Rating the severity of medication administration errors: A systematic review

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DECLARATION

I, Liezl Soné Botha, student of the North-West University 22746404, solemnly declare that this dissertation with the study title: Rating the severity of medication errors: a systematic review, is the product of my own work. Plagiarism was continuously avoided, and no intentional infringement of intellectual property was committed. Reference to the original authors and sources of information to substantiate my argument was made to the best of my ability and is credited in the bibliography list and throughout the text.

Liezl Soné Botha

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ABSTRACT

Background: Medication errors are a global problem – endangering human lives and crippling health systems. Its incidence had been demonstrated in many research studies and concomitant factors surrounding the problem have been widely explored. Evidently, a problem regarding the research in this field seems to recur. The jargon and terminology used to describe and differentiate medication errors are haphazard and unstandardized, especially regarding the severity rating of medication errors.

Aim and objectives: The main research aim of this study was to identify elements that could be included in a comprehensive medication error severity rating scale. This was to be achieved by exploring and describing the concepts “severity” and “medication error”; to explore and describe the categorization of medication errors in recent literature; and by providing a summary of constituents of a comprehensive medication administration error rating scale.

Design: A systematic review design was chosen for this study.

Search strategy: Electronic databases available to the North-West University were utilised. These included the following: EBSCO-host, Scopus, Web of Science, SA-epublications and Pubmed central. Studies were selected based on their relevance to the study subject and whether it contained the sought-after information. The PICO-statement was also utilised to assist in the inclusion and exclusion of studies. Research studies were appraised by a tool developed by Alan and Baker (as sourced by Alshehri *et al.*, 2017:873), to determine quality of selected studies.

Data extraction: Quantitative and qualitative data was extracted from the quality appraised studies regarding definitions of “severity” and “medication error”, categorizing of medication errors, and constituents of medication administration severity rating scales. These were represented in various tables and schemes.

Data synthesis: A thematic synthesis approach was followed. Coding of qualitative data led to the culmination of themes. These were used to quantify data that could be presented in histograms and pie-charts. Synthesized results were presented in a narrative fashion. This process was followed for the main objectives of the study in determining the definition of “medication error” and “severity”, the classification of medication administration errors, and summarizing the constituents of medication error severity rating scales.

Results: 17 research reports were used for the data extraction. Themes regarding the definition of “medication error” indicated that certain elements recur in different definitions, which could be used to establish a guideline for defining medication administration errors. The lack of an objective definition of “severity” in research reports was established. Themes on the classification of medication errors indicate that “the five rights” of medication administration is a frequently utilized classification system, as well as that of the NCC MERP. The medication treatment process node should also be considered with classification of errors. Regarding the severity rating tools of medication errors, constituents of a comprehensive medication administration severity rating scale were summarized and closely resembled the categories as presented in the NCC MERP scale with some minor differences discovered.

Conclusion: From the study results, “medication error” can be defined as any treatment process error in the use of a medication caused by a health care provider/user’s deviation from expected actions, irrelevant of harm incurred or not. The following definition for “severity” is presented: The degree of either harm incurred or intervention-acuity required by a medication administration error; with harm ranging from hazard to death, and encompassing errors such as not reaching the patient, negligible errors, errors where action precludes harm, mild, moderate, severe and life-threatening harm. Regarding classification, it is recommended that medication errors should be firstly classified according to the medication treatment process node (medication prescription, transcription, dispensing, administration, documentation and monitoring) and secondly according to type of error (wrong patient, wrong medication (with added deviations related to the drug), wrong route, wrong time, and omission). Relating to the use of a standardised severity rating scale, the use of the NCC MERP scale is recommended, with the consideration of some minor adjustments.

Keywords: medication error; medication administration error; definition of medication administration error; classification of medication error; severity rating of medication error.

OPSOMMING

Agtergrond: Medikasiefoute is ’n wêreldwye probleem wat menselewens bedreig en gesondheidstelsels belemmer. Die voorkoms daarvan is bewys in vele navorsingstudies en bydraende faktore tot die probleem is wyd ondersoek. Klaarblyklik is daar ’n fenomeen in hierdie navorsingsveld wat homself herhaal – die nomenklatuur en terminologie wat gebruik word om medikasiefoute te beskryf en differensieer. Dit blyk lukraak en ongestandaardiseerd te wees, veral ten opsigte van die gradering van erns van medikasiefoute.

Uitkomstes: Die hoof navorsingsdoel van hierdie studie was om elemente te identifiseer wat gebruik kan word in ’n omvattende skaal vir die gradering van die erns van medikasiefoute. Hierdie doel sou bereik kon word deur konsepte “erns” en “medikasiefoute” te ondersoek; die kategorisering van medikasiefoute in huidige literatuur te ondersoek; en ’n opsomming te verskaf van die elemente van ’n omvattende medikasiefoutgraderingsskaal.

Ontwerp: ’n Sistematiese oorsigontwerp is gekies vir hierdie studie.

Soekstrategie: Elektroniese databasisse wat beskikbaar is vir die Noordwes-Universiteit is gebruik. Dit sluit die volgende in: EBSCO-host, Scopus, Web of Science, SA-epublications en Pubmed central. Studies is gekies gebaseer op die relevansie daarvan vir die studie-onderwerp en of dit die gesogte inligting bevat het. Die PICO-verklaring is gebruik vir die insluit en uitskakel van studies. Navorsingstudies is beoordeel volgens ’n instrument deur Alan en Barker (soos in Alshehri *et al.*, 2017:873), om die kwaliteit daarvan te bepaal.

Data ekstraksie: Kwantitatiewe en kwalitatiewe data rakende die definisies van “erns” en “medikasiefout”, die kategorisering van medikasiefoute en die elemente van skale wat die ernstigheid van medikasiefoute meet, is geëkstraheer. Hierdie inligting is uiteengesit in verskeie tabelle en skemas.

Data sintese: ’n Tematiese sintese was die benadering van keuse. Kodering van kwalitatiewe data het gelei tot die vorming van temas. Hierdie temas is gebruik om data te kwantifiseer wat voorgestel kon word in histogramme en sirkel-diagramme. Saamgestelde resultate is narratief voorgestel. Hierdie proses is gevolg vir die hoofuitkomstes van die studie in die bepaling van die definisie van “medikasiefout” en “erns”, die klassifikasie van

medikasietoedieningsfoute en die opsomming van die elemente van medikasiefout-graderingskale.

Resultate: 17 navorsingstudies is gebruik vir data-ekstraksie. Temas rakende die definisie van “medikasiefout” het aangedui dat sekere elemente herhaal in verskillende definisies, wat kan gebruik word as ’n riglyn vir die definiëring van medikasietoedieningsfoute. Die gebrek aan ’n objektiewe definisie van “ernstigheid” in navorsingstudies is vasgestel. Temas rakende die klassifikasie van medikasiefoute dui aan dat die “vyf regte” van medikasietoediening ’n klassifikasiesisteem wat gereeld gebruik word, is, asook dié van die NCC MERP. Die medikasiebehandelingsproses nodes moet ook oorweeg word in die klassifikasie van foute. Rakende die instrumente wat die ernstigheidsgraad van medikasiefoute meet, is ’n omvattende lys elemente opgesom en dit vergelyk op bruikbare wyse met kategorieë wat die NCC MERP voorstel – met klein verskille wat bepaal is.

Gevolgtrekking: Vanuit die resultate kan “medikasiefout” gedefinieer word as enige behandelingsprosesfout tydens die gebruik van medikasie as gevolg van die gesondheidsorgwerker of -gebruiker se afwyking van die verwagte aksies, ongeag of skade aangerig is of nie. Die volgende is die definisie vir “ernstigheid” wat voorgestel word: die graad van óf skade berokken óf die ernstigheid van die intervensie benodig as gevolg van ’n medikasietoedieningsfout, met skade wat wissel van ’n gevaar tot dodelik, wat ook insluit foute wat nie die pasiënt beïnvloed het nie, weglaatbare foute, foute waar skade voorkom is, ligte, matige, ernstige en lewensbedreigende skade. Rakende klassifikasie, is dit voorgestel dat medikasiefoute eerstens geklassifiseer word volgens die node van medikasie-behandelingsproses (medikasievoorskrif, -transkripsie, -reseptering, -toediening, -dokumentering en -monitering), en tweedens volgens die tipe fout (verkeerde pasiënt, verkeerde medikasie (met afwykings ten opsigte van die middel), verkeerde roete, verkeerde tyd en weglating). Ten opsigte van die gebruik van ’n gestandaardiseerde ernstigheidsgraadskaal, word die gebruik van die NCC MEPR-skaal aanbeveel, met inagneming van klein aanpassings.

Sleutelwoorde: medikasiefout; medikasietoedieningsfout; definisie van medikasie-toedieningsfout; klassifikasie van medikasiefout; ernstigheidsgradering van medikasiefoute.

LIST OF ABBREVIATIONS

ANA:	American Nurses' Association
CASP:	Critical Appraisal Skills Programme
CQI:	Continuous Quality Improvement
EPPI:	Evidence for Policy and Practice Information
HIQA:	Health Information and Quality Authority
HREC:	Health Research Ethical Council
HSERC:	Health Science Ethics Review Committee
NCC MERP:	National Coordinating Council for Medication Error Reporting and Prevention
NuMIQ:	Nursing and Midwifery Inquiry for Quality
PICO:	Patient, Intervention, Comparison, Outcome
PICOS:	Patient, Intervention, Comparison, Outcome and Study design
PRISMA:	Preferred Reporting Items for Systematic reviews and Meta-analysis
SPSS:	Statistical Package for the Social Sciences
UK:	United Kingdom
USA:	United States of America
US:	United States
WHO:	World Health Organization

CHAPTER 1 - STUDY OVERVIEW

1.1. Introduction and background

Medication errors are a highly prevalent problem in the health care setting (World Health Organisation ([WHO], 2016a:5). The globality of this problem is reiterated by the large amount of research on this topic (WHO, 2016a:5), with recent national research indicating the same trend (Blignaut *et al.,* 2017:3610). Becker's Health Care (2018) names medication errors as the first current challenge in patient safety concerns, and the WHO's recent launch of the global campaign *Medication without harm* in 2017, rates it the third global patient safety challenge (WHO, 2018b), and this justifies the due threat of this problem to patient safety, as well as the topicality thereof in research.

According to the WHO's research cycle of patient safety, the first step in developing any intervention aimed at bettering patient safety, should be to understand the measure of harm inflicted by a patient safety issue (WHO, 2018c). This statement involves the understanding of the broad problem, which will lead to determining its attributes and finally identifying the "units" of harm. Medication administration errors as a unit of harm, under the umbrella term of medication errors, have been rated by various methods or systems that fragment the consistency in the severity rating and thus the measure of harm done by these errors. Consequently, it should be asked how medication errors are rated, and more specifically – how medication errors are rated in terms of severity of consequences.

Medication errors are a highly prevalent and potentially lethal problem in the global health care setting. According to the WHO (2014d:2) harm is experienced by one in ten hospitalised patients in developed countries while in developing countries this number is estimated to be higher (WHO, 2014:2d). Various studies conducted on medication errors in developing countries support this notion (Alemu *et al.*, 2017:69 Ava *et al.*, 2013:1; Blignaut *et al.*, 2017:3610; Chua *et al.,* 2009:222; Ding *et al.*, 2015:38; Fathi *et al.*, 2017:5; Feleke *et al*, 2015:7; Jennane *et al*, 2011:1; Nguyen *et al.,* 2015:2).

Alemu *et al.* (2017:68) summarized medication administration error prevalence in public hospitals in Southern Ethiopia to be 71 %; while in Iran up to 70 % prevalence of administration errors have been reported (Ava *et al.,* 2013:[4]), and recently in South Africa Blignaut *et al.* (2017:3610) demonstrated that 94 % of patients in public hospitals in the Gauteng Province experience a medication administration error.

Besides the obvious prevalence of this problem, its occurrence is not limited to adult populations. Research indicates high rates of medication errors in paediatric patients (Miller *et al.,* 2007:123; Gonzales 2010:561), as well as the most vulnerable of populations, such as neonatal (Chedoe *et al.*, 2007:512; Truter *et al.*, 2017:5) and geriatric patients (Ernawati *et al.*, 2014:413).

Paediatric patients are often victims of this problem due to difficult medication calculations as Truter *et al.* (2017:5) attribute 26% of medication errors to miscalculations. Miller *et al.* (2007:123) demonstrated in a systematic review of medication errors involving paediatric patients, that in the process of delivering medicine to children, at least 5 – 27 % of those orders are in err. Gonzales' (2010:561) literature review regarding paediatric populations supported the notion of high error prevalence. Geriatrics, due to polypharmacy and other factors, are prone to medication error, as noted by Fialová and Onder (2009:67).

The effect of medication errors runs throughout society. This problem has devastated human lives, and impacted countries economically as well. According to the ground-breaking report by the United States' Institute of Medicine, *To err is human: building a safer health system,* between 44000 and 98000 people die preventable deaths annually (Kohn *et al.* 2000:26). Further, Makary and Daniel (2016:2) concluded in an analysis of the leading causes of death in the United States, that "medical errors" rate at an alarming position number 3, while in the United Kingdom, Agyemang and While (2010:380) indicated the incidence of medication errors in hospitals to be 10 to 20 %.

The economic impact of medical and medication errors cannot be overlooked. An estimated $2 Billion is spent on these errors in the United States of America ([USA] Kohn *et al.* 2000:27), while Agyemang and While (2010:380) indicated that an average hospital may spend a further £1.6 million on medication errors. Also, Choi *et al's.* (2016:428) review of literature indicated a treatment cost of medication error per patient of $8439. Consecutive studies to these effects substantiate the high cost and economic impact of medication errors (Walsh *et al.* 2017:481). These researchers however refute the quality of studies estimating the economic impact of medication errors, due to high variability in terminology, contexts and parameters used. Despite this, Walsh *et al.* (2017:496) agree that evidence suggests high, unnecessary costs and detriment to human life due to medication errors.

Judging from the abovementioned statistics, the reality and severity of medication errors cannot be ignored and warrant extensive research to explore the elusive areas of the problem.

The scientific community has stepped up to the challenge since the release of the previously mentioned Institute of Medicine Report that spearheaded extensive research into the field of medication errors (Jolly & Atkinson, 2010:15).

The extent of research done in the field has led to the conclusion that the medication delivery system is broad, with multiple opportunities for error. Allard's *et al.* (2002:256) review of literature on medication error led to the culmination of stages of medication errors which, for the purpose of this study, represents the medication delivery system. Errors can be classified into four stages namely prescribing, transcribing, dispensing and administration (Allard *et al.,* 2002:256). Prescribing errors are common and severe (Garfield *et al.,* 2013:1151) and often a result of lack of adherence to WHO prescription writing guidelines (Sheikh *et al.,* 2017:63). Dispensing errors are also common and occur to such an extent that the exploration of automated dispensing is suggested (Adnan *et al.,* 2005:189). The final stage – administration - is considered the most error-prone of all stages (Bifftu *et al.,* 2016:2; Ernawati *et al.,* 2014:413; Jennings *et al.,* 2011:2441), and according to Westbrook *et al.* (2010:684) these administration errors are responsible for one third of all harmful medication errors patients receive. To add, Kale *et al.* (2012:933) found that 4000 of 6 million medication doses administered, result in preventable adverse drug events.

It is however important to note that medication error can stretch beyond the abovementioned stages, as Aronson (2009:599) demonstrates by adding manufacturing of medicine and monitoring of therapy as part of the system, albeit under the heading of "treatment process" in medication error. This clearly demonstrates the length of the medication delivery system, and the many opportunities for error.

At this point, scrutiny of the definitions used in the field of medication error is appropriate, since a unique vocabulary is used in this field. Lisby *et al.* (2010:516) conclude in a systematic review of different definitions used to identify and measure medication errors, that terminology is inconsistent and therefore suggest standardisation of such definitions to improve research quality. Studies since have also experienced the same hindrance with "medication error nomenclature" and continue to suggest standardisation (Ackroyd-Stolarz *et al.,* 2006:288; Ava 2013:8; Bifftu *et al.,* 2016:6; Lisby *et al.,* 2010:516; Meyer-Massetti *et al.*, 2011:238; Radley *et al.,* 2013:470; Walsh *et al.,* 2017:495).

Many common terms exist that are regularly used when patient safety in connection with medication is addressed. Yu *et al.* (2005:358) have identified 25 such terms which include

“adverse drug event”, “adverse event”, “medication error”, “medical error” and more of the like. After differentiating the meaning of each term as different organisations have attempted to define it, Yu *et al.* (2005:362) could at best describe the findings, regarding similarities in definitions, as ambiguous.

Even though many terms are used in patient safety – all are not applicable to medication error, and more specifically to medication administration errors - as is the intended direction of this study. Hence, attention is prioritised to deal with definitions of “medication error” and “medication administration error”.

Ferner *et al.* (2006:1013) endeavoured to clarify the term “medication error” by proposing an inclusive definition which states that “medication error is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient”. Aronson (2009:599) also used this definition in his paper on medication errors, while Kavanagh (2017:159) referred to a definition coined in 2009 by the National Patient Safety Agency that describes a medication error as “any incidence where there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing medicine advice, regardless of whether any harm had occurred or was possible.”

These definitions provide a vital exclusivity to the problem being addressed in this study – namely medication administration errors. Both these definitions aim to be inclusive of all possible areas of error in the medication delivery and name the stages “where” medication error can occur. It is specifically at the stage of “medication administration” that the focus is intensified.

As previously mentioned, definitions are vital to direct research. Even though the “medication error” field is wrought with confusing and incoherent definitions and terms, defining these terms from a nursing perspective has also not reached consensus. Many studies refer to the definition of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), which defines a medication error as “…any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use” (NCC MERP, 2018a).

But this definition still is too wide to focus on the act of medication administration that a nurse undertakes. To do so, researchers in the field refer to the five rights of medication administration which McBride-Henry and Foureur (2006:34) deduced from definitions provided by Wolf (1989). These five rights of medication administration are still referred to by Kavanagh (2017:162) as the following: right patient, right medication, right dose, right route and right time, but also adds the right reason, right form, right action, right documentation and right response as prescribed by the Health Information and Quality Authority (HIQA) of Ireland (2015).

Essentially the five rights of Medication Administration is a key guideline to nursing practice to ensure safe medication administration (Kim & Bates*.,* 2013:591). Nursing textbooks also refer to the five rights of medication administration in the context of the nurse's duty to administer medication (Berman *et al.,* 2008:849 & Lynn, 2008:153). Hence, for the purpose of this study, deviation from these guidelines constitutes a medication administration error in nursing.

Nurses, as part of the multi-professional team, are the major administrators of medication to patients (Reid-Searle *et al.,* 2010:226), and thus most commonly the committers of medication administration errors . Mosby's Dictionary (2009:1160) also refers to medication administration as a nursing-specific activity. Nurses can therefore be regarded as the final agent in the medication delivery system. This can be attributed to the fact that nurses spend most of their time administering medication. Leufer *et al.* (2013:214) summarised that medication administration is the most frequently undertaken nursing activity and consumes up to 40% of a nurse's clinical time. Unfortunately, even though this large portion of clinical time is spent on medication administration it has not resulted in ultimate safe patient care as Baghaei *et al.* (2015:15) found an error rate of 94.1%.

In addition, Balas *et al.* (2004:228) investigated the nature and prevalence of medication errors made by hospital nursing staff. They found that only one third of the nurses reported errors and indicated that they made at least one definite error or near error in a 28-day period (Balas *et al*., 2004:228). These errors were reported, and hence are subject to nurses' personal decision to report. By direct observation, the rate of errors can possibly be even higher. Bertdot *et al.* (2016:342) concluded in a systematic review of medication administration errors detected by direct observation method that errors are frequent.

Besides the high rate of medication administration errors, some deviations from the five rights of medication administration are more common than others. Blignaut *et al.* (2017:3610) found

a higher prevalence of dosing errors as well as wrong-time and omission errors. Truter *et al.* (2017:5) have also found dosing, omission and wrong-time errors to be most frequent in a paediatric unit in South Africa. Research by Sheikh *et al.* (2017:63) concluded on medication errors and adherence to prescription writing guidelines that the most common medication administration errors that occurred were omission errors – and specifically in medication classes of antibiotics and bronchodilators. Within the context of serious antibiotic resistance developing world-wide (WHO, 2018e) these errors can have far-reaching consequences.

Clearly the act of medication administration by nurses is an error prone task. This begs the question: why is this stage of medication delivery so error prone and what causes nurses to commit medication administration errors? In a systematic review of causative factors, Keers *et al.* (2013a:1045) list workload, interruptions, patient factors such as acuity, communication factors in prescription and transcription, medication factors such as wrongly dispensed medication, nurse health status and interruptions, as possible causes. Fathi *et al.* (2017:5) substantiate by listing nurses' heavy workload and low nurse to population ratio as major causes and risks in medication error. Blignaut *et al.* (2017:3610) also observed an increased risk for medication error as patient acuity rises.

Evidently, the causes of medication errors are much broader than listed above and include many factors which contribute to the problem. Blignaut (2015:67) combined the following list of factors in table 1.1. contributing to medication administration errors from 70 literature sources:

Table 1.1 Factors contributing to medication administration errors.

Human factors	**Order-related factors**	**Medication-related factors**	**Environmental factors**
➢ Knowledge, educational or training deficit; ➢ Procedures or policy not followed (e.g. not checking the five rights); ➢ Inexperience (including having to work in different, new shifts);	➢ Communication lapses between the physician and the medication administrator; ➢ Communication lapses between the pharmacist and the medication administrator; ➢ Misunderstood orders;	➢ Look-alike medication labels or packaging; ➢ Look-alike or sound-alike medication names; ➢ Wrong medication provided by the pharmacy (including a dosage different	➢ Administering a large number of medications at peak times; ➢ Interruptions or distractions (also multitasking); ➢ Work overload; ➢ High patient to nurse ratio; ➢ High acuity level of patients;

➢ Slips or memory lapses (also negligence); ➢ Psychological factors (e.g. being stressed, emotionally exhausted, discontented or experiencing personal, familial or financial problems); ➢ Physical factors (e.g. being tired or hungry); ➢ Miscalculations of dosages; ➢ Incorrect preparation of medications (including preparing medications too early or unauthorized drug administration); ➢ Incorrect labelling of medications; ➢ Not documenting promptly; and ➢ Failure in transcription of prescriptions.	➢ Confusing instructions (including "prn" prescriptions, omitted or misplaced decimal points or zeros, confusing units of measurement, wrong dosage prescribed or interactive drugs prescribed together); ➢ Frequent changes in prescriptions; ➢ Use of abbreviations in prescriptions; ➢ Illegible prescriptions; ➢ Incomplete prescriptions (including medication charts not rewritten, route, time or dose not clear); ➢ Computerized prescribing; and ➢ Cultural or language barriers between health care professionals.	from that which is prescribed); ➢ Stock distribution problems – medications not available at the institution; ➢ A large variety of drugs are held in the medicine cabinet or medication trolleys are overstocked; ➢ Labels of medications are of poor quality, incorrect or damaged; ➢ Insufficient resources are available; ➢ Different therapeutic dosages are prescribed; ➢ Generic substitution of medications; and ➢ The pharmacy does not pre-prepare medications or mark high alert medications.	➢ Inadequate staffing; ➢ High staff turnover (new staff); ➢ Lack of supervision; ➢ Non-optimal learning climate (including absence of guidelines or supervision) or environment for medication preparation; ➢ Working more than 40 hours per week; ➢ Lack of patient information (e.g. the patient's chart being unavailable, the patient being out of the ward or allergies unknown); ➢ Uncooperative or violent patients; and ➢ Technology failures.

Thus, many factors contribute to nurses making medication administration errors. Research on contributory factors has led to a movement in finding solutions. Ample research is available on interventions and strategies implemented to reduce medication errors, and aid in the further research of this problem. Probably most prominent of these are the reporting of medication administration errors. Though not necessarily directly related to reduction of medication administration errors, it is vital to better understand the problem and find solutions by learning from them (Härkänen *et al.,* 2017:3487).

Unfortunately, error reporting by nurses is a complicated matter. Nurses refrain from reporting medication errors for several reasons. Bifftu *et al.* (2016:4) explain that administrative issues,

discrepancy in definition of a medication error and fear are common reasons. To add, You *et al.* (2015:278) have also previously documented nurses' fear of being implicated, and not recognising an error, as causation.

Failing to recognise or judging an error in a subjective way, has already been documented by Wakefield *et al.* (2005:477), who explain that the nurse's perception of the error determines recognition of and reporting of errors. McBride-Henry and Foureur (2006:38) have similarly concluded on perception issues and added fear of punitive action should they report. This leads to serious ramifications for organisations and the field of medication administration error research, as many, if not most, of errors will go unreported.

