



Effect of automated dose dispensing on medication safety incidents in long-term professional home care

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Abstract	
<p>Automated dose dispensing has been one of the pharmacies' most used services in recent years. According to the Ministry of Social Affairs and Health, the goal of automated dose dispensing is to promote appropriate medical treatment and ensure patient safety so that the patient receives the right medication at the right time.</p> <p>One way of measuring patient safety is medication error reporting systems, which in Finland is called HaiPro. HaiPro is a web-based reporting tool, where health care units' patient safety incidents are reported. The study examines what kind of medication errors have occurred in one of Finland's long-term professional home care and whether automated dose dispensing affects the medication safety compared to medication dispensed manually.</p> <p>The study is a registry-based study where I use municipality's long-term professional home care's HaiPro reports related to medication from January 2010 to September 2022. The number of reports is 1262.</p> <p>Most of the errors (90%) in long-term professional home care were administration errors, dispensing errors were 4% and only 0.5% errors were due to automated dose dispensing. Based on the results I received, automated dose dispensing could be seen as one of promotive factor in medical safety in long-term professional home care. Still, as in home care there are many factors affecting the outcome of medical care, automated dose dispensing itself only does not correct all the medical errors.</p>	
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Abstrakt	
<p>Automatiserad dosdispensering har varit en av apotekens mest använda tjänster under de senaste åren. Enligt Social- och Hälsovårdsdepartementet är målet med automatiserad dosdispensering att främja lämpliga medicinska behandlingar och säkerställa medicinerings säkerheten så att patienterna skulle få ett rätt läkemedel vid rätt tidpunkt.</p> <p>Ett sätt att mäta medicinerings säkerheten är rapporteringssystemet HaiPro. HaiPro är ett webbaserat rapporteringsverktyg, där vårdenheternas patientsäkerhetsincidenter rapporteras. Denna studie undersöker vilken typ av avvikelser som inträffat inom hemsjukvården i en finländsk kommun, och om automatiserad dosdispensering har påverkat medicinerings säkerheten jämfört med läkemedel som har getts ut manuellt.</p> <p>Studien är en registerbaserad studie där jag använder kommunens hemvårds HaiPro-rapporter relaterade till läkemedel från januari 2010 till september 2022. Antalet rapporter är 1262.</p> <p>De flesta avvikelser (90%) inom den undersökta hemvården var administrationsavvikelser, medan antalet dispenserings avvikelser var 4 % och 0.5 % av avvikelser berodde på automatiserad dosdispensering. Baserat på resultaten jag fick, kunde automatiserad dosdispensering möjligen ses som en främjande faktor för medicinerings säkerheten inom hemvården. Inom hemsjukvården finns det dock många faktorer som påverkar medicinerings säkerhetsresultatet, och därför korrigerar den automatiska dosdispenseringen inte alla medicin avvikelser.</p>	
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<p>Tiivistelmä</p> <p>Koneellinen annosjakelu on ollut apteekkien eniten käytetty palvelu viime vuosina. Sosiaali- ja Terveysministeriön mukaan koneellisen annosjakelun tavoitteena on edistää rationaalista lääkehoitoa sekä lisätä potilasturvallisuutta, jotta asiakkaat saisivat oikeat lääkkeet aina oikeaan aikaan.</p> <p>Yksi tapa mitata potilasturvallisuutta on tutkia lääkityspoikkeamia, joita Suomessa kirjataan HaiPro järjestelmään. HaiPro on raportointityökalu, jonne raportoidaan terveydenhuollon yksiköiden potilasturvallisuustapauksista. Tutkimuksessani selvitetään, millaisia lääkityspoikkeamia on raportoitu tutkimani kunnan kotihoidossa vuosina 2010-2022 ja onko koneellinen annosjakelu vaikuttanut lääkityspoikkeamien määrään verrattuna manuaalisesti jaettaviin lääkkeisiin.</p> <p>Tutkimukseni on rekisteritutkimus, jossa käytän tutkimani kunnan kotihoidon lääkitykseen liittyviä HaiPro-raportteja väliltä tammikuu 2010 ja syyskuu 2022. Lääkitykseen liittyviä HaiPro-raportteja tuona aikana oli yhteensä 1262.</p> <p>Suurin osa, noin 90% kotihoidossa tapahtuneista virheistä oli antovirheitä. Jakeluvirheitä oli 4% virheistä ja annosjakelusta johtuvia jakovirheitä vain 0.5%. Saamieni tulosten perusteella koneellisen annosjakelun voidaan katsoa mahdollisesti edistävän lääketurvallisuutta kotihoidossa. Kuitenkin, koska lääkitysturvallisuuteen vaikuttaa monia muitakin tekijöitä, pelkkä koneellisen annostelun käyttöönotto ei ratkaise kaikkia lääkehuoltoon liittyviä lääkityspoikkeamia.</p>	
Avainsanat koneellinen annosjakelu, lääkitysturvallisuus, HaiPro, lääkityspoikkeamat, haittatapahtuma	
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LIST OF ABBREVIATIONS

