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Reporting of medication errors in Estonian hospitals: a cross-sectional mixed-method evaluation

Master's thesis

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Ravimivigade raporteerimine Eesti haiglates: läbilõikeline segameetodil uuring

Magistritöö

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Author’s declaration of originality

I hereby certify that I am the sole author of this thesis. All the used materials, references to the literature, and the work of others have been referred to. This thesis has not been presented for examination anywhere else.

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Abstract

Background: A medication error (ME) is an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient. Unsafe medication practices and MEs are a leading cause of avoidable harm in health care systems across the world. Analysis of MEs can lead to system improvement and reduced risk. Thus, evaluating the ME reporting and associated factors in Estonia is important to improve the quality of healthcare services. **This thesis aims** to conduct a first countrywide analysis of ME reporting in Estonia, focusing on hospitals. **Methods:** Mixed-method empirical study includes a systematic review of national databases for ME collection and a cross-sectional hospital survey consisting of semi-structured interviews with hospital patient safety experts and a quantitative nurses' perception survey. **Results:** In total 49 MEs, including 8 hospital MEs, were registered in national databases from 2016 to 2021. In the years 2019 to 2021, no hospital MEs were registered in national databases. Two-thirds (n = 10) of hospitals have a patient safety incident reporting system but only 5 hospitals have recorded a total of 109 MEs in 2021. Only regional hospitals systematically collect MEs. Nurses' perceptions of why MEs occur were related to *medication package, nursing processes,* and *physician communication*. Experts and nurses agreed that *fear of consequences* is the most important reason why MEs are not reported. **Conclusions:** ME reporting is inconsistent in Estonia. Legal risk, lack of nationally agreed rules, definitions, reporting systems, and fear of consequences are the main barriers to ME reporting in Estonia. Implementing *mandatory patient insurance with mandatory reporting*, promoting *blame-free culture* and *continuous training* would improve the ME reporting. Ensuring *adequate staffing* levels and the use of a *computerised physician order entry* (CPOE) could reduce the incidence of the MEs.

This thesis is written in English and is 54 pages long, including 7 chapters, 19 figures, and 5 tables.

Annotatsioon

Ravimivigade raporteerimine Eesti haiglates: läbilõikeline segameetodil uuring

Taust: ravimiviga (RV) on ettekavatsematu viga raviprotsessis, mis on seotud ravimiga ja mis põhjustab või võib põhjustada patsiendile kahju. Ebaturvaline ravimite kasutamine on kogu maailmas patsiendi välditavate kahjude peamiseks põhjuseks. RVde analüüs saab kaasa aidata patsiendiohutuse parandamisele ja riski vähendamisele. Seega on tervishoiuteenuste kvaliteedi tõstmiseks oluline uurida ja hinnata RVdest teatamist ja sellega seotud tegureid Eestis. Selle lõputöö eesmärk on läbi viia esimene üleriigiline RVde uurimustöö Eestis, keskendudes eelkõige haiglatele. **Metoodika:** Segameetodil empiiriline uuring hõlmab RVsid koguvate riiklike andmebaaside süstemaatilist ülevaadet ja haiglate läbilõikeuuringut, mis koosnes poolstruktureeritud intervjuudest haigla patsiendiohutuse ekspertidega ja õdede kvantitatiivsest küsimustikust. **Tulemused:** aastatel 2016-2021 registreeriti riiklikes andmebaasides kokku 49 RV-d, millest 8 haigla RV. Viimastel aastatel (2019-2021) ei ole riiklikesse andmebaasidesse ühtegi haigla RV registreeritud. Kahel kolmandikul (n = 10) haiglatest on olemas patsiendiohutuse juhtudest teatamise süsteem, kuid 2021. aastal registreeriti kokku 109 RV vaid 5 haiglas. Ainult regionaalhaiglad koguvad süstemaatiliselt RVsid. Õdede arvates olid RVde tekkimise põhjused seotud *ravimipakenditega, õendusprotsessiga* ja *arstidega suhtlemisega*. Eksperdid ja õed nõustusid, et *hirm tagajärgede ees* on kõige olulisem põhjus, miks RVdest ei teatata. **Järeldused:** RVde raporteerimine on Eestis puudulik. Õiguslik risk, riiklikult kokkulepitud reeglite, definitsioonide ja raporteerimissüsteemide puudumine ja hirm tagajärgede ees on RVde raporteerimise peamisteks takistusteks. Kohustusliku patsiendikindlustuse rakendamine, koos raporteerimiskohustusega, süüdistamisvaba kultuuri edendamine ja pidev töötajate koolitus parandaks RVde kogumist ja analüüsi. Piisava töötajate arvu tagamine ja arvutipõhise ravikorralduslehe kasutamine võib vähendada RVde esinemissagedust.

Lõputöö on kirjutatud inglise keeles ning sisaldab teksti 54 leheküljel, 7 peatükki, 19 joonist, 5 tabelit.

List of abbreviations and terms

ADR	Adverse drug reaction
AE	Adverse event
CLIHPA	Compulsory Liability Insurance of Healthcare Providers Act
CPOE	Computerised physician order entry
ECQH	Expert Committee on the Quality of Healthcare
EHIF	Estonian Health Insurance Fund
EMA	European Medicines Agency
EPIC	Estonian Poisoning information Centre
HIS	Hospital information system
HNDP	Hospital Network Development Plan
HP	Healthcare provider
ICA	Inductive content analysis
ICD-10	International Classification of diseases version 10
ICPS	International Classification for Patient Safety
IVCH	Ida-Viru Central Hospital
MAE	Medication administration error
MAH	Marketing Authorisation Holder
ME	Medication error
NERH	North Estonian Regional Hospital
PIL	Patient Insurance Law
PIM	Potentially inappropriate medicine
POI	acronym from *Patsiendi Ohujuhtumi Infosüsteem*
PSI	Patient safety Incidents
SAM	State Agency of Medicines
TCH	Tallinn Children's Hospital
TUH	Tartu University Hospital
WHO	World Health Organisation
WTCH	West Tallinn Central Hospital

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1 Introduction

A medication error (ME) is an unintended failure in the drug treatment process that leads to or has the potential to lead to, harm to the patient [1]. Unsafe medication practices and MEs are a leading cause of avoidable harm in health care systems across the world [2]. Studies show that the incidences of ME were between 6.5% and 7.5% of hospitalised patients [3], [4]. Up to 56.6% of these cases were judged to be preventable [5]. A ME is associated with a significantly prolonged length of hospital stay, increased economic burden, and an almost 2-fold increased risk of death [6]. WHO has estimated that the global cost associated with MEs is 42 billion USD annually [2].

The incidence of MEs has not been studied in Estonia before. However, it has been estimated based on United Kingdom data that 800 000 potentially harmful MEs per year occur in Estonia [7]. Considering the number of hospitalised patients in 2020 [8]happening in Estonian hospitals every day.

An efficient ME recording system is recognized as an important measure to improve medication safety in hospitals [9]. However, the ME recording alone does not improve the health outcomes unless it has clinical ownership and integration with wider safety programs [10].

Despite a decade of discussions and several reports [11]–[14] highlighting the need for the implementation of national patient safety indicators, there is no nationally agreed system for registering and analysing the MEs in Estonia [7]. Few studies have been conducted about patient safety events reporting in Estonia [15]–[19]. However, these have been limited to a few selected hospitals and are not representative of the whole country. A countrywide analysis using both quantitative and qualitative methods focusing on MEs is missing. After years of preparation, Estonia is finally implementing mandatory patient insurance from 2024. The legislation changes include the mandatory MEs reporting and the national database creation for MEs [20]. The current study will set the baseline before the implementation of administrative measures and with a subsequent follow-up evaluation would build a longitudinal case study of international importance.

Problem statement: MEs are a leading course of avoidable harm to patients and increased health care systems costs [2] but there is no countywide analysis done in Estonia about MEs [7].

The current study aims to fill that gap in terms of conducting a first countrywide quantitative and qualitative analysis of MEs reporting in Estonia with a special focus on hospitals.

Research questions:

1. What systems are used in Estonia to register and analyse MEs at the national and hospital levels?
2. Why do MEs occur?
3. Why are MEs not reported?
4. How to reduce MEs?

These problems are analysed at the national, hospital, and individual levels.

Initial hypothesis. ME reporting is very limited in Estonia as there is no national ME reporting system. Hospitals collect and manage the MEs as part of their care quality system. Also, legislation supporting reporting and analysing ME is still missing in Estonia.

2 Problem description

The following section will give an overview of the ME problem based on the literature review. The section opens the background and definition of ME and focuses on the ME collection and reporting in hospitals. Furthermore, insights into the reasons for MEs and how to reduce the hospital MEs are presented.

2.1 Burden of medication errors

Twenty-three years ago, the seminal report “To Err is Human" exposed a hidden patient safety crisis by identifying up to 98 000 patient death in the United States each year due to medical errors, from which 7000 patients die due to avoidable MEs [21]. Since then, patient safety, including medication safety has been advanced in many countries [9], [10], [22]. In the US the MEs are the sixth cause of mortality with 5-10% of the reported MEs classified as harmful [23]. Studies show that the incidence of ME is between 6.5% and 7.5% of hospitalised patients [3], [4]. Up to 56.6% of these cases were judged to be preventable [5].

Transferring the statistics to Estonia means that there may be up to 40 MEs every day in Estonian hospitals. Medication administration errors (MAEs) are the most frequent type of MEs [24]. Transferring data from an Australian study [25] up to 8000 MAEs occur in Estonian hospitals every year.

A ME is associated with a significantly prolonged length of hospital stay, increased economic burden, and an almost 2-fold increased risk of death [6]. Depending on the detection method the share of serious adverse effects caused by MEs is from 0.7% to 1.6% in retrospective studies [26], [27] and from 2.4% to 6.5% in prospective studies [28]. WHO has estimated that the global cost associated with MEs is 42 billion USD annually [2].

WHO has recognised the burden of MEs and launched a global initiative *Medication Without Harm* in 2017 [2]. The initiative is a call for action to reduce the MEs by 50% worldwide by 2023. Incident reporting and learning by health care professionals is one of the important sub-domains (Figure 1).

Figure 1. WHO Medication Without Harm. ©WHO 2018.

The WHO initiative has set the strategy and specific objectives how to achieve the ME reduction target. The first objective is to assess the scope and the nature of avoidable MEs and strengthen the monitoring systems to detect and track the MEs [2]. WHO has issued guidelines for developing patient safety reporting systems already in 2005 [29]. The core concepts in the guidelines are:

- the objective of the reporting system is learning from failures
- reporting must be safe for the reporters
- feedback and recommendations must follow
- sufficient resources must be allocated

2.2 What is a medication error?

To understand and collect the information about MEs, it is important to agree on the definition of a ME.

In 2015, European Medicines Agency (EMA) has issued a "Good practice guide medication error recording, coding, reporting, assessment" where the following definition is proposed: *A medication error is an unintended failure in the drug treatment process that leads to or has the potential to lead to, harm to the patient* [1].

The author has used the EMA definition for MEs as with this definition, a failure is interpreted as a human- or process-mediated error rather than the adverse effect or lack of efficacy of a medicine. The concepts of intentional overdose, abuse, misuse, or off-label use are distinguished from MEs.

The MEs can be broadly classified according to the stage in the medication treatment process - prescribing, dispensing, and administering [30]. International studies have found that most hospital MEs happen in the administration phase [24]. A recent cross-sectional hospital study in Australia identified 57% of all MEs as being medication administration errors (MAEs) [31].

MAE is a subtype of MEs happening after the medication is handed over to a healthcare provider, a patient, or a patient representative. MAE is "any difference between what the patient received or was supposed to receive and what the prescriber intended in the original order" [32]. MAEs are historically defined in nursing as a failure of "5 Rights" (right patient, medication, time, dose, and route). Recently four more "rights" have been added (right documentation, reason, form, and response) [33].

The author has mostly used ME throughout the thesis but in the nurses' questionnaire, the MAE is used as it is a more accurate term for the nursing domain.

To facilitate reporting and learning from MEs, a clear distinction has been made between MEs resulting in adverse reactions, MEs without harm, intercepted MEs (near-miss), and potential errors. This distinction (Figure 2, where the x represents the break in the chain of events) is supported by an enhanced terminology that allows for coding all stages of the medication use process where the error occurred in addition to any clinical consequences [34].

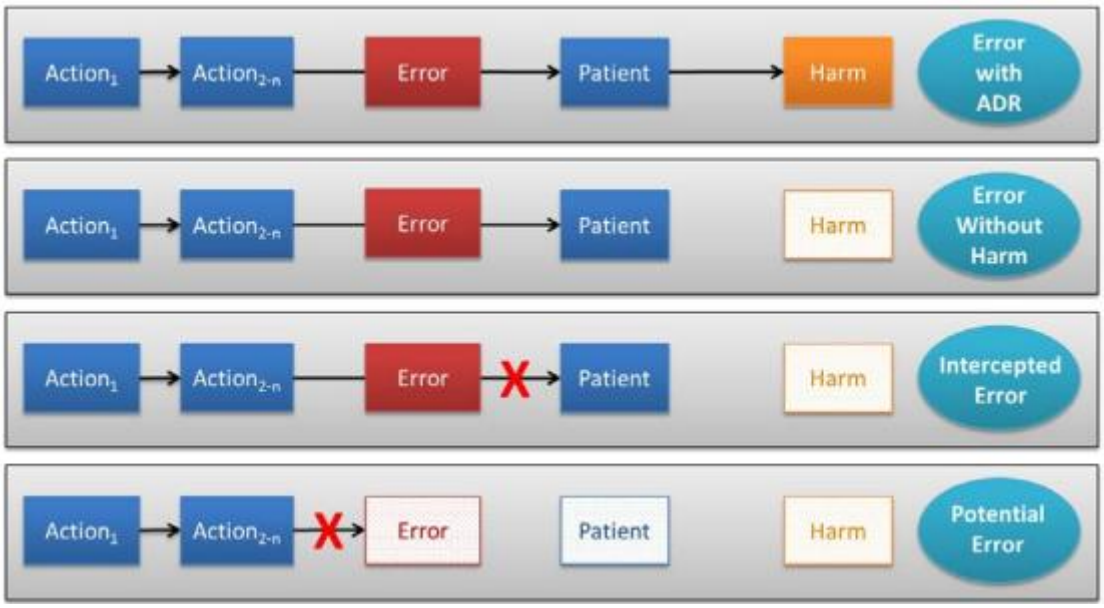

Figure 2. EU Good Practice Guide ME classification. Adopted from Goedecke et al [18].

WHO published a taxonomy report "Conceptual Framework for the International Classification for Patient Safety" (ICPS) in 2009. *The purpose of the ICPS is to enable the categorisation of patient safety information using standardised sets of concepts with agreed definitions, preferred terms, and the relationships between them being based on an explicit domain ontology (e.g., patient safety)* [35]. The ICPS definitions and relations are used also by Social Ministry Patient Safety working group in Estonia as a guideline for harmonising the terms and definitions [36] and by the hospital electronic patient safety management system. An example of the incident type categorisation from ICPS is presented in Appendix 2.

2.3 Medication error collection

Even though patient safety epidemiologic research dates back at least two decades, still all currently available data suffer from significant limitations, mainly in terms of reliability and quality of reporting. Furthermore, most of the knowledge about patient safety events today relates to adverse events, rather than intercepted errors. Previous research has shown that routine incident-reporting systems may report as few as 5% of MEs compared to those detected by case review notes [37]. Identification of MEs is critical for improving patient safety, yet MEs can be challenging to measure.

Several methods have been described in the literature to capture MEs [38]. *Spontaneous reporting* is a gold standard for ME detection but identifies only a fraction of the errors. *Chart review* is the method used for gathering the most epidemiological evidence but in general, it remains an impractical means for routine MEs detection because of the high cost. Another method is to use *trained observers* to detect MEs [38]. While the observation of the actual medication administration is the most accurate way to identify errors, its use is limited due to the high cost [39]. Manual ME detection methods are very important in research, but new *electronic methods* have been developed for quicker and easier detection of MEs, like signal detection from laboratory results or keywords in patient records [38].

Estonian Health Insurance Fund (EHIF) is regularly monitoring treatment quality indicators, including clinical indicators, developed by the Indicator Advisory Board. The surgical adverse events are recorded based on Kokk-Murruste taxonomy, coded with special EHIF quality codes, analysed, and reported in the hospital's annual reports. However, none of the EHIF quality indicators includes the safe use of medications [40].

The voluntary ME reporting is the only source of ME data in Estonia so far. Tartu University Hospital (TUH) and Tallinn Children's Hospital (TCH) have published data about their patient safety incident (PSI) recording system called *POI (Patsiendi Ohujuhtumi Infosüsteem)* [17], [19], [41], including info about MEs. TUH has recorded 5300 PSIs since 2012. ME comprised 7% of all the cases. The number of MEs reported by TUH is still small compared to data from Finland. Therefore, TUH is reinforcing the collection and improving the quality of the data of errors related to medicines [19]

A different approach has been used by Volmer et al. (2012) who looked at the prescription errors [42]. Also, few international studies were analysing drug-drug interactions and potentially harmful multidrug use [43]–[45]. Estonian hospital pharmacists have published a few abstracts based on the reconciliation of patient medication records, predominantly in Tartu University Hospital [46]–[49]. However, none of the studies or audits has evaluated the safe use of drugs across Estonian hospitals.

Nurses' questionnaire is one of the most common methods to study the reasons for medical errors underreporting [50]. Medication administration is a central part of nursing practice and nurses are the most frequent reporters of medical errors in Estonia [19].

Proportions of MAEs reported by nurses might be affected by multiple factors such as the socio-demographic, social, attitude of nurses, and organisational factors [51]. There are few examples of MAE reporting questionnaires in the literature [52], [53]. MAE Survey from Wakefield is well described in the literature [54] and used by several authors across countries [55], [56].