Despite poor reporting of errors hindering the progress toward a solution, different interventions have been designed which attempt to reduce errors made by nurses. Already in 2014 Keers *et al.* (2014:317) conducted a systematic review of the impact of many of these interventions. Technologies such as barcoding, electronic prescriptions and automatic dispensing of medication, as well as learning interventions for nurses have been shown to be successful in reducing medication administration errors. However, Berdot *et al.* (2016:349) in their review of strategies to reduce nurses' medication administration errors, have found no evidence that substantiates success of these interventions.

As previously stated, according to the research cycle of patient safety by the WHO, the step prior to understanding causes of harm and identifying solutions, is to measure harm (WHO, 2018c). Is it possible that solutions to the problem in this regard have proven to be ineffective, due to a lack in the measurement of the problem? It can be hypothesised that for solutions to the problem to be effective, a true measure of the harm needs to be determined. This requires of researchers to understand what the problem truly is and what specifically to focus on. Hence, a means to a measure is needed – a severity rating scale.

But, how are medication administration errors measured? According to the WHO (2018f) calculating the number of patients harmed by health care, as well as the types of events that cause the harm to patients are the essentiality of measuring harm. Determining the incidence of medication errors would be an initial step as Blignaut *et al.* (2015:123) noted. As already established earlier, studies on this topic are numerous and indicate that the prevalence and incidence of medication error in various settings are high (Alemu *et al.*, 2017:27; Ava *et al.*, 2013:21; Blignaut *et al.*, 2017:3610; Chua *et al.,* 2009:222; Dinge *et al.*, 2015:38; Fathi *et al.*, 2017:5; Feleke *et al.*, 2015:7; Jenanne *et al.*, 2011:32 and Nguyen *et al.,* 2015:2).

Further, with high incidence of medication errors and the different types of medication administration errors established, determining which are more important than others is the next step in measuring the harm. Hence the need for a rating of medication administration errors by means of a severity rating scale is emphasized.

It has been noted that many researchers refer to the “severity” of medication administration errors. The impression is that researchers view this attribute of medication administration error as menial and hence qualify severity of medication errors haphazardly. Williams and Ashcroft (2009:319) questioned the reliability of severity ratings of medication errors and concluded that they differ significantly among health care professionals, and hence suggested development of a reliable severity rating scale.

The WHO (2016a) also recognises that “severity” may be a method used to rate medication errors, but also note the lack of mutuality between ratings. Albeit concerned with medication errors in broad terms, the severity rating of medication administration errors can be judged under this heading as well. Consequently, this attribute, severity rating, of medication error and specifically medication administration error, is the focus of this study.

1.2. Problem statement

Medication errors are a substantiated problem in health care. It poses a great threat to patient safety (WHO, 2016a:5). Research on this topic has elucidated many of its problem areas and sparked endeavours toward solutions. One of these areas, under the umbrella of medication error, is a nursing specific activity (Reid-Searle *et al.,* 2010:226 & Shawanha *et al.,* 2016:412) which contributes greatly to the problem – medication administration.

Medication passes through several stages before it reaches the patient (Aronson, 2009:599 & Allard *et al.,* 2002:256). The final stage of medication administration to the hospitalized patient is the most vulnerable to errors of all stages (Baghaei *et al.,* 2015:15; Bertdot *et al.*, 2013:1; Bifftu *et al.,* 2016:2; Ernawati *et al.,* 2014:413 & Jennings *et al.,* 2011:2441).

Many studies have been dedicated toward determining the incidence and prevalence of medication administration errors (Alemu *et al.*, 2017:27; Ava *et al.*, 2013:21; Blignaut *et al.*, 2017: 3610; Chua *et al.,* 2009:222; Dinge *et al.*, 2015:38; Fathi *et al.*, 2017:5; Feleke *et al*, 2015:7; Jenanne *et al*, 2011:Abstract; Nguyen *et al.,*2015:2), who have found prevalence to be high. Research has also been done to determine the causes of medication administration errors (Blignaut, 2015:67; Fathi *et al.,* 2017:5 & Keers *et al.*,2013:1045), as well as various

barriers and issues in reporting of errors (Bifftu *et al.*,2016:4; McBride-Henry & Foureur, 2006:38; Wakefield *et al.*, 2005:477 & You *et al.*, 2015:278). Finally, dedication toward solutions in literature is prominent (Keers *et al.,* 2014:317), but has however proven to be limited in efficacy (Berdot *et al.*, 2016:349).

Considering the research cycle for patient safety by the WHO, measuring harm is the essential step before understanding the causes or determining solutions (WHO, 2018g). In the measurement of this problem, it has been observed that terminology and methods to a measure are problematic. Foremost is a lack of concise terminology and description of medication administration errors (Ava 2013:8; Bifftu *et al.,* 2016:6; Lisby *et al.*, 2010:516; Meyer-Massetti *et al.*, 2011:238; Radley *et al.,* 2013:470 & Walsh *et al.,* 2017:495). "Severity" is one of these terminologies used in the description and rating of medication administration errors (WHO, 2016a:4). This term is found to be wrought with subjective perceptions (McBride-Henry & Foureur., 2006:38; Wakefield *et al.*, 2005:477 & Williams and Ashcroft, 2009:319) and lack mutuality across ratings (WHO, 2016a:4).

Non-concise terminology has shown to their detriment nurses' perception and reporting of errors (Shawahna *et al.,* 2016:413). A lack of consistent and reliable severity rating for medication administration errors (Williams and Ashcroft, 2009:319) has led to few studies referring to severity (Ava *et al.,* 2013:9), even though many rating scales for medication errors exist (Dean & Barber, 1999:57, Taxis *et al.*, 2002:239; NCC MERP, 2018a & Westbrook *et al.*, 2010:685).

Throughout literature, researchers committed to this topic, have mentioned the issue of discrepancy in medication error terminology (Ackroy-Stolardz *et al.,* 2006:288; Ava 2013:8; Bifftu *et al.,* 2016:6; Lisby *et al.,* 2010:516; Meyer-Massetti *et al.*, 2011:238; Radley *et al.,* 2013:470 and Walsh *et al.,* 2017:495) and inconsistency in severity rating of medication administration errors (McBride-Henry & Foureur, 2006:38; Wakefield *et al.*, 2005:477 & Williams and Ashcroft, 2009:319 & WHO, 2016a:4) in this research area, possibly due to the numerous methods or tools to rate the severity of medication errors. No concise and comprehensive severity rating scale is available to adequately determine harm caused by medication errors.

1.3. Research questions

From the problem statement above, the following research questions follow:

- How can the concepts “severity” and “medication error” be defined in the context of nursing medication administration errors from a review of literature?

- How can medication errors be categorized from recent literature?

- What constituents could be summarized to develop a comprehensive medication administration error severity rating scale?

1.4. Aim and objectives

The research aims for this research study are as follow:

The aim of this study is to identity elements to be included in a comprehensive medication error severity rating scale.

The three research objectives include the following:

- To explore and describe the concepts of “severity” and “medication error” in the context of nursing medication administration errors, by means of a review of literature; and

- To explore and describe the categorization of medication errors in recent literature; as well as

- To provide a summary of constituents required in the development of a comprehensive medication administration error severity rating scale.

1.5. Research design

Research design is a common term used in research literature and seems to be at times used interchangeably with the term “study design” and “research approach”. Creswell (2014:3) best simplifies the definition of research design as a broad way of investigating something. This overarches the research method – the specific ways of arriving at an answer by the process of gathering data, analysing, and interpreting findings, while being rigorously disciplined in the steps to arrive at the answer (Botma *et al*., 2010:199); and is ultimately informed by the research problem and question that have been identified to represent a knowledge gap (Creswell, 2014:3).

The approach to addressing the knowledge gap in this study, is a systematic review, which incorporates quantitative and qualitative aspects of data synthesis.

1.6. Theoretical framework

A theory is defined by Brink *et al.* (2012:21) as a systemic explanation of a phenomenon which is described by statements. Burns and Grove (2005:754) detail their definition of theory as a view of a phenomenon, consisting of defined concepts and statements. These can be used to control, explain, describe and predict a phenomenon (Burns & Grove, 2005:754). To add, Botma *et al.* (2010:187) refer to "themes" in research and indicate that the researcher should acknowledge the interrelatedness of their research to already existing research and how the topic fits into a broader theoretical framework.

When considering the theory applied to a certain phenomenon, a model is used to schematize and structure the abstractness of a theory as Brink *et al.* (2012:26) explain, which can then be applied to reality.

In the light of the topic of this research namely medication administration error, it is regarded as a patient safety issue in the health care setting (WHO, 2018b). Hence, the application of a patient safety model as theoretical basis for this study is suitable. Emmanuel *et al.* (2008:14) suggested a patient safety model for health care, from which to investigate aspects of patient safety, such as the severity of medication administration errors, as depicted in figure 1.1.

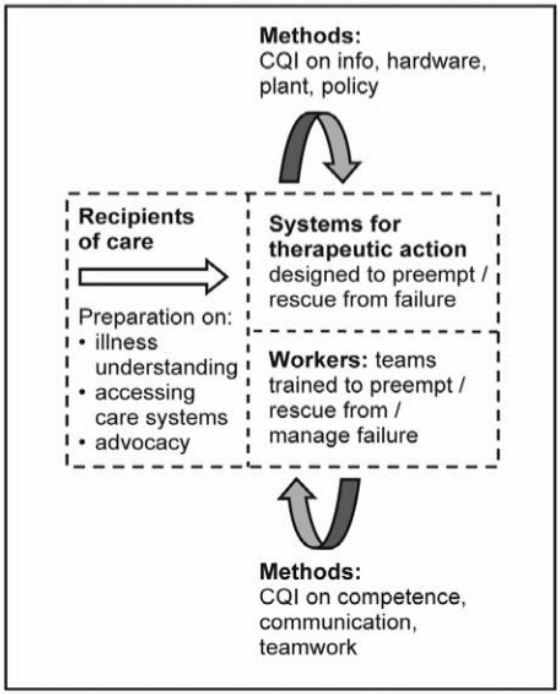

Figure 1.1 A patient safety model (Emanuel *et al.,* 2008)

In this model there are four depicted domains: the workers in health care, the recipients of health care and stakeholders, the systems and infrastructure for therapy interventions and the

methods used for continuous feedback to improve on quality by means of continuous quality improvement (CQI) (Emanuel *et al.,* 2008:14). The model indicates the interrelationship between the different domains and the environment by broken lines separating them (Emanuel *et al.,* 2008).

It is with this theoretical assumption of patient safety issues, that research regarding the severity of medication administration errors is conducted. Specifically, the focus is on the domain of systems for therapeutic action, as it is attempted to enhance the system of health care delivery by improving on the severity rating of medication administration errors.

1.6.1. Concept clarification

Concept clarification specific to this study will follow in this section.

Medication – a substance or drug used for healing (Mosby Dictionary, 2009:1160).

Medication administration – the preparing, administering, and evaluating of medications, whether prescribed or not prescribed, as a nursing-specific activity (Mosby, 2009:1160).

Medication error – "any incidence where there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing medicines advice, regardless of whether any harm has occurred or was possible" (Kavanagh, 2017:159).

Medication administration error – a deviation in the five rights of medication administration as a nursing-specific activity, which include deviation from Kavanagh's (2017:162) summary which include: right patient, right medication, right dose, right route and right time, but also adds the right reason, right form, right action, right documentation and right response.

Severity rating – a method of scoring medication errors WHO (2016:4a), by rating the intensity of or the severity of the medication error based on set criteria.

1.7. Meta-theoretical assumptions

1.7.1. View of the world

The world was created and is sustained by God. It was intended to benefit and consequently improve the life and wellbeing of its human inhabitants, as well as bring glory to its Creator. With the fall of man into sin, harm and error were manifested into this world and into every aspect of life. Consequently, the world is filled with manifestations that cause disease, pain

and deterioration to the world and its inhabitants. Medication administration errors is a type of harm manifested within the health care context.

In the context of this study, the world is seen as the health care setting, where nurses, as well as other health care personnel, and patients as its inhabitants, interact with each other by giving and receiving therapeutic interventions. Medication administration is thus such a therapeutic interaction, which has become wrought with error – causing harm to the receivers of the intervention, in ranges of severity.

Assuming the steadfastness of errors and the harm caused by them in this world, it is paramount for the administrators of medication to know their errors, be able to judge their severity and consequently strive to reduce and prevent their errors.

1.7.2. View of man

"Man" is an inhabitant of this world. In the context of the study, "man" is seen in two distinct roles: the administrator of therapeutic interventions namely the health care provider; and the receiver of therapeutic interventions, namely the patient.

Man is an autonomously functioning entity, who chooses to guide and gauge their behaviour in the world by divine principle and leading such as that of the Holy Spirit, and worldly guidelines such as policies, procedures, rules and regulations.

In the context of this study, man is the therapeutic agent with administrator behaviour in error by the standards of medication administration, thus causing a medication administration error. The receiver of care is the recipient of the error and harm is the outflow of the medication administration error.

By considering the severity of the medication administration error, both the administrator and recipient of medication can understand better the consequences of errors and take steps to address the severest and most harmful errors.

1.7.3. View of health

Health is a state of physical, mental, spiritual and social wellbeing. Berman *et al.* (2008:295) explain that traditionally "health" would be the absence of disease of infirmity but is now a much more personal and comprehensive definition. Essentially health is seen as the

subjective state within which receivers of care find themselves. The administrator of care can either improve or detriment the state of health by their interventions.

In light of this study, the “health” of the patient or receiver of medication, is damaged by various medication administration errors, in various degrees of severity.

1.7.4. View of nursing

Nursing is the art of caring for an individual or individuals in areas of their lives which they may not be able to do permanently or temporarily. Berman *et al.* (2008:11) refer to nursing in various themes such as an art, a science, a holistic and adaptive profession. Hence nursing is seen in the context of this study as the provision of therapeutic intervention, specifically administration of medication, with the intention to cause minimal or no harm in the quest to improve health of the recipient.

1.8. Research method

Under research method, the protocol and registration of the systematic review, eligibility criteria for research articles, the search strategy, data collection process, data coding, synthesis of results and research dissemination will be discussed.

1.8.1. Eligibility criteria

Deciding the eligibility of research articles, the inclusion and exclusion criteria of studies act as determining factors for eligibility. To inform the inclusion and exclusion criteria, the review question and the PICOs statement were used:

Population: the phenomena of medication errors;

Intervention: the use of a tool or method to rate the severity of a medication error;

Comparison: there is no intervention to compare to, therefor not applicable; and

Outcome: a measurement of severity.

The PICOS statement was used to create three simple questions which were used to decide the eligibility of research documents to include in this review. This is further explained under the search strategy.

1.8.2. Search strategy

The search strategy of this review includes the approach to search and the inclusion and exclusion criteria.

Many authors suggest foremost the use of online databases (Gerrish & Lacey, 2010:290; Grove *et al*., 2013:476; Parahoo, 2010:139). Online databases available to the North-West University which were used for this study are the following: EBSCO-host, Scopus, Web of science, SA-epublications and Pubmed central.

Gerrish and Lacey (2010:291) emphasise a sensitive search strategy which will be sensitive to include all possible studies, but also very specific to include highly relevant studies. The search terms that were used to search online databases were derived from the PICO-statement as already discussed. The terms that were included in the database searches were the following:

(Medication) AND (error OR mistake) AND (nurse*) AND (severe* OR harm OR serious* OR extent)

The subject expert as well as the subject librarian were consulted on the search terms used and consensus was reached that it would most likely lead to the sought-after research documents.

The meticulous documentation of searches, identification of relevant studies and onward screening of those studies, deciding on their eligibility for inclusion and final inclusion of specific studies for use in the review, necessitated a documentation system. Authors (Grove *et al*., 2013:476 & Polit & Beck, 2012:666) suggest the use of the PRISMA flow-chart for this purpose.

As part of the search strategy, the software programme named The Evidence for Policy and Practice Information-reviewer (EPPI-reviewer) was applied. EPPI-reviewer is an essential tool in the organisation and tracking of information (Gough *et al*., 2012:106). The Cochrane Community (2018) values the use of EPPI-reviewer due to its encompassing features and functions that enables authors to write complex reviews.

In the search for studies, the first phase of the PRISMA flow chart was utilised – namely identification and documentation accordingly. The EPPI-reviewer programme was utilised to

assist in managing the large volume of articles and to exclude duplicated studies or articles. This was done with the assistance of an experienced EPPI-reviewer user.

Ensuring that all relevant research documents were included in this review, inclusion and exclusion criteria were developed and applied to all research documents obtained after the search of online databases with the specified search terms. The inclusion and exclusion criteria applied follows:

Inclusion and exclusion criteria:

Inclusion criteria are a fundamental aspect to consider when deciding on what studies to include in the systematic review and which not. These criteria necessitate the determination of specific characteristics of studies such as the publication year, language and study design (Gerrish & Lacey, 2010:289), and set explicit boundaries to the specific data sought from research studies. The inclusion criteria will have an effect on the validity and generalisability of the review result (Parahoo, 2010:138), and must therefore be explained and explicitly stated.

During the first phase of the search, the following inclusion criteria were applied:

- research articles about medication- and medication administration error with a nursing context or reference;
- research articles which used a tool or scale to determine the severity of those medication errors; and
- articles that had an outflow of measurement of those errors.

Excluded documents were as follow:

- research documents did not refer to the administration of medication by humans;
- research documents on the subject that did not contain any reference to a severity rating scale or method;
- research documents that did not have a measure of severity;
- any grey literature; and
- research documents published more than five years ago (at the time of review), were not attainable without cost and were not translatable.

To simplify this process, three questions were designed which embodied the inclusion criteria for the review:

1. Is the main theme of the article medication administration errors or medication errors?
2. Did the article make use of a severity rating scale or tool to measure the errors, which produced a “measurement” of severity?
3. Are the errors referred to in the nursing context?

Addendum B contains the eligibility table, demonstrating the selection of studies based on the three eligibility questions and is further explained in chapters 2 and 3.

1.8.3. Study selection

Gerrish and Lacey (2010:289) list the process of quality assessment of studies and articles as the next step in the systematic review. This step follows in the PRISMA flow chart in the phase of screening and eligibility – where duplicates are removed (by means of EPPI-reviewer and hand searching) and studies assessed for their eligibility to be included in the study.

As already described, the list of obtained research articles was firstly sifted automatically and by hand. Relevant titles were sifted, after which abstracts were read and articles included and excluded according to relevancy. The final list of articles was scrutinised according to the three questions to ensure that the content of the research article was relevant to the research questions.

To follow, the included articles were subjected to scrutiny regarding their scientific attributes and quality. To execute this step, Botma *et al*. (2010:244) suggest the use of a second person or expert to judge the articles selected, as well as the use of specific tools to assist in discerning the scientific standard of the study or article. Institutions dedicated to quality health care and best practice information provide tools for critical appraisal. These include the likes of the Critical Appraisal Skills Programme (CASP) (2018) the Joanna Briggs Institute (2017) and the Johns Hopkins Centre for Evidence Based Practice.

However, due to the uniqueness of the research reports required for this study, the quality appraisal checklist as compiled by Alan and Barker was used. This checklist is described by Alsherhi *et al.* (2017:873), and is discussed in detail under 2.2.2.3.

1.8.4. Data-collection process

Data extraction is concerned with the consequent and consistent capturing of specific data from each study included in the systematic review (Gerrish & Lacey, 2010:289). Basically, the

sought-after information is extracted from the research study and compiled with all the other extractions, by means of a specific tool (Ten Ham-Baloyi & Jordan, 2015:124).

Tools can be developed to assist in retrieving the relevant information from the studies. Suggested data to incorporate into the tool are the type of report or article, the year of publishing, methodology such as the sample size (Polit & Beck, 2012:659), more specifically pertaining to the study – the PICO criteria (Ebling Library, 2018), and most importantly the study findings (Polit & Beck, 2012:670).

The following preliminary data-extraction table 1.2 has been developed which is believed to address the review question. This table provides a broad overview of the specific constituents sought after in the research articles.

Table 1.2 Preliminary data extraction table

Research report title and author	Year of publish	Type of research document (study, policy etc.)	Type(s) of medication administration error investigated	Deviation in the five rights of medication administration	Definition of severity used	Tool/method used to determine severity of error	Described characteristics of the method/tool used	Author' s perception of the severity of the medication administration error

Refinement of the data extraction table led to the development of three tables, which focus on the three main constituents sought after in the research articles. Firstly, is the table concerned with the definitions of medication error and severity used within the study. Secondly is the table seeking the classification of medication errors – specifically what medication errors have been researched in the article and what were the findings. Thirdly is the table regarding the severity rating tool used in the article and the constituents thereof. These tables are presented in chapters 2 and 3.

1.8.5. Data items / Data coding

Heuristic data coding involves the discovery of "meaning" within qualitative data, without specific formulae (Saldaña, 2016:9). This implies the cyclical and dynamic process which data is subjected to in order to find the meaning and linking of data (Saldaña, 2016:9) – with a flexible approach.

Data pertaining to the definition of severity ascribed to medication errors and "severity" in various research articles; the classification of such medication errors in terms of the type of error and the severity rating scale used to rate these errors and the constituents thereof, were the data items sought in the research.

These data items were extracted as explained above, and then subjected to coding, to establish recurring themes. This process was facilitated by the use of tables and graphs to represent the main themes identified and to enhance the interpretation and description thereof – which follows in the synthesis of the results.

1.8.6. Synthesis of results

A meta-synthesis approach was used in this review – specifically thematic synthesis. This method is described by Snilstveit *et al.* (2012:414) to be sufficient to synthesise data from qualitative and quantitative studies and represent findings in tables and charts.

The three-step process by Thomas and Harden (2008:4) suggests coding of text, descriptive theme development and analytical theme generation. This process of thematic synthesis was used to finally answer the research questions and conclude on the review.

1.8.7. Research dissemination

Regarding dissemination of research results, Brink *et al.* (2012:58) define research dissemination as the communicating of research findings to audiences it is intended for, in an appropriate way. They suggest a comprehensive research report that explains the whole research process as well as the results of the study. Clear, concise, accurate and objective information is emphasised, and the report should hold scientific value to the scientific community (Brink *et al.*, 2012:58).

Dissemination of the research is, according to Sharma (204:336), the pinnacle of the whole research process. This can take many forms which include a research report, oral presentation or a poster presentation (Gerrish & Lacey, 2010:480-484), the most common being the research report (Sharma, 2014:336).

For the above-mentioned reason, this systematic review research report will be disseminated in the form of a scientific article about the method used and the result it attained in the discovering of the severity ratings of medication administration errors. This report will be completed when the review is finished and has been approved by the institution for publication. The targeted audience is the scientific community purposed in the line of medication error research, to contribute to the body of knowledge in these regards.

Yet, before this dissemination can happen, the research study project is to be examined by the institution within which it was produced - in this case, the North-West University. The dissemination of research findings in terms of chapter layout will be discussed in following sections.

1.9. Rigour

Maintaining and adhering to procedure, accuracy and consistency is the basis for rigour and the ultimate determinant of the strength of a research design (Gerrish & Lacey, 2010:532). The systematic review requires as much adherence to rigour and standards as any other study.

To maintain rigour in this study, it is foremost important to develop and adhere to the review protocol, as already discussed. This already is a substantial step as the review protocol must be transparent and reproducible, hence leaving little to no room for making assumptions about the results of the review to suit the researcher's preferred overall outcome for the study.

Secondly, experts and a subject librarian were consulted throughout the development of the review protocol and in the execution of the review. Scientific resources on the methodology of the systematic review have been used throughout the process. A detailed bibliography is provided to make sure all sources used and consulted, are traceable to any reader.

1.9.1. Risk of bias in individual studies

Influences that will ultimately impact the outcome of a study, by misinterpretation or misrepresentation of results, are defined by Brink *et al*. (2012:208) as bias. Polit and Beck (2012:176) list common reasons for bias and name researcher's subjectivity, inadequate study design and flawed implementation as some. Others, such as sample imbalances and participant influences (Polit and Beck, 2012:176), are reasons not concerning this study. Burns and Grove (2005:213) clearly state the importance of identifying possible sources of bias and implementing measures to prevent them from influencing research outcomes.

Regarding researcher bias - Gerrish and Lacey (2010:289) name the need for a second reviewer upfront. For this reason, a second reviewer – the subject expert – has been involved in various steps of this review.

Critical appraisal of research articles by a researcher can also be a source of bias. To limit this threat to rigour, the researcher used a set tool to equally evaluate all prospective included studies – thus the same criteria for inclusion was used to appraise studies for inclusion and bias in individual studies mitigated. An internationally recognised appraisal tool was used to this end.

