participant-oriented, non-leading, and clearly worded (Kallio et al., 2016; Papastavrou & Andreou, 2012). The researchers then discussed and made additional modifications including an introductory section for smooth induction of participants to the subject and included short, conversational, open-ended, and one-dimensional questions.

Data analysis

Data analysis included the transcription of the discussions, data coding and analysis based on the thematic analysis method (Table 1). Interviews were transcribed verbatim by the moderator in order to produce an accurate record of everything said in each of the focus-group interviews (Wilkinson & Birmingham, 2003). Transcripts were organized and coded by two researchers separately (SV and GS). Data analysis was based on the inductive method and the thematic approach was employed. There are various techniques used for data analysis in the inductive method, however thematic analysis is among the most common ones (Papastavrou et al., 2014; Ritchie & Lewis, 2004). The aim of this analysis is to archive in a detailed and systematic manner the coding and themes resulted from the interviews or observations of the participants (Ritchie & Lewis, 2004; Wilkinson & Birmingham, 2003). Researchers discovered topics that emerge from the discussions, and then verified and expanded these topics through the data. The process was repeated for finding any additional topics that could emerge from the transcribed discussions (Papastavrou et al., 2014; Papastavrou & Andreou, 2012; Ritchie & Lewis, 2004). Then the researchers compared their coding, discussed and interpreted the content of several statements and reviewed the differences between their coding. Codes along with the respective wording were grouped based on their content and similarity. Researchers repeatedly performed this task until consensus was reached (Table 1). Codes with similar content were grouped together forming separated thematic categories. The objective of this effort was the continuous analysis and synthesis of categories into themes that were directly linked to the interview data.

Ethical Aspects

The study was approved by the National Ethics Committee (ΕΕΒΚ ΕΠ 2018.01.92) according to the national law, and by the research committee of the Ministry of Health (0479/2018) of the Republic of Cyprus. Access to the field of research was granted by the hospital administration and the ward management. Participants' names were replaced by a code (i.e., Nurse1, Nurse2 etc.) in order to maintain their anonymity and all data gathered were discarded after data analysis was finalized.

Results

From the analysis of data collected from the two focus groups, initially thirty-three different thematic categories were derived from the codes, however after further analyzing the data and discussing the initial categories, researchers concluded in only four themes (Table 2). These were (a) Professional practice environment and related factors; (b) Person related factors; (c) Drug related factors; (d) Processes and Procedures. However, Professional practice environment and related factors was the dominant theme.

Professional practice environment and related factors

Nurses raised several issues regarding their professional practice environment and working conditions. Many aspects of their work environment were pointed out as major medication error contributing factors. Additionally, specific work conditions constitute factors that in their view were significantly contributing to errors.

The presence of family members and relatives visiting the patients during medication rounds, and the interruptions and/or distractions during medication administration created a prone to errors working environment. Interruptions and/or distractions were caused by relatives or visitors or from other reasons like personnel, phone calls, and patients:

"When we are interrupted during the medication process the chance of making mistakes increases significantly. Common causes of interruptions are relatives, doctors, telephones or changes in the prescriptions while administering the medicines (Nurse 7)

"Wrong dose or even the wrong medicine may be administered when the nurse is interrupted during administration. Interruptions by colleagues or doctors are often during the afternoon shift." (Nurse 1)

Staffing level was also an important factor that contributes to errors according to nurses. They claimed that with lower staff numbers it is more likely to omit several tasks that shouldn't be omitted in order to finish the tasks on time:

"Staffing is too low and does not allow us to wash our hands before administering medicines, not only the oral but the parenteral drugs as well to each patient. There is just not enough time". (Nurse 5)

"All shifts are understaffed. This means that some tasks may be left unfinished in order to manage to administer medicines on time" (Nurse 9)

It was made clear by the participants that shift (morning, evening and night shift) was also a factor associated with medication errors. They emphasized that the night shift is usually understaffed and that nurses feel physically fatigued at night:

"*For me there is a big problem in the administration of medicines at the night shift. It takes much longer to finalize medication administration at night shift"* (Nurse 6)

"At the end of the night shift, nurses are often more exhausted. This can make them prone to errors. You get tired at night." (Nurse 3)

When participants were asked to discuss if there was a difference in the errors made between weekends and weekdays, they stated they do not believe that there is any difference. However, some of them expressed the view that maybe less errors are made in weekends because of a less busy atmosphere in the ward. They stated that medical wards, in comparison with other wards, are more demanding when it comes to medication rounds, indicating that the type of ward could also be an associated factor:

"In our ward the work is not affected much if it is weekend or holiday. In surgical wards, for example, there are no planned surgeries during weekends, so in surgical wards there is maybe less workload during weekends. But not in this ward". (Nurse 7)

"I do not think there is much difference. The atmosphere in the ward can be less noisy or busy, but visitors and interruptions are still there and in addition, often the staff is reduced during weekends". (Nurse 11)

As derived from the discussions, communication problems varied from communication lapses between ward staff (especially nurses and doctors), between staff and patients or between the ward and other hospital

departments. Prescriptions that cannot be read and the absence of an electronic prescription system seemed to be an error contributing factor according to nurses:

"When a drug therapy needs to change or discontinued, is not always reported on time or not at all, and the nurse administering medicines may not be informed on time". (Nurse 4)

"I think communication is problematic especially between doctors and nurses because we have to wait for the doctor to sign the treatment chart, therefore the administration of a certain drug may be delayed" (Nurse 12)

Regarding leadership and ward management, participants agreed that leadership could have an important role. They stated that when the management of the ward does not take into consideration the problems that may lead to errors, then the occurrence of errors increases:

"When we report the problems to the management they seem not to be listening. And it is in the good conscience of each nurse how we will carry out a task." (Nurse 13)

"*I think the leader has a decisive role. For example, if the leader does not emphasize on safety or errors, then the rest of the staff will do the same. The leader sets the example. Staff will follow*." (Nurse 2)

Moreover, the organization of work has an impact on medication errors according to nurses. For example, it seemed that there are two basic types of work allocation in the wards. One is when a number of patients are assigned to a nurse, so that nurse has to provide all the care needed solely for these patients only. Another type is when specific tasks are assigned to a nurse, so one nurse for example is responsible for administering all medicines to all inpatients. Nurses supported that organizational aspect of nursing work and allocation of tasks to the available shift staff, affects the occurrence of errors:

"In night shifts medication rounds are carried out by only one nurse, usually the most experienced one. In morning shift things may be different." (Nurse 2)

"There are two ways to administer drugs. One way, which is mostly applied in the morning shift, each nurse is assigned a number of patients and is responsible for their nursing care including administering their medication. But at night shifts, only one administers medicines to all patients in ward, and this is problematic." (Nurse 6)

Person related factors

Some attributes of the nurse administering the medicines or some characteristics of the patient, may have an impact on the number of errors made, according to participants. In particular, for nurses, person related factors included work experience, lack of knowledge, work engagement, mental and/or physical fatigue. However, experience was a controversial issue as participants did not agree whether it has an impact on errors. Experience and knowledge were considered intertwined by nurses, however, being conscientious, seemed to be a more important factor according to nurses from just being experienced.

"I don't think it has to do with experience. I think it has to do with the individual. If you are conscientious and careful in your work you will make fewer errors, no matter how experienced you are" (Nurse 7)

"The experience and knowledge you gain when you administer many drugs for many years is important. I think an experienced person can avoid many mistakes." (Nurse 9)

For patients, health condition and age are factors that may influence the occurrence of errors. In addition, it was stressed by nurses that when a patient is prescribed a high number of medicines the possibility of error may increase, indicating that polypharmacy is a serious risk factor

"It has to do with the patient's condition, take for example a patient who cannot swallow tablets and we have to crush them for administration, it's easy to make a mistake in such circumstances. It can be very difficult to administer medicines to these patients" (Nurse 9)

"…our patients are usually in a difficult health condition and they take many and different types of medicines and they often need catheterization…" (Nurse 1)

Drug related factors

During the discussions the following medication related factors have emerged: availability of medicines/shortages, preparation and administration method/technique, route and time of administration.