2.4 Why medication errors occur?

Several conceptual categories have been presented in the literature for why MEs occur. These categories include individual staff characteristics (knowledge and skills); policy- and procedure-related issues; communication; and systems issues [54].

Individual characteristics include mistakes related to lack of knowledge, inexperience, failure to correctly calculate the medication dose [57], preparing the medicines for administration, or failure to operate medical devices like infusion pumps [54]. Many of the knowledge-based errors happen in the prescription phase [24].

Issues related to policies and procedures can happen both due to the absence of, or failure to follow the procedures. Examples are, not checking the patient's identity, administering the wrong medicines, or lack of standard protocols for high-risk medications, such as respiratory muscle relaxants, anticoagulants, or antiarrhythmics[58], [59].

Failure in communication is the third category of reasons why MEs frequently occur. These include transcription errors, use of abbreviations, illegible handwriting [60], use of verbal orders instead of written orders, failure to document medications, and using various brand names instead of international non-proprietary names (INN) of medicines [54], [58], [61].

System issues are the fourth category of reasons why MEs occur. Common systems issues are related to doctors' and nurses' workload [60], frequent distractions and interruptions, and nurses rotating between wards [62]. The pharma industry contributes to MEs by producing look-alike and sound-alike drug names, confusing and unclear labeling, and confusing packaging of doses [54], [62].

There are more ways to classify MEs.

Contextual classification examines the time, place, and persons involved. Medication administration errors and prescribing errors are the most common type of errors,

followed by drug dispensing errors [24], [63]. MEs caused by nurses or midwives are more prevalent than errors caused by doctors, pharmacists, or by patients [64].

Modal classification defines the ways how the errors happen, like an omission, substitution, etc.

Psychological classification, shown in Figure 3, is useful for the prevention of the errors, as it explains the errors rather than merely describing them [30], [65].

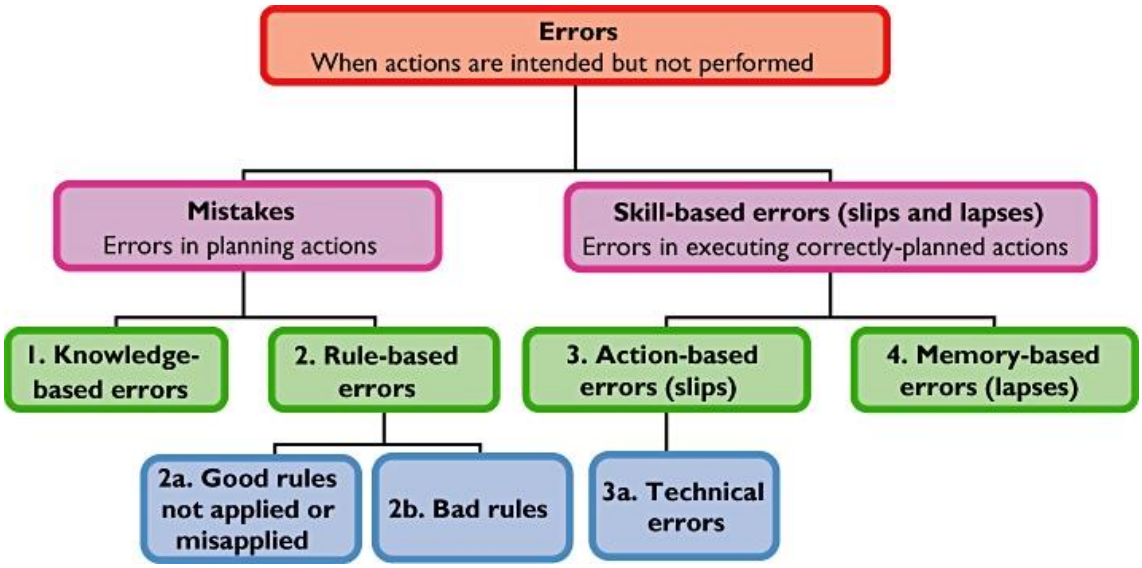

Figure 3. The classification of MEs based on a psychological approach (reproduced from Ferner and Aronson) [65].

Estonia has participated in a pilot study of implementing MEs online reporting system DokuPIK. The analysis of reported MEs by pharmacists revealed the key reasons for mistakes are '*wrong dose'*, '*clear indication but no drug prescribed*', and *interactions*. The most common causes were identified as '*lack of knowledge'*, '*organisation*', and '*workload*' [48]. The same reporting system was followed up for six-month in a 900-bed hospital in Estonia. The findings confirmed earlier international studies that patients over 65 years have a higher risk of MEs [63], [66]. The types of errors were '*documentation errors'*, '*dosing errors'*, '*contraindications'*, and '*double prescriptions'*. Most errors were caused by a '*lack of knowledge'* [49].

2.5 Why are medication errors not reported?

Different countries have different approaches to ME reporting [29]. The reporting can be voluntary or mandatory. Mandatory reporting may lead to litigation. Ethically and professionally healthcare providers should not be obliged to report MEs. Voluntary reporting should be encouraged for learning and developing a safety culture. On the other hand, mandatory reporting has been more efficient in collecting the ME reports [9]. The United States has implemented mandatory reporting of MEs resulting in harm and voluntary reporting of near misses. This system has been criticised and suggested that policymakers should penalise health care providers for not reporting MEs independent of their character to capture more MEs [67]. Analysis of MEs can lead to system improvement and reduced risk if the errors are detected, reported, and used to design better patient-care practices and systems [9].

The need for patient safety incident reporting has been presented in several health care reports in Estonia [12]–[14]. The State Agency of Medicines (SAM) is responsible for collecting ME reports from pharma companies, health care professionals, and patients in Estonia for the EU pharmacovigilance system. The reporting is voluntary for health care providers [34].

Accurate incident reporting systems are dependent on the ability of the medical professionals to a) recognise an error has occurred; b) believe the error is significant enough to be reported; and c) overcome the embarrassment of having committed a ME and the fear of punishment [59].

A recent meta-analysis has analysed common barriers to medical error reporting based on 30 publications from the years 2005 to 2020 (including MEs) [50]. Seven common themes were identified. The most frequent theme was *fear of consequences*, which was an especially important factor in studies conducted outside of the United States. Suggesting that relative maturity of the system is reducing the fear of consequences. Less important factors were *lack of feedback, work climate/culture, poor understanding of ME and the importance of reporting ME, time consumption, lack of reporting system, and personal factors* [50].

The personal criminal liability of healthcare professionals who have made a ME has been an important barrier to the development of ME reporting in Estonia [68]. The new

Compulsory Liability Insurance of Healthcare Providers Act (CLIHPA) or formerly referred to as 'Patient insurance law' (PIL) obliges healthcare providers (HP) to gather evidence and document information about all avoidable adverse events resulting in harm to the patients, including wrong medication, wrong dose, corrupted medication due to HP actions or misuse of medication. HP must analyse AEs, develop, and document prevention methods and submit the AEs to the patient safety database. HPs have time until 01.07.2024 to develop the above-mentioned systems [20]. The CLIHPA explanatory memorandum is emphasising the importance of the blame-free culture and detachment of the AE insurance case procedures from the criminal prosecution. To incentivise medical professionals to report the AEs, they are freed from the criminal prosecution in case the AE was reported to the patient safety database [20].

As fear is the most common barrier to ME reporting there is a lot of discussion about the need for **non-punitive culture** in healthcare. The idea is well proven in other high-risk industries, like aviation [69]. Feedback to participants and targeted improvement in the workplace are also important to maintain the enthusiasm of the employees to report the incidences [18], [69].

2.6 How to reduce medication errors?

Contributory factors to MEs are manifold and include medication reconciliation, the quality of prescriptions and drug distribution systems, adherence to the procedures and nurses' workload, and individual knowledge and skills [62]. Several qualitative and quantitative studies have evaluated the possibilities to reduce the MEs in hospitals [32], [70], [71].

Authors Singer and Vogus have created a comprehensive model for improving patient safety presented in Figure 4. The model ties together factors from different areas into three main interventions: Enabling, Enacting, and Elaborating [72].

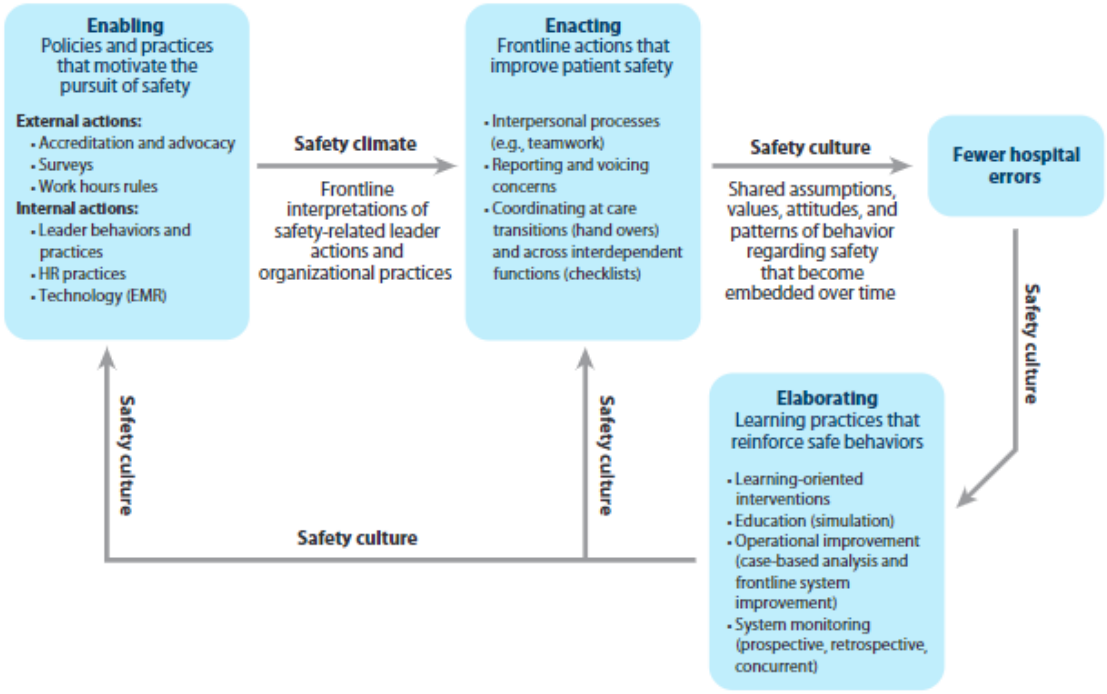

Figure 4. Model for improving patient safety by Singer and Vogus [72]

Enabling refers to external and internal actions in hospitals, that raise awareness and emphasize safety. *External factors* are including the *legal basis* for ME reporting, work hours legislation, and epidemiological studies. *Internal factors* include leaders' behaviour, human resources (HR) practices, and technology for reporting [72]. Research has identified information technology as an important mechanism for enabling a safety culture, but at the same time, its efficacy in reducing hospital errors is heavily dependent upon the organisation's cultural readiness to make use of it. Two of the most studied technologies are computerised physician order entry (CPOE) and electronic medical records. A meta-analysis from 2014 has concluded that implementing CPOE is associated with a greater than 50% decline in preventable MEs [73]. A recent literature review evaluated the effectiveness of different interventions to reduce MEs and concluded that medication reconciliation, electronic prescribing systems, barcoding, feedback, and dispensing systems in surgical wards may reduce MEs [71].

HR practices include staff selection, continuous training, and adequate staffing[72]. Studies are showing that an adequate level of nurse-to-patient ratio is associated with better care [74] and reduced patient mortality, and length of stay and could be cost-saving for hospitals [75].

Enacting includes frontline actions to surface and resolve threats to safety, like facilitating patient safety culture, teamwork, reporting MEs, and using standardised protocols in the transition of care [72].
Elaborating means systematically reflecting on and learning from performance. This includes voluntary reporting of near misses to be able to learn from them, and regularly analyse the reported MEs followed by education and operational improvements [72].

High-risk medicines. Studies have analysed the frequency of MEs with different medicines groups and have identified 'high alert' medicines more frequently involved in MEs. Most often cited 'high alert' medicines are antimicrobial, opioids, insulin, parenteral potassium infusions, and anticoagulants [25], [63], [64].

As MEs are more prevalent in **elderly patients**, a list of potentially inappropriate medicines (PIM) was created by 7 EU country's scientists, including Estonia. In total 282 drugs from 34 therapeutic groups were identified which are PIM for elderly people. The list can be used as a clinical practice guide in hospitals [45].

A systematic **medication reconciliation** – the process of comparing a patient's medication orders to the medications that the patient has been taking – is a common intervention and can reduce MEs by 45% [62], [71]

Leaning from the data and **dissemination of knowledge** is crucial for developing patient safety practices [18].

An effective, non-punitive incident reporting, which includes reports of near-misses and system problems in addition to actual accidents, can facilitate learning from the incidents and dissemination of the knowledge for improved patient safety. Feedback to participants and targeted improvements in the workplace are also important to increase the reporting [69].

3 Methodological process

The thesis represents a **pragmatic worldview** as described by Creswell [76]: "*Instead of focusing on methods, researchers emphasize the research problem and question and use all approaches available to understand the problem..... This applies to mixed methods research in that inquirers draw liberally from both quantitative and qualitative assumptions when they engage in their research"*[76].

The **mixed-method approach** has been selected by the author. The mixed-method approach combines qualitative and quantitative approaches. Qualitative research is an approach for exploring and understanding the meaning individuals ascribe to a social problem and quantitative research is for testing objective theories by measuring and examining the relationship among variables. The core assumption is that combining qualitative and quantitative data yields additional insight into the research question [76].

Following research designs and methods are used to explore the research topic.

Systematic review strives to comprehensively identify, appraise, and synthesize all the relevant data on a given topic [77]. Although systematic reviews are commonly used for literature search and clinical studies evaluation, the methodology can be used for all systematic reviews. Systematic reviews typically involve a detailed and comprehensive plan and research strategy to reduce bias. There are many publications about conducting systematic reviews [77], [78], but the author has adopted the simplest 5-step approach [79]. The five steps followed are: framing the question, identifying relevant databases, assessing the relevance of databases, summarizing the data, and interpreting the findings.

Grounded theory is a qualitative research design of inquiry from sociology in which the researcher derives a general, abstract theory of a process, action, or interaction grounded in the views of participants. This process involves using multiple stages of data collection and the refinement and interrelationship of categories of information [76]. **Inductive content analysis (ICA)** was used for qualitative information analyse. ICA is finding content categories and sub-categories by using iterative coding of the transcript, followed by comparing, grouping, and sub-dividing groups of codes [80].

Survey research provides a quantitative or numeric description of trends, attitudes, or opinions of a population by studying a sample of that population. It includes cross-

sectional and longitudinal studies using questionnaires or structured interviews for data collection—with the intent of generalizing from a sample to a population [81]. The author has used a quantitative questionnaire and semi-structured interviews for information collection. A **semi-structured interview** is a type of survey that employs a blend of closed- and open-ended questions, often accompanied by follow-up why and how questions [82]. Both quantitative and qualitative methods have been used to analyse the information from the interviews. A **cross-sectional** design (collects data at one point of the time) was selected for the study due to time constraints. However, the design of the study allows to repeat the study after the implementation of the mandatory ME reporting in Estonia to evaluate the nurses' perceptions change, thus creating a longitudinal study.

Purposive sampling was selected by the author. Purposive sampling is also known as judgment sampling where a researcher is using their expertise to select a sample that is most useful to the purposes of the research [83]. There are several strategies and mixed-method designs available [84], but the author has selected the Criterion-i strategy which emphasises similarity and selection is based on predetermined criteria [84]. The predetermined criterion for the selection of participants for **experts' interviews** was a responsibility for patient safety or medical error recording systems. For the **nurses' questionnaire,** the predefined criterion was implemented in the selection of the participating ward in each hospital. Internal medicine was chosen as a specialty because it has the highest prevalence of MEs due to a big use of medications [4], [66].

Descriptive studies allow the discovery of new meaning, describe what exists, determine the frequency with which something occurs, and categorise information [85]. The types of quantitative research design (descriptive and analytical) enable obtaining a clear picture of characteristics and differences between groups. **Correlational** analyses were used on scale type of data. Correlational research involves the systematic investigation of relationships between two or more variables identified. The primary intent of correlational studies is to explain the nature of relationships, not to determine cause and effect [85].

The thesis adopts the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations [86] by following the STROBE 22-item checklist for cross-sectional studies.

4 Methods and participation

This section provides detailed information about the study methods. The study period was from October 2021 to March 2022. The primary purpose of this study is to evaluate the current situation of ME collection in Estonia. As the MEs are not researched in Estonia before, a cross-sectional survey research method was chosen. A mixed-method design was used to collect quantitative and quantitative data to understand where the MEs are reported, the reasons why the MEs occur, and why they are not reported. The instruments for data collection were a systematic national ME **database review**, semi-structured **interviews** with hospital patient safety experts, and a quantitative nurses' perception **questionnaire**.

4.1 National database survey

To get a broad view of the current situation and answer the first research question "*What systems are used in Estonia to register and analyse hospital MEs?"*, a systematic review of ME reporting databases was performed from October 2021 to January 2022. The author has sent information requests via an email to all national institutions that are involved in medicines surveillance or patient safety, asking for information about all MEs recorded since 2016. The focus was especially on hospital MEs. In total 6 national institutions or organisations were identified, and full details are presented in Appendix 3.

State Agency of Medicines (SAM) is collecting voluntary reports from marketing authorisation holders, healthcare providers, and the public about MEs as part of the EU pharmacovigilance surveillance[87].

Estonian Poison Information Centre (EPIC) gives medical advice to the population and health care providers about poisoning (including ME-related) through its hotline [88].

Expert Committee on the Quality of Healthcare Service (ECQH) gives a second opinion to the patients about healthcare quality [89].