1.9.2. Risk of bias across studies

Liberati *et al.* (2009) states that bias across studies can influence the accruing evidence of a review by means of selective reporting and publication bias.

Bias was reduced using a variety of data bases from which to obtain research reports. Also, resource lists of included reports were scrutinised for possible inclusion of other reports. Critical appraisal was done using a reliable tool.

1.10. Ethical considerations

Ethical considerations have become a pertinent and prudent part of research. Considering institutional as well as national policies and guidelines on ethical research conduct are vital to ensure quality research. Ethicalities in research provide a safety net not only for the participants and the community within which research is conducted, but also for the researcher and research community.

In South Africa, the National Health Research Ethics Council (HREC) was established as the research ethics executive, which birthed from the National Health Act 61 of 2003 (Brink *et al.,* 2012:34). From the HREC, research institutions such as the North-West University developed their own committees and guidelines to ensure ethical standards in research are upheld.

Ethical standards in research with human participants or animal subjects are comprehensive and specific. According to Brink *et al.* (2012:34) these fundamental principles namely beneficence, justice and respect for persons should be upheld during the entire research process. These principles apply heavily when qualitative and experimental research is undertaken, but in the case of a systematic review such as is the case of this study, guidelines are less concise since the participants in the study are neither human nor animal. Regardless, ethics still apply to the systematic review.

Wager and Wiffen (2011:130) explain that in the process of preparing and publishing a systematic review, many authors are left without significant guidelines on ethics. They suggest authors pay attention to factors such as duplicate publications, plagiarism, transparency and accuracy when dealing with publications and studies.

From literature it becomes apparent that most authors on the topic of ethics in systematic reviews refer to reviews done to add to evidence-based practice or synthesising the data from studies to come to a medicinally therapeutic conclusion as Grove *et al.* (2013:468) explain.

Ethics in reviews that use human participant studies, require ethical questioning since some of the studies might be unethical in some respects (Vergnes *et al.,* 2010: abstract).

According to the Research Ethics Guidebook (2018), ethics in systematic reviews are important, as it is not always clear what ethical considerations the author of the review article has used in their research. They therefore suggest asking oneself questions regarding how existing work or the researcher will be treated to ensure fairness and accuracy; as well as whether the research being reviewed raises ethical problems (The Research Ethics Guidebook, 2018).

In addition to continuously questioning the research being reviewed, aspects such as the ethics committee of the institution the study is being done at, the scientific committee, bias and plagiarism contribute to making a study ethical. The ethics committee is a selected group of experts at an institution, whom are responsible for reviewing the research proposals of prospective masters and doctoral students. Brink *et al*. (2012:45) explain that their role is to review proposals for possible unethical conduct which might harm society. A checklist is used to determine these factors and can serve as a guide to researchers when preparing their proposals.

Again, these guidelines focus mainly on human participant studies, and aim to protect the rights of the participants. But, also the adherence to scientific standards can be an ethical issue. Brink *et al*. (2012:43) state that ethical standards should be upheld in protection of scientific integrity. This particularly pertains to fabrication of information, manipulation of methods used, manipulation of data in any way and plagiarising.

In this systematic review, it was possible for the researcher to fabricate information to suit the expected outcomes of the study. The researcher could have also manipulated data obtained to ensure that some score of severity is achieved, even if the review concludes on no severity rating. Also, the researcher could have plagiarised information from other authors and even manipulated the review protocol already developed, to suit the desired outcome. All of these could be considered as unethical behaviour in research.

To ensure ethicality in these regards, this researcher aimed to firstly submit the research proposal to the ethics and scientific committee to ensure ethical standards were maintained. The proposal was accepted by the Health Science Ethics Review Committee (HSERC) (Approval number: NWU – 00095 – 18 – A1). Concerning plagiarism, the researcher made

every effort to prevent this and used technology provided by the university to scan for and locate plagiarised wording, which could be corrected.

To prevent manipulation of the review protocol and ultimately the research methodology, the researcher rigorously stuck to the review protocol, no matter the outcome of the review. Articles selected were appraised before being included – this ensured that unethical studies could be detected and removed. The appraisal tool used is internationally respected and therefore added to an attempt to keep the appraisal unbiased from the researcher's side. Also, a second reviewer was used to ensure an unbiased approach and appraisal of studies.

As previously stated, Wager and Wiffen (2010:133) emphasise being transparent about the research. This involves stating all contributors to the research, regardless of what the contribution may have been. This is to declare conflicts of interest and possible bias that might have developed (Wager & Wiffen, 2010:133).

Further, duplicate publications and ownership are also aspects to consider. Wager and Wiffen (2010:130) name authorship of a publication as important and hence will be regarded when reviewing articles in this systematic review. Duplication publication occurs when the same article is published in different journals with slight differences and can influence results of syntheses if one study is accidentally used twice. For this reason, the EPPI-review programme was utilised to electronically exclude duplicate publications and hence, aim to be ethical in gathering of data.

Wager and Wiffen (2010:133) reiterate that accurate findings should be drawn from studies. This might also require two reviewers to come to the same conclusion on the findings of the study, to prevent the researcher from skewing findings to suit his/her agenda.

Lastly, the researcher has undergone ethical training to ensure the researcher's awareness and sensitivity towards ethical issues.

1.11. Outline of chapters

Chapters in this study are outlined in a traditional fashion, followed by addenda and appendices.

Different authors suggest slightly differing structures to follow in writing the research report. Mouton (2001:112) suggests a logical flow for the layout of the research report. He suggests flowing from the research problem which is divided into chapters one (covering the background

and research problem) and two (dealing with the literature review); the research design in chapter 3 which elaborates on the methodology used for the research; evidence generated through the research in chapter 4 (discussing the results of the research) and finally the conclusions drawn, after the results are discussed, in chapter 5 (Mouton, 2001:114).

Derived from the NuMIQ (Nursing and Midwifery Inquiry for Quality) template, there are two formats that can be followed: the research article format, and the traditional format. The traditional format was chosen for this research report, although the second chapter which is traditionally a literature review will describe the research methodology in more detail seeing that the entire study is a review. The following chapters are included:

Chapter 1: Overview of the study

Chapter 2: Research methodology

Chapter 3: Study findings

Chapter 4: Evaluation of the study and recommendations for nursing practice, research and education.

1.12. Conclusion

This chapter has been dedicated to an overview of the study. The background to the problem statement for this study has been discussed and provided a roadmap to the development of the research questions and their attributes. Elements of the research design and method have been explained and all provide an introduction to the following chapters – which aim to describe more thoroughly each component of this study.

CHAPTER 2 - RESEARCH METHODOLOGY

2.1. Introduction

In light of the systematic review research design chosen for this study, the methodology should follow suit. Methodology is the specific steps in the way to arrive at an answer to the research question (Botma *et al*., 2010:199), thus a method to an answer. In this study, the systematic review will be applied to gather, analyse and interpret data.

Botma *et al*. (2010:241) define a systematic review as a type of research review that aims to summarise research on a topic, in a strict, reproducible, critically methodological and objective fashion. Polit and Beck (2014:355) emphasize the use of a research question and meticulous data collection plan, while Gough *et al.* (2012:5) reiterate the importance of stating a clearly defined method or protocol for the systematic review, to allow full transparency and replication of the process (Polit & Beck, 2014:355). Parahoo (2010:474) defines this method very simply as the synthesis of the analysis made from specifically identified data or research studies.

The recurring premise of this method of research is noted: it uses primary research as its source of data (Gerrish & Lacey, 2010:284) – thus research on research as Parahoo (2010:134) describes it; requires a narrow perspective on the research question to find exactly and only what is sought after in research (Gerrish & Lacey, 2010:287); and is strict about methods and steps taken to arrive at a conclusion, as well as the total reproducibility of the process.

The scientific underpinning of the systematic review lies within its ability to rigorously search for and exhaust all sources and to aggregate results into a meaningful narrative on a specific topic (Grant & Booth, 2009:100). Ten Ham-Baloyi and Jordan (2016:121) support the use of systematic reviews, specifically in nursing, as it informs evidence-based practice in the clinical setting, as well as the in policy making (Snilstveit *et al*., 2012:309). Gough *et al*. (2013) also state that the systematic review has the ability to not only indicate what is known, but also what is not known, which allow it to demonstrate uncertainties in findings and inform future research.

2.2. The systematic review method

It is made evident by authors in the systematic review that a logical, strict and reproducible review protocol must be established and followed rigorously. In addition, Brink *et al.* (2012:

52) explain the logical process of conducting research should flow from a question to an answer. This research process is divided into four phases: conceptual-, empirical-, interpretive- and communication phase (Brink *et al*., 2012:54-58). Within this research process, the systematic review steps are subdivided. These steps ultimately represent the review protocol.

The review protocol is arguably the most important and largest feature of the systematic review (Gerrish & Lacey, 2010:289) which is considered to be paramount to the success of the review. In the application of a systematic review, different authors propose a sequential and meticulous process to be followed. Botma *et al*. (2010:241) propose a process involving eight steps, whereas Gough *et al*. (2012:8) suggest a seven-stage process and Grové *et al.* (2013:480) ten steps. Slight differences exist within these proposed processes but are largely similar in the sequence of proposed undertaking of the systematic review.

The eight-step process of conducting a systematic review proposed by Botma *et al*. (2010:241) was chosen to serve as framework for the review protocol of this study. The steps flow from identification of the research problem, review protocol development, research report locating, selection of appropriate research, judging the quality of the research, data collection, findings summary and finally, dissemination of results (Botma *et al.*, 2010:241).

Therefore, the review protocol that was used in the conduct of this research study on the severity rating of medication errors, is explained in eight steps under the broader research process phases, as depicted in the following figure 2.1.

2.2.1. Conceptual phase
- **2.2.1.1. Step 1:** Identify the problem
- **2.2.1.2. Step 2:** Develop a review protocol

2.2.2. Empirical phase
- **2.2.2.1. Step 3**: Locate relevant research reports
- **2.2.2.2. Step 4:** Select relevant research reports
- **2.2.2.3. Step 5:** Appraisal of individual studies for inclusion

2.2.3. Interpretive phase
- **2.2.3.1. Step 6:** Extract data

2.2.4. Communication phase
- **2.2.4.1. Step 7:** Synthesise and summarise findings
- **2.2.4.2. Step 8:** Document and disseminate findings

Figure 2.1 The research process

2.2.1. Conceptual phase

Conceptualising the research problem is a time-consuming and strenuous activity, which allows for the researcher to identify a research problem, study existing literature on the topic, establish the need and purpose of conducting new research, develop a solid research question and finally deciding on a research methodology and elements to be studied (Brink *et al*., 2012:54-55).

Within this conceptualising phase of the research process, the systematic review commences with the first two steps as proposed by Botma *et al*. (2010: 241) in identifying the problem and developing a review protocol.

2.2.1.1. Step 1: Identify the problem

Problem identification mostly stems from clinical practice (Botma *et al*., 2010:241), but can also be identified in existing research. In the case of this review, the problem was identified through a review of existing research. The introduction of this study encompasses this search for and synthesis of research on the matter.

As already explained in the problem statement, severity ratings are ascribed to medication- and medication administration errors, but consistency, uniformity and objectivity across these ratings, in a multitude of research reports, are lacking. The problem is thus discrepancy in severity ratings of medication errors, due to a lack of a uniform, objective and consistently applicable severity rating scale, as evidenced by the different severity rating scales found in research reports.

To add, there is no existing research aiming to gather different ratings of severity, in the context of medication – and medication administration errors, which can add to the development of an comprehensive severity rating scale for medication errors. This therefore represents the problem identified through thorough search and examination of existing research on the topic of medication errors and rating of the severity thereof.

From the problem that has been identified, a research aim is developed. The aim of this study is to identify elements to be included in a comprehensive medication administration severity rating scale. This aim is achievable by manageable objectives which are to firstly explore and describe the concepts of severity and medication error in the context of nursing medication administration errors; to explore and describe the categorization of medication errors in recent

literature; and to finally provide a summary of constituents to consider for the development of a comprehensive medication administration error severity rating scale.

Consequently, to achieve the above-mentioned objectives, the development of a review question follows. Gerrish and Lathlean (2015:337) emphasise the need for structure in the review question and hence the PICO-structure. The review question is therefore informed by the research questions and objectives of this study.

The PICO or PICOS format is recommended by many authors (Botma *et al*., 2010:242; Gough *et al*., 2012:69 & Grove *et al*., 2013:474). PICO/PICOTS is an acronym derived from the Cochrane Handbook for Systematic Reviews of Interventions and according to Grove *et al.* (2013:474) each letter takes a specific meaning: P – the patient group or population of interest; I – the intervention being investigated; C – the comparison intervention against the investigated intervention; O – the desired outcome of the investigation and finally the T – indicating time frame and an additional S – indicating the study design, which is not used in this study.

In the investigation of existing research for the constituents of medication administration error severity rating scales, the PICO format is applied to research reports about medication errors:

Population: the phenomena of medication errors;

Intervention: the use of a tool or method to rate the severity of a medication error;

Comparison: there is no intervention to compare to, therefore not applicable; and

Outcome: a measurement of severity.

This PICO-statement for the review question, subsequently dictates the inclusion and exclusion criteria for the research reports to be used in the review.

Inclusion criteria are a fundamental aspect to consider when deciding on what research reports to include in the systematic review and which not. These criteria necessitate the determination of specific characteristics of studies such as the publication year, language and study design (Gerrish & Lacey, 2010:289), and set explicit boundaries to the specific data sought form research studies.

The inclusion criteria will have an effect on the validity and generalisability of the review results (Parahoo, 2010:138), and must therefore be explained and explicitly stated. Firstly, research

reports about medication administration errors, which refer to or use a tool or instrument to determine the severity of medication and medication administration errors and measure the severity of those errors, constitute the primary inclusion criteria. In addition, research reports that investigate medication errors made by nurses will be included – no other health care professional or member of the health care team. This specification thus allows for this matter to be reviewed with exclusivity to the nursing context. As stated in the introduction section of this research report, a medication administration error is constituted by a deviation in the five rights of medication administration for nurses. Hence, reference to this the aim is to include research reports that make specific reference to these deviations. Research reports that did not have reference of these specifics, were automatically excluded.

Secondly, all published, peer-reviewed research reports were used in this study. Also, publications no older than five years were included as this is considered to be recent literature by several subject-specific journals (American Nurses Association [ANA], 2016). Publications available in English were included. These two criteria were stated to ensure that all possible data on the use of severity rating methods or tools were included for review in this study which were still relevant.

2.2.1.2. Step 2: Develop review protocol

The review protocol is essential for the systematic review to be successful (Gerrish & Lacey, 2010:289). Gerrish and Lacey (2010:289) propose a list of elements to include in the review protocol, namely: the background and reason for the review; review questions, inclusion and exclusion criteria of studies, articles and literature; search strategy for literature; appraisal strategy for included studies, articles and literature; a data extraction strategy; strategy to analyse findings; dissemination of findings plan and finally a timetable and estimated costing of the project. The eight steps of the systematic review as suggested by Botma *et al*. (2010:241) were used to guide the formation of the review protocol for this systematic review.

This review protocol plan has been submitted in the research proposal for evaluation by the scientific committee NuMIQ, as well as the ethics committee of the North-West University Potchefstroom Campus (HREC). Two elements of the protocol – timetable and costing – were removed from the final dissertation as it was deemed irrelevant for examination.

2.2.2. Empirical phase

The empirical phase denotes the gathering and judging of data (Brink *et al*., 2012:56). Within this phase of the research process, the third and fourth steps in the systematic review are involved, namely locating research reports and selecting research reports.

2.2.2.1. Step 3: Locate research reports

Searching for literature is considered to be a time-consuming and tedious step in the review process (Brink *et al*., 2012:56). Parahoo (2010:139) emphasises the use of librarians and other experts in the field to assist in the search for relevant studies for the review.

Since this systematic review uses published, peer-reviewed, research reports, most of the research reports were found on electronic internet-based sources. Many authors suggest foremost the use of online databases (Grove *et al.,* 2013:476; Gerrish & Lacey, 2010:290; Parahoo, 2010:139). Online databases available to the North-West University which were used for this study were the following: EBSCO-host, Scopus, Web of Science, SA-epublications and Pubmed central.

Gerrish and Lacey (2010:291) emphasise a sensitive search strategy which will be sensitive to include all possible studies, but also very specific to include highly relevant studies. To achieve this balance, it is suggested to use specific search terms and synonyms, as well as the use of Boolean operators to narrow the results of online searches (MIT Libraries, 2018).

The search terms used for online databases were derived from the PICO-statement as already discussed. The terms that were included in the database searches were the following:

(Medication) AND (error OR mistake) AND (nurse* AND severe*) OR (harm OR serious* OR extent).

2.2.2.2. Step 4: Select research reports

Selecting studies are based on sensitivity and specificity (Ten Ham-Baloyi & Jordan, 2016:123). To this effect Gerrish and Lacey (2010:291) explain that sensitivity increases the number of reports that are possible candidates for inclusion, while specificity aims to reduce the number of reports by excluding non-relevant reports. Ten Ham-Baloyi and Jordan (2016:124) emphasise the importance of meticulous documentation throughout this phase.

Regarding sensitivity, as explained earlier, a large number of studies were located using the set search terms. Hence, the search has been sensitive to allow for all possible applicable literature to be included in the review. Conversely, specificity in this review has been applied through the process of excluding duplicated research reports, irrelevant titles and abstracts and finally judging the full text research reports' content applicability to the review.

The final judging of the content of full text research reports for applicability to the review, was guided by the three questions the researcher asked related to each research report:

1. Is the main theme of the article about medication administration errors or medication errors?
2. Is the article making use of a severity rating scale or tool to measure the errors, which produces a "measurement" of severity?
3. Are the errors referred to in the nursing context?

The research report should have positively answered all three questions to be included in the review. In the case of only two positive answers being obtained by the researcher, a co-reviewer was asked to assist in deciding whether the research report was applicable to be included in the review.

2.2.2.3. Step 5: Appraisal of research reports

Steps taken to minimise bias and error in the design, conduct and analysis of a study, indicate the quality of any given study (Gerrish & Lacey, 2010:292). Appraisal of studies involves a process of asking questions about the study at hand, to determine whether it is of good or poor quality (Boland *et al.,* 2014:64). Boland *et al.* (2014:63) emphasise that this step is important to ensure that reliable studies which add to the rigour of a review, be included.

Appraisal of studies requires the researcher to critique the components of a study namely the title and abstract, literature review, methodology, results, recommendations and validity and reliability of any given study (Parahoo, 2006:406). In addition, and more important, is the scrutiny of a study's validity, reliability, and bias (Boland *et al.,* 2014:65).

Botma *et al.* (2010:244) suggest use of a second person or expert to judge the research reports selected. This increases the internal consistency of the review according to Ten Ham-Baloyi and Jordan (2016:124), which will ultimately influence the quality of the review.

Regarding quality appraisal tools, Boland *et al.* (2014:68) suggest that specific tools be used based on the study design of the specific study being appraised. Therefore, suggesting the use of known tools already available, and to diligently note why specific tools have been chosen (Boland *et al.*, 2014:70).

Therefore, a tool designed by Alan and Barker to appraise studies, specific to medication error, was used. This appraisal tool is used by Alsherhri *et al.* (2017:873) in their systematic review on medication error rates in mental health hospitals. The checklist includes the following items which are either present or not in the given study: stating aim and objective of the study, a definition of outcome, clearly specified and defined error categories, a denominator, the study setting, methods of collecting data, validity and reliability measures as well as the study limitations (Alsherhi *et al.,* 2017:873). Studies which proved to be of sufficient quality – a rating of at least 75% - were used for data extraction. Percentages were calculated by dividing the items satisfactorily addressed in the research report out of the maximum items relevant to that report.

2.2.3. Interpretive phase

The interpretive phase of the research process involves the processing of raw information by means of analysis and interpretation, into a usable piece of information (Brink *et al.,* 2012:57). Under this heading, the step of data extraction is further elaborated on.

2.2.3.1. Step 6: Data extraction

Data extraction is a process whereby the sought-after information in quality appraised research reports is summarised into a data extraction table (Boland *et al.,* 2014:87). During this process specific data to extract should be identified, a data extraction table designed, co-working considered, completion of the extraction forms and final reporting of the findings should be done (Boland *et al.,* 2014:88). Following these steps, data synthesis and communication phases can follow.

Presentation of data which can answer the review question is ultimately the aim of data extraction (Boland *et al.,* 2014:88), hence, emphasising the conciseness of a data extraction plan. For this reason, data extraction tables were developed to organize data.

Two main components drive the data extraction for this study, namely the PICO-statement (see 2.2.1.1.) and the three inclusion questions (see 2.2.2.2.), which were used during the

selection phase of this study. This assisted in developing the pilot-table (Table 2.1.) – which resulted in the ultimate three tables in which data was further organised (Table 2.2, 2.3 & 2.4).

Elements already addressed in the appraisal step (namely title of the article, year of publication, and methodology – related elements) were not repeated in the final extraction tables.

Table 2.1 Piloted data extraction table

Research report title and author	Year of publish	Type of research document	Type(s) of medication administration error investigated	Deviation in the five rights of medication administration	Definition of severity used	Tool/method used to determine severity of error	Described characteristics of the method/tool used	Author' s perception of the severity of the medication administration error

Table 2.2 Table for definitions of medication error and severity

Author	Definition of "medication error"	Definition of "severity"

Table 2.3 Table for classification and system/method

Author	Classification of medication error	Classification system/ method

Table 2.4 Table for severity rating and tool constituents

Author	Severity rating tools	Constituents

2.2.4. Data synthesis and communication phase

The last phase of the research process involves the final synthesising of information into usable information that is then documented and communicated in an appropriate way (Brink *et al.,* 2012:58). This requires a suitable method of data synthesising and communication format that would reach the intended audience.

2.2.4.1. Step 7: Synthesis and summary of findings

Synthesis of research findings is not merely a list of observed findings from data but should aim to increase knowledge by building up elements or ideas into an intertwined whole (Gough *et al.,* 2012:180). To answer the specific research questions and achieve the objectives of this study, a meta-synthesis was chosen to present the findings from the data.

Meta-synthesis is concerned primarily with qualitative data from research studies and articles (Polit & Beck, 2014:363). Grove *et al.* (2013:489) define it as "…the systematic compiling and integration of qualitative study results to expand understanding and develop unique interpretation of study findings in a selected area". To this regard a meta-summery aim to identify the state of knowledge on a certain topic from research reports (Grove *et al.,* 2013:490). In contrast, a meta-analysis is concerned with the statistical significance of the findings synthesised from the selected studies (Grove *et al.,* 2013:482).

With these definitions in mind, it was thought to be of more value to conduct a meta-synthesis, the reason being the qualitative nature of the information sought from studies, and not the statistical and "number" value of the findings. Information about medication or medication administration error; the deviation in the five rights of medication administration; the severity rating method thereof; the score or severity rating ascribed to the error are the qualitative data sought in studies, which was analysed and synthesised in a narrative way.

Different methods exist to analyse and synthesise qualitative and quantitative data. Meta-analytical methods are implied when an aggregative or statistical outcome is desired from quantitative studies. A narrative method is usually applied when data from qualitative studies is reviewed. In the case of this study, the data was attained from quantitative and qualitative studies which means that the data might be statistical/numerical as well as text based. Hence a method was used that would accommodate both. For this reason, a meta-synthesis, incorporating a narrative report, was chosen since Snilstveit *et al.* (2012:414) state that, just as narrative

approaches can be used to synthesise qualitative studies, it can be used the same for quantitative studies. The thematic analysis method lends itself best to narrative presentation of findings.
The thematic synthesis aims to incorporate both qualitative and quantitative studies in the coding of text to find main themes, around which findings are organised. This method's strength lies in these characteristics (Snilstveit *et al.*, 2012:417) and its structured way of representability of findings in tables and charts. Thomas and Harden's (2008:45) research and use of this method were essentially consulted to perform the synthesis.

For synthesising data by means of thematic synthesis Thomas and Harden (2008:45) supplied a three-stage process starting with the coding of text, then developing of descriptive themes and finally generation of analytical themes. As explained by Cruzes and Dyba (2011) the aim is to answer a specific research question, by identifying recurring themes, analysing and concluding on them in a systematic review. The thematic synthesis is a lengthy process and within these three steps of Thomas and Harden, processes occur, namely data extraction, coding, translation of codes into themes, creating models from higher order themes and final assessment of the trustworthiness of a synthesis (Cruzes & Dyba, 2011).

The data extraction table served as a guide to code text in the research reports and to find the themes sought for. These themes were then described and the whole presented in the review findings of this document (Chapter 3).

2.2.4.2. Step 8: Documenting and disseminating findings

Final documentation and dissemination of the research results and interpretation thereof, are the pinnacle of the research process (Boland *et al.,* 2014:127). All previous research stages culminate in this final phase which will ultimately demonstrate the answering of the research questions and contribution to the greater body of knowledge.