"A drug that is not available at the time of administration, then it will not be administered. This is an omission." (Nurse 3)

"With injectable medicines administration sometimes can be tricky. Several things may go wrong, like a vein rupture, or some injectable drugs must be reconstituted in a specific way before administration, administered at a certain rate, etc." (Nurse 1)

Processes and Procedures

Another medication error risk factor that came to light from the discussions was the absence of standard and written operation procedures. For example, it seemed that there was no standard procedure to handle problems with medication shortages or availability issues. There was no written standard procedure on medication preparation and administration. Many processes were completed based on the nurses' experience, knowledge and goodwill:

"When I give a medicine via gastrostomy or nasogastric tube, or to a patient with infection, I wash and disinfect my hands afterwards. If I administer a drug intravenously, however, I will not wash or change gloves." (Nurse 8)

"We prepare the medicines for administration before the medication round begins, we place them on the trolley and the administration begins later, sometimes up to approximately two hours later, it depends on the workload" (Nurse 9)

Discussion

This study aimed to explore the perceptions of nurses in two medical wards, regarding the factors associated with MAEs and in addition, supplement the findings derived from an observational study that was undertaken in these two wards. The focus groups' method and thematic analysis were used for collecting and analyzing the data. Professional practice environment and related factors was the dominant theme. Participants emphasized that problems such as communication lapses, leadership and management, staffing, interruptions and/or distractions, busy atmosphere in the ward, have an impact on the MAEs numbers. Many of these findings were also reported by previous research (Fahimi et al., 2008; Härkänen et al., 2015; Keers et al., 2013b).

Nurses stated that understaffing is an important factor contributing to errors and can lead to substandard health outcomes. Omissions are also increased when staffing level was low and tasks were skipped (i.e., hand washing before drug administration and especially intravenous) in order to have finalized medication rounds on

time. Furthermore, more errors may occur at the night shift in comparison with morning shifts, particularly when the night shift is understaffed, according to nurses. This was explained by the fact that at the night shift they may feel physically fatigued and this may lead to errors. Previous studies indicated that the number of errors on night shift was consistently higher than the day shift and this phenomenon was attributed to physical and mental fatigue (Brady et al., 2009; Reinke et al., 2015). Regarding interruption or distractions, many studies revealed that indeed these are error contributing factors (Brady et al., 2009; Härkänen et al., 2015; Zhao et al., 2019).

Nurses are often interrupted during their shift by people, pagers, telephone, and this constitutes a risk factor for errors (Kavanagh & Donnelly, 2020). Nurses expressed the view that communication issues, such as not being able to communicate with the doctor when needed, for a change in the drug therapy or a dosage change for instance, can lead to medication errors or delays in the administration or even omissions of a dose. Communication lapses were found to be a risk factor for medication errors in similar studies (Keers et al., 2013a; Elizabeth Manias et al., 2019; Pandya et al., 2019). An association between nursing leadership with error rates was previously reported (Cooper, 1998; Squires et al., 2010; C. A. Wong et al., 2013). In this study, participants mentioned that leadership is a substantial parameter when it comes to errors. Effective leadership fully integrates safety strategic objectives into all of an organization's systems, while ineffective leadership is associated with system failures and a negative safety culture (Cooper, 1998; Squires et al., 2010). Positive nursing leadership can improve the unit's safety culture and has been associated with nurses' safety culture perceptions and behaviors (Moody et al., 2006).

For nurses, attributes such as experience, knowledge, professional consciousness, mental and/or physical fatigue, seemed to have a role in medication errors numbers and this finding is in accordance to previous studies (Härkänen et al., 2015; Keers et al., 2013a; Elizabeth Manias et al., 2019). Studies have shown that some medication errors could be attributed to either a lack of knowledge about the medication or a lack of knowledge about the patient (Escrivá Gracia et al., 2019; Härkänen et al., 2015). In this study, nurses did not fully support the view that work experience is a substantial factor when it comes to medication errors. However, there is evidence that the severity of errors does reduce as clinical experience increases (Sears et al., 2016; Westbrook et al., 2011). However, other studies have suggested that experience is not always associated with fewer errors (Chang & Mark, 2009; Koren et al., 1983). Instead, professional engagement, conscientiousness or good mental and/or physical condition were nurses' key attributes for enhancing medication safety (Härkänen et al., 2015; Keers et al., 2013a; McDowell et al., 2009).

Professional conscientiousness was a term that came out from the discussions and from participants' narratives. Nurses explained during discussions, that due to different personal aspects, each individual nurse values and understands differently professional ideals, commitment to professional standards, and may have different motives when carrying out their nursing tasks. They may have different job satisfaction levels, different perceptions of their profession or of the important role that their work has for patients. This could explain why some nurses are more conscientious than others, thus more careful and sensitive when providing nursing care to patients and therefore less likely to fall into erroneous actions, including medication errors. Studies exploring the development of professional conscientiousness among professionals, nurses included, seem to support these statements made by nurses (Enns & Shapovalova, 2015; Jasemi et al., 2019; Mohammadi et al., 2020; Petrenko, 2014).