ADE	adverse drug event
ADD	Automated dose dispensing
CMR	collaborative medical review
DDI	drug-drug interactions
Fimea	Finnish Medicines Agency
HaiPro	Reporting System for Safety Incidents in Health Care Organizations (Finland)
MERs	medication error reporting system
WHO	World' health organisation

1. INTRODUCTION

The number of patients who are cared for in their homes is increasing. They are more often old, frail and use multiple medications. According to a study conducted in Sweden concerning long-term professional homecare's adverse events, adverse events affected over a third of patients in homecare. Adverse events were mostly preventable and resulted in temporary harm that led to a need of extra healthcare resources. (Schildmeijer et al., 2018)

Automated dose dispensing is often promoted to increase medical safety and, according to Fimea's report, nurses and health care units' assumption was that automated dose dispensing increased medical safety (Fimea, 2022). In this research, my aim is to evaluate whether this assumption is correct. By evaluating one municipality's long-term professional home care's HaiPro reports, I will determine what kinds of safety incidents there have been and how automated dose dispensing (ADD) has affected the number of incidents.

According to Fimea's report and different studies conducted in Finland and Sweden, there is variation between findings of how ADD has affected medical safety. (Bardage et al., 2014; Fimea, 2022; Sinnemäki, 2020; Tahvanainen et al., 2021) There are also differences depending on whose opinions are evaluated. Most of the earlier studies have been conducted with questionnaires analysing nurses' knowledge and opinions of the subject, but not so much relying on confirmed data. In addition, most of the studies conducted with HaiPro are done in hospitals.

Registry-based data of medication errors that I use is a collection of medical safety incidents in long-term professional homecare. It provides a broad insight into the medical safety incidents concerning older people living at home.

2. LITERATURE REVIEW

2.1. Patient safety

Patient safety is part of the quality and safety of health care. Patient safety can be divided into safety of equipment, safety of care and safety of medication (Figure 1). Safety of medication can further be divided into drug safety and medication safety. Drug safety, also known as pharmacovigilance, refers to the drugs' pharmacological properties, i.e., safety that comes with the drug molecule itself. Adverse drug events consist of adverse drug effects and reactions that occur when using the drug. Medication safety refers to safety that comes with medication and applies to various parts of healthcare organisations. Medication safety includes measures to prevent, avoid and correct adverse events associated with the use of medicines. (Stakes ja lääkehoidon kehittämiskeskus Rohto, 2006; Wittich et al., 2014)