Boland *et al.* (2014:128) suggest that in the final discussion and conclusion section of the research report, the researcher should make specific reference to the following: evidence found and hindrances in the process; the review question and the answering thereof; alignment of research findings with previous or other research in the field; the strengths and limitations of the included studies and the review process chosen; generalizability of the findings; the conclusions drawn from the review and finally implication and suggestions for future research. Findings, limitations and conclusions of this study follow in chapters 3 and 4.

2.3. Conclusion

The systematic review requires meticulous work by the researcher. The process from problem identification to final dissemination of new knowledge to the research community is lengthy and requires expert assistance and guidance for the process to be successful.

The above stated methodology was applied rigorously to ensure the reliability and validity of the systematic review process, which will ultimately lead to valuable knowledge addition to the community. In this chapter the research methodology was discussed. In chapter three the research results are presented.

CHAPTER 3 - STUDY FINDINGS

3.1. Introduction

This chapter is dedicated to the explanation of the review findings. At first attention will be given to the academic literature selection, the eligibility screening of research reports, critical appraisal thereof as well as the data extracted. Thereafter data will be synthesised, and conclusions and considerations made accordingly. This chapter contains references to addenda for large-scale tables and figures.

3.2. Academic literature selection

Academic literature for this review has been selected based on the predetermined eligibility criteria. Prior to the selection of relevant literature for data extraction, a thorough search had to be done. This lengthy process was done according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and is represented in the figure 3.1.

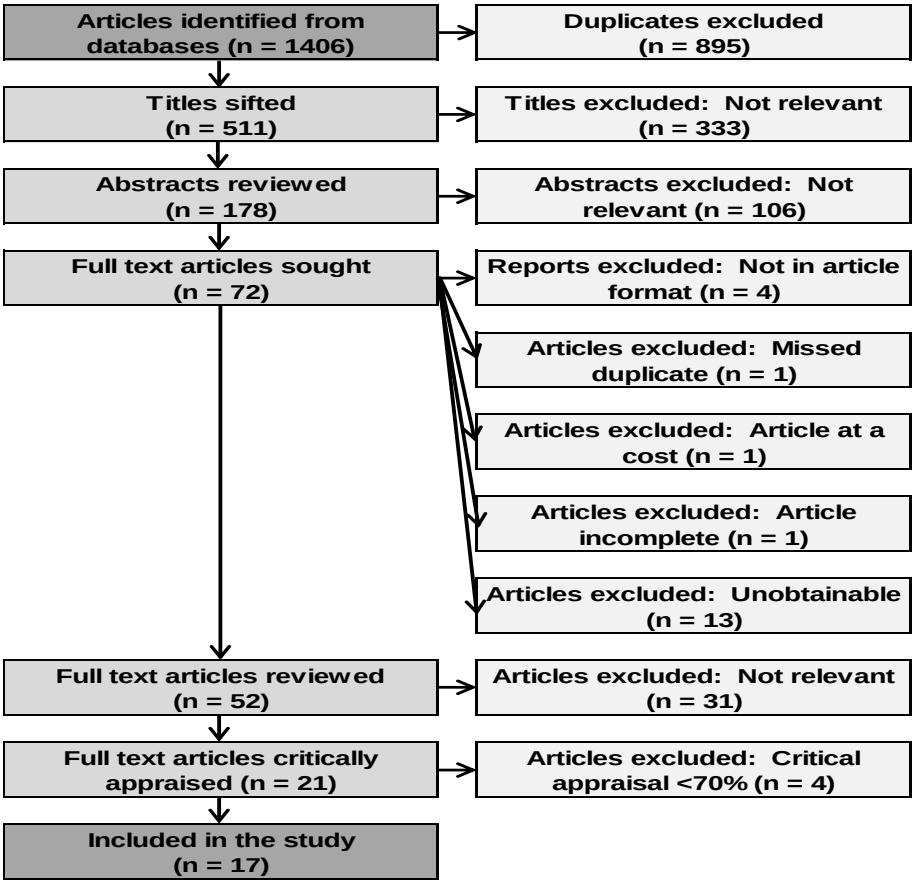

Figure 3.1 PRISMA flow chart

Firstly, literature relevant and applicable to the study had to be identified. During this phase of the PRISMA, a detailed search of databases had to be done. Databases EBSCO-host, Scopus, Web of science, SA-publications and Pubmed central were searched. The search terms were determined by the researcher, with assistance from the study leader and expert in the field, as well as the subject librarian. These search terms were as follows:

(Medication) AND (error OR mistake) AND (nurse*) AND (severe* OR harm OR serious* OR extent).

The search delivered a total of 1406 record. Duplicates were removed by means of the EPPI-reviewer software and delivered a total of 511 titles. Thereafter, the titles were screened for relevancy and applicability to the research direction. This was carried out by the researcher, as well as an external reviewer and the subject expert, whom agreed on the final list of 178 titles, after 333 titles were excluded.

Subsequently, 178 abstracts were read and assessed by the researcher for relevancy and applicability. This process was supported by the eligibility criteria and search terms used during the initial search. During this “screening” phase of the PRISMA statement, 106 abstracts were excluded, which left a total of 72 abstracts which met the inclusion criteria.

During the “screening” phase some exclusions had to be made: 1 title was a book, which is not included for this review; three more titles were PhD studies, of which the scientific published articles could not be obtained and were excluded (thus n=4 reports were not in article format); one title a “missed duplicate”, which was then excluded; one article appeared to be incomplete, despite attempts to find the complete article, and was therefore excluded. Due to costs, one article had to be excluded and finally 13 full articles remained unobtainable at the time of review, despite exhaustive options to obtain. Hence, a total of 20 titles were excluded from the list.

Eligibility screening followed the previous phase in the PRISMA-statement. A total of 52 full text articles were obtained for screening for eligibility. These articles were read in full by the researcher. During this phase the researcher made use of an “eligibility table” to assist in finding the sought-after information in the article. This table represents the author and title of the research article; the three eligibility questions and the final verdict whether the research report was to be included or not. The table is represented in Addendum B.

Eligibility screening was based on the set questions, which delivered 21 research articles that contained the sought-after data and that were thus included for the critical appraisal step.

3.3. Critical appraisal

Critical appraisal of the type of research articles obtained for this review posed a significant problem: most are retro- or prospective design. Scientifically sound critical appraisal checklists for specifically these types of documents do not exist. This posed a challenge to a novice researcher. To overcome the problem, it was decided with the guidance or the supervisor, to implement an appraisal check list that would allow the evaluation of the most significant aspects of the study and hence decision on its quality.

Allan and Barker's criteria for medication error research, as described by Alshehri *et al.* (2017:873), were implemented. This measure was taken to refine the appraisal of research articles and increase the rigour of the review. The criteria described by Alshehri *et al.* (2017:873) include the following aspects to be sought for in articles suitable for use in medication error research: the study objectives, explanation of outcome, categories of errors stated and defined, explanation of data collection methods, the study setting, the denominator used and finally consideration of validity, reliability and limitations. This critical appraisal tool has been implemented unmodified and is available in Addendum F.

Elements from Allan and Barker's criteria were allotted a 1 if present, 0 if absent or noted as not applicable (NA). Scores were calculated as a percentage from all applicable elements. As explained in previous sections, any research article obtaining a critical appraisal score below 75% was excluded from further review. The critical appraisal scoring of all the articles is available in ADDENDUM F.

The following table 3.1 represents the 17 reports that passed critical appraisal and are used for data extraction.

Table 3.1 Quality assessment of methodology, strength and weakness of research reports

Author & date	Title	Setting	Methodology	Strength/ weakness	Critical appraisal score
Abbasi *et al.* (2015)	Accuracy of harm scores entered into an event reporting system	Unknown (United States of America)	**Sample:** n = 85 nurses completed survey **Data collection:** demographic data and survey that measures the accuracy of harm scores entered into event reporting system. **Data Analysis:** statistical analysis – interrater reliability using Kappa statistics and Spearman correlations.	**Strength:** 82% response rate of surveys. The harm scale used to rate harm scenarios is clearly described. **Weakness:** Data collection was done only from two nursing units out of 20 in the organization, and hence not representative of the whole institution, or broader application.	88%
Alharbi *et al.* (2016)	A comparative study of voluntarily reported medication errors among adult patients in intensive care (IC) and non-IC settings in Riyadh, Saudi Arabia	Saudi Arabia	**Sample:** N = 31399 patients admitted during study period, n = 390 voluntarily reported medication errors during study period. **Data collection:** voluntarily reported medication error reports. Medication safety committee reports and patient medical records for demographic data and medication error related information. **Data analysis:** Statistical analysis – all data categorised and expressed as frequency.	**Strength:** Logistic regression analysis and statistical significance at $p<0.05$ was used. Sample adequate. **Weakness:** High probability of underreporting of medication errors.	75%

Author & date	Title	Setting	Methodology	Strength/ weakness	Critical appraisal score
Arain *et al.* (2016)	Should health care aides assist with medications in long-term care?	Canada	**Sample**: n = 220 error reports from two long term care facilities. **Data collection:** medication error rates, types and severity. Health status of residents who received oral medication assistance. **Data analysis:** Chi-Square test and Fisher extract test at 95% confidence level for inferential statistics.	**Strength**: A mixed method approach led to more and broader results about the research topic. **Weakness:** Underreporting of errors suspected. Human perception of errors influenced results and had a poor response rate.	75%
Bertsche *et al.* (2008)	Prioritising the prevention of medication handling errors	Germany	**Sample:** N = 1376 errors observed, n = 833 medication handling errors observed. **Data collection:** medication handling errors, risk scores of errors, classification of errors. **Data analysis:** frequencies, prevalence according to the Wilcoxon-test.	**Strength:** the observational design allowed for better detection and notation of errors. **Weakness**: Findings might not be generalisable to other settings and nurse variables might influence the findings of the study.	87.5%

Author & date	Title	Setting	Methodology	Strength/ weakness	Critical appraisal score
Cottney & Innes (2015)	Medication-administration errors in an urban mental health hospital: A direct observation study	Britain	**Sample:** N = 174 medication rounds observed, n = 139 errors observed. **Data collection:** Direct observation of nurse medication rounds, **Data analysis:** Regression analysis to identify potential error predictors.	**Strength:** 4177 opportunities for errors were observed- hence a large sample was obtained. **Weakness:** findings not completely generalisable. By direct observation, only external factors that lead to error can be observed, and not internal factors.	75%
Cousein *et al.* (2014)	Effect of automated drug distribution systems on medication error rates in a short-stay geriatric unit	France	**Sample:** N = 615 opportunities for errors during ward stock period, and N = 183 opportunities for errors during the unit dose dispensing system period. **Data collection:** direct observation of nurse medication rounds, demographic data of patients, nurses, medication administered and the nursing unit. **Data analysis:** statistical analysis of rates of medication errors, comparison of two rounds' collected data using the Student's *t*-test and chi-square test.	**Strength:** study periods were divided into three periods over two years. **Weakness**: certain drug administrations were not included in the study and the setting allowed for some errors to escape detection.	75%

Author & date	Title	Setting	Methodology	Strength/ weakness	Critical appraisal score
Elden & Ismail (2015)	The importance of medication errors reporting in improving the quality of clinical care services.	Egypt	**Sample:** N = 21843 observed doses during pre-test phase, and N = 3814 doses observed during post test phase. **Data collection:** direct observation of medication errors during pre and post-test phases. Error reports. **Data analysis:** Quantitative analysis of patient outcome and medication stages.	**Strength:** quantitative and qualitative analysis of reports assisted to provide insight into medication error stages, root causes and effects on patients. **Weakness:** Hawthorne effect has possibly influenced the results.	87.5%
Gharekhani *et al.* (2014)	Frequency, types, and direct related costs of medication errors in an academic nephrology ward in Iran.	Iran	**Sample:** N = 406 patients, N = 7762 medication orders. **Data Collection:** direct observation of pharmacotherapeutical rounds and detection of errors by clinical pharmacists. **Data analysis:** Statistical Package for the Social Sciences (SPSS) software was used, as well as Spearmen test for correlation. A *p*-value <0.05 was considered statistically significant.	**Strength:** study stretched over 18 months **Weakness:** findings not generalisable to other settings.	75%

Author & date	Title	Setting	Methodology	Strength/ weakness	Critical appraisal score
Hammour & Jalil (2016)	Medication errors in voluntarily reported incidents at a Jordanian hospital	Jordan	**Sample:** all medication error reports January 2014 to March 2015. **Data collection:** from medication incident reports – patient demographics, origin and nature of the medication error and medication associated with the error. **Data analysis:** retrospective analysis using SPSS.	**Strength:** reports used for analysis were mostly good quality and contained relevant data. **Weakness:** voluntary nature of the investigation might result in fewer number of medication errors detected.	75%
Härkänen *et al.* (2014)	The factors associated with medication errors in adult medical and surgical inpatients: a direct observation approach with medication record reviews.	Finland	**Sample:** 32 nurses from four wards from four shifts – 1000 medication administrations. 122 electronic patient records. **Data collection:** direct observations of medication errors, demographic data of nurses and patients, nurse-patient ratio's and subjective information about the nurse and the ward. **Data analysis**: multi-professional team estimated the potential severity according to the NCC MERP classification system, logistic regression to determine the association between medication errors and related factors.	**Strength:** medications errors were directly observed, and patient records were reviewed by a multi-professional team. **Weakness:** convenience sampling was used.	87.5%

Author & date	Title	Setting	Methodology	Strength/ weakness	Critical appraisal score
Ohashi *et al.* (2017)	Evaluation of intravenous medication errors with smart infusion pumps in an academic medical centre	United States of America	**Sample;** 55 inpatients and 3 nursing units. 181 medication administrations observed. **Data collections:** infusing medication, dose, rate, prescribed medication compared with the prescription. Handling of infusing pumps and lines compared with hospital policy. **Data analysis:** frequency, type and severity of the errors.	**Strength:** standardised scales to measure severity were used in the study. **Weakness:** not a long-term study – hence the results do not reflect results over a longer period.	75%
Nguyen *et al.* (2013)	The effect of a clinical pharmacist-led training programme on intravenous medication errors: a controlled before and after study	Vietnam	**Sample:** 516 medication doses prior to intervention and 688 doses after intervention. **Data collection:** direct observation of nurses' medication rounds. Compared to the prescription, hospital policies and procedures, manufacturers guidelines and literature. **Data analysis:** generalised estimating equations to assess the effect of the prevalence on relevant error doses.	**Strength:** rigorous study design. **Weakness:** some statistical measurements were redundant and not significant.	87.5%

Author & date	Title	Setting	Methodology	Strength/ weakness	Critical appraisal score
Rishoej *et al.* (2018)	Identifying and assessing potential harm of medication errors and potentially unsafe medication practices in paediatric hospital settings: a field study	Denmark	**Sample:** Four paediatric wards. **Data collection:** directly observed medication errors or potentially unsafe medication practices. **Data analysis:** descriptive statistics for potential harm of observation.	**Strength:** direct observation of errors added to reliability of study. **Weakness:** Hawthorne effect could influence error occurrence.	75%
Schnock *et al.* (2017)	The frequency of intravenous medication administration errors related to smart infusion pumps: a multihospital observational study.	United States of America	**Sample:** 10 hospitals. **Data collection:** two observers compared intravenous medication, labelling thereof, rate of infusion with the prescription. **Data analysis:** frequency of errors and severity according to the NCC MERP.	**Strength:** medication errors were observed in 10 hospitals for 7 months. **Weakness:** Hospital selections were not random – bias could be present.	75%

Author & date	Title	Setting	Methodology	Strength/ weakness	Critical appraisal score
Sears *et al.* (2016)	The relationship between nursing experience and education and the incidence of reported paediatric medication administration errors	Canada	**Sample:** 18 hospitals, 372 surveys collected. **Data collection:** Paediatric Medication Administration Error – survey collected self-reported data from nurses. **Data analysis:** descriptive statistics, as well as multi linear regression.	**Strength:** the tool used had face, content and construct validity. **Weakness**: self-report was utilised which could affect the number of errors reported.	75%
Shrestha & Ramanath (2015)	Study and evaluation of medication errors in medicine and orthopaedic wards of a tertiary care hospital	India	**Sample:** 200 inpatient cases from a 1050 bed hospital. **Data collection:** patient case history, diagnosis, mediation prescriptions, progress charts, nurse administrations, laboratory investigations. Different types of medication errors, the possible contributing factors, and omitted doses. **Data analysis:** descriptive statistics	**Strength:** the study indicated gaps in the operation of the hospitals and need for organised systems for reporting medication errors. **Weakness:** inclusion of participants was based on willingness.	87.5%

Author & date	Title	Setting	Methodology	Strength/ weakness	Critical appraisal score
Sulaiman *et al.* (2017)	Evaluating medication errors for hospitalized patients: The Jordanian experience	Jordan	**Sample:** 15 nurses, 283 patients, 803 medication errors and 6396 opportunities for error. **Data collection:** patient demographic data from medical files, directly observed medication preparation errors, chart reviews collected data on discrepancy between prescriptions, transcription and medication administration records. **Data analysis:** descriptive statistics using Statistical Package for Social Sciences.	**Strength:** two methods of medication error detections were used. **Weakness:** only one nursing unit from the hospital was included, and observations were non-consistent – hence not representative of medication errors during any given time.	87.5%

3.4. Study characteristics

Studies that were finally suitable for data extraction, after quality appraisal, demonstrated a recurring characteristic – the use of retrospective and prospective studies.

Prospective studies are described by Mosby (2009:1529) as particularly aimed at demonstrating the relationship between elements and characteristics of those elements. Prospective studies necessitate the researcher to follow the group of participants or subjects over a period of time, to establish whether correlations among elements are casual or actually associated which can produce a measure of risk (Mosby, 2009:1529).

Retrospective studies on the other hand, deal with past incidence. The relationship between elements and characteristics thereof are hence made from actions that occurred in the past (Mosby, 2009:1619). Most of the studies used in this review, made use of prospective and retrospective approaches.

The sources of data used by research reports are also significant. Errors were detected by direct observation of the errors, document analysis and self-reported errors by nurses. As an exception – Elden and Ismail (2015) and Sulaiman *et al.* (2017) used a combination of direct observation and document analysis, whereas only one report by Shrestha and Ramanath (2015) utilised document analysis only. In the following figure 3.2. a pie chart reflects the number of reports that utilised different methods to detect errors.

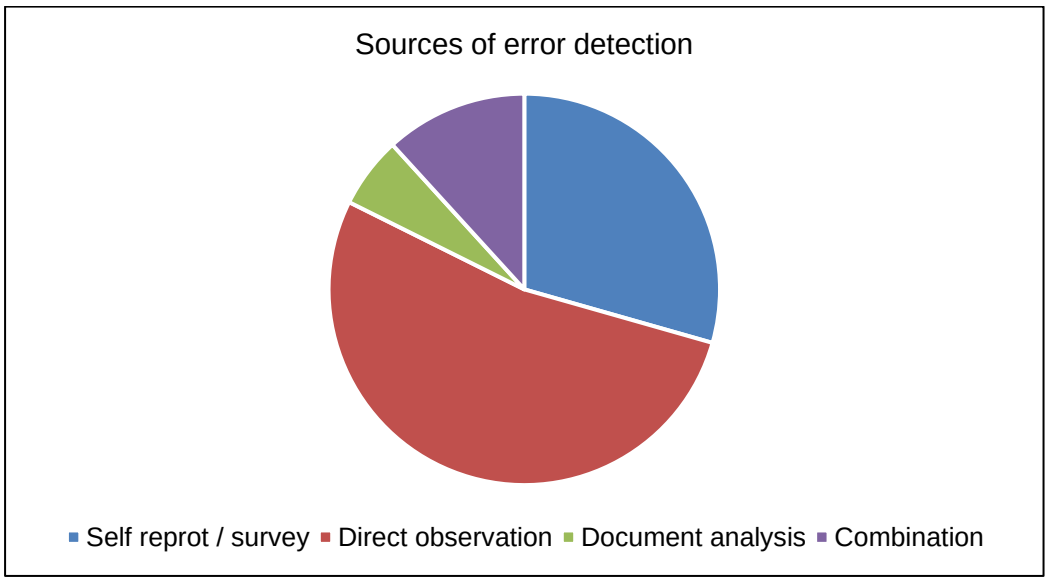

Figure 3.2 Sources of error detection in research reports

Research reports included for this review were from studies conducted in various countries. Medication error research is apparently more prevalent in developed countries when compared to developing countries even though the medication error problem is more prevalent in developing countries. Figure 3.3. depicts the number of studies from developing and developed countries.

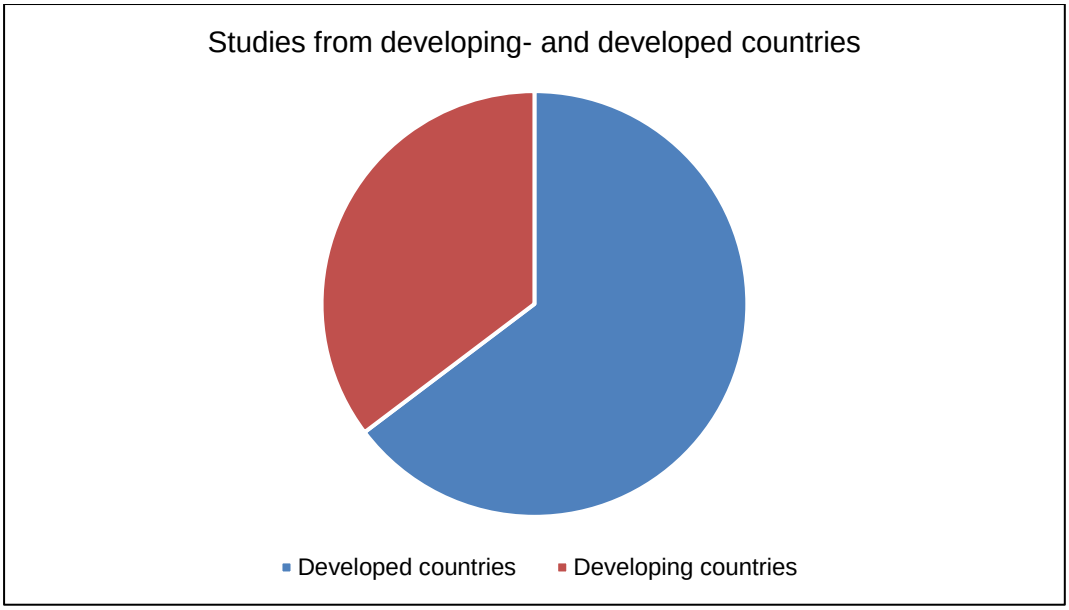

Figure 3.3 Studies from developing and developed countries

3.5. Data extraction, synthesis and discussion

In order to maintain a logical flow for simplified reading, data extraction, synthesis and discussions are provided per objective. Thus, for objective one, data extraction will be followed by data synthesis and the discussion thereof before objective two is addressed.

3.5.1. Data extraction, synthesis and discussion of objective one

Objective one: To explore and describe the concepts of “severity” and “medication error” in the context of nursing medication administration errors, by means of review of literature.

3.5.1.1. Data extraction pertaining to the definitions of “severity” and “medication error”

The following table 3.2. represents the data extracted from seventeen critically appraised research reports. The definitions ascribed to medication error and severity in these reports are represented. Colours are used to code different recurring themes. It is important to note that authors quoted the definitions in certain cases, and hence could be from secondary sources.

Table 3.2 Definition of medication error and severity data extraction table

Author	Definition of "medication error"	Definition of "severity"
Abbasi *et al.* (2015)	Medication errors are a part of patient safety events – no specific definition provided. No clear definition provided.	No clear definition provided.
Alharbi *et al.* (2016)	"an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing medicine advice, regardless of whether any harm has occurred".	No clear definition provided.
Arain *et al.* (2016)	"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".	No clear definition provided.
Bertsche *et al.* (2008)	Error identified by deviation from standards such as hospital guidelines of the local drug and hygiene committees, information in the corresponding summary of product characteristics and physicians' prescriptions in the chart.	No clear definition provided.
Cottney & Innes (2015)	Baker et al 2002 "a dose administered differently than as prescribed on the patient's medication chart".	No clear definition provided.
Cousein *et al.* (2014)	MAE is a dose of medication administered that deviates from the doctor's order."	No clear definition provided.
Elden & Ismail (2015)	"Medication errors are errors in drug ordering or prescription, dispensing, preparing the medicine, administering and monitoring".	No clear definition provided.
Gharekhani *et al.* (2014)	"Medication error is the failure in the treatment process that leads to or has the potential to lead to harm to the patient".	No clear definition provided.
Hammour & Jalil (2016)	Errors occurring at any stage in the ordering or delivering process of medications. And as a failure of completion of planned action of the medication as intended, or the use of wrong plan to achieve the aim.	No clear definition provided.