Regarding patients' characteristics, health condition and age were the two factors that are associated with errors, according to nurses. This finding is in agreement with previous research, where a bad patient's condition found to be related with medication errors (Härkänen et al., 2015; Keers et al., 2013a). Nurses also emphasized that it is more likely to make a medication error when caring for an elderly patient. However, research shows that medication errors are detected in pediatric wards as well (S. Choo et al., 2017; Sears et al., 2013b).

Nurses emphasized that the availability of medicines was an important factor that could contribute to errors. In particular, when some medicines that had to be administered were not available or there was a shortage from the hospital pharmacy, the risk of error was increased. This finding has also been reported in previous research (Miljković et al., 2019). In addition, the number of medicines taken by the patients was also a significant error risk

factor. There is evidence that the frequency of medication errors is high in patients with polypharmacy (Koper et al., 2013; WHO, 2017d). According to nurses some patients are prescribed different types of medicines simultaneously, a phenomenon associated with medication errors. Drug related factors, such as the pharmaceutical form or the administration route, were not considered to be important error contributing factors by nurses in this study, instead they pointed out that is rather the patient's condition that will increase the risk of an error and not the type of medicine. Previous research indicates that there is an increased risk for medication errors with injectable drugs (Fahimi et al., 2008; Härkänen et al., 2015). Furthermore, nurses admitted that occasionally they have to omit certain tasks which they consider less necessary or time consuming (e.g., not confirming patient's name) in order to administer medicines on time. These omissions constitute medication errors (Härkänen et al., 2015; Kalisch & Xie, 2014) and the fact that nurses are used to operating under these conditions in their daily practice is indicative of the negative safety culture in the ward.

It was obvious that even though nurses considered medication safety as an important parameter of the care provided, the discussions revealed a suboptimal level of safety. Participants' narratives have shown that working environment conditions, communication procedures, standard practices regarding the medication process, ward management and leadership are not supporting the development of a positive safety culture in the ward. Nurses' attitudes and behaviors that determine an adequate level of commitment to safety were absent. For example, several infection prevention principles or even the five right principles when administering medication to patients were not always followed. In some cases, according to nurses, it should be expected that under these problematic conditions some actions needed to be omitted or performed in an inferior way in order to manage to carry out medication rounds on time. It was obvious that the general safety culture in both wards was problematic. Nurses' narratives indicated the absence of a total quality management system in the wards. Systems and processes, including medication prescription, preparation and administration were not carried out according to a written protocol but rather on experience and on the notion "this is the way we do things here". The importance of leadership and the commitment of managers toward safety is crucial for facing these safety obstacles (Cooper, 1998; Squires et al., 2010; C. A. Wong et al., 2013). Relevant training programs or motivation plans for staff are also necessary for enhancing safety attitudes (Cooper, 1998). Focus group discussions in this study revealed that many of these parameters were problematic.

Finally, several findings from the focus group study are in alignment with the findings acquired from the observational study. For example, both studies revealed that some medication attributes, such as route of administration, and some patients' characteristics (i.e., polypharmacy) were factors related with MAEs. Also, both studies revealed that some nurse characteristics (e.g., age or work experience) were not significantly related with errors. However, focus group discussions indicated that, according to nurses, the working environment related factors was the primary category of error-contributing factors, but the observational study indicated that the working environment related factors (i.e., shift, staffing, interruptions) were not significantly related with errors, which suggests that there is some gap between staff's perceptions of error contributing factors and observed contributing factors. Furthermore, some findings that derived from the focus groups discussions could not have been obtained by the observational study. For example, the unavailability of a medicines or the patient's poor health condition were not assessed during the observational study and thus were not investigated for associations with errors. Similarly, the problematic procedures that created a prone to error environment (i.e., communication problems, leadership), came to light via focus group discussions, but were not detected during the observational study and thus not reported. It can be concluded that both methodological approaches are very useful in assembling the medication safety puzzle of a hospital unit, and if both methods are simultaneously employed then a more comprehensive and realistic picture of the medication errors problem can be composed.