Estonian Health Insurance Fund (EHIF) monitors hospitals' service quality through a series of Quality of Health Care metrics [40]. Specification of the information request was about the use of ICD-10 diagnosis codes X40-X44. Those codes are from the chapter

Accidental poisoning by and exposure to noxious substances and refer to accidental use or poisoning with different medicines.

The Estonian Chamber of Disabled People (ECDP) [90] and **Estonian Patients Union** (EPU) [91] are patient representative organisations and support patients with know-how and legal advice.

The source of data for the organisations is voluntary reporting (SAM), liability claims (ECQH), financial claims (EHIF), medical advice (EPIC), and legal advice (ECDP, APU).

Registered ME numbers and hospital ME numbers were requested from all institutions. The author reviewed the data and added it to the excel database. Descriptive statistics, describing the number of MEs, hospital MEs, and related medicines, was used to analyse the data.

4.2 Cross-sectional hospital survey

The objective of the mixed-method hospital survey was to answer the research questions: "What systems and processes are used in Estonian hospitals for reporting MEs?" and "What is the perception of hospital nurses why MEs occur and why they are not reported?".

To get a complete understanding of why MEs occur and why they are not reported, **quantitative data** were collected from questionnaires and interviews in hospitals. Additionally, **qualitative data** with open-ended questions was collected from participants to help explain the quantitative survey findings. The quantitative part of the study allows for analysis of data from a large number of participants across all hospitals and complements it with qualitative information about hospitals' existing MEs recording practices and patient safety culture to find confounding factors. Descriptive and analytical methods were used to find variances and correlations between variables.

The hospital survey is a cross-sectional study of Estonian hospitals. A list of hospitals was obtained from Hospital Network Development Plan (HNDP) [92]. Hiiumaa Hospital and Haapsalu Neurological Rehabilitation Centre were excluded from the list as there was

a very small or no internal care ward based on Health Board statistics [93]. A flow diagram of the inclusion and exclusion of hospitals is presented in Figure 5.

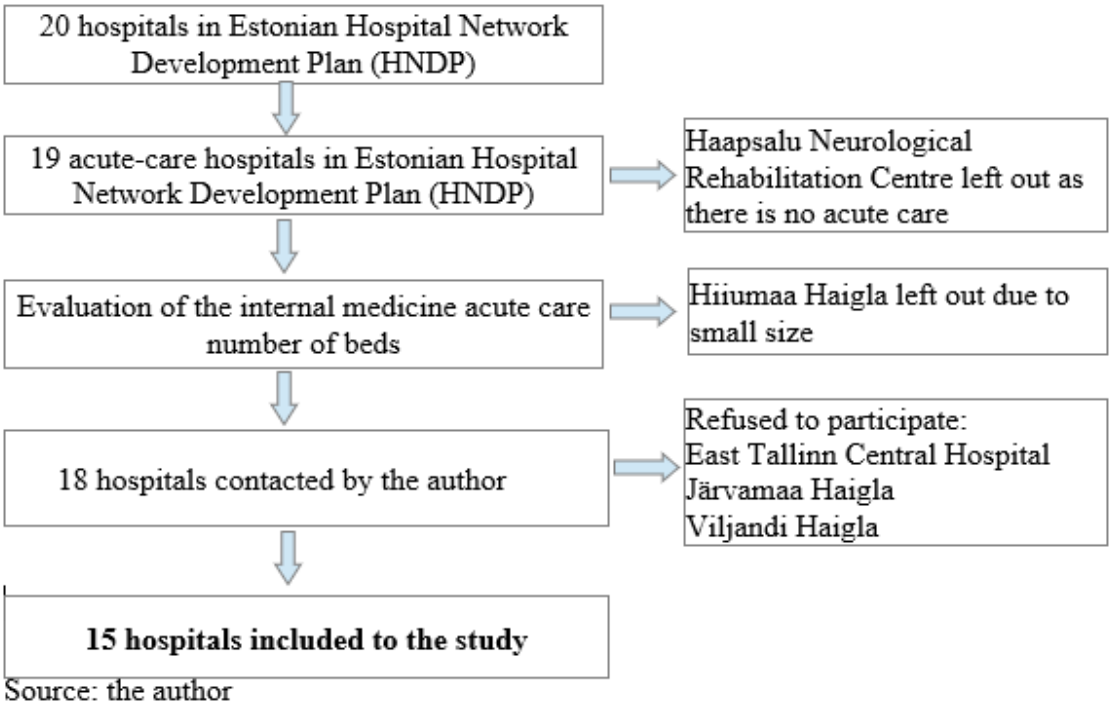

Figure 5. Flow diagram of the inclusion and exclusion of hospitals into the cross-sectional hospital survey.

All 18 hospitals' management was contacted via e-mail to obtain permission to carry out the interviews and nurses' survey. Three (3) hospitals refused to participate. Viljandi hospital was busy implementing the Patient safety system and was planning a large patient safety culture study at the same time. Järvamaa hospital did not specify the reason for the refusal. East Tallinn Central Hospital (ETCH) after thorough evaluation refused. The objections are further discussed in chapter 6.

The total number of hospitals participating was 15, which is 75% of all HNDP hospitals and 79% of all hospital beds in HNDP hospitals[93].

The hospital experts' and nurses' surveys employed a non-random purposive sample. One ward from each hospital was selected. The predefined criteria for the wards are: significant size, providing active medical care, using a large variety of medications regularly, and agreeing to participate.

In most hospitals, the internal diseases ward was best matched to the predefined criteria. In regional and central hospitals where multiple internal disease departments exist, the

author together with hospital management selected the participating ward, best matching the criteria. In Pärnu hospital and IVCH, the whole internal diseases clinic participated with all its wards. TCH does not have internal care ward, therefore the acute infections ward was selected. The list of participating hospitals and departments is shown in Appendix 4.

The participating wards together have 657 hospital beds, which is 47% of the total number of therapeutic beds in HNDP hospitals (based on 2020 data)[8].

4.2.1 Expert interviews

The objective of the expert interviews was to collect quantitative and qualitative information on all research questions at the hospital level using semi-structured interviews.

Interviews were conducted in 15 participating hospitals by the author from January to February 2022. The interview consisted of 9 questions (presented in Appendix 5).

Interviews were conducted with 23 experts. The inclusion criteria for expert selection were:

- The participant was responsible for the patient safety or care quality in the hospital.
- The participant agreed to participate in the study

All study hospitals were represented by one or two experts. Most of the interviews were conducted face to face (17), four experts were interviewed via Team's video call, one expert by phone, and one expert preferred to answer by email. All interviews were in Estonian. All experts were asked the same nine questions, but additional questions may have emerged from the answers. The interview was conversational and lasted from 20 to 30 minutes.

The answers to the first four quantitative questions (Electronic hospital information system (HIS), electronic medication record, patient safety incidence recording system, and anonymity of incident reporting) were numerically coded by the author and added to the database together with the nurses' survey data.

The answers to the five qualitative open-ended questions were transcribed by the author. The qualitative questions were analysed using inductive content analysis (ICA).

4.2.2 Nurses' survey

To understand why the MEs happen and often go unreported and answer the corresponding research questions, the nurses' perception survey was conducted in all 15 participating hospitals from January to March 2022. For the nurses' survey the author has used principles and guidelines from the "Hospital Survey on Patient Safety Culture: User's Guide" [94]. The inclusion criteria for participants were:

- The participant worked in the selected study ward during the study period
- The participant was a nurse or an assistant nurse who was involved in patient care
- The participant agreed to participate in the study

The data were collected using a structured self-administered paper questionnaire. A paper survey was chosen as the studies show that the response rates are higher with paper surveys compared with web-only surveys (69% vs 54%) [94].

The MAE nurses' perception questionnaire was adopted and translated into Estonian by the author and then translated into Russian by the translation agency Luisa. The English questionnaire is presented in Appendix 6. Estonian and Russian language questionnaires are available from the author by request.

The questionnaire contained 75 questions and four sections. Nurses were asked to answer all questions based on their personal experience in the ward.

Section A consisted of 29 statements about reasons **why medication administration errors occur**, and the respondents were asked to indicate agreement with each item using a Likert 6-point scale, where responses range from 1 = strongly disagree to 6 = strongly agree.

Section B consisted of 16 statements about reasons **why medication administration errors are not reported**, and the respondents were asked to indicate agreement with each item using a Likert 6-point scale, where responses range from 1 = strongly disagree to 6 = strongly agree.

In section C, respondents are asked to **estimate the percentage of errors reported** on their respective units using a 10-point scale. Each point corresponds to a percentage range (e.g. point 3 = 31 - 40 percent). Non-intravenous and intravenous medicines related errors were asked separately. Respondents were also asked to estimate the percentage range of all MAEs reported overall in the ward. The percentage ranges were presented in 10 clusters 0- 20%, 21-30%, 31-40% etc. An additional question was asked to quantify the **number of MAEs occurred** in the ward during a week (absolute number).

The final, fourth section collected respondent **demographic data**. Collected information concerning respondent nursing education, position, frequency of administering non-intravenous and intravenous medications, working full time or part-time, experience as a nurse, and experience in the current ward.

The last question was an **open-ended question**: *Do you have any suggestions for improving the current system for monitoring medication errors?*

Data collection

After the permission was received from the hospital management, the author agreed on the survey timing with the department's head nurse and delivered the required number of questionnaires personally or by a courier. To separate the hospitals different coloured paper was used for the questionnaires for each hospital. Each questionnaire was accompanied by a cover letter and an envelope. The cover letter is presented in Appendix 7. The cover letter introduces the study and the author, gives the information that the survey is approved by the hospital management and the participation is voluntary and anonymous. To motivate the respondents and as a sign of gratitude, candy was promised to all respondents. Candies were delivered to the departments together with questionnaires.

Once completed, the questionnaires were sealed to the attached envelope and returned to the head nurse. The hospital had from 10 days to 3 weeks to collect the surveys back from the nurses. The time depended on the nurses' work schedule and to some extent from the Covid-19 situation in hospitals. The anonymity of the respondents was protected as the envelopes were only opened by the author after all responses were collected.

After all nurses' questionnaires were returned a unique identification number was added to each questionnaire. Microsoft Excel was used to insert the data retrieved from questionnaires and the expert interviews' quantitative questions.

Data analysis

In total 250 questionnaires (n = 250) were returned to the author. One questionnaire was empty, and one questionnaire was corrupt and was left out of the analyse. Participants were excluded from analysis if less than 50% of questions were answered (n = 4). The flow chart with respondent numbers is presented in Figure 6.

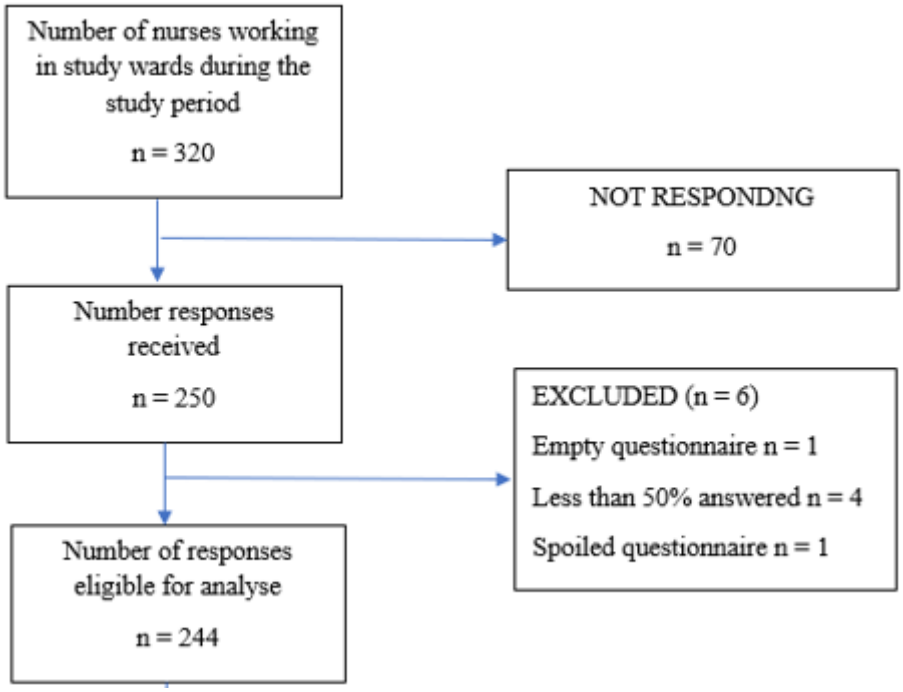

Figure 6. Nurses' questionnaire respondents flow chart.

Subsequently, the existing data were imported into the IBM Statistical Package for Social Sciences (SPSS) software and analysed with IBM SPSS program version 28. All data were numerically coded. The missing data were coded 99, as is common in SPSS analyse. Descriptive statistics were used to find frequencies for nominal and ordinal variables. Frequencies were expressed in absolute values and percentages and illustrated with graphs. Nominal variables were the data collected through expert interviews about systems used in hospitals and the demographic questions about nurses' education, position, and time allocation. Ordinal variables were the data collected through sections A and B of the questionnaire where respondents gave their answers on a 6-point Likert-type scale. The answers were 'Strongly Disagree', 'Moderately Disagree', 'Slightly

Disagree', 'Slightly Agree', 'Moderately Agree', and 'Strongly Agree'. In the data analyse percentages of three answers showing agreement were added together to calculate the 'Agreement rate' percentage. Also mean, mode, and standard deviation were calculated.

Section C of the questionnaire about percentages of reporting errors for non-intravenous and intravenous medications was measured using scale variables. For scale type of variables descriptive and analytical statistics were used to find frequencies and correlations in the data. Correlational research involves the systematic investigation of relationships between two or more variables identified.

For a better overview and concise correlational analyse the author has used the dimension reduction by factor analysis to create subscales. Factor analysis refers to a collection of statistical techniques designed to examine interrelationships among large numbers of variables to reduce them to a smaller set of variables and to identify clusters of variables that are most closely linked together (factors) [85]. Principal components exploratory-factor analysis with Varimax orthogonal rotation was used to determine if the individual items could be combined into subscales. Individual items needed a factor loading of .35 or greater to be included in the factor. Seven subscales emerged for section A: "Reasons why MAEs occur". The author has merged the two subscales into relevant subscales based on their content. The final five subscales for section A are:

- Medication packaging related
- Physician communication related
- Pharmacy processes related
- Nursing processes related
- Nurses' knowledge and skills related

Three subscales for section B emerged:

- Organisation culture related
- Disagreement over the definition and reporting effort

- Fear

The demographic data and information gathered from expert interviews about different electronic health information systems, electronic medication charts, patient safety incident reporting systems, and anonymity of error reporting were used as independent variables to find correlations with the dependent variables (nurses' perception in sections A, B, and C). One-way analysis of variance (ANOVA) was used for finding the differences between two or more groups. One-way ANOVA analysis allows determining the presence of differences between groups by testing one independent variable and one dependent variable at a time. ANOVA is expressed by the F statistic, which is calculated by dividing the mean square variance between groups by the mean square variance within groups [85]. Post hoc tests have been performed after ANOVA determining the location of group differences with the Tukey Honestly Significant Difference (HSD) test.

Qualitative data collected with the last open question 'How to improve the MAEs reporting systems?' was analysed using inductive content analysis (ICA) and the findings were merged with the qualitative expert interview findings.

4.3 Ethical considerations and reliability of the study

4.3.1 Ethical considerations

Ethical principles and regulations were followed during the study. The study was performed following the core principles of the Declaration of Helsinki [95]. As patients' treatment was not in any way interfered with and the author did not obtain any patient personal data, an ethics board permission was not required. Approval and permission for the hospital study were obtained from all hospitals' managements. In the hospitals, where a local trial committee is established, formal approval was obtained. Participation in the interviews was voluntary, and the anonymity of participants and the confidentiality of the responses were guaranteed. All participants received an explanatory e-mail (hospital managers and experts) or a cover letter (nurses) explaining the objectives of the study and providing the author's contacts. All participants could contact the author by phone or e-mail during and after the study. Individual expert answers are not published, and hospital MAE data are not tied to individual hospitals. The exceptions are the data that were already published on a hospital website or presented at a conference.

Paper questionnaires were delivered to a head nurse of the ward and were collected by the head nurse. This could raise the concern if the participation in the survey was truly voluntary. The respondents could decline the participation or submit empty or partially filled questionnaires. The anonymous responses were sealed to an unmarked envelope before returning to the head nurse. The head nurse did not see the answers. An individual nurse participating in the nurses' survey was not identified. The survey did not collect respondents' personal data unrelated to their workplaces, like sex, age, or family status. The author could not identify individual respondents. The hospitals will receive consolidated reports for their hospital only if more than ten respondents participated. No individual nurses' data will be provided to hospitals.

After the questionnaires were submitted, the respondents agreed to participate, and there was no possibility to remove the data from the database. The database was kept in an author's password-protected computer, with no access for other people. After the defense of the master thesis, the paper questionnaires will be destroyed. The author will keep the electronic data and the metadata to be able to perform a follow-up study in the future.

The potential discomfort of participants was related to the time spent answering the questions. In the author's opinion, the overall benefit from additional knowledge overweights the individual participant's discomfort. The individual hospitals benefit from the survey as they will receive the nurses' survey consolidated results compared with the whole survey results after the completion of the study.

4.3.2 Reliability of the study

Reliable sources related to the study aim and objectives were used for study scientific background descriptions. For scientific publication search MEDLINE, ESTER, PubMed, and Google Scholar were used. Relevant health statistics and information from national health authorities' web pages were used.

Scientific methods were used, and diligence was exercised by the author in data collection, analysis, and interpretation. Data were entered accurately and carefully, and the data were checked by the author repeatedly to discover the data entry mistakes. The study process was documented by the author to ensure reliability and to allow the study to be repeated. Reliable scientific methods were used to analyse the data and the results are presented accurately and honestly.