Author	Definition of "medication error"	Definition of "severity"
Härkänen *et al.* (2014)	" medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while medication is in the control of the health care professional, patient or consumer. "medication error can be defined as an incorrect dose, drug, delivery route, documentation, preparation, time, administration technique, administration of defunct drug, or omission of a prescribed drug."	No clear definition provided.
Ohashi *et al.* (2017)	"error occurring at any stage of the medication use process including prescribing, transcribing, dispensing, administering, monitoring".	No clear definition provided.
Nguyen *et al.* (2013)	"Medication errors were defined as deviations in the drug preparation and administration from the doctor's prescription, hospital policies and procedures, and manufacturer's instructions."	No clear definition provided.
Rishoej *et al.* (2018)	Any preventable event that may cause or lead to inappropriate medication use or patient harm while medication is in the control of the health care professional.	No clear definition provided.
Schnock *et al.* (2017)	"Error occurring at any stage in the medication-use process including prescribing, transcribing, dispensing, administering or monitoring."	No clear definition provided.
Sears *et al.* (2016)	"Any preventable error that has occurred as a result of human mistakes or system flaw that occurred in the process of administering a medication resulting in harm or the potential for harm."	No clear definition provided.
Shrestha & Ramanath (2015)	"failure in the treatment process that leads to, potential to harm the patient. "human errors which lead to prolonged hospitalizations, extra medical interventions, morbidity and even death, sometimes the burden to both patients and hospitals. These errors are preventable. "the failure of the planned action to be completed as intended or use of wrong plan to achieve an aim."	No clear definition provided.

Author	Definition of "medication error"	Definition of "severity"
Sulaiman *et al.* (2017)	"any preventable event that may cause or lead to inappropriate medication use or patient harm."	No clear definition provided.

3.5.1.2. Data synthesis pertaining to the definitions of "severity" and "medication error"

Data synthesis pertaining to the definition of severity will be provided prior to that of medication error.

3.5.1.2.1. Definition of "severity"

The definition of severity is explored in terms of its incidence. Reports were analysed for the reference to severity and then definitions provided. The following table 3.3. records the data obtained.

Table 3.3 Definition of severity data

Definition used in research report	Number of reports
Report with reference to severity of medication error	17
Reports with a definition of severity	0

The definition of "severity" in research articles was found to be lacking. All reports refer to the severity of medication errors but fail to provide an objective or concise definition thereof. During analysis of this aspect it is noticed that the reference to the severity of medication errors and the rating scale to determine its severity is not consistent. Severity seems to be defined by a rating scale alone.

3.5.1.2.2. Definition of "medication error"

Data regarding the "definition of medication" errors includes the presence of a definition in the research report, as well as coding of recurring themes. Table 3.4. indicates the number of reports with a definition of medication error, as well as its origin.

Table 3.4 Definition of medication error data

Definition used in research report	Number of reports
Report with reference to a definition of medication error	16
Reports with no reference to a definition	1
NCC MERP definition	4
Other definitions	13

16 reports state a formal definition of medication error. Only 1 report does not. The definition of medication error as proposed by the NCC MERP is used by 4 reports, and 13 reports use other definitions.

The definitions provided by the research reports have been analysed and coded. Recurring themes have been identified. Table 3.5. below represents recurring codes and the frequency of incidence.

Table 3.5 Frequency of data codes for medication error

Codes identified	Recurrence	Percentage emergence from all research reports
Harm	9	53%
Prescribe/ prescription/ doctor's order	8	47%
Dispensing	4	24%
Preventable	6	35%
Deviation/ differently	9	53%
Preparing/ preparation	3	18%
Administering/ administration	10	58%
Monitoring	4	24%
Event	3	18%
Medicine/ medication/ drug	15	88%
Health care professional/ human	5	29%
Treatment process/ processes	7	41%
Patient/ consumer	7	41%
Potential/ may cause	7	41%
Policy/ instructions/ standards/ guidelines	5	29%

The graph in figure 3.4. schematically represents these codes.

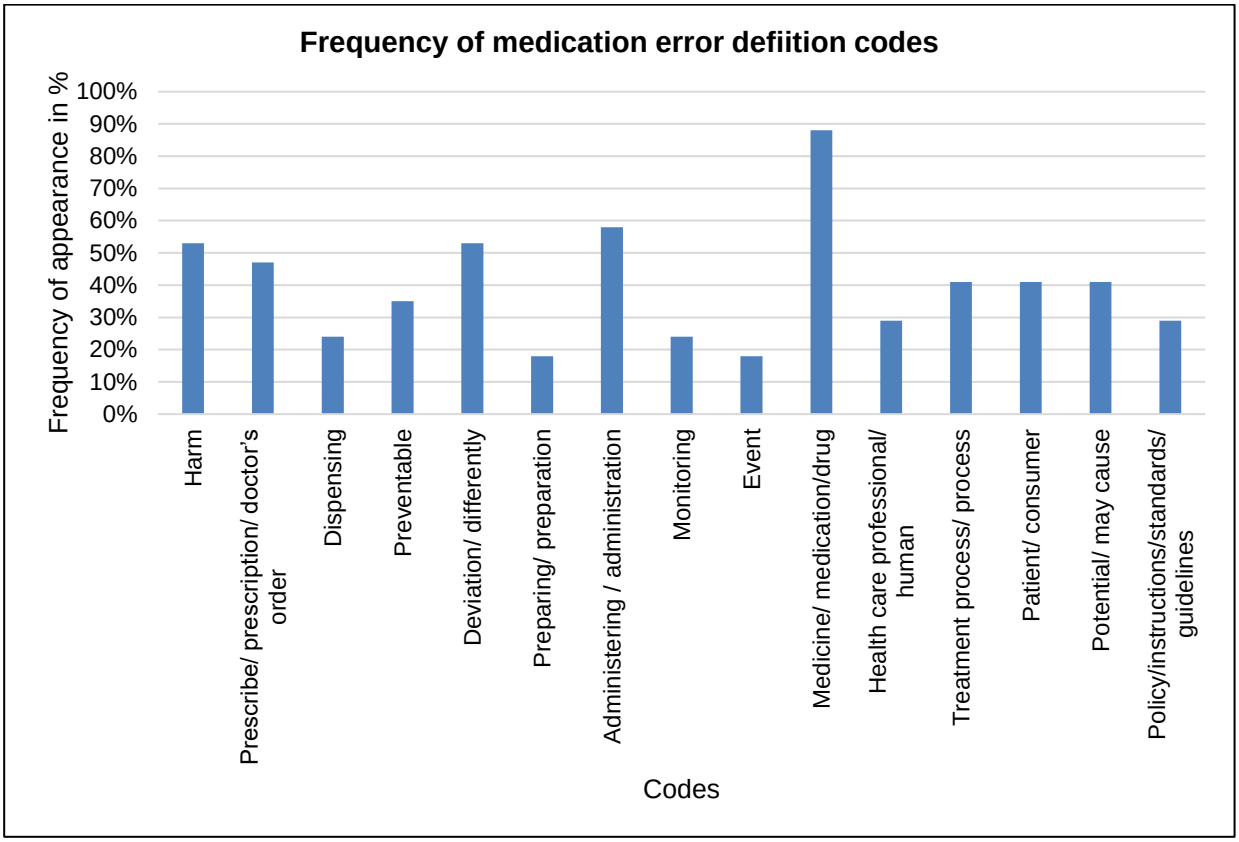

Figure 3.4 Graph of medication error code frequency

The frequency of codes was used to create overarching themes representative of medication error definition. These themes follow in table 3.6. as a matrix of codes.

Table 3.6 Medication error themes

Medication or treatment process	**Potential and actual Harm**	**Parties involved**
Prescription	Event	Patient
Prescribe	Potential	Consumer
Doctor's order	May cause	Human
Dispensing	Harm	
Preparing		
Preparation		
Administering		
Administration		
Monitoring		
Deviation from expectation	**Medicating substance**	
Policy	Medicine	
Instructions	Drug	
Standards	Medication	
Guidelines		

The results show that from the 17 reports, 16 reports defined medication errors. Only 1 had no definition ascribed to medication error. The definition of medication error by the NCC MERP is most consistently used in research reports.

Despite the recurrence of the NCC MERP definition, common codes emerged from the research report's definitions of medication error that were frequent. "Medication" and its synonyms appeared to be most frequent at 88%, followed by "administration (58%) and then "harm" of 47% frequency. After these the words "treatment process", "patient or consumer" and "potential;" appear in 41% of reports." Preventable" occurs in 35% of reports. This is followed by "health care professional" and "policy, guidelines, instructions, standards" in 29% of reports; "Dispensing" and "monitoring" in 24% of reports and followed by "event" and preparing, respectively occurs in 18% of reports.

Themes from these codes were derived and presented in a matrix of themes. Staggered according to incidence of appearance, the medication substance and medication or treatment process are each mentioned in 71% of articles (n = 12), while the parties involved are at 47% (n = 8), deviation from expectation at 41% (n = 7) and harm at 29% (n = 5). To make the definition of medication error flow in a logical manner, the matrix of themes suggests that the definition

should consist of reference to the medication or treatment process that is at flaw. Then, mention of the medication or substance is imperative to align the definition with medication error followed by an indication of the health care professional and which part of their conduct in the medication process is flawed. Reference should then be made to how or what the flawed act transgresses and finally the potential or actual harm possible to the health care user.

3.5.1.3. Discussion of the definitions of "severity" and "medication error"

"Severity" is not defined by any of the research reports used in this review. This might reflect research on these issues globally. Even though the term is used frequently, the meaning thereof is haphazardly applied and interpreted.

The common use of the term is noticed by Grant *et al.* (2019:933), who state that there is no distinction made between the actual and potential harm severity a patient might experience. The severity rating scale employed in the research reports, seems to constitute the definition of severity to the researcher.

This is problematic as severity can then be anything the researcher or reader may want it to be. Hence, the objective damage of a medication error is subject to personal experience or belief. The ongoing subjective interpretation of severity of harm caused by different medication errors can lead this element of medication error research to lack objective standards globally and influence objectiveness of research to these regards. In assuming that "severity" is defined by the severity rating scale used, the recommendation is that the definition should be derived from the scale constituents as is discussed later in this study.

Synthesis of the research results shows that medication error definition is stated in most of the research reports concerned with medication error. The definitions differ widely from report to report. The coding and thematic analysis revealed themes used frequently in these definitions and finally, the definition supplied by the NCC MERP is the only recurring definition.

A total of 16 reports state a definition of medication errors but differ widely. The frequent use of different medication error definitions has been mentioned by Lisby *et al.* (2010:516). Yu *et al.* (2005:358) also noted the many terms used to define medication error, as well as their ambiguous meanings.

A matrix of themes emerged from coding of definitions. The themes identified are “medication or treatment process”; “potential and actual harm”; “parties involved”; “deviation from expectation” and “medicating substance”. Coding and thematic analysis suggest that medication error definitions used in research reports share universal similarities and hence indicate what a globally accepted definition might look like.

A definition should refer to the faulty treatment process, the medication substance, the health care provider involved, the deviation from a standard of guideline and finally harm that might be caused by the deviation. The definition by the NCC MERP is comparable to these themes.

The definition suggested by the NCC MERP is used in four reports. The NCC MERP defines medication error as “…any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use” (NCC MERP, 2018a).

Using the NCC MERP’s definition is suggested, as it is already frequently used in research reports, it is globally available and accessible to researchers, health care professionals and lay persons. The definition is, however, long and difficult to remember. The overuse of detail might cause confusion. On the other hand, it provides exclusivity and precise defining of the medication error. Based on the themes emerging from the review, a shortened definition of medication error might be: Any treatment process error in the use of a medication caused by a health care provider/user’s deviation from expected actions, irrelevant of harm caused or not.

To conclude, findings indicate that medication error definitions are used frequently in research reports. These differ widely. Thematic analysis suggests that certain themes should be mentioned in a proper medication error definition. Global standardisation thereof is needed to unify research in these regards. The use of the NCC MERP definition is a possible solution to the problem.

3.5.2. Data extraction, synthesis and discussion of objective 2

Objective two: To explore and describe the categorization of medication errors in recent literature

3.5.2.1. Data extraction pertaining to the categorization of medication errors

The following table represents the data extracted from research articles about the types of medication errors. It is important to note that some this data is not directly quoted from the reports but is inferred. Codes are in colour.

Table 3.7 Classification of medication error data extraction table

Author	Classification of medication error	Classification system/ method
Abbasi *et al.* (2015)	No medication error classification or differentiation is made.	No reference to classification system or method.
Alharbi *et al.* (2016)	Refer to type of medication errors: prescribing error, omission error, wrong time, unauthorized drug, wrong drug preparation, wrong administration technique, deteriorated drug, monitoring error, compliance error, and other such as system error, documentation error, delay in dose, extra doses/ wastage, wrong practice/policy violation.	No reference.
Arain *et al.* (2016)	documentation, dose omission, extra dose, extra dose in package, incorrect drug, incorrect time, frequency scheme error, incorrect narcotic count, not performed where indicated, wrong dose strength, wrong duration, wrong resident, wrong storage, wrong technique, other.	No reference.
Bertsche *et al.* (2008)	Medication handling errors, administration errors, storage errors.	Refer to hospital guidelines, local drug and hygiene committees and physician's prescription. Not traceable.
Cottney & Innes (2015)	Dose omission, incorrect dose, incorrect form, incorrect time, incorrect drug, incorrect technique, monitoring error, incorrect route, incorrect strength, incorrect patient.	NCC MERP classification.
Cousein *et al.* (2014)	Wrong dosage, wrong drug, wrong time of administration, omission.	Allan and Barker (1990)
Elden & Ismail (2015)	Stages of medication delivery: prescription of medicine, dispensing of medicine, preparing the medicine for administration, administering the dose using the appropriate route and method, monitoring the effect of the medicine on the patient.	Dar El Sheefa hospital guidelines.

Author	Classification of medication error	Classification system/ method
Gharekhani *et al.* (2014)	Classified according to medication error nodes: prescription errors, transcription errors, administration errors	Pharmaceutical Care Network Europe Foundation classification system.
Hammour & Jalil (2016)	Types of reported medication errors: missed doses, wrong time, wrong doses, wrong medication, wrong patient, adverse drug events, inappropriate storage, wrong route, duplication of medication, incomplete label.	No reference.
Härkänen *et al.* (2014)	Phases of medication process: prescribing, administration, documentation, dispensing, preparing. As well as types of medication errors: wrong technique, omission, defunct drug, wrong time, wrong dose, wrong preparation, wrong drug, wrong route, wrong documentation, other.	No reference.
Ohashi *et al.* (2017)	Medication error in any stage of the medication use process including prescribing, transcribing, dispensing, administering, monitoring. Including types: wrong dose, wrong rate, wrong concentration, wrong medication, known allergy, omitted medication, delay of rate of medication change, no rate documented on label, incorrect rate on label, patient identification error, no documented order.	Bates *et al.* (1995)
Nguyen *et al.* (2013)	Medication errors classified by types; preparation errors – wrong drug, wrong dose, wrong dosage form, deteriorated drug, wrong preparation technique; administration errors – omission, unordered drug, wrong administration technique.	Taxin & Barber (2004).
Rishoej *et al.* (2018)	Stages of the medication process: prescribing, preparation, administration.	NCC MERP
Schnock *et al.* (2017)	Medication error types in the medication-use process include wrong patient, wrong medication, wrong dose, wrong route and wrong time.	Husch *et al.* (2005).
Sears *et al.* (2016)	No classification of medication errors made according to the medication process.	No reference.

Author	Classification of medication error	Classification system/ method
Shrestha & Ramanath (2015)	Commonly occurring medication errors are prescription error, administration error, transcription error and dispensing error. Prescription errors: dosage related errors, absence of frequency, absence of route, wrong route and frequency. Administration errors: omission errors, wrong time, wrong dose, wrong route, administration after discontinuation. Transcription errors: omission from transcribing index, errors in wrong frequency, wrong dose transcription. Dispensing errors: wrong drug dispensing, wrong dosage form, wrong dose dispensed.	Reference multiple sources.
Sulaiman *et al.* (2017)	Types of administration errors: dose omission, unauthorised dose, wrong route, wrong administration technique, wrong time, extra dose error. Types of transcription errors: omission, wrong frequency, discontinued order. Types of dispensing errors: wrong drug error, wrong dosage form, wrong quantity. Types of prescribing errors: wrong route, wrong instructions.	Lisby *et al.*

3.5.2.2. Data synthesis pertaining to the definitions of "severity" and "medication error"

Analysis of the classification systems of medication errors consisted of identifying the presence of such a classification system, the recurrence of classification systems or methods and referencing made to the certain classification system used. The following table indicates the data obtained from analysis.

Table 3.8 Classification systems for medication errors data

Classification method	Number of reports
Classifications of medication errors	15
No classification of medication errors	2
Classification methods without references	4
Classification methods with references	11
NCC MERP classification of medication errors	2
Classification with references to known authors on the topic	7

From the 17 reports, 15 classified the medication errors. Two research reports made no specific reference to any classification of medication error (Abbasi *et al.,* 2015 and Sears *et al.,* 2016). The other 15 reports mentioned classification of medication errors, with mentionable differences.

Classification or categorisation of medication errors differs significantly. Some authors mention and classify the medication errors, but without reference to an already established classification system or known author's method. A total of 4 reports refer to classification of medication errors in this way namely Alharbi *et al.* (2016); Arain *et al.* (2016); Hammour and Jalil (2016) and Härkänen *et al.* (2014). The other 11 reports notably reference the sources from which the classification of types of medication errors were made and describe it sufficiently.

Seven reports refer to classification methods or types of medication errors and reference the original authors and explain the classification of errors as medication errors sufficiently (Cousein *et al.*, 2014; Gharekhani *et al.,* 2014, Ohashi *et al.,* 2017, Nguyen *et al.,* 2013, Schnock *et al.,* 2017; Shrestha & Ramanath, 2015 and Sulaiman *et al.,* 2017). Two reports refer to local guidelines. Elden and Ismail (2015) refer to a local classification system used in the hospital of study, which is adequately referenced and traceable in the research article. The other refers haphazardly to "hospital guidelines, local drug and hygiene committees and physician's prescription" without further referencing or description (Bertsche *et al.,* 2018). Cottney and Innes (2015) and Rishoej *et al. (*2018) reference the NCC MERP classification of medication errors and hence classify their research accordingly. The NCC MERP classification of medication errors is also the only recurring method used.

Inferred from the abovementioned, the classification of medication errors is not consistently applied across studies of this type.

Analysis of the different types of medication error classifications led to the coding of recurring aspects. These codes are represented in the following table 3.9 of frequencies of appearance. Although codes might have appeared more than once in an article, the maximum count for an article would be one. For example, if "wrong dose" was inferred in different contexts (for instance for prescription or administration phases), it would still only be counted as one article mentioning this type of error. Following is graph 3.5. – depicting the percentage of frequencies of codes.

Table 3.9 Frequency of recurring codes

Code	Frequency of appearance in percentage
Omission error	59%
Wrong time/ duration	53%
Wrong patient/ patient identification error	29%
Wrong dose/ frequency/ concentration	65%
Wrong drug/ medication	59%
Wrong route/ form	47%
Prescription error	47%
Documentation error	18%
Transcription error	24%
Preparation/ technique/ handling error	29%
Administration error	65%
Dispensing error	29%
Monitoring error	24%

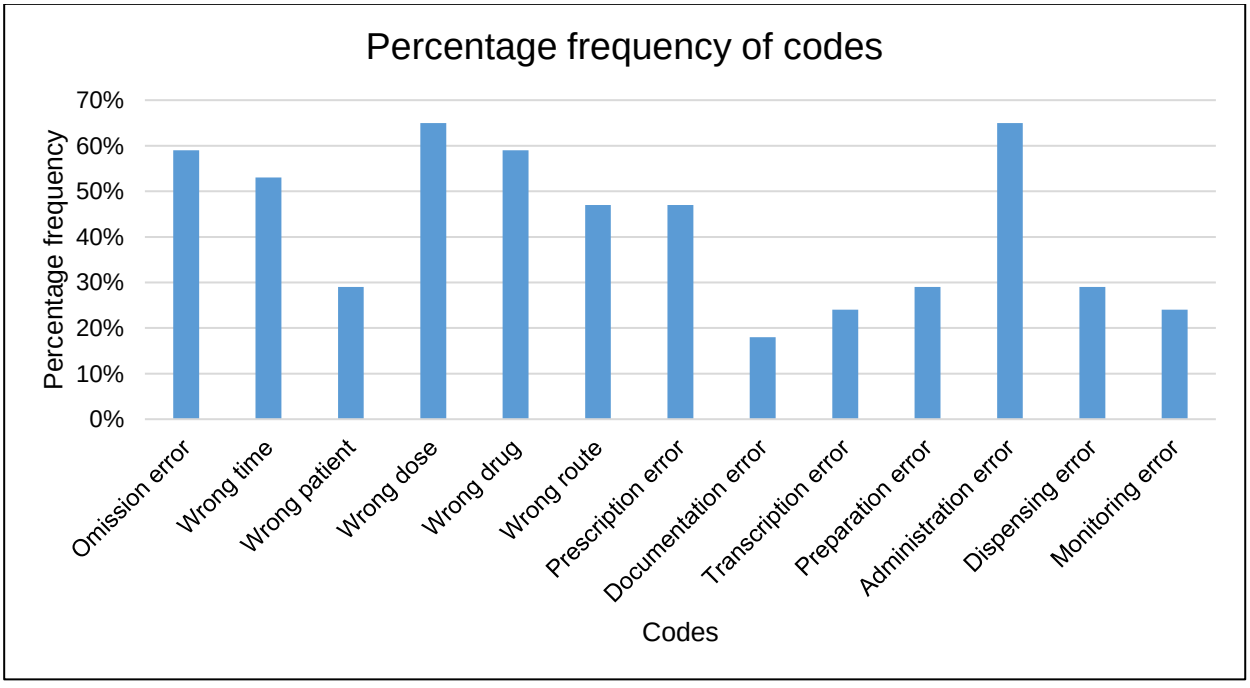

Figure 3.5 Graph of classification of medication error code frequencies percentages

From the codes in this section of data, it is inferred that certain types of medication errors are more generally categorized in research dealing with these issues, and hence it is suggested that

these be included in the standardisation of classification systems. “Administration” errors and “wrong dose” errors are most prevalent at 65%. These are followed by “omission” and “wrong drug” errors at 59%. Least mentioned error types include “monitoring” and “transcription” errors (24%) and “documentation” errors (18%).

There are also two distinctions made in the research reports regarding the classification of medication errors. These are the different terminologies used to describe the medication errors namely “types of medication errors” and “medication process/ nodes of medication use/ stages of medication delivery”. They are recurrently used in the research reports, but interchangeably and not consistently. The percentage of appearance of these terms is depicted in table 3.10.

It is important to note that only 15 from the 17 reports made mention of classification of medication errors. Hence the percentages are calculated according to this.

Table 3.10 Classification of medication errors code frequency

Code	**Percentage frequency**
“Types of medication errors”	65%
“Medication process / nodes of medication use/ stages of medication delivery”	41%

These two themes in classifying medication errors are central to the classification of medication errors. The previous table 3.9 depicted the most frequent terms used under these overarching themes. These codes were arranged under these main themes to create a matrix of codes, presented in table 3.11.

It is important to note that the frequencies are calculated from the reports that explicitly use the term “types of medication errors” and “medication process/nodes of medication delivery/ stages of medication deliver”, and hence not representative of all the reports, but only of the 15 reports that used these terms to classify medication errors.

Table 3.11 Matrix of recurring codes under main themes

Types of medication errors	**Medication process/ nodes of medication use/ stages of medication delivery**
Omission	Preparation
Time error	Administration
Wrong drug	Prescription
Wrong route	Transcription
Wrong patient	Dispensing
Wrong dose	Monitoring
	Documenting

Derived from the code frequencies as in the table above, it becomes apparent that medication errors can be classified in a medication process which includes medication prescription, transcription, dispensing, administration, documentation and monitoring. The types of medication errors recurring are wrong patient, wrong medication (with added deviations related to the drug), wrong route, wrong time, and omission error.

Medication administration as a code appears frequently. It can be regarded as a part of the medication use process. Within the act of administering medication, certain types of errors can occur. From literature on nursing, the five rights of medication administration are used as main themes. Codes were obtained from the extracted phrases which fit under these five rights (even though it is termed as “wrong” in the reports).