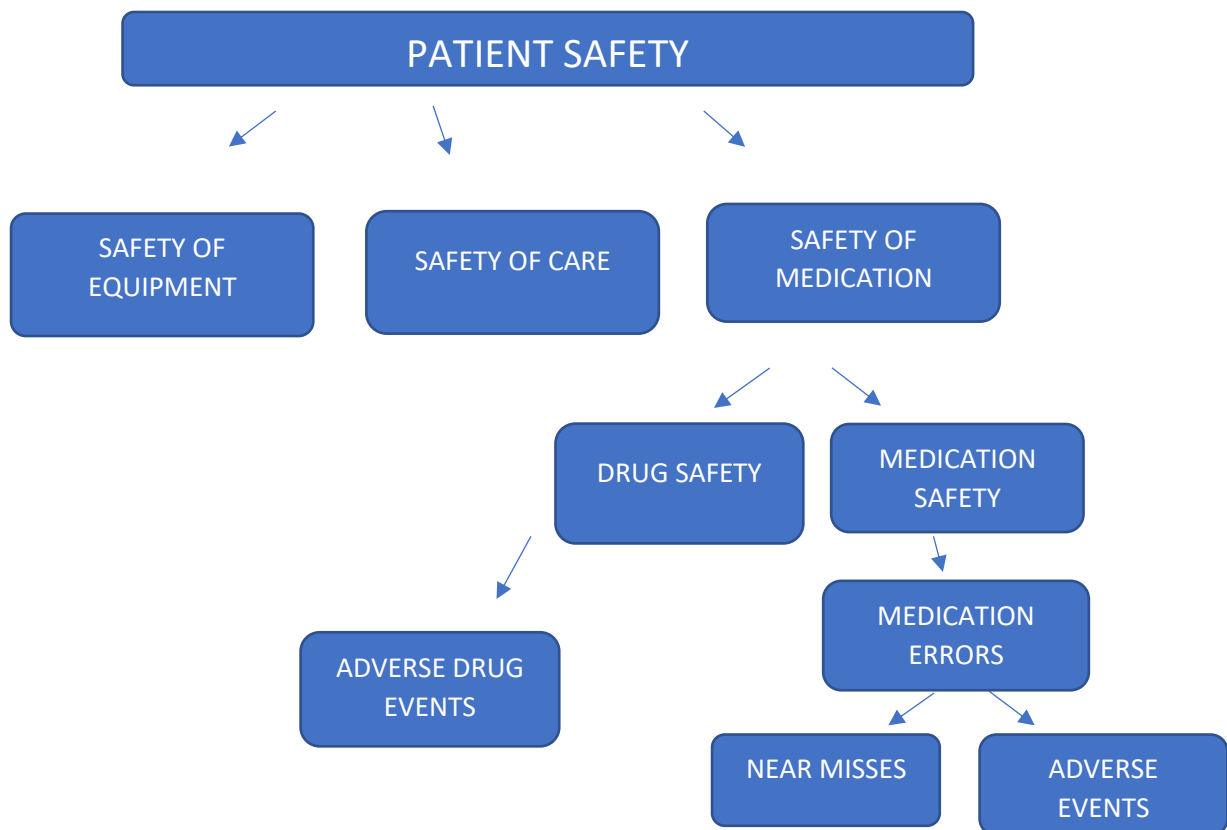


Figure 1. Concepts related to patient safety (Stakes ja lääkehoidon kehittämiskeskus Rohto, 2006).

According to WHO's patient safety program from 2005, enhancing the safety of patients includes three actions: preventing adverse events, making adverse events visible and reducing their effects when they occur. The executive board of the WHO had recommended already in 2002 its member states to pay more attention to safety of patient care and to create reporting tools for the help of creating safer health care. After that, several reporting tools have been developed over the world. (World Health Organization, 2005a) Finland's most commonly used reporting tool is Awanic's HaiPro (Kuusisto et al., 2019). All the reporting systems are made for professionals to learn from the errors that have occurred. It is also very important to understand that reporting errors does not make any difference; it is the response to the errors that matters. (World Health Organization, 2005a)

Finland has a patient safety strategy, which has been created to promote patient safety. One of the aims of the 2009 strategy was to gather all medication errors and improve patient safety by learning from these errors and developing the working methods of health care. (Ministry of Social Affairs and Health, 2009) In the recent Client and Patient Safety Strategy for 2022-2026 of the Ministry of Social Affairs and Health, Finland's vision is to be the world's model country for client and patient safety in 2026 (Ministry of Social Affairs and Health, 2022a).

The pharmacotherapy plan is one of the medication safety tools that strives towards safer patient care. The pharmacotherapy plan is mandatory in all health care units. It is important that the pharmacotherapy plan is made to guide the medical process. (Ministry of Social Affairs and Health, 2021)

2.1.1. Patient safety incidents and medication errors

Based on articles by Ehsani et al.; Encinosa and Hellinger; and Vincent et al., Järvelin et al. calculated that patient safety incidents cost Finnish healthcare over 400 million per year (Ehsani et al., 2006; Encinosa and Hellinger, 2008; Järvelin et al., 2010; Vincent et al., 2001). The amount of costs can be doubled, if all indirect costs are calculated. However, all consequences caused by patient safety incidents cannot be measured in money. Adverse events can also cause much unnecessary suffering and even patient deaths. (Järvelin et al., 2010)

Although in each stage of a patient care safety is the priority, medication errors still occur. Those errors can be related to e.g. prescribing, ordering, dispensing, or administering medication. (Stakes ja lääkehoidon kehittämiskeskus Rohto, 2006)