The validity and reliability of the Nurses' survey were guaranteed by using an existing questionnaire validated in the United States in 2005 [61]. However, the questionnaire was not validated or piloted in Estonia. Cronbach's alpha was used to evaluate the validity and reliability of the questionnaire in Estonia. Cronbach's alpha is a common measure for evaluating the internal consistency of a Likert-type scale; it is expressed as a number between 0 and 1. An alpha value above 0.7 is considered an acceptable level of a questionnaire's internal validity [96]. Cronbach's alfa was also used to evaluate the validity of the sub-scales. All alpha values for the whole questionnaire and its sections were above the threshold value of 0.7 (0.88-0.97) showing high validity and internal consistency. Alpha values for instrument scales and subscales and subscale details are presented in Appendix 8.

Plagiarism was avoided in the thesis. All sources are correctly cited and are listed in the bibliography at the end of the thesis. Only evidence-based sources were used. To ensure the objectivity author's personal opinions, feelings and values were left aside.

5 Results

This chapter gives the results of the systematic national database review and the cross-sectional hospital survey. The hospital survey includes an analysed overview of experts' views on ME reporting and the nurses' perceptions about MEs from the quantitative nurses' questionnaire. The variances and correlations between different factors combined from expert interviews and nurses' questionnaires are presented in the last section.

5.1 National database survey

ME data were received from 4 organisations (SAM, ECQH, EHIF, EPIC). Two Estonian patient organisations replied that they do not record individual patient cases due to personal data protection reasons.

State Agency of Medicines

SAM's reply to the inquiry included 81 cases of adverse events with medications (Figure 7).

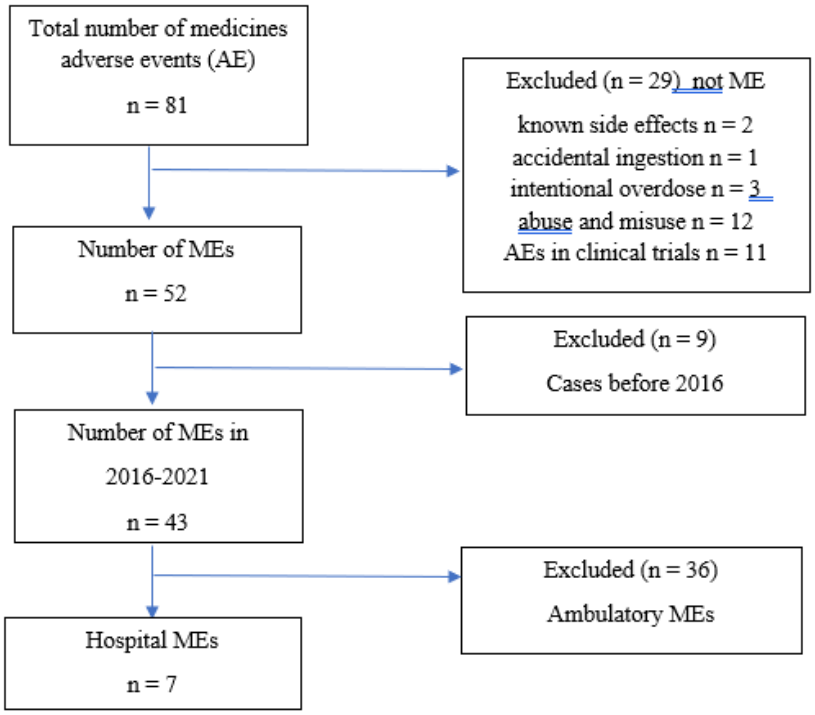

Figure 7. Flow chart of the SAM MEs from 2016 to 2021

The final sample was 7 hospital ME cases which were individually analysed. 3 cases were reported in 2018, 1 case in 2017, and 3 cases in 2016. In the years 2019 to 2021, no MEs were reported from hospitals. SAM MEs are presented in Figure 8.

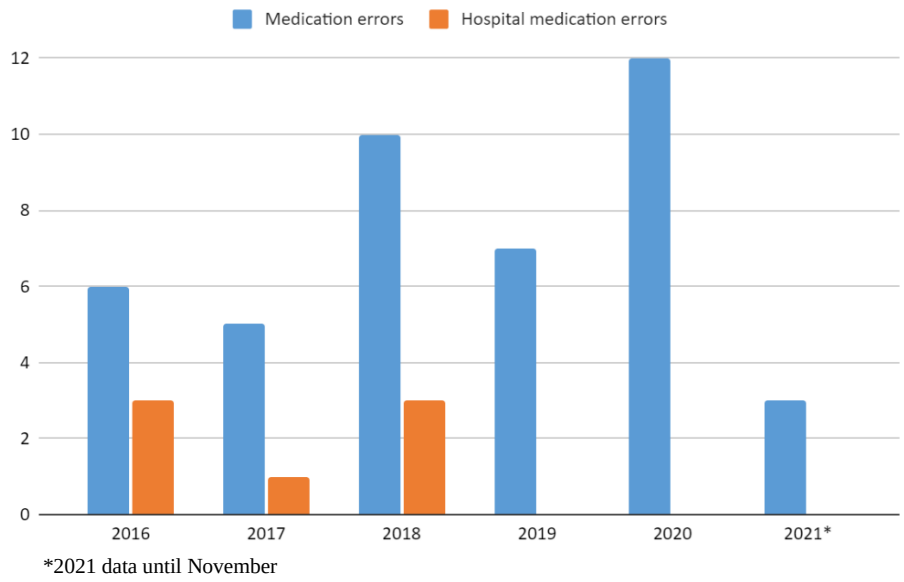

Figure 8. MEs and hospital MEs reported in State Agency of Medicines 2016-2021.

All 7 cases were classified as serious, 4 of the cases ended with patient death, in one case patient partially recovered and in 2 cases at the time of the report, the patient was not recovered. Suspected medicines involved in cases were diazepam, haloperidol, methotrexate, rivaroxaban, metoclopramide, quetiapine, meropenem, enoxaparin sodium, nepafenac. In 5 cases the connection with the medicine was considered possible or probable and in 2 cases was not possible to evaluate.

Expert Committee on the Quality of Health Care

According to ECQH public report, the committee has received a total of 1076 applications from 2016 to 2021. In 257 cases an erroneous behaviour was established and in 169 cases it was considered a medical error [97].

SM replied to the information request on 16.11.2021. Of the total 6 MEs identified, 2 cases were reported from 2018, 3 cases from 2017, and 1 case from 2016. No ME cases were reported in the years 2019, 2020, and 2021. The total number of errors and the number of MEs from 2016 to 2021 are shown in Figure 9.

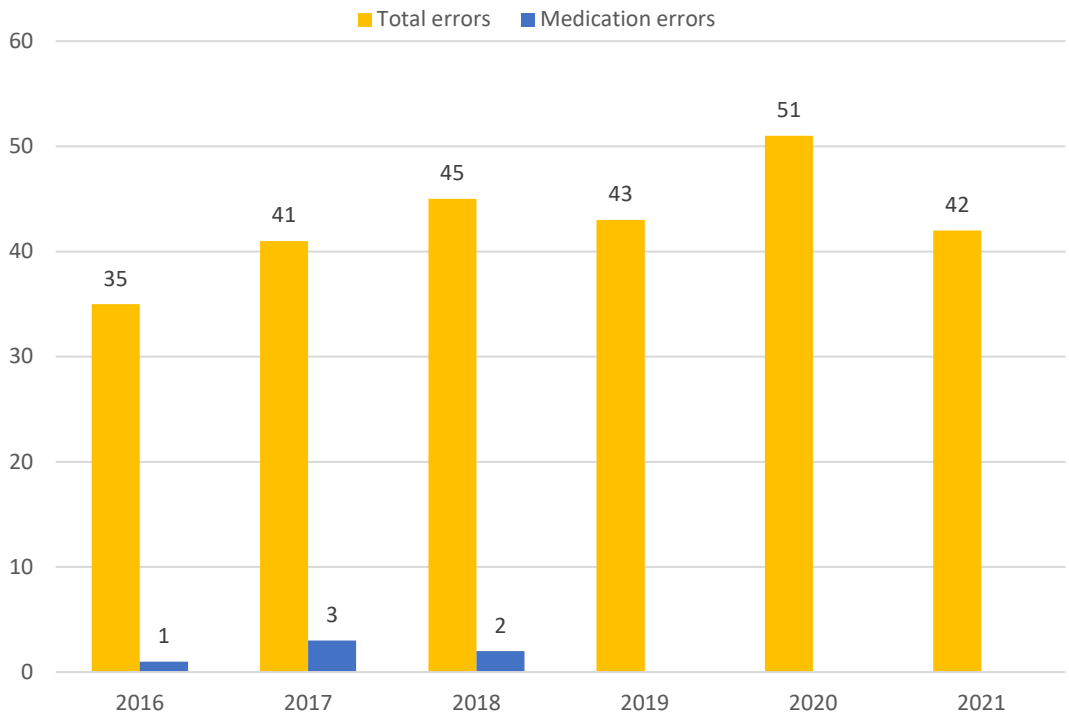

Figure 9. Healthcare quality claims processed by Expert Committee on the Quality of Health Care from 2016-2021

5 cases were related to prescription errors by doctors in ambulatory care. In two cases doctors violated the psychotropic and narcotic drug prescription rules. One case was about digoxin use on elderly patients requiring three patient's hospitalisations due to digoxin toxicity. And 2 ambulatory cases were related to communication issues with patients. The only hospital ME case was related to contraindicated haloperidol use in the hospital in 2017. No further details are given about the severity of the cases.

Estonian Health Insurance Fund

EHIF has replied to an information request on 21.10 21. ICD-10 codes X40-X44 have never been used and there are no other indicators in the EHIF database to find or filter the MEs.

Estonian Poison Information Centre

EPIC has answered on 13.10.2021. EPIC has not received any calls from hospitals about ME in 2017 - 2021. Hospitals are not using EPIC as it is primarily a helpline, and the hospitals can solve the cases without external help.

To sum up, 49 MEs were registered from 2016 to 2021 in Estonia. In total 8 MEs were reported from hospitals. In the years 2019 to 2021, no hospital MEs were registered in any national databases.

5.2 Cross-sectional hospital survey

75% of all HNDP hospitals (N=18) participated in the hospital survey (n = 15).

5.2.1 Expert interviews

Participants. The total number of experts interviewed with semi-structured interviews was 23. One or two experts were interviewed from each hospital. The position of the expert depended on the size of the hospital. In regional hospitals where patient safety departments exist, the quality or patient safety specialists were interviewed. In central hospitals quality heads were interviewed, whereas in local hospitals either the head doctor or the head nurse is responsible for patient safety. The distribution of experts participating is presented in Figure 10.

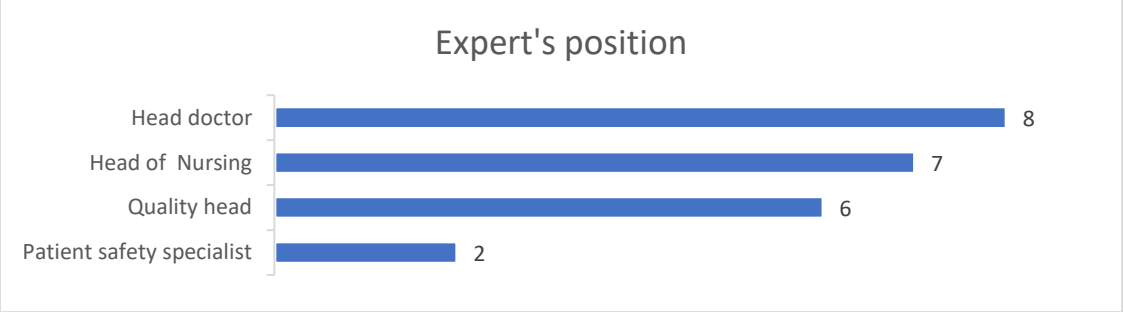

Figure 10. Position of respondents to the expert interview.

The respondents were almost equally distributed among quality or patient safety specialists (n = 8), hospital clinical heads (n = 8), and head nurses (n = 7).

Hospital information system (HIS). Estonian hospitals use 4 different hospital information systems (HIS). Tartu University Hospital and its network hospitals (South_Estonian Hospital, Põlva Hospital, and Valga Hospital) (n=4) are using eHL. North-Estonian Regional hospital and its network hospitals (Läänemaa Hospital and Raplamaa Hospital) (n=3) are using Ester2. The rest of the hospitals are using either Liisa (n=4) from Medisoft or Ester3/Heda (n=4). Liisa is the only system having computerised

physician order entry (CPOE). However, the CPOE is not always implemented across all departments and clinics in the hospital.

ME reporting systems. One-third of the hospitals (n=5) are using an electronic patient safety incident (PSI) recording system called POI, one-third of hospitals (n=5) have a paper-based PSI recording system and one-third of hospitals (n=5) do not have any PSI recording system in place (Figure 11). One hospital implemented the POI just a few months before the survey.

Figure 11. ME reporting system used in hospitals.

Anonymous reporting. POI allows incident reporters to stay anonymous except in one hospital where the POI reporting is done at the department level, not individually. Paper-based reporting system does not provide an option to stay anonymous.

ME managing process. POI has a built-in incident management process where each incident is forwarded to relevant persons for review and each case ends with a decision. Five hospitals do not have specific incident handling procedures in place, and they are using the Ad Hoc processes for each case depending on the severity and nature of the case. The data about ME recording and management are seen in Figure 12.

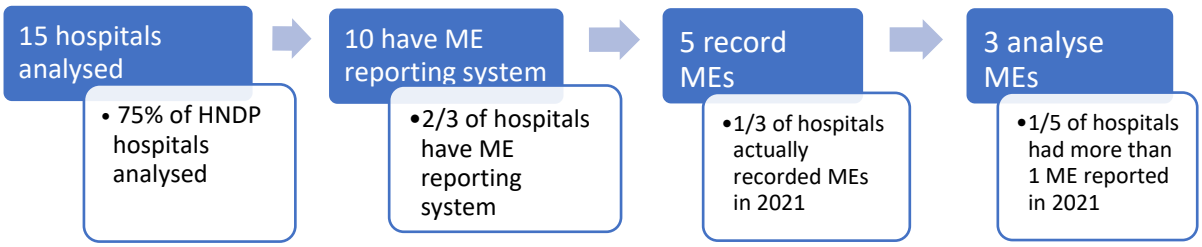

Figure 12. Flow of MEs recording, management and analyse in hospitals.

Number of MEs reported. Out of the 10 hospitals that have either POI or paper-based reporting systems in place, only 5 hospitals had any medical errors recorded in 2021. In total 2093 patient safety incidents were reported in hospitals in 2021, out of which 5% (n

= 109) were related to medicines. The majority (n = 107; 98%) of the recorded medicines-related records came from regional hospitals: TUH 70 incidents, NERH 28 incidents, and TCH 9 incidents. No expert was able to answer the question of how big a percentage of all MEs is recorded as there is no data about the incidence of MEs in Estonia.

Reasons why medication errors are not reported.

The most often mentioned reasons why MEs are not reported, the experts brought out *fear of the negative consequences* and *lack of clear definition,* and *missing reporting rules*. Other reasons mentioned were *low priority* and *low awareness* of the need for reporting; *time and effort* required to report and feeling that the medical error recording is a *finger-pointing system***.**

What are the aspects of a good medication error reporting system?

Two-thirds of experts consider *blame-free culture* the most critical feature for medical error reporting. Half of the experts pointed out that the patient safety incidents recording system should be *integrated with HIS* to make the reporting and analysis quicker and easier. Additional aspects mentioned by experts were the importance of having *common rules and definitions* across Estonia; *mandatory patient safety training* for all healthcare employees; and the need for additional *patient safety and quality resources* in hospitals. *Reporter anonymity* was a controversial topic as some experts believe it is important, but others believe blame-free culture and clear safety purpose of reporting are more important and should eliminate the need for anonymity.

How to reduce medication errors?

Six experts suggested that *computerised physician order entry (CPOE)* is an important element for ME reduction and *improved documentation* of medication administration to discover MEs early on. Six experts pointed out the importance of focusing on *root cause analysis*. One of the experts also suggested that we should not focus too much on patient safety incident recording but use the *knowledge from other countries* and implement evidence-based prevention strategies for reducing errors.

What are the plans for the future?

Most hospitals are thinking about how to improve patient safety. Of nine hospitals, without electronic incident reporting systems, six are planning to implement the

electronic PSI system. The options considered are the POI or development in Heda. Seven hospitals are reinforcing patient safety by additional *training for employees*. TUH, NERH, and Pärnu Hospital are jointly developing e-learning videos. Five hospitals are planning to add *dedicated resources* to patient safety and quality. The hospitals where the POI is already in use, are focusing on reinforcing the *blame-free culture* and *improved reporting*. Few experts also mentioned support from the *hospital pharmacies* and *clinical pharmacists* in medication safety improvement. Additional efforts mentioned were *reinforcement of patients*, regular patient safety *questionnaires for employees and patients, and better documentation* of nursing and treatment processes.

The overall situation in hospitals.

All **regional hospitals** have established a PSI reporting system with employee training and dedicated employees. The cases are regularly analysed, communicated, and reported in hospital annual reports. The plans involve the development of the reporting systems, regular mandatory training for all employees, and developing a blame-free culture.

Network hospitals are harmonising their systems with the respective regional hospital and implementing the processes and systems for PSI reporting. However, the process is still in progress.

The rest of the hospitals have different levels of awareness about PSI reporting, ranging from watchful waiting to full readiness of PSI systems. Even if the PSI reporting system is implemented, the processes, communication, and training are in the development phase.

5.2.2 Nurses' survey

Participants. In total 77.6% of nurses (n = 249) working in participating hospitals' internal wards during the study period (N = 320) answered the survey. A number of questionnaires received from each hospital are seen in Figure 13.