From the above data analysis, it becomes apparent that the classification system of medication errors is not standardised. The established classification systems that do exist are also not applied consistently in research to these concerns. The classification system proposed by the NCC MERP seems to be the only consistently used system, albeit only twice.

Lastly, medication errors seem to be grouped under two main themes namely “types of errors” and “medication stages or the medication process”. In terms of classification of medication errors, these themes are suggested to be considered in the development of such a classification system. Clear distinctions should be made among these.

3.5.2.3. Discussion of the classification of medication errors

Most reports used in this review classify medication errors by some means. Referenced classification systems were used in in more than half of the reports. Known authors' classification systems were used in 7 of the reports, while others referenced local guidelines and protocols. The NCC MERP classification system appeared twice. It is also the only recurrently used classification system in this review.

Coding of themes in the classification of medication error, leads to the culmination of terms used frequently. Two terms stand out – medication error "types" and "medication process/ node of medication use/ stages of medication delivery". These terms provide a division in medication error classification, namely that there are processes in medication delivery, under which certain types of medication errors can happen.

This division is apparent in literature as well. Allard *et al.* (2002:256) classify medication errors according to processes or medication delivery stages namely, prescribing, transcribing, dispensing and administration. A more recent study by Ernawati *et al.* (2014:416) also used these stages and added system and monitoring errors.

Further coding of terms revealed that the abovementioned medication delivery stages are also present in reports used in this review. Those that frequently appear are administration, prescription, transcription, and with the addition of preparation. The most frequently mentioned is administration errors, which appear in 65% of reports.

This is significant as literature has shown that the administration stage is the most error prone stage of all. Alemu *et al.* (2017:68) found this to be true in published literature and found the same trend in the hospital of their study, where administration errors were most common among all other errors (Alemu *et al.*, 2017:71).

Under the stage of medication administration, different "types" of errors occur. The "five rights" of medication administration have been described by many nursing textbooks as the guidelines to safe medication administration for nurses (Berman *et al.,* 2008:849 & Lynn, 2008:153). Kim and Bates (2013:592) state that these are the right patient, right medication, right dose, right route and right time. Deviation from these guidelines therefore constitutes a medication administration error in the nursing context.

Coding of themes in classification of “medication administration” error, revealed that “wrong dose” error was mentioned most often at 65%, followed by “omission” and “wrong drug” error occurring at 59%. Thereafter “time” error is prevalent at 53%. Wrong route at 47%, and wrong patient follow at 29%.

From this coding it is clear that the five rights of medication administration are frequently used as a classification system for specifically medication administration errors, and hence a suggested method to standardise the classification of these errors in research globally. However foundational and traditional this method of classification has been, criticism of it is also rising.

Martyn *et al.* (2019:113) argue that ensuring medication safety is not as linear as the framework of the five rights. Specifically, Martyn *et al.* (2019:109) explain that medication administration is integrated in other nursing activities with various organisation factors affecting the ability of the nurse to comply with the five rights of medication administration. The suitability of such a simple framework is challenged by Martyn *et al.* (2019:113) and suggests that frameworks be developed that consider the real challenges in nursing as well as the critical thinking and person-focused care they employ.

The NCC MERP classification systems use the outcome of the patient and the severity to classify medication errors (NCC MERP, 2020). This system assesses the presence of an error and whether harm or death has resulted from the error (NCC MERP, 2001). A taxonomy is provided to assist health care establishments in describing the error and co-factors that lead thereto. The taxonomy classifies the medication errors by type and name: dose omission; improper dose; wrong strength, form, technique, route, drug, rate, duration, time, patient and monitoring (NCC MERP, 2001). This classification system is elaborate and does not explicitly classify medication administration errors. It is observed that classification is more related to the severity of the incident than the type of medication error itself.

To conclude on the classification of medication error: administration errors are most common; types of errors recorded under administration, mostly relate to the five rights of medication administration. However, this classification has been challenged in recent literature for over-simplification of the medication administration process, the NCC MERP system appears more elaborate and less user-friendly. Classifying medication administration errors according to the five rights has been a standard of measurement clinically, as well as in research. From these review results, it is recommended that medication errors be firstly classified according to the medication treatment process node (medication prescription, transcription, dispensing, administration,

documentation and monitoring) and secondly according to type of error (wrong dose, wrong patient, wrong medication (with added deviations related to the drug), wrong route, wrong time, and omission).

3.5.3. Data extraction, synthesis and discussion of objective three

Objective three: To provide a summary of constituents required in the development of a comprehensive medication administration error severity rating scale

3.5.3.1. Data extraction of the constituents of medication administration error severity rating scales

The following table 3.12 represents the data extracted from research reports about the type of severity rating tool used in their report, as well as the constituents thereof. During coding of this data, challenges were experienced as categories were not clear-cut or well defined, but rather flowed from one another on a continuum with several overlapping areas in the spectrum. To mitigate this challenge, the maximum defined severity categories described in included articles (nine) were used to code the data, superimposing these categories so that one given category from an article describing less categories could circumscribe several of these continuum-measures. The rationale for this method of coding is to provide a synthesizable yet comprehensive overview of severity rating scales.

Table 3.12 Severity rating tools data extraction table

Author	Severity tool	Constituents
Abbasi *et al.* (2015)	Agency for healthcare research and quality (AHRQ) Common Formats Harm Scale version 1.2.	Harm classified: Death: dead at the time of assessment. Severe harm: bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life. Moderate harm: bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm. Mild harm: minimal symptoms or loss of function, or injury limited to additional treatment, monitoring and/or increased length of stay. No harm: event reached patient, but no harm was evident.

Author	Severity tool	Constituents
Alharbi *et al.* (2016)	Harm Category A to I. A is defined as minor, I is death. No obvious reference to the origin of the categorization tool and no detailed explanation thereof.	No explanation or reference. Harm Category A to I. A is defined as minor, I is death
Arain *et al.* (2016)	Seems like the author's own severity classification system.	Hazard: a hazard or hazardous situation that has been identified as having the potential to escalate to a close call or harmful event. Close call: an event or circumstance that has the potential to cause a harmful event but did not actually occur due to corrective action and/or timely intervention. No apparent harm: an event or circumstance where at the time of the event or reporting of the event the patient does not appear to suffer any harm but could do so in the future. Minimal harm: an event or circumstance where there is minimal harm to the patient. Moderate harm: an event or circumstance where there is moderate harm to the patient. Severe harm: an event or circumstance where there is severe harm to the patient. Death: an event or circumstance causing death in which the most likely cause is due to an error that occurred in the course of receiving care.
Bertsche *et al.* (2008)	Mention the use of risk scores, but not severity rating.	No constituents noted.
Cottney & Innes (2015)	Classification done according to Haw, C., Stubbs, J & Dickens, G. 2007. An observational study of medication administration errors in old-age psychiatric inpatients. *International journal for quality in health care,* 19(4):210-216.	Classification: Errors of doubtful or of negligible importance; errors likely to result in minor adverse effects or worsening condition, errors likely to result in serious adverse effects or relapse, or errors likely to result in fatality.

Author	Severity tool	Constituents
Cousein *et al.* (2014)	No name ascribed to the method of severity rating.	Physicians classified errors in the following categories: no harm, minimum harm without monitoring expected, monitoring, and need for therapy or intervention.
Elden & Ismail (2015)	NCC MERP Taxonomy. 2012	Potential errors: circumstances or events that have the capacity to cause error. Prevented errors: errors that did not reach the patient. Harmless errors: errors that reached the patient and did not cause harm. Harmful errors: errors that reached the patient and caused harm.
Gharekhani *et al.* (2014)	NCC MERP harm categories A-I 2013	No error: category A: circumstances for events that have the capacity to cause harm Error, no harm: category B: error occurred but error did not reach the patient. Category C: error occurred that reached the patient but did not cause harm. Category D: error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and or required intervention to preclude harm. Error, harm: category E: an error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention. Category F: an error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization. Category G: an error occurred that may have contributed to or resulted in permanent patient harm. Category H: an error occurred that required intervention necessary to sustain life. Error, death: an error occurred that may have contributed or resulted in patient death.

Author	Severity tool	Constituents
Hammour & Jalil (2016)	Rating tool as referenced: Westbrook, J.I., Reckmann, M., Li, L., Runciman, W.B., Bruke, R., Lo, C. *et al.,* 2012. Effects of two commercial electronic prescribing systems on prescribing error rates in hospital in-patients: a before and after study. PLoS Med. 2012,9e1001164.	Medication errors classified according to the following categories: Insignificant and minor: one which if omitted would probably have no effect on the patient's outcome. Moderate: one which if current practice continued could be potentially undesirable for patient's outcome. Major and serious: one which if current practice continued could be determinable for patient's outcome.
Härkänen *et al.* (2014)	NCC MERP Harm categories A-I 2014	Category A (no error) to I (patient death)
Ohashi *et al.* (2017)	NCC MERP harm index A to I 2011	A: capacity to cause error. B: an error occurred but did not reach the patient. C: errors unlikely to cause harm despite reaching the patient. D: error that would have required increased monitoring to preclude harm. E: errors likely to cause temporary harm. F: errors that would have caused temporary harm and prolonged hospitalization. G: errors which have produced permanent harm H: errors that would have been life threatening. I: error that would have likely resulted in death.
Nguyen *et al.* (2013)	No specific tool mentioned. Refer to clinical severity of medication errors.	Mention a validated scale from 0 (labelled as no harm) to 10 (death).

Author	Severity tool	Constituents
Rishoej *et al.* (2018)	Potential harm scores by the Danish Patient Safety Database.	potential harm scored: 1: no harm: potentially no harm. 2: mild: potentially mild transient harm that does not require any intensified treatment or care. 3: moderate: potentially transient harm that requires intensified treatment. 4: severe: potentially permanent harm that requires increased treatment or other harm that requires acute treatment. 5: death: potentially fatal.
Schnock *et al.* (2017)	NCC MERP Harm score index. 2015	No description of scale provided. Reference to the NCC MERP scale leads to presumption of categories A to I, ranging from opportunity for error to death.
Sears *et al.* (2016)	No specific severity tool used.	No description of severity tool provided.
Shrestha & Ramanath (2015)	NCC MERP medication error categories A to I. 2005	A: circumstances that have capacity to cause error. B: an error occurred but did not reach the patient. C: error occurred that reached the patient but did not cause patient harm. D: an error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and or required intervention to preclude harm. E: error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention. F: an error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization. G: an error occurred that may have contributed to or resulted in permanent patient harm. H: an error occurred that required intervention necessary to sustain life. I: an error occurred that may have contributed to or resulted in the patient's death.

Author	Severity tool	Constituents
Sulaiman *et al.* (2017)	NCC MERP Index for categorisation of medication errors. 2005	Category A (hazard) Categories B, C and D (actual error with no harm). Categories E, F, G and H (actual error with harm). Categories I (actual error that resulted in death).

3.5.3.2. Data synthesis of severity rating tools

Analysing the severity tools used in the research reports delivered the following themes under which further analysis was undertaken: firstly, the report mentioning and applying a certain severity rating scale which delivered a severity rating of the medication errors which they researched. Also, some severity rating scales were more prevalent than others – the recurrent appearance of certain known scales has significance to be analysed. These results are shown in table 3.13.

Table 3.13 Severity rating tools data

Severity rating of medication errors	Amount of reports
Reports with a severity rating	17
NCC MERP classification system	7
Other classification system	10

All the reviewed reports mention severity rating of the errors investigated and deliver a severity rating of those errors within the context of the study.

The NCC MERP severity rating scale is used in 7 of the reports (Elden & Ismail, 2015; Gharekhani *et al.,* 2014; Härkänen *et al.,* 2014; Ohashi *et al.*, 2017; Schnock *et al.,* 2017; Shrestha & Ramanath, 2015 and Sulaiman *et al.,* 2017). Within the NCC MERP classification systems, differences have also been detected. Elden and Ismail (2015:245) also refer to the NCC MERP taxonomy to categorise medication errors according to patient outcomes and describe the categories as potential errors, prevented errors, harmless errors and harmful errors.

These 7 reports refer mainly to the traceable NCC MERP categorisation of medication errors to define their potential to cause damage or rate the severity of the medication error. It is noticed

that the terms are used interchangeably whether referring to “potential to cause damage or harm” or “severity of the medication error”. In all eight reports the scale is described and referenced.

The other ten reports used different rating scales, or no recognizable scale at all. Alharbi *et al.* (2016:5) refer to a scale similar to that of the NCC MERP but lacks any objective reference to the source of the scale and hence is not considered to have used this specific scale. These include reports by Arian *et al.* (2016), Sears *et al.* (2016) and Bertsche *et al* (2018).

Arain *et al.* (2016) extensively describe the severity rating used to rate the errors researched, but it also lacks any reference. Here the severity of errors is described under the following headings: Hazard, close call, no apparent harm, minimal harm, moderate harm, severe harm and death.

Sears *et al.* (2016) explain the use of severity rating of medication errors in relation to the nurses’ experience in practice. In the report the severity rating method or tool is not clearly described and lacks reference. In this report it is not clearly stated or apparent in what terms the severity of medication errors is referred to or what specifics are considered when ascribing severity. Along with the previously mentioned report of Arian *et al.* (2016), these reports overall lack objective severity rating tools that can be easily understood and reproduced.

To add, Bertsche *et al.* (2018) explain the method used to determine the severity of medication errors researched but lacks reference to an objective resource. In this report, the severity is referred to in terms of patient outcomes caused by each error. This report refers to risk scores related to the patient outcomes that each error would cause.

Nguyen *et al.* (2013) also do not explicitly state the name of the method they used to measure the severity of medication errors. The report does however refer to the original authors of the method implemented, namely Dean and Barber (1999) – A validated, reliable method of scoring the severity of medication errors. This method refers to ten scores with ranges within which the severity of the errors is placed and represents the outcomes of the patient from minor to severe.

On the other hand, other reports have used different severity rating tools which is adequately explained and referenced. Abbasi *et al.* (2015) refer to the Agency for Healthcare Research and Quality (AHRQ) and the Common Formats Harm Scale version 1.1. and version 1.2. This tool is also used in the institution where medication errors were investigated. This report aims to determine whether the instrument used in medication error measurement delivered accurate results.

Cottney and Innes (2015) refer to a severity classification system described by Haw *et al.* (2007). Within this classification system this report refers to four types of classifications and is related to the adverse effect the patient would experience in case of the incidence of an error. This method used has been clearly explained and referenced.

Cousein *et al.* (2014) make use of an internally developed classification system that categorises classified errors into three categories based on the extra intervention needed for the patient should the error occur. This classification method is not referenced and is briefly described.

Hammour *et al.* (2016) refer to a classification system described by Westbrook *et al.* (2012). Severity is referred to in terms of the clinical importance and the effect the error would have on the patient outcome. Three classifications are described and referenced in this report.

Rishoej *et al.* (2018) make use of the Danish Patient Safety reporting system. The report references this resource and describes six scores that describe the harm the patient may experience and extra care and treatment that the adverse incident would require.

It is evident that all research reports mention severity rating scales to rate the severity of the medication error a patient encounter. It is significant that 7 reports specifically use the NCC MERP system to rate the severity of a medication error. It is inferred that the primary use of this scale in all research that aims to rate the severity of medication errors could assist in standardising severity ratings globally.

As explained earlier, it was difficult to find clear-cut delineation for codes or themes due to the continuity of the different continuums presented by the various severity rating scales. Therefore, quantification of code incidence was deemed superfluous. Rather, an attempt to synthesize extracted data was undertaken in the form of presenting different continuums under themes derived from codes that were similar. To this end, table 3.14. presents different continuums for categories of harm as presented by all included articles that provided adequate information to do so. Articles that lacked adequate information included the following: Alharbi *et al.* (2016); Bertsche *et al.* (2008); Nguyen *et al.* (2013); and Sears *et al.* (2016). If articles professed to use the NCC MERP scale but did not describe it, the wording from the NCC MERP scale was copied in for completeness. Constituents are numbered 1 to 9 (the maximum number of categories provided from all scales), with 1 being least severe and 9 being most severe. Cells of varying sizes in subsequent lines indicate how many of these constituents are grouped together in each

individual category used and also contain the exact wording used by each included report to delineate these set points in given continuums.

Table 3.14 Synthesis of different continuums of severity rating scales

Author	Constituents								
	1	2	3	4	5	6	7	8	9
Abbasi *et al.* (2015)			No harm: event reached patient, but no harm was evident.		Mild harm: minimal symptoms or loss of function, or injury limited to additional treatment, monitoring and/or increased length of stay.		Moderate harm: bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm.	Severe harm: bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life.	Death: dead at the time of assessment
Arain *et al.* (2016)	Hazard: a hazard or hazardous situation that has been identified as having the potential to escalate to a close call or harmful event.	Close call: an event or circumstance that has the potential to cause a harmful event but did not actually occur due to corrective action and/or timely intervention.	No apparent harm: an event or circumstance where at the time of the event or reporting of the event the patient does not appear to suffer any harm but could do so in the future.		Minimal harm: an event or circumstance where there is minimal harm to the patient.		Moderate harm: an event or circumstance where there is moderate harm to the patient.	Severe harm: and event or circumstance where there is severe harm to the patient.	Death: an event or circumstance causing death in which the most likely cause is due to an error that occurred in the course of receiving care.

Author	Constituents								
	1	2	3	4	5	6	7	8	9
Cottney & Innes (2015)			Errors of doubtful or negligible importance		Errors likely to result in minor adverse effects or worsening condition		Errors likely to result in serious adverse effects or relapse	Errors likely to result in fatality	
Cousein *et al.* (2014)			No harm	Monitoring required	Minimum harm without monitoring expected	Need for therapy or intervention			
Elden & Ismail (2015)	Potential errors: circumstances or events that have the capacity to cause error.	Prevented errors: errors that did not reach the patient.	Harmless errors: errors that reached the patient and did not cause harm.		Harmful errors: errors that reached the patient and caused harm.				

Author	Constituents								
	1	2	3	4	5	6	7	8	9
Gharekhani *et al.* (2014)	No error: category A: circumstances or events that have the capacity to cause harm	Error, no harm: category B: error occurred but error did not reach the patient.	Category C: error occurred that reached the patient but did not cause harm.	Category D: error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and or required intervention to preclude harm.	Error, harm: category E: an error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.	Category F: an error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	Category G: an error occurred that may have contributed to or resulted in permanent patient harm.	Category H: an error occurred that required intervention necessary to sustain life.	Error, death: an error occurred that may have contributed or resulted in patient death.
Hammour & Jalil (2016)			Insignificant and minor: one which if omitted would probably have no effect on the patient's outcome.		Moderate: one which if current practice continued could be potential undesirable for patient's outcome.		Major and serious: one which if current practice continued could be determinable for patient's outcome.		

Author	Constituents								
	1	2	3	4	5	6	7	8	9
Härkänen *et al.* (2014)	No error: category A: circumstances for events that have the capacity to cause harm	Error, no harm: category B: error occurred but error did not reach the patient.	Category C: error occurred that reached the patient but did not cause harm.	Category D: error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and or required intervention to preclude harm.	Error, harm: category E: an error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.	Category F: an error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	Category G: an error occurred that may have contributed to or resulted in permanent patient harm.	Category H: an error occurred that required intervention necessary to sustain life.	Error, death: an error occurred that may have contributed to or resulted in patient death.
Ohashi *et al.* (2017)	A: capacity to cause error.	B: an error occurred but did not reach the patient.	C: errors unlikely to cause harm despite reaching the patient.	D: error that would have required increased monitoring to preclude harm.	E: errors likely to cause temporary harm.	F: errors that would have caused temporary harm and prolonged hospitalization	G: errors which have produced permanent harm	H: errors that would have been life threatening.	I: error that would have likely resulted in death.

Author	Constituents								
	1	2	3	4	5	6	7	8	9
Rishoej *et al.* (2018)			1: no harm: potentially no harm.		2: mild: potentially mild transient harm that does not require any intensified treatment or care.	3: moderate: potentially transient harm that requires intensified treatment.	4: severe: potentially permanent harm that requires increased treatment or other harm that requires acute treatment.		5: death: potentially fatal.
Schnock *et al.* (2017)	No error: category A: circumstances for events that have the capacity to cause harm	Error, no harm: category B: error occurred but error did not reach the patient.	Category C: error occurred that reached the patient but did not cause harm.	Category D: error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and or required intervention to preclude harm.	Error, harm: category E: an error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.	Category F: an error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	Category G: an error occurred that may have contributed to or resulted in permanent patient harm.	Category H: an error occurred that required intervention necessary to sustain life.	Error, death: an error occurred that may have contributed to or resulted in patient death.

Author	Constituents								
	1	2	3	4	5	6	7	8	9
Shrestha & Ramanath (2015)	A: circumstances that have the capacity to cause error.	B: an error occurred but did not reach the patient.	C: error occurred that reached the patient but did not cause patient harm.	D: an error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and or required intervention to preclude harm.	E: error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.	F: an error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization .	G: an error occurred that may have contributed to or resulted in permanent patient harm.	H: an error occurred that required intervention necessary to sustain life.	I: an error occurred that may have contributed to or resulted in the patient's death.
Sulaiman *et al.* (2017)	Category A (potential error without harm)	Categories B, C and D (actual error with no harm).			Categories E, F, G and H (actual error with harm).				Categories I (actual error that resulted in death).

After converging all articles' data into nine constituents, it was deemed necessary to firstly, by means of inductive reasoning, converge certain constituents to find broad themes of harm versus no harm, after which deductive reasoning was required to better describe each of the constituents under these themes. This meant describing in detail what each constituent would include based on descriptions provided from different reports. This process leads to the following conclusions:

- Medication errors can be divided into three overarching themes, viz. potential errors, harmless errors and harmful errors;
- Medication errors can also be divided into two overarching themes, namely those not leading to increased monitoring and treatment, and those that do;
- Harmless errors are errors that were either prevented from reaching the patient, reached the patient but had no impact on the patient's health status, or required monitoring to ensure that no harm was to come to the patient; and
- Harmful errors included transient harm irrespective of treatment required or not, temporary harm requiring an increase in treatment time or effort, long-lasting or permanent harm, harm to the extent of requiring measures to sustain life, and death.

Following this, figure 3.6. presents the hierarchy of medication errors with a detailed description of each constituent of a comprehensive medication administration severity rating scale:

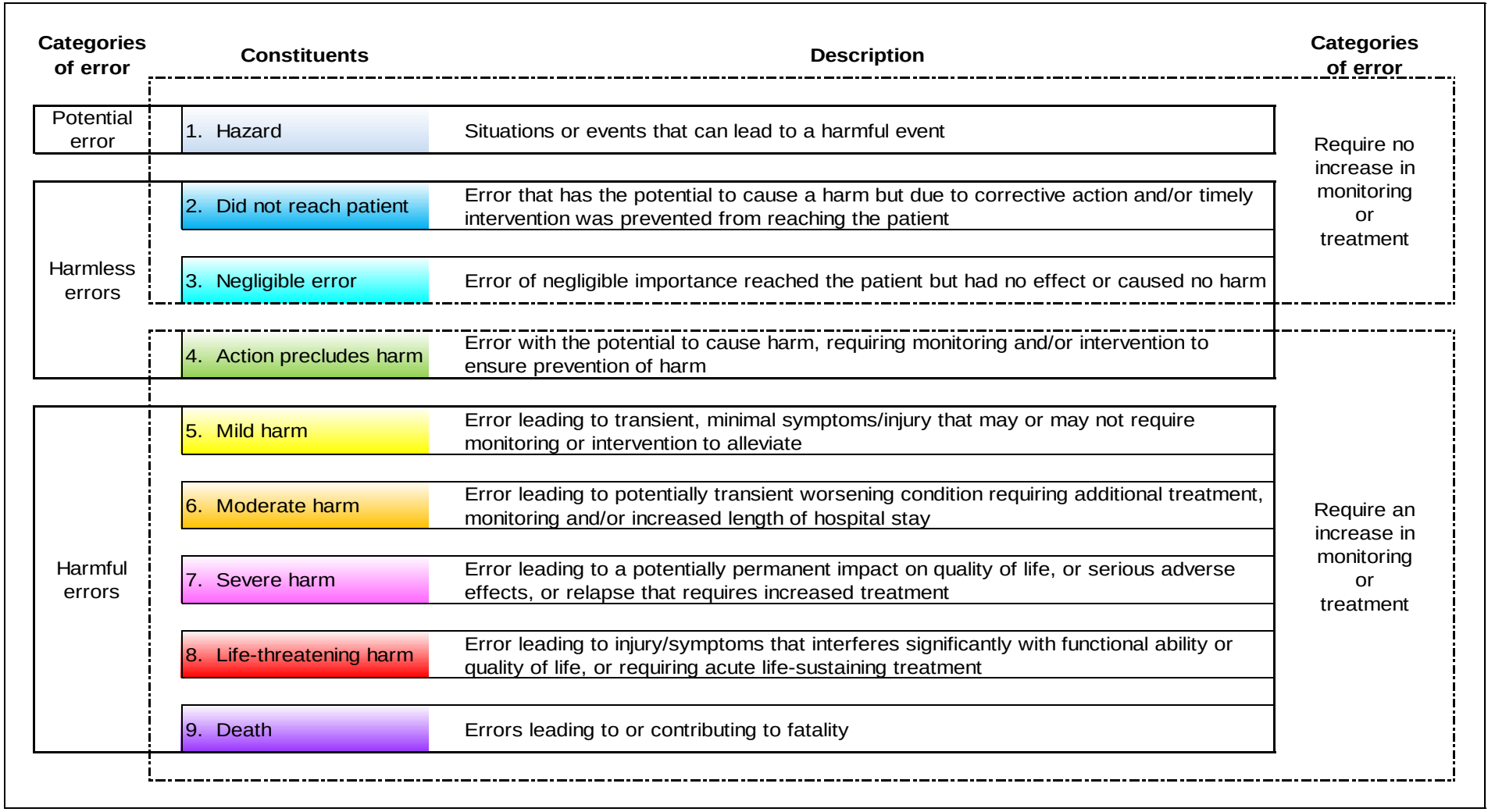

Figure 3.6 Summary of medication administration error severity rating scale constituents

3.5.3.3. Discussion of severity rating tool constituents

In this review, research reports were analysed for the presence of severity rating tools, and the recurrence of certain tools. Results show that all reports used a severity rating scale of some sort, and that the one proposed by the NCC MERP is the most prevalent.