Limitations

A qualitative design and a purpose sampling approach in two medical wards was followed in this study, meaning that findings cannot be generalized to other nurses (Papastavrou et al., 2014; Papastavrou & Andreou, 2012). Nurses working in different settings may have different perceptions regarding the causes of medication errors. In addition, considering the sensitivity of the research topic, and despite the encouraging environment within the focus groups, some participants may have been reluctant to express their views if it would diverge from the rest of the group (Papastavrou et al., 2014; Ritchie & Lewis, 2004). Despite these limitations, this study collected nurses' perceptions of medication errors in two medical wards and supplemented the findings of the previously completed observation study, thus, it can be used as a guide for developing programs for preventing medication errors in similar wards.

Conclusion

Nurses' perceptions confirm that medication errors problem is a multifactorial and multidimensional phenomenon that needs collective efforts to be minimized and decrease the possibility of placing patients at risk. Error contributing factors have their roots in the working environment conditions, and in the attributes of the medicines, staff, and patients involved in the medication process. In order to develop targeted interventions to tackle the medication errors problem in hospitals, a clear picture of the underlying conditions contributing to the problem must be ascertained. It is suggested, when feasible, to use different methodological designs for collecting and analyzing data regarding the medication errors problem, because different methods may reveal different risk factors that cannot be obtained only by one method. Taking into account nurses' perception of the MAEs causes is important for effectively addressing factors that contribute to medications errors and for improving patient safety.

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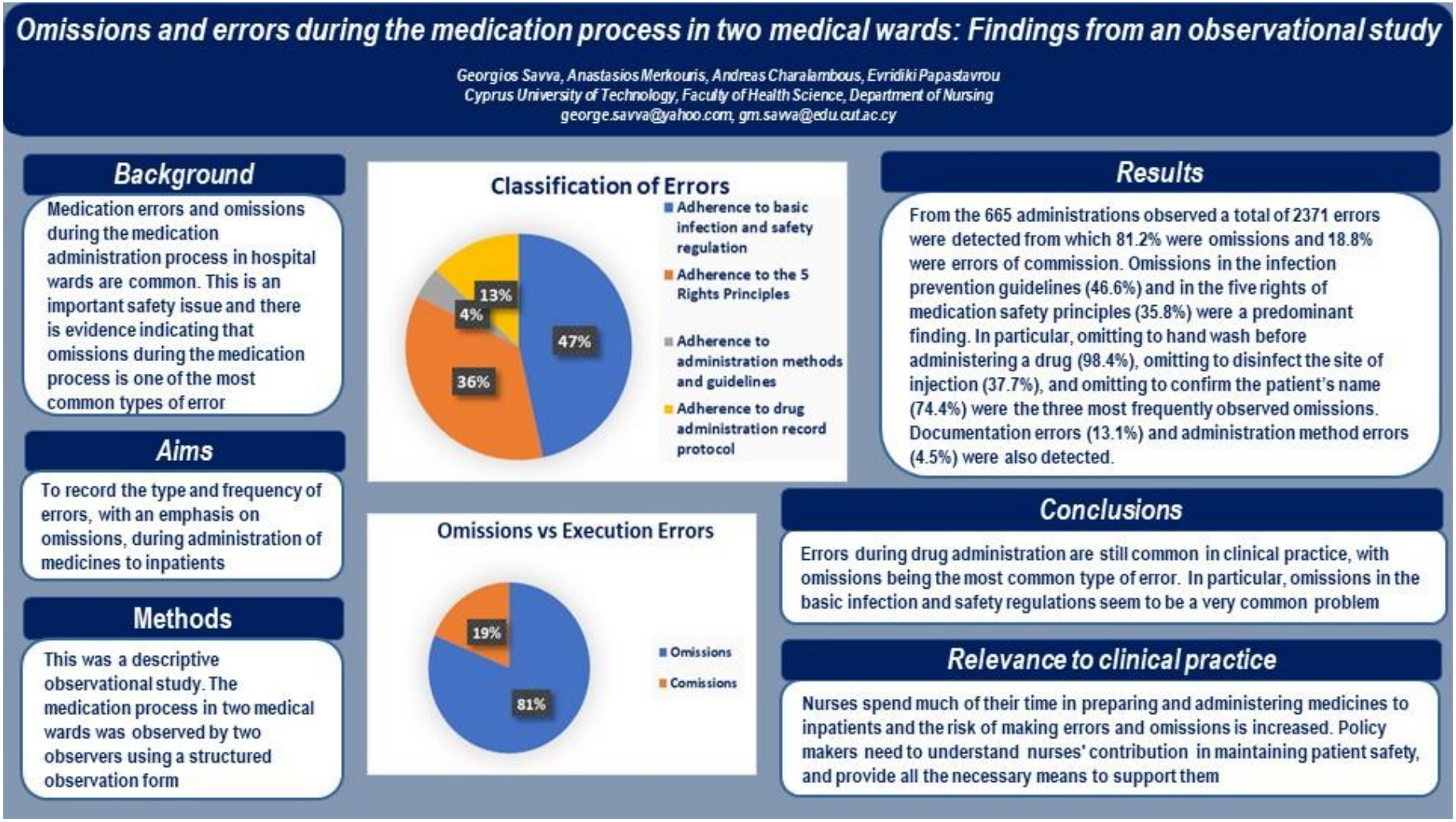
3. Poster presentation presented at the European Academy of Nursing Science (EANS) winter e-summit on 19/02/2021