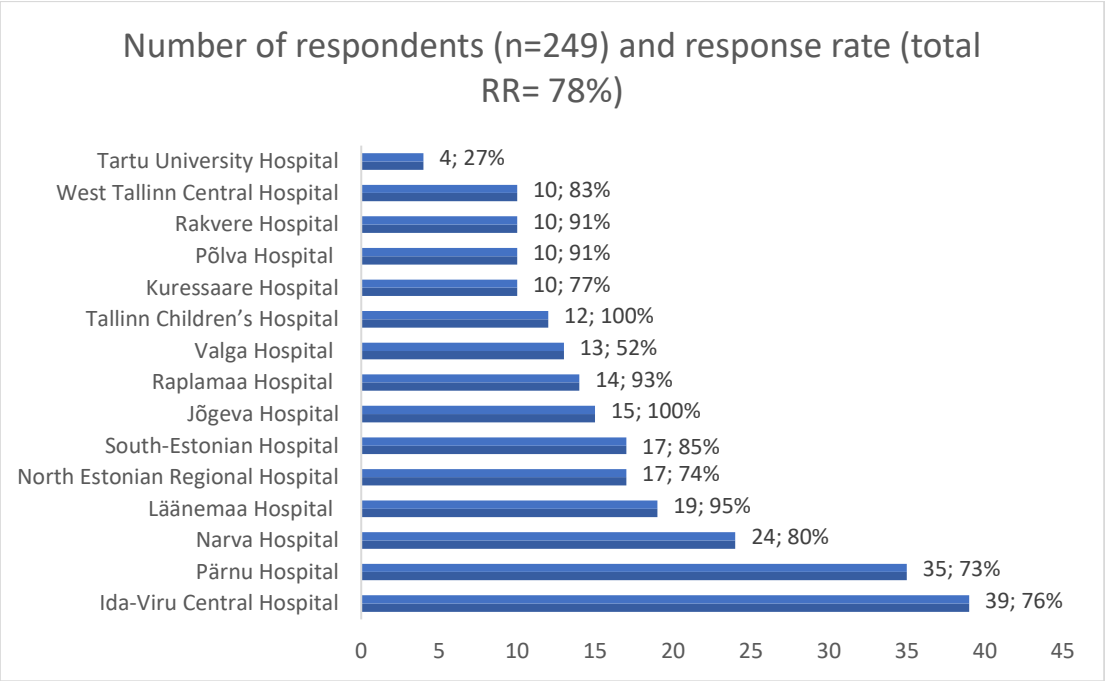

Figure 13. Number of responses and response rates from each participating hospital.

Ida-Viru Central Hospital and Pärnu Hospital had more respondents than others as the questionnaire was carried out in the whole Internal disease clinic. The overall response rate was 78%. Tartu University Clinic and Valga Hospital had lower response rates than other hospitals 27% and 52% respectively. After data cleaning 244 answers were analysed.

Demographic characteristics

On average 97% of respondents answered the demographic questions. Questions were asked about education, position, and work experience. The full results are seen in Appendix 9.

The most frequent **education** was baccalaureate-level education 55% followed by middle-level specialised education (31%). **Position:** from all participants, 77% worked as nurses, 16% as assistant nurses, and 5% as head nurses (Figure 14).

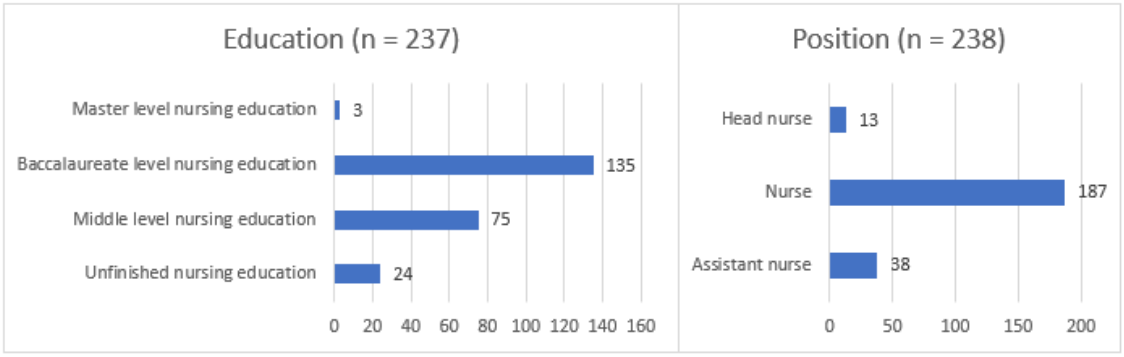

Figure 14. Nurses' survey participants education and position demographic data.

More than half (53%) had worked over a decade as a nurse and more than a third (37%) worked more than 10 years in the same department (Figure 15)

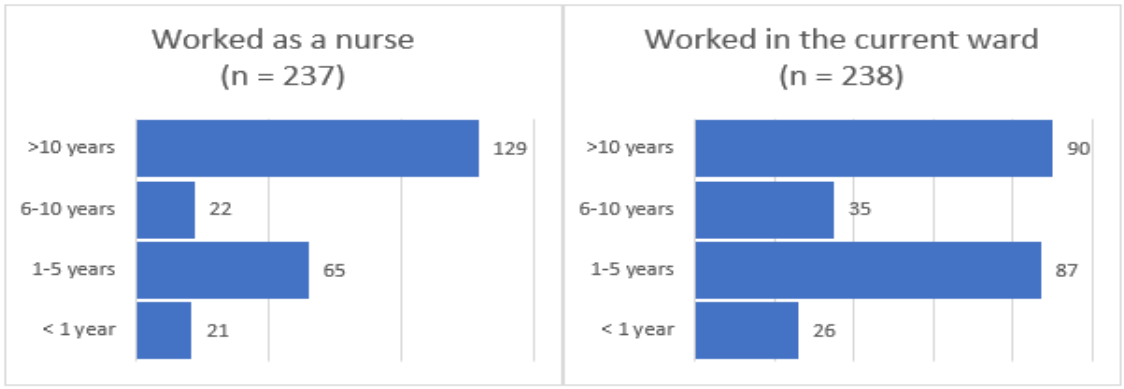

Figure 15. Nurses' survey participants experience demographic data

Additional questions were asked about exposure to the medication administration and work time. Most of the respondents worked full time (78%) and often administered both intravenous (IV) drugs (94%) and non-IV drugs (81%).

Nurses' perception of the causes of medication administration errors (MAE)

The analysis showed that the most reported factor associated with MEs (75% of respondents agreed) was '*Unit staffing levels are inadequate*' with the most frequent answer 'strongly agree' (mode = 6), followed by 68% agreement that '*Physicians change orders frequently*'. '*Many patients are on the same or similar medicines', 'illegible physician orders'*, and '*frequent interruptions of nurses'* were also brought out as frequent reasons for MAEs. Nurses´ perceptions top five reasons for MAE are presented

in Table 1 in ascending order by the agreement rate. The mode shows the most frequent answer for each answer.

Table 1. Nurses' perceived top five reasons for MAEs.

	Agreement rate %, r	**Mean**	**Mode**	**Std. Deviation**
Q23. Unit staffing levels are inadequate.	75,4	4,53	6	1,593
Q6. Physicians change orders frequently.	68,4	4,00	4	1,430
Q15. Many patients are on the same or similar medications	63,5	3,95	5	1,646
Q4. Physicians' medication orders are not legible.	62,6	3,70	4	1,551
Q22. Nurses are interrupted while administering medications to perform other duties.	61,9	3,79	4	1,622

All questions concerning pharmacy role in MAE (questions 9-12) had a high number of missing answers, indicating that the question was not relevant for Estonian hospitals or the question was not understood by respondents. The perceived least five reasons (excluding pharmacy-related reasons) for MAEs are presented in Table 2. A full list of responses is shown in Appendix 10.

Table 2. Nurses' perceived five least important reasons for MAEs.

	Agreement rate %, r	**Mean**	**Mode**	**Std. Deviation**
Q27. Equipment malfunctions or is not set correctly (e.g., IV pump).	24,6	2,35	1	1,373
Q18. Nurses on this unit have limited knowledge about medications.	22,9	2,39	1	1,376
Q17. On this unit, there is no easy way to look up information on medications.	17,6	2,17	1	1,372
Q20. When scheduled medications are delayed, nurses do not communicate the time when the next dose is due.	13,9	2,06	1	1,251
Q21. Nurses on this unit do not adhere to the approved medication administration procedure.	7,8	1,59	1	0,960

Most of the nurses did not find the factors related to nurses' knowledge or skills being reasons for MAEs. Reasons like *nurses' adherence to the medication administration procedures, knowledge about medicines, equipment is not set properly*, *communication with other nurses*, or *looking for information about medicines*, the most frequent answer was 'strongly disagree' (mode = 1) and the mean score was below 2.4.

Looking at the subscale analysis, 'medication package related' (mean = 3.59), 'nursing processes related' (mean = 3.55), and 'physician communication related' (mean = 3.21) factors contributed to the MAEs occurrence. Factor subscales 'pharmacy related' (mean = 2.61) and 'nurse related' (mean = 2.50) were not considered strong reasons for the MAEs.

Nurses' perceptions of the reasons why MAE are not reported.

The main reasons why nurses believe MAEs are not reported are related to fear and organisation culture: '*Nurses could be blamed if something happens to the patient as a result of the medication error*' (75.4% agreement rate) and '*No positive feedback is given for passing medications correctly*' (72.2% agreement rate). Also, inadequate management response is found to be an important factor why MAEs are not reported: '*When med errors occur, nursing administration focuses on the individual rather than looking at the systems as a potential cause of the error*' (66.8% agreement rate). Nurses´ perceptions of top five reasons why MAEs are not reported are presented in Table 3 in ascending order by the agreement rate.

Table 3. Nurses´ perceptions of top five reasons why MAEs are not reported.

	Agreement rate %	**Mean**	**Mode**	**Std. Deviation**
Q42. Nurses could be blamed if something happens to the patient as a result of a medication error.	75	4,40	6	1,605
Q43. No positive feedback is given for passing medications correctly.	72	4,42	6	1,750
Q45. When med errors occur, nursing administration focuses on the individual rather than looking at the systems as a potential cause of the error.	67	4,09	5	1,602

Q37. The patient or family might develop a negative attitude toward the nurse or may sue the nurse if a medication error is reported.	60	3,71	4	1,743
Q40. Nurses fear adverse consequences from reporting medication errors.	60	3,70	4	1,676

The least relevant reasons for non-reporting of MAEs (the most frequent answer is "strongly disagree", mode = 1) are related to nurses' '*agreement with ME definition*' (agreement rate 15%) and '*recognizing the MAEs occur'* (agreement rate 25%). Reporting time burden (agreement rate 25%) and expectation level of proper medication administration (agreement rate 26%) were also no issues for most nurses (mean <2.5). Nurses´ perceptions of the least five reasons why MAEs are not reported are presented in Table 4 in ascending order by the agreement rate.

Table 4. Nurses´ perceptions for least five reasons why MAEs are not reported.

	Agreement rate %	**Mean**	**Mode**	**Std. Deviation**
Q41. The response by the nursing administration does not match the severity of the error.	27	2,74	2	1,487
Q38. The expectation that medications be given exactly as ordered is unrealistic.	26	2,47	1	1,565
Q33. Contacting the physician about a medication error takes too much time.	25	2,52	1	1,461
Q31. Nurses do not recognize an error occurred.	25	2,48	1	1,375
Q30. Nurses do not agree with the hospital's definition of a medication error	15	2,17	1	1,323

The full list of received reasons why MAEs are not reported is presented in Appendix 11 in ascending order by agreement rate.

Nurses' perception of a percentage of each type of error reported on their unit.

The third part of the questionnaire (section C) asked nurses to estimate the percentage of reported errors on their unit for different types of MAEs separately for non-intravenous (non-IV) and intravenous (IV) drugs and total for all errors.

Overall, 66% of nurses answered that 0-20% of all errors are reported in their unit. Only 1.5% of nurses believed that all MAEs are reported while 14.5% believed > 50% of MAEs are reported. The split of all answer frequencies is illustrated in Figure 16.

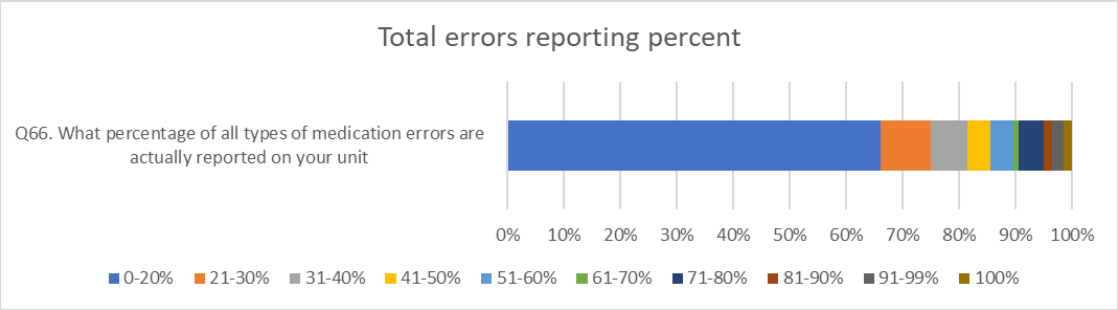

Figure 16. Percent of nurses based on their perception of reporting all IV and non-IV MEs combined in their unit.

The most frequently reported medical errors mean values of the responses and standard deviations are presented in Table 5.

Table 5. Top 3 types of MAEs reported for non-IV and IV drugs.

	Mean	**Std. Deviation**
Types of Non-IV Medication Errors		
Q49. Wrong dose	2.24	2.292
Q50. Wrong drug	2.32	2.600
Q51. Medication is omitted	2.41	2.330
Types of IV MEs		
Q60. Medication is omitted	2.33	2.315
Q62. Medication administered after the order to discontinue has been written	2.33	2.349
Q65. Wrong rate of administration	2.35	2.354

Most frequently reported errors are '*omitted medicines'* for both non-IV (mean = 2.41) and for IV medications (mean = 2.33), '*wrong rate of administration for IV medication'* (mean = 2.35), '*medication administered after the order of discontinuation is written'* (IV mean =2.33), and '*wrong drug"* for non-IV drug (mean = 2.32). Section C had a higher number of missing answers ranging from 22 to 39 missing values. The full list of reporting

frequency answers, missing values, mean, and standard deviation are presented in Appendix 12.

0-20% reporting was the most frequent answer (54.4-78.8%) for all non-IV and IV MAE types. Graphs with the percentages of nurses who answered what percent of MAEs are reported in their unit are presented in Figure 17 for non-IV drugs and in Figure 18 for IV drugs.

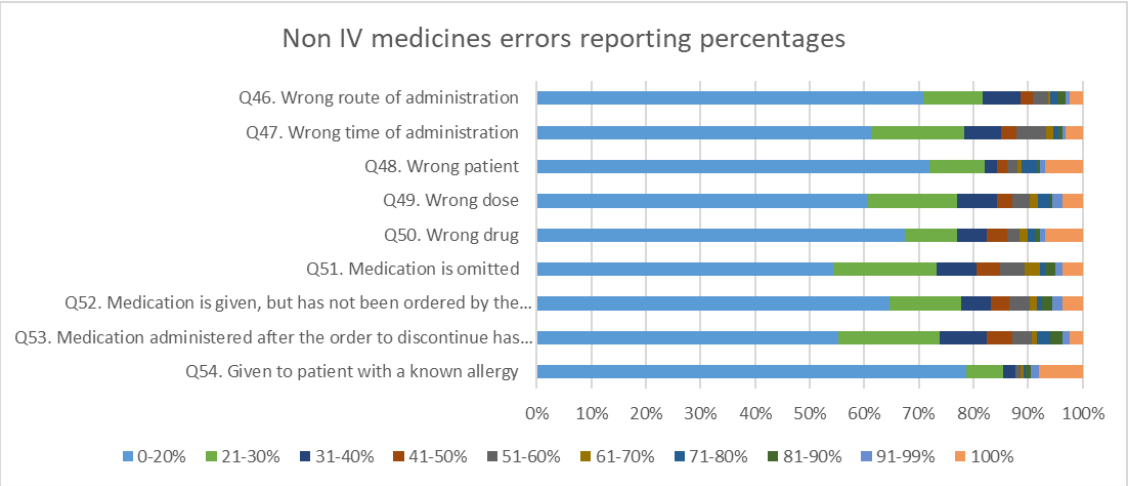

Figure 17. Percent of nurses based on their perception of reporting non-IV MEs in their unit.

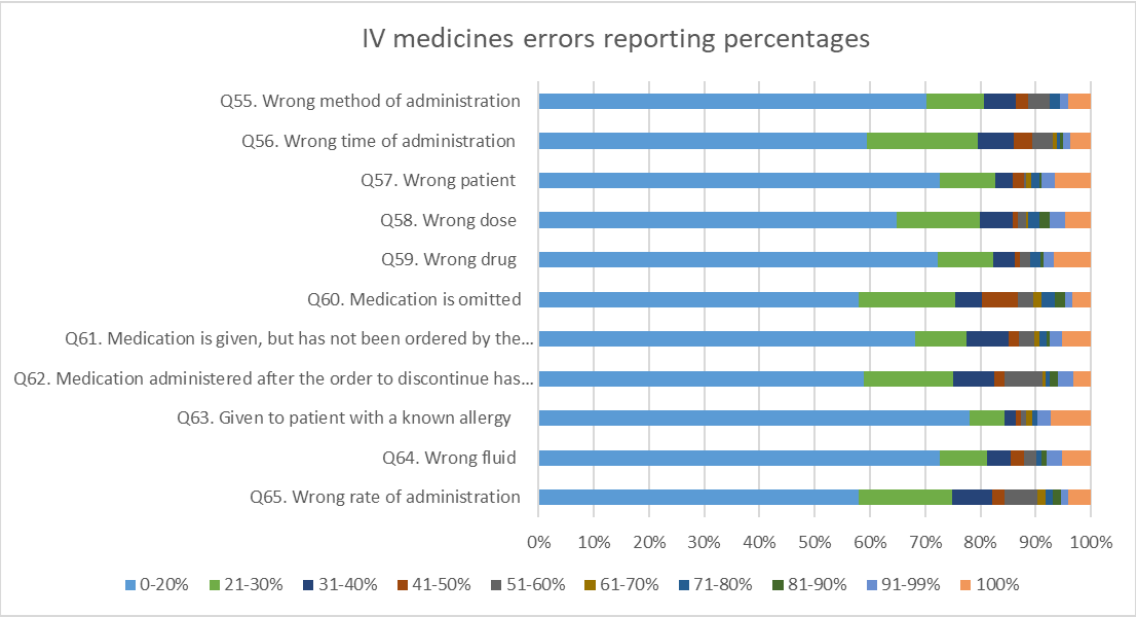

Figure 18. Percent of nurses based on their perception of reporting IV MEs in their unit.