Many severity rating tools exist, a fact which influences the objectiveness of the severity ratings and influences research to these regards. Keers *et al.* (2013b:241) noted in their research that the most prevalent severity rating scales are those of the NCC MERP and that of Dean and Barber (1999). Coincidentally, their research also showed that still many studies used other published severity rating scales (Keers *et al.,* 2013b:241).

Differences in severity rating scales can influence the objectiveness of ratings. Already, Williams and Ashcroft (2009:319) suggested that the consistency of severity ratings of medication administration errors is a problem due to health care professionals judging severity significantly differently. This was recently supported by Fahmy *et al.* (2018:4) by emphasizing the complex process of judging potential severity.

Considering the frequent use of the NCC MERP's severity rating scale, it could be suggested that this scale be used more consistently in research in this context to assist in standardising the objectivity of ratings. This scale is described by Fahmy *et al.* (2018:2) as an ordinal scale which is easily used by health care workers with knowledge of the context and outcome of the medication error being rated. Changes in the level of care needed by the patient due to the medication error are the guideline provided by the NCC MERP to classify errors (Gates *et al.,* 2019:934). This is evident in the index provided by the NCC MERP, which is represented in a pie chart (NCC MERP, 2020) with sections from A to I – each indicating a category of error which is defined by a description of the intervention necessary to treat the patient due to the medication error. This then translates into the severity of the error.

The frequent use of the NCCMERP scale is noted by Forrey *et al.* (2007:175) who conclude in their research that the interrater agreement for this tool is significant. Despite this, the reliability of the severity rating index for research purposes was challenged by Snyder *et al.* (2007:1007). Also, Fahmy *et al.* (2018:4) conclude in their research report that correlation is weak when the NCC MERP and Dean and Barber's methods are used for assessing medication administration errors. Gates *et al.* (2019:934) are also sceptical of the NCC MERP classification of actual and potential harm due to errors and note the detrimental effect on comparison between studies due

to inconsistent tool use and information provided. Gates *et al.* (2019:933) also criticize the lack of international use of this method.

Despite the conflicting views of authors on the use of the NCC MERP's severity rating scale and classification of medication errors, its topicality and consistent use in research reports, as determined by this review, and the ease of access and applicability could be reasons to use this tool.

Thematic analysis of these issues revealed that many constituents of medication administration severity rating scales coincide with the categories used by the NCC MERP. Below, figure 3.7 provides the NCCMERP pie chart used for severity rating.

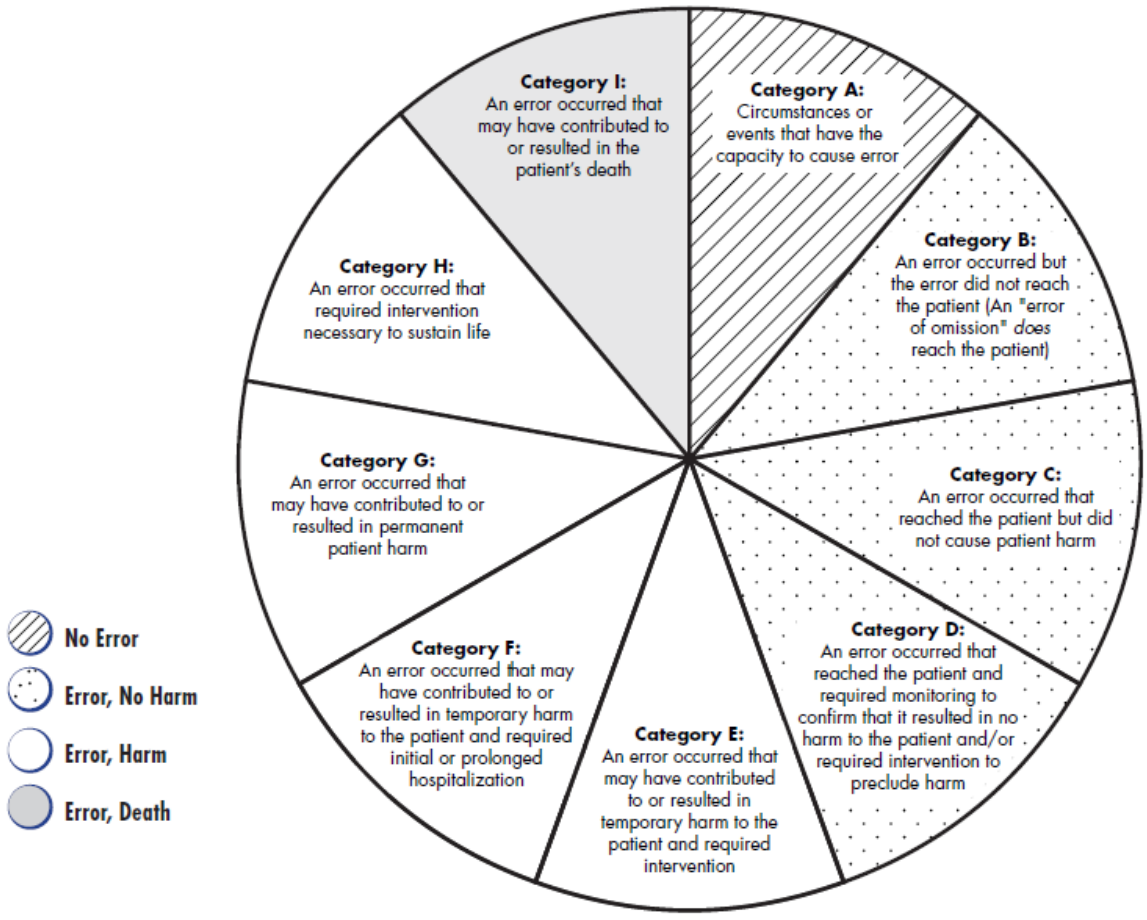

Figure 3.7 The NCC MERP severity rating scale (NCC MERP, 2001)

Some minor differences, though important to note, can be described from a comparison between this well-known tool and the constituents as derived from the systematic review. These are presented in table 3.15.

Table 3.15 Comparison between constituents derived from the systematic review and the NCC MERP severity rating scale

Component	Systematic review constituents	NCC MERP	Discussion
Overarching themes of errors	Potential error; harmless error; and harmful error. Also, requires no increase in monitoring or treatment; or require an increase in monitoring or treatment.	No error; error, no harm; error, harm; and error, death.	The NCC MERP distinguishes two categories for error and death, while these were grouped together in the systematic review. The systematic review adds the need for treatment or not.
Categories within scales	1. Hazard: Situations or events that can lead to a harmful event	Category A: Circumstances or events that have the capacity to cause error	Similar
	2. Did not reach patient: Error that has the potential to cause harm but due to corrective action and/or timely intervention was prevented from reaching the patient	Category B: An error occurred but the error did not reach the patient (An "error of omission" does reach the patient)	NCC MERP specifies omission as this category of error. However, no evidence from the systematic review supports this. It could be argued that omission could lead to more serious categories of harm.
	3. Negligible error: Error of negligible importance reached the patient but had no effect or caused no harm	Category C: An error occurred that reached the patient but did not cause patient harm	Similar
	4. Action precludes harm: Error with the potential to cause harm, requiring monitoring and/or intervention to ensure prevention of harm	Category D: An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm	Similar
	5. Mild harm: Error leading to transient, minimal	Category E: An error occurred that may have	From the systematic review, this category also

Component	Systematic review constituents	NCC MERP	Discussion
	symptoms/injury that may or may not require monitoring or intervention to alleviate	contributed to or resulted in temporary harm to the patient and required intervention	includes errors that do not require monitoring or intervention and is transient in nature even in the absent of such actions.
	6. Moderate harm: Error leading to potentially transient worsening condition requiring additional treatment, monitoring and/or increased length of hospital stay	Category F: An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	The systematic review results include errors that require additional treatment for worsening condition, even though this might not imply prolonged hospitalization as prescribed by the NCCMERP.
	7. Severe harm: Error leading to a potentially permanent impact on quality of life, or serious adverse effects, or relapse that requires increased treatment	Category G: An error occurred that may have contributed to or resulted in permanent patient harm	Systematic review results add serious adverse effects or relapse to the NCCMERP's permanent patient harm classification of this category.
	8. Life-threatening harm: Error leading to injury/symptoms that interferes significantly with functional ability or quality of life, or requiring acute life-sustaining treatment	Category H: An error occurred that required intervention necessary to sustain life	Systematic review results add injury or symptoms that significantly interferes with functional ability of quality of life and does not limit this category to only life-sustaining intervention like the NCC MERP.
	9. Death: Errors leading to or contributing to fatality	Category I: An error occurred that may have contributed to or resulted in the patient's death	Similar

To conclude, it is thought that the use of the NCC MERP severity rating scale in research reports about medication errors, could assist in standardising results and hence help to work toward a solution. However, some minor additions could add value to this scale, notably the option to categorize medication administration errors by the need for intervention or monitoring, and several small additions to categories of harm descriptions.

3.6. Chapter summary

In this chapter, results of the systematic review were provided. The processes of critical appraisal, data extraction and data synthesis were described in detail, leading to the discussion of outcomes per objective. A definition for medication error was provided, while the use of the constituents derived from the medication administration severity rating tools for the definition of severity was necessitated. Medication errors are recommended to be categorized according to treatment node as well as error type, while constituents for a severity rating scale closely resembling the NCC MERP tool was recommended, providing for a few additions to this widely-used tool. In the last chapter, the study will be evaluated, limitations thereof discussed and recommendations made for nursing practice, research and education provided as derived from the study results.

CHAPTER 4: EVALUATION OF THE STUDY, LIMITATIONS, AND RECOMMENDATIONS FOR NURSING PRACTICE, RESEARCH AND EDUCATION

4.1. Introduction

This chapter focuses on an evaluation of the study, the conclusion of the review findings, the limitations of the review and the recommendations resulting from its findings.

4.2. Findings

The definition of severity in research reports has been found to be lacking. Despite mentioning severity in terms of medication error, there is no clear and concise definition ascribed to the term. Grant *et al.* (2019:933) explain that the term *severity* is commonly used in research, but that a distinction between potential and actual harm severity is not stated. This discrepancy further complicates the actual meaning the researcher attaches to “severity”.

Research relating to severity of medication errors, and then standardising of the term in research reports, is suggested to be beneficial and could improve objectiveness in research to these regards. In an attempt for providing a preliminary basis on which to expand, it is recommended that severity should be defined according to the nine categories of harm derived from the systematic review. Thus, severity can be defined as the degree of either harm incurred or intervention-acuity required by a medication administration error; with harm ranging from hazard to death, and encompassing errors not reaching the patient, negligible errors, errors where action precludes harm, mild, moderate, severe and life-threatening harm.

The definition of medication errors seems to be a persistently occurring element of medication error research reports. Most reports refer to a definition of medication error. The most common is that by the NCC MERP. Other definitions are also utilized.

The importance of definition for medication error is reiterated by Aronson (2009:599) in terms of its ability to describe medication errors and develop strategies to prevent them. Lisby *et al.* (2010:507), as well as Gates *et al.* (2019:931), noted the recurrence of different definitions and concluded on a systematic review and the inconsistent use thereof. Standardisation is strongly suggested by these authors.

The use of the NCC MERP definition of medication error is also suggested, as it is most frequently used already by researchers, internationally available and is line with the findings of the thematic analysis of medication error definitions done in this review. Consistent use of this definition by the NCC MERP has been noted by Lisby *et al.* (2010:516). Research reports since have frequently used this definition as well as observed in this review.

To conclude, findings indicate that medication error definitions are used frequently in research reports. These differ widely. Thematic analysis suggests that certain themes should be mentioned in a proper medication error definition. Global standardisation thereof is needed to unify research to these regards. The use of the NCC MERP definition is a possible solution to the problem. A shortened definition of medication error might be: Any treatment process error in the use of a medication caused by a health care provider/user's deviation from expected actions, irrelevant of harm incurred or not.

Classification or categorisation of medication error is also a persistent element in research regarding medication error. It has been found that classification of medication errors by type and medication process or node of medication use differs among reports, thus indicating a lack in standardisation. This notion is also reported by Grant *et al.* (2019:932), especially in terms of medication related harm classifications.

Thematic analysis revealed that a distinction is made in research reports between medication error "types" and "medication process/ node of medication use/ stages of medication delivery". Administration of medication is the most error prone stage of medication delivery, and certain "types" of medication errors occur in this stage. Coding of themes revealed most frequently mentioned types of administration errors were dose, omission, drug and route errors.

These types of errors studied reflect the "five rights" of medication administration, that have been described by many nursing textbooks as the guidelines to safe medication administration for nurses (Berman *et al.,* 2008:849 & Lynn, 2008:153). These findings are consistent with the recommendations made by Kapaki (2018). This author describes the classification of medication errors as those made prior to administration and those upon administration. Categories according to Kapaki (2018) are those originally suggested by Safren and Chapanis in 1960 which are the wrong patient, time, dosage, medicine, route, omission of a dose and administration of and extra dose.

This review also revealed that the system to classify medication errors as proposed by the NCC MERP is most consistently used in research reports in this review. This can indicate an increasing trend to use this classification system, but the use of the five rights of medication administration to determine types of errors seems to be imbedded in the core of research in medication administration errors.

In conclusion, medication errors should be firstly classified according to the medication treatment process node (medication prescription, transcription, dispensing, administration, documentation and monitoring) and secondly according to type of error (wrong dose, wrong patient, wrong medication (with added deviations related to the drug), wrong route, wrong time and omission).

Severity rating tools or methods have been found to be used inconsistently. The review found that even though most reports rated the severity of medication errors studied in the reports, there were differences in the constituents of the methods. The method proposed by the NCC MERP was the most common method used.

Grant *et al.* (2019:931) agree that severity or harm rating tools are used inconsistently across studies, and that no tool has been universally incorporated. This influences the ability to compare results across studies. However, from the synthesis of the systematic review, the following conclusions based on scales currently in use to assess severity of medication administration errors were drawn:

- Medication errors can be divided into three overarching themes, viz. potential errors, harmless errors and harmful errors;
- Medication errors can also be divided into two overarching themes, namely those not leading to increased monitoring and treatment, and those that do;
- Harmless errors are errors that were either prevented from reaching the patient, reached the patient but had no impact on the patient's health status, or required monitoring to ensure that no harm was to come to the patient; and
- Harmful errors included transient harm irrespective of treatment required or not, temporary harm requiring an increase in treatment time or effort, long-lasting or permanent harm, harm to the extent of requiring measures to sustain life, and death.

The WHO (2019h) published a bulletin with a newly-developed classification system for patient safety incidents. As part of this classification system, Cooper *et al.* (2018:499) state that the parameters used for their explanation of harm ratings, are symptom duration, loss of functionality

and the intervention required due to the incident. This correlates with what has been found in this review.

However, with the already well-established NCC MERP classification system, it is suggested that the consistent use of this method could assist in standardising severity ratings globally. Its use is supported by various authors. Garfield *et al.* (2013:1155) found in a systematic review that the tool has sufficient validity and reliability. The inter-rater reliability of the tool is also perceived as fair in a study by van Doormaal *et al.* (2008:652). Findings are thus encouraging toward the use of the NCC MERP system. The following contributions to this existing scale could add value:

- The option to categorize medication administration by either measure of harm caused or the need for intervention or not;
- For category B of the NCC MERP, “omissions” should not be seen as part of this category, as omissions could lead to harm (for example antibiotic resistance, relapse, or disrupted therapeutic medication effect) and should thus not be included in the “no harm” domain of classification;
- In category E of the NCC MERP, errors fitting this category should not be limited to those requiring monitoring or intervention, but also those which cause harm that is by nature transient without these actions;
- Relating to category F of the NCC MERP, errors requiring additional treatment for worsening patient condition irrespective of effect on hospitalization duration should be added to this delineation;
- Category G of the NCC MERP should also include serious adverse effects or relapse caused by these errors; and
- For category H of the NCC MERP, provision should be made for errors that cause injury or symptoms that significantly interfere with functional ability or quality of life.

4.3. Evaluation of the study

This study can be evaluated by the achievement of set objectives and whether the PRISMA-checklist’s elements are present.

The foremost aim of the study was to identify elements that should be included in a comprehensive medication administration error severity rating scale. To achieve this, the following objectives were set:

- To explore the concept of “severity” and “medication error” in the context of nursing medication administration errors;
- To explore and describe the categorization of medication errors in recent literature; and
- To provide a summary of constituents required in the development of a comprehensive medication administration error severity rating scale.

The first objective was addressed by a literature review that shed light on the inconsistent use of both these terms. Thematic analysis of the different definitions used by research reports, substantiated that inconsistencies still exist in “medication error” definitions, but that the use of a definition provided by the NCC MERP could assist in standardisation of the definition. The definition of “severity” is shown to be absent in research reports. Definitions for medication error and severity were derived from study results.

The second objective was addressed by means of thematic analysis of the different classification systems found in reports. The conclusion is that classification systems also differ among reports. From the study findings, categorization of medication errors is recommended to be done firstly according to the medication treatment process node, and then according to the type of error.

Thirdly, a summary of constituents derived from currently used severity rating scales was provided to address objective three. These closely resembled the categories from the existing NCC MERP scale, although some additions and omissions were suggested.

After evaluation of the study by means of objectives being met, the study was also evaluated by the PRISMA-checklist, which follows in table 4.1. and was found compliant with prerequisites for a systematic review.

Table 4.1 Prisma checklist

Section	Checklist item	Section	Comment
Title			
Title	Identify the report as a systematic review, meta-analysis, or both.	Abstract	Rating the severity of medication errors: a systematic review.
Abstract			
Structured summary	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	Abstract	All but the registration number was provided in the abstract.
Introduction			
Rationale	Describe the rationale for the review in the context of what is already known.	1.1. Introduction and background 1.3. Research questions	
Objectives	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	1.4. Objectives and aims	
Methods			
Protocol and registration	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Chapter 1	Chapter one contains information on the methodology and the protocol for the review.

		1.8.1. Protocol and registration 2.2.1.2. Step 2 Develop review protocol.	
Eligibility criteria	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Chapter 1 1.8.2. Eligibility criteria 1.8.3. Search strategy 1.8.4. Study selection	
Information sources	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	1.8.3. Search strategy 2.2.2.1. Step 3: locate research reports	No contact with authors was necessary.
Search	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	1.8.3. Search strategy 2.2.2.1. Step 3: locate research reports	Described under these headings.
Study selection	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	1.8.3. Search strategy 1.8.2. Eligibility criteria 2.2.2.2. Step 4: Select research reports 2.2.2.3. Step 5: Appraisal of research reports	Selection based on eligibility criteria and quality appraisal.

Data collection process	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	1.8.5. Data-collection process. 2.2.3.1. Step 6: Data extraction	
Data items	List and define all variables for which data was sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	1.8.6. Data items/ coding 2.2.2.2. Step 4: Select research reports	
Risk of bias in individual studies	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	1.9.1. Risk of bias in individual studies	
Summary measures	State the principal summary measures (e.g., risk ratio, difference in means).	1.8.7. Synthesis of results	Narrative report after thematic analysis leading to meta-analysis.
Synthesis of results	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	1.8.7. Synthesis of results 2.2.4.1. Step 7: Synthesis and summary of findings	
Risk of bias across studies	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	1.9.2. Risk of bias across studies.	
Additional analysis	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	1.9. Rigour	

Results			
Study selection	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	3.2. Academic literature selection	
Study characteristics	For each study, present characteristics for which data was extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	3.4. Study characteristics	
Risk of bias within studies	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	1.9.1. Risk of bias in individual studies	
Results of individual studies	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	3.5. Data extraction 3.6. Synthesis of results	
Synthesis of results	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	3.6. Synthesis of results	
Risk of bias across studies	Present results of any assessment of risk of bias across studies (see Item 15).	1.9.2. Risk of bias across studies	
Additional analysis	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).		Not done

Discussion			
Summary of evidence	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	4.1. Findings	
Limitations	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	4.4. Limitations	
Conclusions	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	4.5. Recommendations 4.6. Conclusion	
Funding			
Funding	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Not applicable	

4.4. Limitations

- This review is limited in terms of the primary research used. The eligibility criteria caused many reports to be excluded. This could have led to the exclusion of valuable reports. However, the narrow scope could have improved the specificity of the review and improved the rigour of the study – a prerequisite for a systematic review of high quality.
- The absence of a second reviewer could have influenced the results of the review as the chances for researcher bias are higher. The use of a standard tool for critical appraisal, study supervision and strict data extraction guidelines mitigated this limitation to some extent.
- The data extraction process, as well as data analysis, was done by subjective analysis. Hence, the results obtained are influenced by the researcher's perceptions. Again, the use of strict extraction guidelines and study supervision mitigated this limitation.

4.5. Recommendations

Overall, recommendations made by this review aim for the global standardisation of a medication error definition, classification and severity rating scales.

Firstly, is the standardisation of terminology – specifically the definition of medication error and severity in this context. This is thought to improve clear and concise terminology which can guide the users of medication error data.

Secondly, it is recommended that a comprehensive severity rating scale for medication errors be developed, or that already established methods be employed consistently in all research.

Specifically addressing above recommendations, the following is suggested:

- The following definition for "medication error" is presented: Any treatment process error in the use of a medication caused by a health care provider/user's deviation from expected actions, irrelevant of harm incurred or not.
- The following definition for "severity" is presented: The degree of either harm incurred or intervention-acuity required by a medication administration error; with harm ranging from hazard to death, and encompassing errors not reaching the patient, negligible errors, errors where action precludes harm, mild, moderate, severe and life-threatening harm.
- Regarding classification, it is recommended that medication errors should be firstly classified according to the medication treatment process node (medication prescription, transcription,

dispensing, administration, documentation and monitoring) and secondly according to type of error (wrong patient, wrong medication (with added deviations related to the drug), wrong route, wrong time, and omission).

- Relating to the use of a standardised severity rating scale, the use of the NCC MERP scale is recommended, with the consideration of previously made suggestions for improvement.

4.5.1. Recommendations for nursing practice

The review has detected in the literature review that nurses are the most common committers of medication errors, and the last link in the medication delivery system. They are also most afraid to report such mistakes out of fear. But nurses are the ones who are most able to identify and report medication errors. This review can add value in terms of the definition, classification and severity rating systems that need standardisation, that could then assist nurses in reporting errors.

By standardising the definitions, classifications and severity ratings, nurses could have more assurance to identify and report medication errors.

In-service training on medication errors, the classification thereof and rating the severity of these errors are suggested as better insight into the problem might preclude some harm following negligent errors.

The use of a standard severity rating scale in hospitals as part of the adverse-event reporting system is recommended. This will motivate further interventions aimed at reducing medication administration errors in hospitals.

4.5.2. Recommendations for nursing research

Nursing research regarding the severity rating of medication is suggested to be important for the continuation of research in the medication error field. It is thought that research regarding nurses' role in the rating of medication error severity and classification of medication errors could be beneficial for the field.

Further, nursing research into the ease of use and value added by the use of the suggested comprehensive severity rating scale could also assist in the refinement and establishment of such a scale.

This study focused on harm done to patients because of medication administration errors. An emerging field of interest is the harm experienced to the well-being of nurses following their

committing of a serious medication error. It is recommended that further research should address this niche.