Appendix VII. Table 22. Inter-observer reliability testing

Table 22. Inter-observer reliability testing

Error Category		Item	Agreement (%)	Cohen's kappa coefficient	P value
Adherence to basic infection and safety regulation		Wash hands before administering medication	100	1	<0.001
		IV equipment placed only in disinfected areas	100	1	<0.001
		Disinfect site of injection	96.5	0.93	<0.001
Adherence to the 5 rights of medication Safety	Right Medicine	Read medicine's name on label for at least one second	96.5	0.83	<0.001
		Medication is prepared by the nurse who will administer it	100	n/a*	n/a*
	Right Dose	Confirm the strength indicated on label for at least 1 sec	100	1	<0.001
		Confirm the dose from prescription for at least 1 sec	96.5	0.92	<0.001
		Confirm the dosage at eye level for syringes	92.9	0.88	<0.001
	Right Patient	Read patient name from medication record	97.6	0.82	<0.001
		Ask patient to confirm his/her name	100	1	<0.001
	Right Route	Read administration route on label at least one second	94.1	0.81	<0.001
	Right Time	Medicine administered at the right time	100	n/a*	n/a*
Adherence to administration methods and guidelines		Infusion rate is in accordance to manufacturer instructions	100	1	<0.001
		Prepare the medication right before the administration	100	1	<0.001
		The medicine is injected at the correct site and/or angle	97.6	0.85	<0.001
Adherence to drug administration record protocol		The nurse who administered the drug records the event	100	1	<0.001
		The time of the administration is accurately recorded	100	1	<0.001

*No statistics were computed because observers' ratings were constant (and identical)

Appendix VIII. Focus Group Guide

Focus group discussion guide for capturing nurses' perceptions of medication administration errors associated factors

A. Introductory Comments & Basic Discussion Rules

1. Welcome and acquaintance of participants
2. Explanation of the reason of the meeting and how the discussion will be conducted. The purpose is to outline views on the safety of drug administration to inpatients and, in particular, if there are errors or omissions in the medication process what are the reasons and why they may occur.
3. Participation is voluntary. But active participation from everyone is required.
4. The anonymity of the participants is absolutely and strictly guaranteed. Names are not recorded, but notes will be taken on matters mentioned during the discussion. The information obtained from the discussion will be confidential and in no way will they be able to be linked back to the participants.
5. There are no right or wrong answers or statements. The purpose is simply to record opinions and reflections.
6. Participant are invited to express themselves freely.
7. There will be a free dialogue but without interrupting the one who has the floor.
8. The discussion will be recorded so that the main conclusions of the discussion can be analyzed. It is reminded that the participation is voluntary after the information you received.

B. Questions for introduction to the topic

1. Do you think that mistakes or omissions can occur when administering medicines to inpatients?

2. What would you consider as an error or omission during the administration of medicines to inpatients?

3. Do you think that mistakes or omissions occur in your department when nurses administered medication? If so, how often would you say they happen? Give some examples of mistakes or omissions that may occur.

C. Main questions

4. In your opinion, what factors may be related to the appearance of errors;

5. Are there any working environment related factors that you would say can contribute to errors or omissions? (e.g., staffing, day, shift, visit, communication, electronic system)

6. Are there any individual related factors that you would say may contribute to errors or omissions? (e.g., experience, fatigue, patient)

7. What other factors would you say can contribute to errors or omissions? (e.g., medicine, equipment, other)

D. Group Closing & Summary

1. Do you have anything else to say on the subject?
2. Summary of what was said and of the important data recorded
3. Last chance for comments or additional statements
4. Thanking the participants and ending the discussion