When analysing the type of MAEs when nurses believed that 100% of errors are reported in their unit, the *drug administration for a patient with a known allergy*, *wrong drug*, and

wrong patient, ranked highest (6.6-8.0% of respondents) similarly for IV and non-IV drugs.

The incidence of errors.

175 nurses (71.7%) answered the question, '*How many medication errors occurred in your unit during last week?*'. Of respondents, 65% (n = 114) of nurses did not notice any errors in their unit during a week. Thirty-five percent (n = 61) of nurses observed 1 to 20 mistakes in their unit during a week. Nurses' perception of the incidence of MEs during the last week is presented in Figure 19.

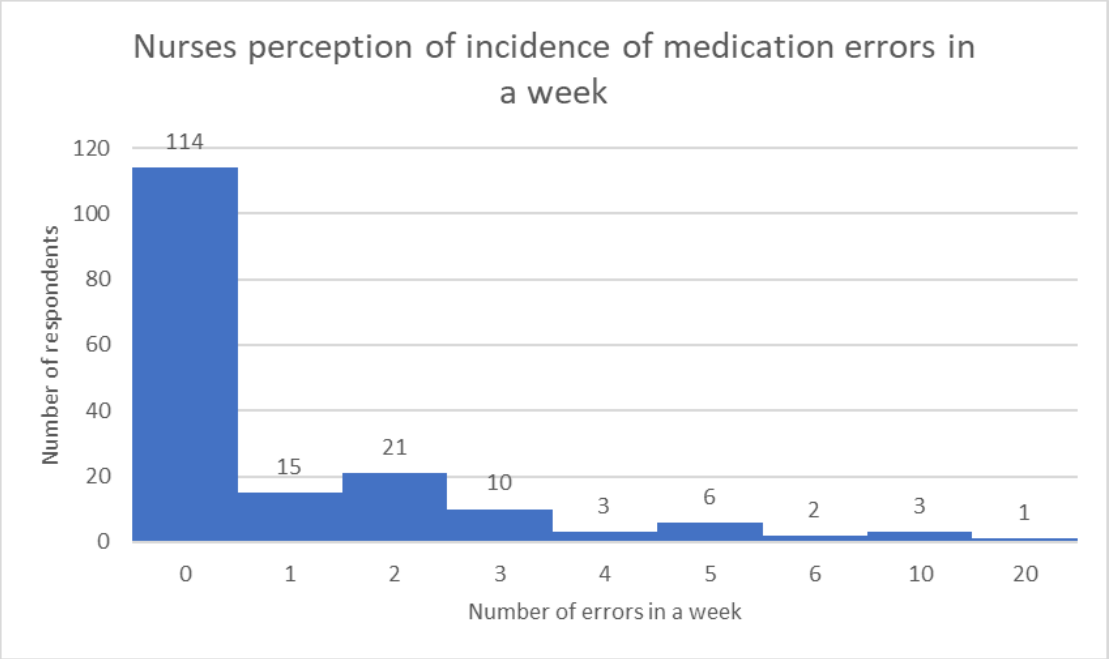

Figure 19. Nurses' perception about number of MEs occurred in their unit during a week.

In one hospital all participating nurses reported 0 mistakes during the last week and in one hospital one nurse stated 20 mistakes were done during a week. To calculate the ME rate per patient the author has divided the mean MAE of each hospital by the number of beds in the unit. The ME rate per one hospital bed is 3.87% (1.58-6.15% CI 95%).

To the open question, *'Do you have any suggestions for improving the current system for monitoring medication errors?*' fourteen (5.7%) nurses replied. Half of the replies (n = 7) were related to the ME reporting and another half (n = 7) were suggesting improvements to reduce the ME occurrence. **Reporting improvement**: three comments from different hospitals were about the lack of information that the ME reporting system exists (all the hospitals have a medication reporting system). Three comments stressed the need for

positive encouragement, open and blame-free culture, and additional training. One comment was about an integrated ME reporting system with HIS. **Reducing MEs**: Three comments from different hospitals stressed the issue of too high nurses' workload. Three comments suggested improved communication with physicians (computerised physician order entry, avoid oral medication orders, clear orders). One nurse suggested an improved work process between nurses.

5.3 Variances and correlations

In a subscale one-way ANOVA analysis, there was no significant difference **between** groups based on any of the **demographic parameters** (education, position, experience, usage of medications, work time) on any subscale (reasons why MEs occur, why MEs are not reported, percentage of non-IV and IV MEs reported).

A one-way ANOVA test between hospitals' responses was performed. In sections A (why MAEs occur) and B (why MAEs are not reported) were no significant differences between hospitals. The difference only came from the questionnaire section C error reporting subscale $F(14, 214) = 5.392$, $p < .001$. Post hoc Tukey Honestly Significant Difference (HSD) test showed that TUH responses were significantly different from other hospitals. TUH had a higher MAE reporting rate than other hospitals ($X = 8.18$ vs 1.2-3.5). ANOVA on the number of MAEs that occurred in a week showed a significant difference between groups $F(14, 160) = 3.145$, $p < .001$. Again, TUH had a higher mean number of MAEs versus other hospitals ($X = 5.0$ vs 0-3.18). No conclusions can be drawn from the difference due to the low response rate and the low number of respondents from TUH. Type I error (false positive) cannot be ruled out.

One-way ANOVA test did show significant variance **between hospital information system (HIS)** and 'Physician communication related' sub-scale $F(3, 240) = 11.47$, $p < .001$. Post hoc comparisons using the Tukey HSD indicated that Liisa and Ester3/Heda users perceived significantly less MAEs related to physician communication than Ester2 and eHL users ($X = 2.83$, 3.0 vs 3.51 and 3.83, respectively). In the more detailed analyse it was evident that the difference is driven by variance related to '*physicians' medication orders are not legible'* where Liisa significantly outperforms Ester3/Heda, Ester 2, and eHL ($X = 2.59$ vs 3.57, 4.26, and 4.58, respectively).

Differences between different patient incidence reporting systems. Hospitals using POI had a significantly higher (mean = 2.80) '*number of MEs occurred during last week*' versus hospitals using a paper system (mean = 1.75) based on ANOVA post hoc comparison with Tukey HSD.

Anonymity of the reporting. One-way ANOVA test did show significant variance depending if PSI reporting is anonymous or not. There was a significant difference for MAEs reported both for non-IV $F(1, 220) = 9.04$, $p = 0.003$ and IV medicines $F(1, 217) = 15.39$, $p < 0.001$ and for percent of all MAEs reported $F(1, 224) = 14.96$, $p < 0.001$. For all groups (non-IV, IV and all) there was a significantly higher reporting percentage for anonymous reporting.

There was no significant difference between anonymous reporting or not and the number of MAEs occurred during a week.

6 Discussion

This section discusses the initial hypothesis, key results, and previous studies, and tries to answer the research questions. The key findings of this study are upbrought and the limitations of this study are examined. Furthermore, proposals for future research and conclusions are presented at the end of the chapter.

6.1 Burden of medication errors

Hospital MEs are highly prevalent [3], [4]. Transferring data about the incidence of hospital MEs from the literature there could be between 12500-14500 MEs per year in Estonian hospitals. The current study was not designed to evaluate the number of MEs in hospitals. However, the nurses' questionnaire had a question about the number of medication administration errors during a week in their unit. According to nurses´ estimation ME rate is close to data from literature with 3.9% of ME per hospital bed and with an average stay of 6.2 days. The overall ME rate according to literature is 6.5-7.5% [3], [4] and the MAEs are about 47- 57% of all MEs [5], [31].

Considering literature data and our results it is possible that as many as 2000 MAEs happen in therapeutic wards in Estonia annually. Most of them cause no harm to the patient. The rate of serious adverse events in the literature varies between 0.7% -6.5% [5], The number of MEs causing serious harm may be between 14 and 130 cases per year in Estonia.

6.2 Medication error collection

It is known from the previous international studies that voluntary reporting only captures a small fraction of the errors [98].

Medication error collection on the national level.

The study demonstrates that there is no systematic ME registration on the national level. Two organisations – SAM and ECQH have a national registry of MEs. The MEs are reported voluntarily to the SAM as part of the pharmacovigilance surveillance or submitted as a claim to the ECQH for health care service quality assessment. In total 49

MEs were registered from 2016 to 2021 in Estonia. Hospital cases comprised 8 of 49 reported cases. The initial hypothesis was confirmed.

Medication error collection in hospitals.

This is the first cross-sectional study of ME reporting in Estonian hospitals. The study represents data from 75% of HNDP hospitals. Three hospitals refused to participate the survey. The ETCH Study committee gave three reasons for refusal: 1. the hospital has not yet implemented a ME reporting system and therefore most survey questions are irrelevant; 2. Nurses' survey will only represent the perspective of one ward and will not be generalisable to the whole hospital or the whole of Estonia; 3. evaluation of reported errors percentage is not possible as the total number of errors is unknown. The first two issues are addressed in the survey as ETCH data would have been incorporated into the cross-sectional survey with sufficient power to make it representative. In the last point, ETCH is referring to a known issue of under-reporting of the voluntary error reporting systems [38] and is correctly pointing out the issue of lacking denominator information in Estonia as there have been no studies performed. The survey objective was to evaluate the perception of the nurses about MAE reporting and MAEs observed during a week gave an estimation about the MAE incidence.

The results show that 10 hospitals out of 15 have a patient safety incident reporting system in place, but only 5 hospitals had any MEs recorded in 2021. Effectively only regional hospitals (NERH, TUH, and TCH) systematically register and analyse MEs. Out of 109, MEs recorded in 2021, 107 (98%) were reported from regional hospitals. The percentage of the reported MEs from all MEs was not possible to evaluate as no hospital has measured the real incidence of the MEs.

The experts from regional hospitals brought out that the system is often seen as a *finger-pointing system*. One regional hospital is trying to raise the rate of self-reported incidences with regular communication and feedback, but the rate is still less than half. The hospitals where the PSI system is in place, but the number of registered cases is low, are bringing out the *low awareness* and *low priority* as reasons for not reporting.

The hospitals using POI had a significantly higher mean of MAEs than hospitals using a paper reporting system. The difference can be explained by the increased nurses'

awareness and vigilance about patient safety and MEs in the hospitals where POI is implemented.

The majority of nurses (66%) admitted that only 0-20% of errors are reported in their unit. Only 1.5% of nurses believed that all MAEs are reported, while 14.5% believed > 50% of MEs are reported. The 0-20% reporting was the most frequent answer (54.4-78.8%) for all types of non-IV and IV ME types. Mistakes like *omitted medicines, wrong rate of IV administration, medication administered after the order discontinuation,* and *wrong drug* were reported more frequently than other types of errors, indicating that those could be the most frequent type of MAEs. MAEs like *drug administration for a patient with a known allergy, wrong drug,* and *wrong patient* were considered more serious as more nurses (6.6-8.0%) said that they are always reported.

The hypothesis, that hospitals are registering the MEs through their local patient safety incident reporting systems, was partly confirmed.

6.3 Why medication errors occur?

The research questions about why ME occur, and **why they are not reported** were studied through nurses' questionnaire and therefore concerned mainly the medication administration errors. Overall nurses' response rate of 78% is very high and gives a good overview of nurses' views on why MAEs occur and why they are not reported.

According to the Wakefield categorisation, MAEs can occur due to *individual staff characteristics (knowledge and skills); policy- and procedure-related issues; communication;* and *systems issues* [54]

Nurses' perception was that the MAEs were related to **system issues**. The highest-rated single statement was '*Unit staffing levels are inadequate'.* More than 75% of nurses agreed that it is a reason why MEs occur. Also '*frequent interruptions during medicines administration'* and *'many similar medications'* were mentioned.

The second area was a **failure in communication**, where *physician communication related* aspects were important for nurses: '*Physician frequent changes of medication orders', 'Physicians' medication orders are not legible'*. There was a significant difference between groups using different hospital information systems (HIS) and the

'*physician communication related'* sub-scale. The difference was driven by variances related to '*Physicians' medication orders are not legible*' where Liisa outperformed the other HISs. The difference is explained as Liisa is the only HIS that has computerised physician order entry (CPOE). This finding is confirming the findings from the literature that CPOE can reduce MEs by half. Mistakes related to illegible handwriting, use of abbreviations, and use of brand names instead of international nonproprietary names (INN) are avoided with the use of CPOE.

The factors related to **individual characteristics** like nurses' knowledge, communication, and skills were not considered contributing factors for MEs by nurses. Estonian nurses feel confident about their level of knowledge and skills. Nurses' education, position, experience, usage of medications, or work time did not make any difference in nurses' perception of why MEs occur.

Policies- and procedures were not considered top reasons for MAEs. However, the questions about *frequent changes of brand names (use of cheaper generics)* and *pharmacists are not available 24 hours a day*, got an agreement rate of 61% and 59.9% respectively. Furthermore, the statement "*All medications for one team of patients cannot be passed within an accepted time frame*" got a 58.6% agreement rate.

6.4 Why are medication errors not reported?

Currently, the healthcare professional can be held personally liable for the harm to the patient due to an ME. The lack of nationally agreed-on rules and definitions, and the threat of criminal liability of health care professionals, do not motivate the voluntary ME reporting [68].

The Estonian authorities are aware of the need to improve patient safety in the Estonian healthcare system. The need for legal changes, harmonised definitions, rules, and patient safety incident reporting system has been highlighted in several reports [12]–[14]. Ministry of Social Affairs has been preparing a new mandatory patient insurance law for many years, but it has been stalled due to political reasons. Finally, the new Compulsory Liability Insurance of Healthcare Providers Act was approved by parliament on 13.04.2022 and will come into force from 01.07.2024. The new law is implementing mandatory PSI reporting into the central database. Reporting is incentivised by freeing

the healthcare professionals from personal liability if the error is recorded in the database. This is an important step to start collecting analysing and learning from MEs to improve the medicines' safety in Estonia. Most hospitals still need to start building the reporting systems. The study showed that the presence of a PSI reporting system was important, but not enough, without dedicated resources, systematic employee training, and frequent communication in the hospitals. This confirms the findings from other countries that patient safety awareness and blame-free culture are the most important factors [50].

Experts brought out '*fear of the negative consequences'* and '*lack of clear definition'* as two main reasons why MEs are not reported in hospitals. Nurses' survey confirmed that sub-scales '*fear of consequences' and 'organisation culture'* are the most important reasons, why MEs are not reported. However, '*disagreement with ME definition'* had a low agreement rate suggesting that nurses understand what MAE is but are afraid to report the errors. There was a significantly higher reporting of MAEs in the hospitals where the ME reporting is anonymous. Those findings are well correlated with international studies [50], [53] and with the previous findings from patient safety studies in Estonian hospitals [17], [19].

MEs can occur at any phase of the medication therapy process, but most frequently during medication administration [24]. Nurses are the last defence line for patient safety, and they are trained to implement the **five rights** of medication administration*: right patient, right drug, right time, right route,* and *right dose*. Findings from the nurses' questionnaire show that the nurses understand the *definition of the MAE* and believe they can *recognise when the error has occurred,* but they *are afraid* to report the MAEs.

The most important factor expressed by experts and nurses for improved ME reporting is a '*blame-free culture'.* This is in line with international knowledge and confirmed by the nurses' questionnaire findings that *fear of consequences* is the most important barrier to reporting [50]. Priority is to create a PSI reporting system, which was brought out by several experts as a plan to improve patient safety in their hospital. The survey did not show a significant difference in ME collection rate between electronic and paper PSI. However, the ease of reporting is an important factor according to international studies [50]. An *integrated PSI reporting system with HIS to facilitate the ME reporting* was mentioned by several experts and by one nurse in the study. Aspects like *clear definitions, mandatory training,* and *additional resources* were also considered important by experts

and nurses. According to experts, several hospitals are planning to implement *electronic ME reporting systems*, *patient safety training* for employees, and reinforce the *blame-free culture*. Again, those responses are in line with the WHO recommendations for an effective PSI reporting system [29] suggesting that Estonian hospital experts are aware of the need for ME reporting and of the typical barriers.

6.5 How to reduce medication errors?

Defining strategies for the reduction of MEs was not the primary aim of the study. Few suggestions came out from the study findings and the expert interviews. Medication treatment is a complex process. Following the Singer and Vogus model [72], the following activities can reduce the MEs in hospitals and improve medication safety.

Enabling. The most important **external enabling factor** would be the new mandatory ME reporting obligation from 2024. This puts pressure on all HPs to start creating the systems and build awareness in their organization. It would be important to follow the WHO guidelines [29] for building an effective and learning-oriented reporting system. Another important area is the employment law regulating working hours and overtime. It is well known that in Estonia there is a shortage of health care professionals, both physicians, and nurses. The study confirmed the problem as the **adequate staffing** issues were the most frequently mentioned factor by nurses and the nurses' open-ended comments stressed the issue of too **high nurses' workload**. The staffing problem however can be considered also an **internal enabling factor**, as the staffing decisions are done on the individual HP level. An internal enabling factor is a technology. Six experts considered **CPOE to reduce the MEs.** Furthermore, the nurses' survey also confirmed that in the hospitals where the CPOE is in use, the MAEs related to physician communication are less relevant than in other hospitals. A recent meta-analysis has found that CPOE can reduce MEs by 50% [73].