4.5.3. Recommendation for nursing education

Training nurses and nursing students in the reality of medication errors, as well as the correct medication handling, could prevent or reduce further medication errors occurring. It is also suggested that training on standardised methods of medication error reporting be endeavoured to assist in detection of medication errors.

Training on the use of a severity rating scale is important to foster a culture of reporting errors effectively and with precision.

Nurses should be trained to understand the various nodes of the medication treatment process wherein medication errors could occur to increase attentiveness to hazards.

Nursing students should still be trained in the use of the five rights, as these still provide a foundation to be aware of where errors could occur.

4.5.4. Recommendations for policy

Health care institutions are recommended to establish policies on medication error and to align it with globally standardised methods and classification systems. This review's findings suggest that use of the NCC MERP classification of medication errors, as well as the severity ratings, be used to do so.

Policy should provide for regular training opportunities on medication error related topics.

4.6. Conclusion

This chapter covered the review findings, evaluation of the review, limitations and recommendations.

Definitions for "medication error" and "severity" were formulated, categorization for medication errors described, and constituents summarized for the development of a severity rating tool.

Although limitations to the study were set, the objectives of the study were deemed to have been met satisfactorily and in line with the PRISMA guidelines provided.

Several recommendations for medication safety in general, nursing practice, nursing education and nursing policy were developed and outlined.

With this, this systematic review is concluded.

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ADDENDUM A: PRISMA CHECKLIST

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	

Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	

Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	

ADDENDUM B: ELIGIBILITY SCREENING

No	Author and date	Title	1. Medication errors /medication administration errors?	2. Severity rating scale/tool used, and severity rating outcome?	3. In a nursing context?	Included/ excluded?
1	Abbasi *et al.* (2015)	Accuracy of harm scores entered into an event reporting system	1	1	1	Included
2	Al-Faouri *et al.* (2014)	A five years retrospective study of reported medication incidents at a Jordanian teaching hospital: patterns and trends	1	1	1	Included
3	Alharbi *et al.* (2016)	A comparative study of voluntarily reported medication errors among adult patients in intensive care (IC) and non-IC settings in Riyadh, Saudi Arabia	1	1	1	Included
4	Alshehri *et al.* (2017)	Frequency and nature of medication errors and adverse drug events in mental health hospitals: a systematic review	1	1	0	Excluded
5	Andersson *et al.* (2018)	Factors contributing to serious adverse events in nursing homes	1	0	1	Excluded
6	Arain *et al.* (2016)	Should health care aides assist with medications in long-term care?	1	1	1	Included

7	Ayani *et al.* (2016)	The epidemiology of adverse drug events and medication errors among psychiatric inpatients in Japan: the JADE study	1	0	0	Excluded
8	Baqir *et al.* (2014)	Reducing unacceptable missed doses: pharmacy assistant-supported medicine administration	1	0	0	Excluded
9	Baril *et al.* (2013)	Technology and medication errors: impact in nursing homes	1	1	1	Included
10	Bataille *et al.* 2014)	High-alert medications in a French paediatric university hospital	1	0	0	Excluded
11	Berdot *et al.* (2016)	Interventions to reduce nurses' medication administration errors in inpatient settings: A systematic review and meta-analysis	1	0	1	Excluded
12	Bertsche *et al.* (2018)	Prioritising the prevention of medication handling errors	1	1	1	Included
13	Breuker *et al.* (2017)	Medication errors at hospital admission and discharge: risk factors and impact of medication reconciliation process to improve healthcare	1	1	1	Included
14	Breuker *et al.* (2017)	Medication errors at hospital admission and discharge in Type 1 and 2 diabetes	1	1	1	Included
15	Campino *et al.* (2016)	Medicine preparation errors in ten Spanish neonatal intensive care units	1	0	1	Excluded

16	Carnes *et al.* (2015)	Aged-care nurses in rural Tasmanian clinical settings more likely to think hypothetical medication error would be reported and disclosed compared to hospital and community nurses	0	0	1	Excluded
17	Chi *et al.* (2016)	An evaluation of the epidemiology of medication discrepancies and clinical significance of medicines reconciliation in children admitted to hospital	1	1	1	Included
18	Cottney & Innes(2015)	Medication-administration errors in an urban mental health hospital: A direct observation study	1	1	1	Included
19	Cousein *et al.* (2014)	Effect of automated drug distribution systems on medication error rates in a short-stay geriatric unit	1	1	1	Included
20	D'aquino *et al.* (2015)	Drug-related incidents in a hospital: Input to improving management	1	0	0	Excluded
21	Dolejs *et al.* (2017)	Medication errors in injured patients	1	1	0	Included
22	Elden & Ismail (2015)	The importance of medication errors reporting in improving the quality of clinical care services	1	1	1	Included
23	Ferrah *et al.* (2017)	Systematic review of the prevalence of medication errors resulting in hospitalization and death of nursing home residents	1	0	1	Excluded
24	Gates *et al.* (2018)	Preventable adverse drug events among inpatients: a systematic review	0	0	0	Excluded
25	Gharekhani *et al.* (2014)	Frequency, types, and direct related costs of medication errors in an academic nephrology ward in Iran	1	1	1	Included

26	Alan (2018)	Reducing harm to patients caused by avoidable adverse drug reactions	1	0	0	Excluded
27	Hammour &Abdel Jalil (2016)	Medication errors in voluntary reported incidents at a Jordanian hospital	1	1	1	Included
28	Härkänen *et al.* (2014)	The factors associated with medication errors in adult medical and surgical inpatients: a direct observation approach with medication record reviews	1	1	1	Included
29	Hedlund *et al.* (2017)	Systematic evidence review of rates and burden of harm of intravenous admixture drug preparation errors in healthcare settings	1	0	1	Excluded
30	Ohashi *et al.* (2017)	Evaluation of intravenous medication errors with smart infusion pumps in and academic medical centre	1	1	1	Included
31	Kovacevic *et al.* (2018)	Accuracy of medication safety report severity level among disciplines at a tertiary academic medical centre	0	0	0	Excluded
32	Lan *et al.* (2013)	Medication errors in paediatric nursing: assessment of nurses' knowledge and analysis of the consequences of errors	1	0	1	Excluded
33	Lan *et al.* (2013)	Medication administration errors made by nurses reflect the level of pharmacy administration and hospital information infrastructure	0	0	0	Excluded

34	Lehnbom *et al.* (2014)	Impact of medication reconciliation and review on clinical outcomes	1	0	0	Excluded
35	Levkovich *et al.* (2017)	Understanding how medications contribute to clinical deterioration and are used in rapid response systems: A comprehensive scoping review	0	0	0	Excluded
36	Manias *et al.* (2013)	Medication errors in hospitalised children	1	0	1	Excluded
37	Mathaiyan *et al.* (2016)	Prescription, transcription and administration errors in out-patient day care unit of a regional cancer centre in South India	1	0	1	Excluded
38	Björkstén *et al.* (2016)	Medication errors as malpractice-a qualitative content analysis of 585 medication errors by nurses in Sweden	1	0	1	Excluded
39	Metsälä & Vaherkoski (2013)	Medication errors in elderly acute care - a systematic review	1	0	1	Excluded
40	Nanji *et al.* (2016)	Evaluation of perioperative medication errors and adverse drug events	1	0	0	Excluded
41	Patty & Miller (2014)	New approach to assessment of medication safety in a community hospital	1	0	0	Excluded

42	Nguyen *et al.* (2013)	The effect of a clinical pharmacist-led training programme on intravenous medication errors: a controlled before and after study	1	1	1	Included
43	Nguyen *et al.* (2015)	Medication errors in Vietnamese hospitals: prevalence, potential outcome and associated factors	1	0	1	Excluded
44	de Azevedo *et al.* (2015)	Prevalence of medication-related incidents in an intensive care unit	1	0	1	Excluded
45	Rishoej *et al.* (2018)	Identifying and assessing potential harm of medication errors and potentially unsafe medication practices in paediatric hospital settings: a field study	1	1	1	Included
46	Sahithi *et al.* (2015)	Assessment of medication errors in psychiatry practice in a tertiary care hospital	1	1	1	Included
47	Schnock *et al.* (2017)	The frequency of intravenous medication administration errors related to smart infusion pumps: a multihospital observational study	1	1	1	Included
48	Schwendimann *et al.* (2018)	The occurrence, types, consequences and preventability of in-hospital adverse events - a scoping review	0	1	0	Excluded

49	Sears *et al.* (2016)	The relationship between nursing experience and education and the occurrence of reported paediatric medication administration errors	1	1	1	Included
50	Shrestha &Ramanath (2015)	Study and evaluation of medication errors in medicine and orthopaedic wards of a tertiary care hospital	1	1	1	Included
51	Sulaiman *et al.* (2017)	Evaluating medication errors for hospitalized patients: The Jordanian experience	1	1	1	Included
52	Valle *et al.* (2017)	Medication incidents in an outpatient emergency service: documental analysis	1	0	0	Excluded

ADDENDUM C: CRITICAL APPRAISAL SCORE

	Article author	Type of study	Aim/objective of the study stated	Explanation and defined outcome of the	Error categories specified	Error categories defined	Denominator used and explained	Data collection methods explained	Study setting explained	Validity and reliability measures taken	Study limitations considered	Score
1	Abbasi *et al.* (2015)	**Quality improvement project**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**0**	**1**	**8/9 = 88%**
2	Al-Faouri *et al.* (2014)	**Retrospective**	**1**	**1**	**1**	**0**	**NA**	**1**	**1**	**0**	**0**	**5/8 = 62 %**
3	Alharbi *et al.* (2016)	**Retrospective**	**1**	**1**	**1**	**0**	**NA**	**1**	**1**	**0**	**1**	**6/8 = 75%**
4	Arain *et al.* (2016)	**Mixed method**	**1**	**1**	**1**	**0**	**NA**	**1**	**1**	**0**	**1**	**6/8 = 75%**
5	Baril *et al.* (2013)	**Voluntary reporting process**	**1**	**1**	**0**	**0**	**NA**	**1**	**1**	**1**	**0**	**5/8 = 62.5%**
6	Bertsche *et al.* (2008)	**Prospective observational**	**1**	**1**	**1**	**1**	**NA**	**1**	**1**	**0**	**1**	**7/8 = 87.5%**
7	Breuker *et al.* (2017)	**Prospective observational**	**1**	**1**	**1**	**0**	**NA**	**1**	**1**	**0**	**0**	**5/8 = 62.5%**
8	Cottney & Innes (2015)	**Prospective direct observational**	**1**	**1**	**1**	**0**	**NA**	**1**	**1**	**0**	**1**	**6/8 = 75%**
9	Cousein *et al.* (2014)	**Before and after observational**	**1**	**1**	**1**	**0**	**NA**	**1**	**1**	**0**	**1**	**6/8 = 75%**

10	Elden & Ismail (2015)	**Pertest/ post-test intervention**	**1**	**1**	**1**	**1**	**NA**	**1**	**1**	**0**	**1**	**7/8 = 87.5%**
11	Gharekhani *et al.* (2014)	**Prospective cross-sectional**	**1**	**1**	**1**	**0**	**NA**	**1**	**1**	**0**	**1**	**6/8 = 75%**
12	Hammour & Jalil (2016)	**Retrospective study**	**1**	**1**	**1**	**0**	**NA**	**1**	**1**	**0**	**1**	**6/8 = 75%**
13	Härkänen *et al.* (2014)	**Cross-sectional observational**	**1**	**1**	**1**	**0**	**NA**	**1**	**1**	**1**	**1**	**7/8 = 87.5%**
14	Ohashi *et al.* (2017)	**Prevalence**	**0**	**0**	**1**	**1**	**NA**	**1**	**1**	**1**	**1**	**6/8 = 75%**
15	Nguyen *et al.* (2013)	**Controlled before and after study**	**1**	**1**	**1**	**1**	**NA**	**1**	**1**	**0**	**1**	**7/8 = 87.5%**
16	Rishoej *et al.* (2018)	**Observational**	**1**	**1**	**1**	**0**	**NA**	**1**	**1**	**0**	**1**	**6/8 = 75%**
17	Sahithi *et al.* (2015)	**Prospective observational**	**0**	**1**	**1**	**0**	**NA**	**1**	**0**	**1**	**1**	**5/8 = 62.5%**
18	Schnock *et al.* (2017)	**Prospective point prevalence**	**1**	**1**	**1**	**0**	**NA**	**1**	**1**	**0**	**1**	**6/8 = 75%**
19	Sears *et al.* (2016)	**Prospective descriptive**	**1**	**1**	**0**	**0**	**NA**	**1**	**1**	**1**	**1**	**6/8 = 75%**
20	Shrestha & Ramanath (2015)	**Prospective observational**	**1**	**1**	**1**	**1**	**NA**	**1**	**1**	**0**	**1**	**7/8 = 87.5%**
21	Sulaiman *et al.* (2017)	**Prospective observational**	**1**	**1**	**1**	**0**	**NA**	**1**	**1**	**1**	**1**	**7/8 = 87.5%**

ADDENDUM D: EPPI REVIEWER 4 INFORMATION

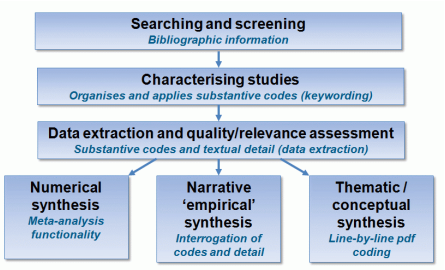
Features

EPPI-Reviewer 4 is the EPPI-Centre's comprehensive online software tool for research synthesis. It is a web-based software program for managing and analysing data in literature review and has been developed for all types of systematic review such as meta-analysis, framework synthesis and thematic synthesis.

Systematic review

EPPI-Reviewer 4 has the functionality to help manage your systematic review through all stages of the process from bibliographic management, screening, coding and right through to synthesis.

It manages references, stores PDF files, facilitates qualitative and quantitative analyses and allows easy export of review data to enable use with other software programmes.



The software allows multiple concurrent users to access the system and being web-based allows members of a review group to be located in different geographic locations.

EPPI-Reviewer 4 supports many different analytic functions for synthesis including meta-analysis, empirical synthesis and qualitative thematic synthesis. It allows you to present your data in summary diagrams and customisable reports.

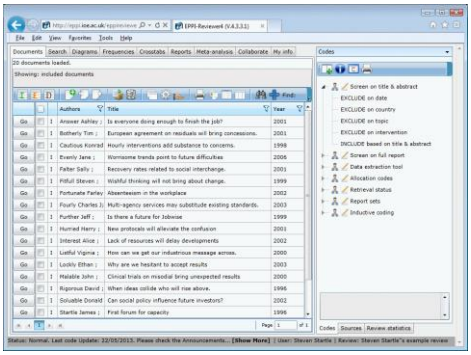
Recent additions to the software include text mining, data clustering, classification and term extraction which are leading to new possibilities in the field of systematic reviewing.

The only system requirements to run EPPI-Reviewer 4 are that you must be connected to the internet and your computer will need to have the free Microsoft Silverlight browser plug-in installed. This plug-in is available for both PCs and Macs and is available here.
You can start using EPPI-Reviewer 4 today by signing up for a free one month trial here!

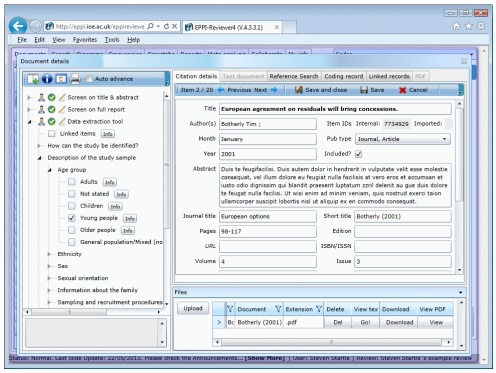
Detailed features and functions

A more detailed description of its many functions include:

Reference management



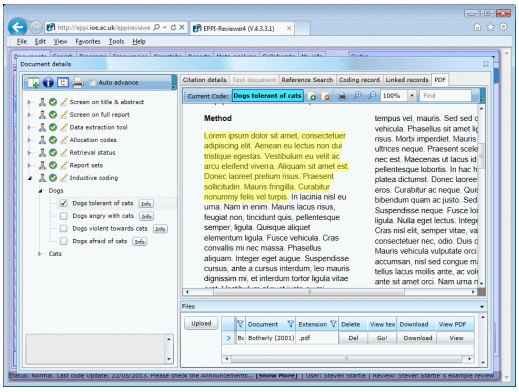
- Managing the thousands of references that often result from comprehensive searches of electronic databases
- Importing references in a wide variety of 'tagged' formats
- Duplicate checking using 'fuzzy logic'. (Potential duplicates can be checked manually and / or automatically classified as duplicates, depending on how similar they are.)
- Document storage: store the original document file (such as pdf, doc etc) along with the study record.
- 'Linked documents': the 'unit of analysis' in a systematic review is usually the study, but there are often multiple publications originating from the same study; EPPI-Reviewer 4 helps reviewers to use the correct 'unit'.
- Direct access to PubMed through web services. EPPI-Reviewer 4 makes use of this capability to allow direct searching and search result data transfer from PubMed.



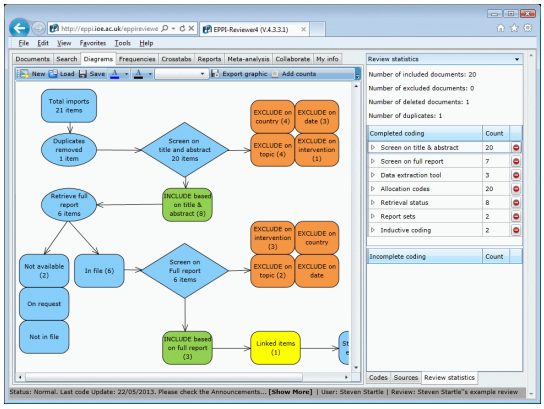
Study classification and data extraction

- Flexible coding schemas for classifying studies:
  - Inclusion / exclusion / eligibility criteria;
  - Codes for descriptive 'mapping' of research activity.
  - Codes to capture detailed information about a study.
- Concurrent multi-user classification: multiple users can classify studies independently and then compare their results; EPPI-Reviewer 4 works throughout this process, producing summary discrepancy reports and an interface to facilitate the process of agreeing final decisions.
- Bulk application / removal of codes to selected studies
- Calculation of common measures of effect (odds ratios, risk ratios, risk differences, standardized mean differences, mean differences) from a variety of statistics (2 x 2 tables, means, standard deviations, confidence intervals, p, t and r values).
- Text mining: automatic term recognition and document clustering.

Synthesis



- Running meta-analyses (fixed and random effects models); calculating I-squared and supporting sub-group analyses using analogue to the anova
- A powerful search engine enabling users to search by categories and text and combine searches using Boolean terms
- Producing reports of categorical, numeric and textual data in a wide variety of formats from frequency reports, crosstabs and full-text reports, to tabular summary reports and summary statistics of numeric data
- Text mining functionality. Automatic document clustering, using text mining, is one way of describing the range of studies you have identified at the click of a button. Text mining can assist with searching by identifying significant terms in the documents you have already included.
- Inductive coding functionality. This allows line by line coding of textual data and organising and structuring these codes graphically into 'conceptual relationship diagrams to display analytic and descriptive themes found through inductive coding.
- Fulltext reference searching using the uploaded pdfs.
- Diagrams to summarise e.g. qualitative syntheses and theories of change for interventions.



Review Management

- The ability to create an unlimited number of non-shareable reviews.
- Allocation of classification tasks (e.g. screening / data extraction) to individual users.
- Work progress reporting.
- Individual reviewer permissions (forthcoming)
- Review flow charts which update automatically (e.g. with counts of how many studies have been included / excluded according to which criterion in order to generate PRISMA flow-diagrams).
- Easy export of review data to enable use with other software programmes and to enable long term independent storage of data.

Under development

We have been developing ways of using emerging text mining technologies in systematic reviews. Currently used during the searching and screening stages of a review, you can read a paper which outlines their potential published in Research Synthesis Methods*. We have also written up our early findings in the NCRM Newsletter and in a poster presented at the 2011 Cochrane Colloquium. Methods to use these technologies are still in their infancy and require significant further evaluation. While automatic

term recognition and document clustering are available for all users, document classification often requires significant server processing time and support; therefore this technology is not yet generally available in EPPI-Reviewer. However, if you would like to use a classifier in your review, please contact us to discuss your particular requirements.

Citing EPPI-Reviewer 4

Thomas J, Brunton J, Graziosi S (2010) EPPI-Reviewer 4: software for research synthesis. EPPI-Centre Software. London: Social Science Research Unit, UCL Institute of Education.

ADDENDUM E: ETHICAL CLEARANCE CERTIFICATE

Private Bag X1290, Potchefstroom
South Africa 2520

Tel: 018 299-1111/2222
Fax: 018 299-4910
Web: http://www.nwu.ac.za

Research Ethics Regulatory Committee
Tel: 018 299-4849
Email: nkosinathi.machine@nwu.ac.za

ETHICS APPROVAL LETTER OF STUDY

Based on approval by the North West University Health Research Ethics Committee (NWU-HREC) on 06/09/2018, the NWU Health Research Ethics Committee hereby approves your study as indicated below. This implies that the North-West University Research Ethics Regulatory Committee (NWU-RERC) grants its permission that, provided the special conditions specified below are met and pending any other authorisation that may be necessary, the study may be initiated, using the ethics number below.

Study title: Rating the severity of medication administration errors: A systematic review.
Study Leader/Supervisor (Principal Investigator)/Researcher: Dr AJ Blignaut
Student: LS Botha

Ethics number:

N	W	U	-	0	0	0	9	5	-	1	8	-	A	1
Institution				Study Number						Year			Status	

Status: S = Submission; R = Re-Submission; P = Provisional Authorisation; A = Authorisation

Application Type: Systematic review
Commencement date: 2018/09/08 **Risk:** **Minimal**
Expiry date: 2019/09/30

Approval of the study is initially provided for a year, after which continuation of the study is dependent on receipt and review of an annual (or as otherwise stipulated) monitoring report and the concomitant issuing of a letter of continuation.

Special in process conditions of the research for approval (if applicable):

- If there are any changes to the data extraction rubric to be used in the study, it should be submitted to the HREC for review and approval, before it is implemented in the study.

General conditions:

While this ethics approval is subject to all declarations, undertakings and agreements incorporated and signed in the application form, the following general terms and conditions will apply:

- *The study leader/supervisor (principle investigator)/researcher must report in the prescribed format to the NWU-HREC:*
  - *annually (or as otherwise requested) on the monitoring of the study, whereby a letter of continuation will be provided, and upon completion of the study; and*
  - *without any delay in case of any adverse event or incident (or any matter that interrupts sound ethical principles) during the course of the study.*
- *The approval applies strictly to the proposal as stipulated in the application form. Should any amendments to the proposal be deemed necessary during the course of the study, the study*

ADDENDUM F: PROOF OF ETHICAL TRAINING

NWU®
NORTH-WEST UNIVERSITY
NOORDWES-UNIVERSITEIT
YUNIBESITI YA BOKONE-BOPHIRIMA

Private Bag X6001, Potchefstroom
South Africa 2520
Tel: 018 299-1111/2222
Web: http://www.nwu.ac.za

Health Sciences Ethics Office for Research, Training and Support
Tel: 0182992089
Email: minrie.greeff@nwu.ac.za

30 April 2018

Dear Ms Liezl Soné Botha

PROOF OF ATTENDANCE AND ASSESSMENT

This letter certifies that you have attended the 2 day ethics training and successfully completed the associated assessment.

The Basics of Health Research Ethics

(Accreditation number: PSB002/037/01/2018 from University of Free State CPD accreditation department accredited by the HPCSA)

Presenter: Prof Minrie Greeff (Head of the Health Sciences Ethics Office for Research, Training and Support) on **7 and 8 March 2018.**

This letter of attendance, as proof of ethics training and assessment, is valid for 3 years and expires on the 8 March 2021 (Where applicable, Ethics CEUs awarded: 14 CEUs).

Yours sincerely,

Prof Minrie Greeff
Head of Health Sciences Ethics
Office for Research, Training and Support

Prof Awie Kotzé
Executive Dean
Faculty of Health Sciences

ADDENDUM G: PROOF OF LANGUAGE EDITING

Declaration

This is to declare that I, Annette L Combrink, accredited language editor and translator of the South African Translators' Institute, have language-edited the dissertation by

L.S. Botha

orcid.org/0000-0003-2624-0638

with the title

Rating the severity of medication administration errors: a systematic review

Prof Annette L Combrink
Accredited translator and language editor
South African Translators' Institute
Membership No. 1000356
Date: 28 March 2020