Enacting. This includes all front-line activities. In the study, nurses feel confident about their teamwork and communication with each other. The issue they see with the communication with the doctors as open-ended comments suggested improved **communication with physicians** (avoid oral medication orders, clear orders). The standard operating procedures, treatment, and care guidelines should be considered. The work process can be improved to reduce MEs. Nurses brought out the '*frequent*

interruptions during medicines administration' and *'patients receiving many similar medications'* as reasons for MAEs. The simple solution as a special "Do not disturb" vest is already in use in TUH. Different patient identification strategies, like wrist bands and bar codes, can reduce the 'wrong patient' or 'wrong medicine' type of MAEs. Collaboration with pharmacists and the focus on high-risk medications are important activities to reduce the MEs. Some experts have brought out the plan to hire clinical pharmacists or collaborate more with pharmacies.

Elaborating - learning practices that reinforce safe behaviors is perhaps the most important aspect to improve patient safety. Increased awareness about patient safety is needed on all levels in Estonia. Starting with the authorities and hospital management and finishing with the patients. In recent years there have been increased awareness among pharmacists, doctors, and nurses as several patient safety conferences have been held in Estonia. Tartu University is organising patient safety education courses in recent years. Yet, more work is needed to effectively reduce the MEs.

6.6 Study limitations

This study has several limitations. First, the data from hospitals were collected using a non-randomised purposive sample. The expert interviews reflected the situation in most of the hospitals, making it representative, but the selection bias cannot be ruled out. For the nurses' survey overall high participation rate of 77.6% was achieved and overall consistency between hospitals was high. It makes the results representative but the generalizability of this sample to other wards and settings cannot be evaluated within the scope of the current study. As the response rate varied from 27% to 100% between hospitals, the self-selection bias can have some impact on the responses.

Second, the nurses' study focuses on nurse perceptions as to why MAEs occur and why they are not reported. Identification of the actual reasons for why MAEs occur and finding the relative importance of different reasons why MAEs are not reported are beyond the scope of this study. The rate of MAEs per patient is calculated using the mean of observed MAEs in a unit during a week. It is an estimation based on the internal care wards and cannot be extrapolated to the other wards, like emergency or surgical care units. It is a conservative calculation as the mean number of estimated MAEs per week was used for each unit. One could argue that the highest number of MAEs stated per unit would give

a more realistic view. The author felt that using the highest MAE number would emphasise a single nurse's perception too much and would increase the risk of an error.

The author has selected a paper survey for nurses' questionnaire. There are some limitations related to paper surveys [94]. The questionnaires were distributed by head nurses, who could influence the nurses' willingness to participate. There were no possibilities for the author to send reminders to the hospitals. Delivery and collection of paper surveys needed to be organised additionally and there could be data transcribing errors. A paper survey is less environmentally friendly than an electronic questionnaire. However, the benefit of a paper survey is the higher response rate [94] and the author has taken the necessary precautions to ensure the accuracy of the data.

A questionnaire validated in the United States [54] was used for the nurses' survey. The author adopted the questions and translated the questionnaire into Estonian. However, the final questionnaire and the translation were not validated nor piloted before the use of the questionnaire in Estonia. The translation was done by the author who is a health care professional and has expertise in the topic. The final questionnaire contained a block of questions that were not relevant to Estonia. The pharmacy-related statements Q9-Q12 had the most missing answers. It can be explained by the fact that a pharmacy is not directly involved in the administration of medicines in Estonian hospitals. Therefore, all questions regarding pharmacy errors (Q9-Q11) received a low agreement rate of 0-1,6%. However, the question 'Q12 *Pharmacists are not available 24 hours'* received a high agreement rate of 61%, suggesting that respondents probably rather agreed with the statement than considered that it is a reason for an error. When using the questionnaire in Estonia in the future the pharmacy-related questions could be eliminated.

In the situation when overall ME reporting is very low and most of the respondents have never reported a MAE, section C with detailed questions about reporting different types of MAEs, was excessive and significantly skewed towards the answer 0-20%. The author believes that 0% should have been a separate answer choice. It could have been sufficient to ask a single question, like '*Have you ever reported a MAE*?', to find a proportion of nurses who have reported MAE. However, the author finds that a detailed view is appropriate in future follow up studies and it is important to have a comparable baseline with the same methodology.

6.7 Next steps

WHO has set the objective to reduce the level of severe avoidable harm related to medications by 50% over 5 years globally [2]. Estonia still needs to achieve the first objective to assess the scope and the nature of avoidable harm and strengthen the monitoring systems to detect and track the harm. The WHO guidelines for medical error reporting and learning systems [29] give good guidance for building an effective system.

To raise the awareness of all stakeholders about the burden of medical errors and build safer healthcare there is a need for a study to evaluate the incidence of medical errors (including MEs) in Estonian hospitals. The study should be a randomised cross-sectional study of all hospital therapy areas. Different aspects, like incidence, prolongation of hospital stay, and cost should be evaluated. The most effective method is a medical chart review combined with interviews or observation. Unfortunately, this type of evaluation is very expensive. For routine ME monitoring innovative electronic surveillance systems based on trigger phrases or laboratory results could be developed.

Due to new legislation, all hospitals must uplift their readiness to collect, report, and analyse the MEs, to be ready for mandatory patient safety incidents reporting by 01.07.2024. A year after the mandatory patient safety incidents reporting, the repeated nurses' questionnaire would give valuable insight into the changes in nurses' perceptions and remaining or new barriers to the ME reporting. The longitudinal study would allow to quantify the impact of mandatory reporting implementation in a country and produce scientific information with an international value.

Once the MEs reporting is established in hospitals, the MEs should be part of the EHIF clinical quality indicators [40]. This would increase the HPs motivation to monitor and analyse the MEs and eventually decrease the burden of MEs.

6.8 Final conclusions

Following conclusions based on study findings can be drawn:

1. There is no systematic hospital ME reporting on a national level in Estonia.

2. Lack of nationally agreed-on rules and definitions, and the threat of criminal liability of health care professionals, do not motivate the voluntary ME reporting.

3. Despite 66% of hospitals having a ME reporting system, only regional hospitals systematically record and analyse MEs.

4. Dedicated patient safety resources, systematic employee training, and communication are more important success factors for ME reporting than the presence of an electronic PSI reporting system.

5. The average MAE rate of 3.9% per patient was detected by the nurses.

6. Medication package related, nursing processes related, and physician communication related factors contribute to the MAEs occurrence.

7. 66% of nurses admit that only 0-20% of MAEs are reported in their unit

8. Anonymous reporting increases the likelihood of the MAE reporting.

9. Fear of negative consequences and organisation culture are the most important barriers to the ME reporting in hospitals.

10. Blame-free culture, PSI reporting system, clear definition, employee training, and additional resources are the main factors to improve the ME reporting in hospitals.

11. Computerised physician order entry and adequate staffing level are key factors to reduce medication errors based on the study findings.

12. Further studies are needed to measure the incidence of the MEs in the hospitals.

7 Summary

This thesis aimed to analyse the hospital medication errors reporting at national, hospital, and individual levels. The author of this thesis conducted a systematic national database review and a cross-sectional hospital survey including semi-structured experts' interviews and a quantitative nurses' perception questionnaires.

The systemic national database review confirmed the initial hypothesis that MEs reporting on the national level is very limited. Lack of nationally agreed-on rules and definitions and fear of criminal liability prevents the ME reporting by HC professionals.

The hypothesis, that hospitals are registering the MEs through their local patient safety incident reporting systems, was partly confirmed. Despite two-thirds of hospitals having a ME reporting system in place, only three regional hospitals are systematically recording and analysing MEs.

The average MAE rate is 3.9% per internal care patient. Medication package related, nursing processes related, and physician communication related factors contribute to the MAEs occurrence. 75% of nurses believed that inadequate staffing level is the reason for MEs.

66% of nurses admit that only 0-20% of errors are reported. Hospitals' safety experts and nurses agree that the biggest barrier to ME reporting is the fear of consequences. Dedicated patient safety resources, systematic employee training, anonymous reporting, and blame-free culture are the key success factors for increased ME reporting.

To sum up, ME s are an important burden on patient safety and healthcare systems. Estonia does not have systematic ME reporting at the national or hospital level. The new Compulsory Liability Insurance of Healthcare Providers Act will oblige healthcare providers to implement a patient safety incident reporting system from mid-2024. Mandatory reporting, harmonised rules and definitions, and reduced fear of personal liability should reduce the barriers to reporting considerably. Ensuring adequate staffing levels and the use of a computerised physician order entry (CPOE) could reduce the MEs.

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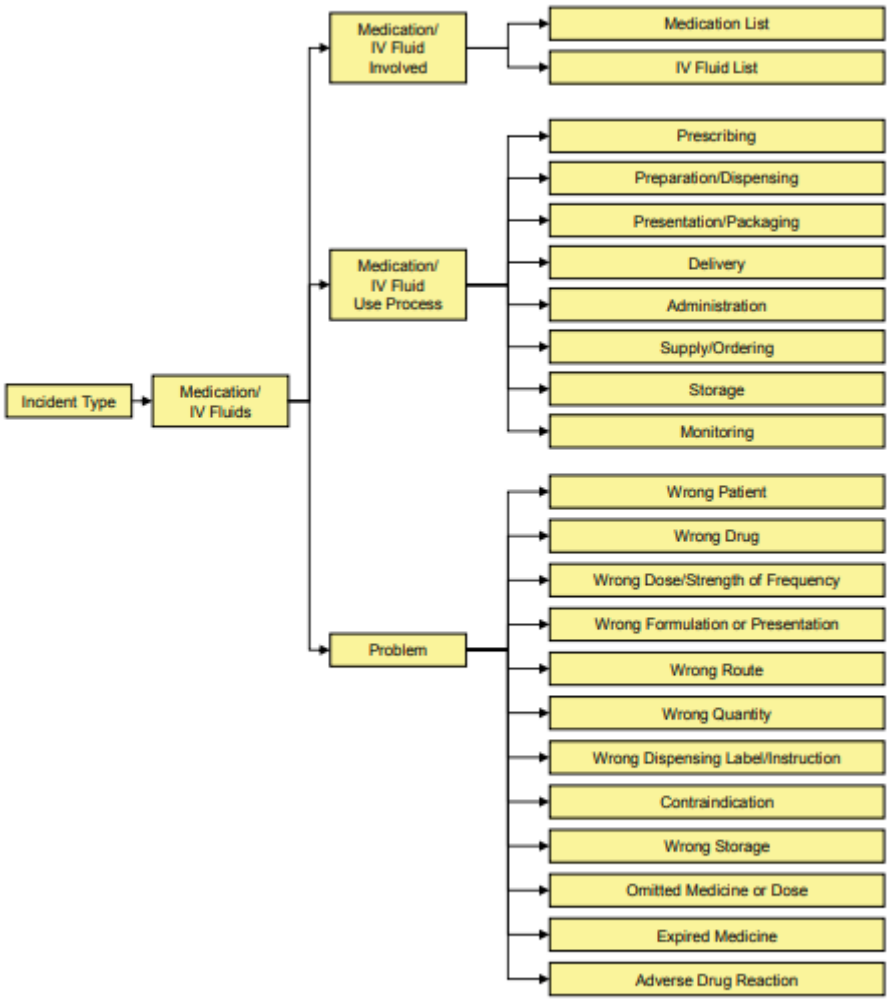
Appendix 2 – ME categorisation example from ICPS

Incident Type – Medication/IV Fluids



Appendix 3 – List of national organisations involved in ME monitoring

Name of the institution and web page	Abbreviation	Description
State Agency of Medicines (Ravimiamet) www.ravimiamet.ee	SAM	A governmental body under the Ministry of Social Affairs for recording, reporting, and assessing the suspected adverse reactions and errors in prescribing, storing, dispensing, preparing for administration, or administering a medicinal product for human use. Collecting pharmacovigilance information (including MEs) from marketing authorisation holders, health care providers, and the public.
Estonian Poison Information Centre (Mürgistusteabe-keskus) www.16662.ee	EPIC	An information centre with a hotline under the Estonian Health Board to advise the population and health care providers about poisoning. All inquiries have been recorded since 2008. Voluntary reporting and directed primarily for medical advice.
Expert Committee on the Quality of Healthcare Service (Tervishoiuteenuse kvaliteedi ekspertkomisjon) www.sm.ee	ECQH	An advisory committee under the administration of the Social Ministry, whose aim is to provide for patients an independent assessment of the quality of health care services and based on the assessment results advise Health Board, Estonian Health Insurance Fund or Health Care provider. Providing a second opinion about healthcare quality to the public.
Estonian Health Insurance Fund (Haigekassa) www.haigekassa.ee	EHIF	A national solidarity-based health insurance EHIF is a contract partner to Health Care Organisations (HCO) and monitors HCO service quality through a series of Quality of Health Care metrics. Financial organisation focussed on contract partners' quality monitoring and settling financial claims.
The Estonian Chamber of Disabled People (Eesti Puuetega Inimeste Koda) www.epikoda.ee	ECDP	A non-governmental umbrella organisation for Estonian disability organisations. Directly not involved with individual patients. Official patient representative in governmental health care decision-making bodies.
Estonian Patients Union (Eesti Patsientide Liit) www.patsiendid.ee	EPU	A non-governmental patient representative organisation that has been initiated, managed, and funded by patients. Advising patients in organisational and legal matters.

Appendix 4 – List of hospitals and its departments participating in the cross-sectional survey

Name of the hospital and abbreviation		**Department participating in nurses' survey**
Regional hospitals		
1	Tartu University Hospital (TUH)	General internal diseases ward
2	North Estonian Regional Hospital (NERH)	Internal diseases II ward
3	Tallinn Children's Hospital (TCH)	Acute infections ward
Central hospitals		
4	Pärnu Hospital	Internal diseases clinic
5	Ida-Viru Central Hospital (IVCH)	Internal diseases clinic
6	West Tallinn Central Hospital (WTCH)	Neurological diseases ward
General and local hospitals		
7	Kuressaare Hospital	Internal diseases ward
8	Narva Hospital	Internal diseases ward
9	Rakvere Hospital	Internal diseases ward
10	South-Estonian Hospital	Internal diseases ward
11	Jõgeva Hospital	Internal diseases ward
12	Läänemaa Hospital	Internal diseases ward
13	Põlva Hospital	Internal diseases ward
14	Raplamaa Hospital	Internal diseases ward
15	Valga Hospital	Internal diseases ward

Appendix 5 - Semi-structured experts' interview questions

Question	Purpose
1. Which Electronic hospital information system (HIS) your hospital is using?	How are MEs recorded? Why are MEs not recorded?
2. Does your HIS have an electronic medication record?	Why did ME occur?
3. Does your hospital record medication errors?	How are MEs recorded?
4. What system is used? (Are reporters anonymous?)	How are ME recorded? Why are ME not recorded?
5. What do you do with reported medication errors? What procedures and measures are existing?	How are ME recorded? Why are ME not recorded?
6. Do you have the info on how big % of all medication errors are reported?	How are ME recorded?
7. In your opinion, what is the reason for not reporting medical errors?	Why are ME not recorded?
8. In your opinion, what are the features of the best medication error reporting system?	Why are ME not recorded?
9. What are the plans for patient safety in your hospital?	How to reduce MEs?

Blue – quantitative questions

Black – qualitative open-ended questions

Appendix 6 – Nurses MAE questionnaire

Medication Administration Error Survey

The purpose of this survey is to seek input, based on your clinical experience, from the head and staff nurses on the occurrence and reporting of medication administration errors and the extent to which errors are reported on your unit. This survey will take approximately 5 - 10 minutes to complete. All responses will be kept strictly confidential. Thank you for your time and cooperation!

Definition of Medication Administration Errors (MAEs): For the purposes of this survey, MAEs are defined as errors related to the actual ingestion, injection or application of individual medication doses (e.g., wrong method of administration, wrong patient, wrong additive).

A. Reasons Why Medication Errors Occur On Your Unit. Please circle the number that best reflects the extent to which you agree that the following reasons contribute to why medication errors occur on your unit.

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Slightly Agree	Moderate Agree
1. The names of many medications are similar.	1	2	3	4	5
2. Different medications look alike.	1	2	3	4	5
3. The packaging of many medications is similar.	1	2	3	4	5
4. Physicians' medication orders are not legible.	1	2	3	4	5
5. Physicians' medication orders are not clear.	1	2	3	4	5
6. Physicians change orders frequently.	1	2	3	4	5
7. Abbreviations are used instead of writing the orders out completely.	1	2	3	4	5
8. Verbal orders are used instead of written orders.	1	2	3	4	5
9. Pharmacy delivers incorrect doses to this unit.	1	2	3	4	5
10. Pharmacy does not prepare the med correctly.	1	2	3	4	5
11. Pharmacy does not label the med correctly.	1	2	3	4	5
12. Pharmacists are not available 24 hours a day.	1	2	3	4	5
13. Frequent substitution of drugs (i.e., cheaper generic for brand names).	1	2	3	4	5

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Slightly Agree	Moderate Agree
14. Poor communication between nurses and physicians.	1	2	3	4	5
15. Many patients are on the same or similar medications.	1	2	3	4	5
16. Unit staff do not receive enough information on new medications.	1	2	3	4	5
17. On this unit, there is no easy way to look up information on medications.	1	2	3	4	5
18. Nurses on this unit have limited knowledge about medications.	1	2	3	4	5
19. Nurses get pulled between teams and from other units.	1	2	3	4	5
20. When scheduled medications are delayed, nurses do not communicate the time when the next dose is due.	1	2	3	4	5
21. Nurses on this unit do not adhere to the approved medication administration procedure.	1	2	3	4	5
22. Nurses are interrupted while administering medications to perform other duties.	1	2	3	4	5
23. Unit staffing levels are inadequate.	1	2	3	4	5
24. All medications for one team of patients cannot be passed within an accepted time frame.	1	2	3	4	5
25. Medication charts are not transcribed correctly.	1	2	3	4	5
26. Errors are made in medication chart.	1	2	3	4	5
27. Equipment malfunctions or is not set correctly (e.g., IV pump).	1	2	3	4	5
28. Nurse is unaware of a known allergy.	1	2	3	4	5
29. Patients are off the ward for other care.	1	2	3	4	5

B. Reasons Why Medication Administration Errors Are Not Reported On Your Unit. Please circle the number that best reflects the extent to which you agree that the following reasons contribute to why errors are not reported on your unit.

	Strongly Disagree	Mod. Disagree	Slightly Disagree	Slightly Agree	Mod. Agree
30. Nurses do not agree with hospital's definition of a medication error.	1	2	3	4	5
31. Nurses do not recognize an error occurred.	1	2	3	4	5
32. Filling out an incident report for a medication error takes too much time.	1	2	3	4	5
33. Contacting the physician about a medication error takes too much time.	1	2	3	4	5
34. Medication error is not clearly defined.	1	2	3	4	5
35. Nurses may not think the error is important enough to be reported.	1	2	3	4	5
36. Nurses believe that other nurses will think they are incompetent if they make medication errors.	1	2	3	4	5
37. The patient or family might develop a negative attitude toward the nurse, or may sue the nurse if a medication error is reported.	1	2	3	4	5
38. The expectation that medications be given exactly as ordered is unrealistic.	1	2	3	4	5
39. Nurses are afraid the physician will reprimand them for the medication error.	1	2	3	4	5
40. Nurses fear adverse consequences from reporting medication errors.	1	2	3	4	5
41. The response by nursing administration does not match the severity of the error.	1	2	3	4	5
42. Nurses could be blamed if something happens to the patient as a result of the medication error.	1	2	3	4	5
43. No positive feedback is given for passing medications correctly.	1	2	3	4	5
44. Too much emphasis is placed on med errors as a measure of the quality of nursing care provided.	1	2	3	4	5
45. When med errors occur, nursing administration focuses on the individual rather than looking at the systems as a potential cause of the error.	1	2	3	4	5

C. Percentage of Each Type of Error Reported on Your Unit. Based on your experience, please circle the number that best represents what percentage of each type of medication error you believe is actually reported on your unit.

	Percentage Reported								
Types of Non-IV Medication Errors	0 - 20	21- 30	31- 40	41 - 50	51 - 60	61 - 70	71 - 80	81 - 90	91 99
46. Wrong route of administration	1	2	3	4	5	6	7	8	9
47. Wrong time of administration	1	2	3	4	5	6	7	8	9
48. Wrong patient	1	2	3	4	5	6	7	8	9
49. Wrong dose	1	2	3	4	5	6	7	8	9
50. Wrong drug	1	2	3	4	5	6	7	8	9
51. Medication is omitted	1	2	3	4	5	6	7	8	9
52. Medication is given, but has not been ordered by the physician	1	2	3	4	5	6	7	8	9
53. Medication administered after the order to discontinue has been written	1	2	3	4	5	6	7	8	9
54. Given to patient with a known allergy	1	2	3	4	5	6	7	8	9
Types of IV Errors									
55. Wrong method of administration	1	2	3	4	5	6	7	8	9
56. Wrong time of administration	1	2	3	4	5	6	7	8	9
57. Wrong patient	1	2	3	4	5	6	7	8	9
58. Wrong dose	1	2	3	4	5	6	7	8	9
59. Wrong drug	1	2	3	4	5	6	7	8	9
60. Medication is omitted	1	2	3	4	5	6	7	8	9
61. Medication is given, but has not been ordered by the physician	1	2	3	4	5	6	7	8	9
62. Medication administered after the order to discontinue has been written	1	2	3	4	5	6	7	8	9
63. Given to patient with a known allergy	1	2	3	4	5	6	7	8	9
64. Wrong fluid	1	2	3	4	5	6	7	8	9
65. Wrong rate of administration	1	2	3	4	5	6	7	8	9

Appendix 7 – Cover letter to Nurses' survey

INVITATION

You are invited to participate in a cross-sectional hospital nurses' survey.

The study is part of my master's thesis in the Digital Health program at TalTech University. In my work, I study the registration and analysis of medication errors in Estonia.

The administration of medicines in a hospital is a routine but complex and very important nursing activity. It has been estimated based on United Kingdom data that in Estonia could be as many as 800 000 potentially harmful MEs per year. As very little research has been done on this topic in Estonia, we do not know today whether this number is true.

The first step in dealing with medication errors is to report them. My research examines the reporting of medication errors in Estonian hospitals and the attitudes of nurses towards the reporting of medication errors.

Your hospital has agreed to take part in the study. Please fill in the attached questionnaire for your unit.

Your participation is voluntary, but your contribution is important and will help to improve patient safety in the future. The questionnaire takes 5-10 minutes to complete, and your answers are completely anonymous. Data are presented in consolidated form only.

Please place your completed questionnaires in an envelope and return the sealed envelopes anonymously to the head nurse within 7 DAYS. Thank you for completing the questionnaire, please have a candy 😊.

If you have any questions or comments, please email to piret.sell@me.com or call 5073901.

Thank you in advance,

Piret Sell

Appendix 8. Nurses' questionnaire sections and subsections internal validity.

Nurses 'survey sections	**Cronbach α values**
Part A. Why medication errors occur	**0,882**
Medication packaging related Q1. The names of many medications are similar. Q2. Different medications look alike. Q3. The packaging of many medications is similar. Q15. Many patients are on the same or similar medications	0,797
Physician communication related Q4. Physicians' medication orders are not legible. Q5. Physicians' medication orders are not clear. Q6. Physicians change orders frequently. Q7. Abbreviations are used instead of writing the orders out completely. Q8. Verbal orders are used instead of written orders. Q14. Poor communication between nurses and physicians. *Q26. Errors are made in the medication chart.	0,840
Pharmacy processes related Q9. Pharmacy delivers incorrect doses to this unit. Q10. Pharmacy does not prepare the med correctly. Q11. Pharmacy does not label the med correctly.	0,796
Nurses' knowledge, communication, and skills related Q16. Unit staff does not receive enough information on new medications. Q17. On this unit, there is no easy way to look up information on medications. Q18. Nurses on this unit have limited knowledge about medications. Q20. When scheduled medications are delayed, nurses do not communicate the time when the next dose is due. Q21. Nurses on this unit do not adhere to the approved medication administration procedure. Q25. Medication charts are not transcribed correctly. Q27. Equipment malfunctions or is not set correctly (e.g., IV pump). Q28. Nurse is unaware of a known allergy.	0,763
Nurse staffing related Q19. Nurses get pulled between teams and from other units.	0,578

Q22. Nurses are interrupted while administering medications to perform other duties. Q23. Unit staffing levels are inadequate. Q24. All medications for one team of patients cannot be passed within an accepted time frame. Q29. Patients are off the ward for other care.	
Outliers (merged with pharmacy process) Q12. Pharmacy is not available 24 hours a day. Q13. Frequent substitution of drugs (i.e., cheaper generic for brand names).	0,639
Part B Reasons why medication errors are not reported	**0,889**
Organisation culture *Q38**.** The expectation that medications be given exactly as ordered is unrealistic. Q41. The response by the nursing administration does not match the severity of the error. Q43. No positive feedback is given for passing medications correctly. Q44. Too much emphasis is placed on med errors as a measure of the quality of nursing care provided. Q45. When med errors occur, nursing administration focuses on the individual rather than looking at the systems as a potential cause of the error.	0,713
Disagreement over the definition and reporting effort Q30. Nurses do not agree with the hospital's definition of a medication error Q31. Nurses do not recognize an error occurred. Q32. Filling out an incident report for a medication error takes too much time. Q33. Contacting the physician about a medication error takes too much time. Q34. Medication error is not clearly defined. Q35. Nurses may not think the error is important enough to be reported.	0,780
Fear related *Q36. Nurses believe that other nurses will think they are incompetent if they make medication errors. Q37. The patient or family might develop a negative attitude toward the nurse or may sue the nurse if a medication error is reported. Q39. Nurses are afraid the physician will reprimand them for the medication error. Q40. Nurses fear adverse consequences from reporting medication errors. *Q42. Nurses could be blamed if something happens to the patient as a result of a medication error.	0,860
Part C **Percentage of Each Type of Error Reported on Your Unit**	**0,972**
Non-IV Medication Errors Q46. Wrong route of administration	**0,943**

Q47. Wrong time of administration Q48. Wrong patient Q49. Wrong dose Q50. Wrong drug Q51. Medication is omitted Q52. Medication is given but has not been ordered by the physician Q53. Medication administered after the order to discontinue has been written Q54. Given to patient a with a known allergy	
IV Medication Errors Q55. Wrong method of administration Q56. Wrong time of administration Q57. Wrong patient Q58. Wrong dose Q59. Wrong drug Q60. Medication is omitted Q61. Medication is given but has not been ordered by the physician Q62. Medication administered after the order to discontinue has been written Q63. Given to a patient with a known allergy Q64. Wrong fluid Q65. Wrong rate of administration	**0,973**
Nurses' survey sub-scales	
Part A. Why medication errors occur	**0,882**
Medication packaging related (4 questions)	0,797
Physician communication related (7 questions)	0,840
Pharmacy processes related (3 questions)	0,796
Nurses' knowledge, communication, and skills related (9 questions)	0,763
Nursing processes related (5 questions)	0,578
Outliers (2 questions)	0,639
Part B Reasons why medication errors are not reported	**0,889**
Organisation culture (5 questions)	0,713
Disagreement over the definition and reporting effort (6 questions)	0,780
Fear related (5 questions)	0,860
Part C **Percentage of Each Type of Error Reported on Your Unit**	**0,972**
Non-IV Medication Errors (9 questions)	0,943
IV Medication Errors (11 questions)	0,973
Total questionnaire	**0,940**

Appendix 9 – Demographic data of the nurses

	Demographic data	n	%
Education	Unfinished nursing education	24	9,8
	Middle-level nursing education	75	30,7
	Baccalaureate level nursing education	135	55,3
	Master-level nursing education	3	1,2
	Valid total	237	97,5
	Missing	7	2,9
Position	Assistant nurse	38	15,6
	Nurse	187	76,6
	Head nurse	13	5,3
	Valid total	238	97,1
	Missing	6	2,5
Worked as a nurse	< 1 year	21	8,6
	1-5 years	65	26,6
	6-10 years	22	9,0
	>10 years	129	52,9
	Valid total	237	97,1
	Missing	7	2,9
Worked in the current ward	< 1 year	26	10,7
	1-5 years	87	35,7
	6-10 years	35	14,3
	>10 years	90	36,9
	Valid total	238	97,5
	Missing	6	2,5
Working time	Full time	189	77,5
	Part-time	48	19,7
	Valid total	237	97,1
	Missing	7	2,9
How often use non-IV medicines	Never	3	1,2
	Rarely	21	8,6
	Sometimes	15	6,1
	Often	198	81,1
	Valid total	237	97,1
	Missing	7	2,9
How often use IV medicines	Never	0	0,0
	Rarely	6	2,5
	Sometimes	4	1,6
	Often	230	94,3
	Valid total	240	98,4
	Missing	4	1,6

Appendix 10 – Nurses' perceived reasons for MAEs.

	n		Agreement rate %	Mean	Mode	Std. Deviation
	Valid	Missing				
Q23. Unit staffing levels are inadequate.	244	0	75,4	4,53	6	1,593
Q6. Physicians change orders frequently.	241	3	68,4	4,00	4	1,430
Q15. Many patients are on the same or similar medications	244	0	63,5	3,95	5	1,646
Q4. Physicians' medication orders are not legible.	238	6	62,6	3,70	4	1,551
Q22. Nurses are interrupted while administering medications to perform other duties.	244	0	61,9	3,79	4	1,622
Q12. Pharmacy is not available 24 hours a day.	233	11	61,0	4,07	6	1,984
Q2. Different medications look alike.	243	1	60,7	3,67	4	1,654
Q13. Frequent substitution of drugs (i.e., cheaper generic for brand names).	240	4	59,9	3,73	4	1,491
Q24. All medications for one team of patients cannot be passed within an accepted time frame.	243	1	58,6	3,70	4	1,640
Q1. The names of many medications are similar.	243	1	54,1	3,40	4	1,556
Q16. Unit staff does not receive enough information on new medications.	241	3	53,7	3,49	4	1,531
Q3. The packaging of many medications is similar	244	0	52,5	3,33	4	1,590
Q5. Physicians' medication orders are not clear.	243	1	49,9	3,20	4	1,506
Q25. Medication charts are not transcribed correctly.	242	2	49,2	3,23	4	1,484
Q8. Verbal orders are used instead of written orders.	242	2	44,0	3,09	2[a]	1,585
Q29. Patients are off the ward for other care.	234	10	41,3	3,15	2	1,607
Q7. Abbreviations are used instead of writing the orders out completely.	243	1	39,5	2,68	2	1,461
Q26. Errors are made in the medication chart.	241	3	39,4	2,95	4	1,388

Q14. Poor communication between nurses and physicians	243	1	37,7	2,91	2	1,336
Q28. Nurse is unaware of a known allergy.	242	2	31,2	2,74	2	1,376
Q19. Nurses get pulled between teams and from other units.	244	0	30,3	2,59	1	1,677
Q27. Equipment malfunctions or is not set correctly (e.g., IV pump).	241	3	24,6	2,35	1	1,373
Q18. Nurses on this unit have limited knowledge about medications.	244	0	22,9	2,39	1	1,376
Q17. On this unit, there is no easy way to look up information on medications.	240	4	17,6	2,17	1	1,372
Q20. When scheduled medications are delayed, nurses do not communicate the time when the next dose is due.	242	2	13,9	2,06	1	1,251
Q21. Nurses on this unit do not adhere to the approved medication administration procedure.	243	1	7,8	1,59	1	0,960
Q9. Pharmacy delivers incorrect doses to this unit.	238	6	1,6	1,40	1	0,739
Q10. Pharmacy does not prepare the med correctly.	235	9	1,2	1,23	1	0,592
Q11. Pharmacy does not label the med correctly.	236	8	0,0	1,16	1	0,470

Appendix 11 – Nurses' perceived reasons why MAEs are not reported.

	n		Agreement rate %	Mean	Mode	Std. Deviation
	Valid	Missing				
Q42. Nurses could be blamed if something happens to the patient as a result of a medication error.	241	3	75	4,40	6	1,605
Q43. No positive feedback is given for passing medications correctly.	241	3	72	4,42	6	1,750
Q45. When med errors occur, nursing administration focuses on the individual rather than looking at the systems as a potential cause of the error.	237	7	67	4,09	5	1,602
Q37. The patient or family might develop a negative attitude toward the nurse or may sue the nurse if a medication error is reported.	244	0	60	3,71	4	1,743
Q40. Nurses fear adverse consequences from reporting medication errors.	243	1	60	3,70	4	1,676
Q44. Too much emphasis is placed on med errors as a measure of the quality of nursing care provided.	237	7	55	3,78	6	1,691
Q39. Nurses are afraid the physician will reprimand them for the medication error.	244	0	45	3,18	4	1,619
Q35. Nurses may not think the error is important enough to be reported	242	2	44	3,07	1	1,647
Q32. Filling out an incident report for a medication error takes too much time.	228	16	39	3,04	4	1,581
Q36. Nurses believe that other nurses will think they are incompetent if they make medication errors.	244	0	37	2,85	1	1,713
Q34. Medication error is not clearly defined.	229	15	35	2,92	1	1,679
Q41. The response by the nursing administration does not match the severity of the error.	230	14	27	2,74	2	1,487
Q38. The expectation that medications be given exactly as ordered is unrealistic.	241	3	26	2,47	1	1,565
Q33. Contacting the physician about a medication error takes too much time.	241	3	25	2,52	1	1,461
Q31. Nurses do not recognize an error occurred.	240	4	25	2,48	1	1,375
Q30. Nurses do not agree with the hospital's definition of a medication error	222	22	15	2,17	1	1,323

Appendix 12 – Nurses' perceived rates of reporting different types of errors.

	N		Mean	Std. Deviation
	Valid	Missing		
Types of Non-IV Medication Errors				
Q46. Wrong route of administration	219	25	1,90	1,985
Q47. Wrong time of administration	222	22	2,11	2,070
Q48. Wrong patient	218	26	2,21	2,612
Q49. Wrong dose	218	26	2,24	2,292
Q50. Wrong drug	218	26	2,32	2,600
Q51. Medication is omitted	217	27	2,41	2,330
Q52. Medication is given but has not been ordered by the physician	215	29	2,23	2,358
Q53. Medication administered after the order to discontinue has been written	217	27	2,31	2,188
Q54. Given to a patient with a known allergy	212	32	2,10	2,698
Types of IV Medication Errors				
Q55. Wrong method of administration	212	32	2,05	2,258
Q56. Wrong time of administration	214	30	2,14	2,155
Q57. Wrong patient	213	31	2,18	2,628
Q58. Wrong dose	213	31	2,27	2,537
Q59. Wrong drug	210	34	2,18	2,611
Q60. Medication is omitted	212	32	2,33	2,315
Q61. Medication is given but has not been ordered by the physician	213	31	2,23	2,487
Q62. Medication administered after the order to discontinue has been written	216	28	2,33	2,349
Q63. Given to a patient with a known allergy	205	39	2,13	2,688

Q64. Wrong fluid	212	32	2,15	2,523
Q65. Wrong rate of administration	219	25	2,35	2,354