Medication errors can be either near misses or adverse events. Near miss refers to incidents, which could have led to an adverse event and could have caused harm to the patient. Harm has been avoided, because a situation has been detected in time. (Stakes ja lääkehoidon kehittämiskeskus Rohto, 2006) According to the World Health Organisation, an adverse event is defined as an incident, which resulted in harm to a patient. Medical management, in contrast to process or complication of a disease, causes it. The adverse event can be physical or psychological harm, illness or death, caused by health care or social care. The adverse event is not an inevitable consequence of the patient's condition or an expected effect of the treatment received by the patient because of her/his condition. (World Health Organization, 2021)

At the beginning of year 2000, the U.S. Institute of Medicine published a report titled "To err is human: Building a safer health system". The report estimated that 44,000 to 98,000 people in United States hospitals died due to medical errors each year. (Kohn et al., 2000) The report was at the time one of the studies that aroused the health care field to awareness of patient safety issues (Borgert, 2017). According to Pasternack's article from 2006 those results also reflect Finnish figures, which means that in Finland the number of deaths in a year would be from 700 to 1700 (Pasternack, 2006).

According to James Reason's well-known theory of errors, errors are inevitable if human activity is involved in the process. He categorises approaches to the problem as person approach and as system approach. Person approach concentrates on a person who made an error and blames the person for that error. According to Reason's findings, the person approach is still common also in the health care field. One reason is that blaming an individual is emotionally more satisfying than blaming the institution. It is easier for the leaders to blame the person, not the instructions. (Reason, 2000)

In the system approach, errors are seen as consequences. It is accepted that errors occur even in the best organisations. The system approach focuses on finding the reasons for errors in the organisation's systems and figuring out why their defences have failed. Reason claims that

if the system approach is the leading way to handle the errors, we could learn from the errors and make safer working methods. (Reason, 2000)

Reason's Swiss cheese model is a well-known example of how errors occur (Figure 2). Each slice of cheese can be seen as one person doing their work or as a defence against potential error impacting the outcome. One person or one mistake does not cause the hazards. The reason for the error is a combination of multiple incidents that occurred. Reason claims that the holes arise from active failure and latent conditions. Active failures are unsafe actions that physicians, nurses or pharmacists do. Those can be e.g., forgetting to do something, mistakes, or procedural violations. Active failures usually have a straight and short-lived impact. Latent conditions arise from decisions that have been made by management and are related to the organisation's way of working. These can be, for example, lack of instructions or lack of proper management in the organisation. (Reason, 2000)

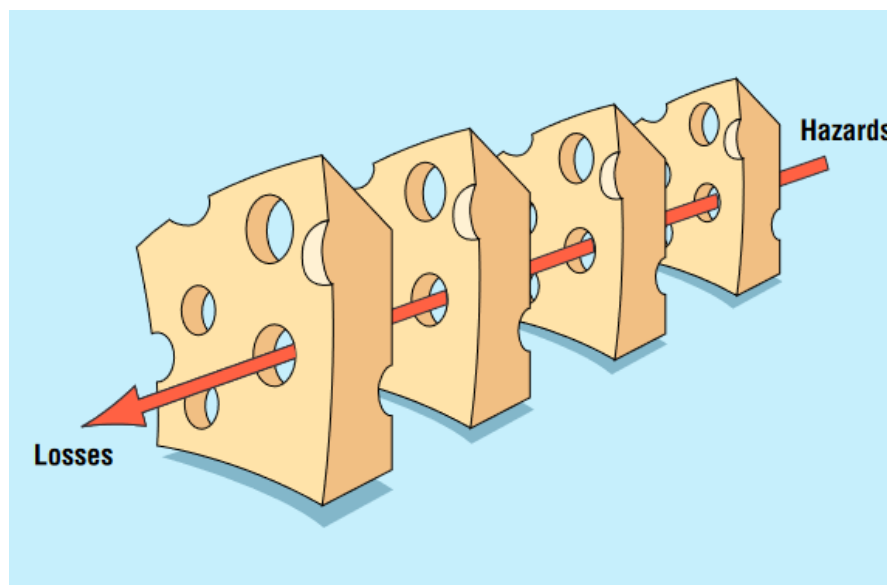


Figure 2. Swiss cheese model which represents how errors occurred (Reason, 2000).

2.2. Medication error reporting systems

Medication error reporting systems (MERS) in healthcare are common in many countries (World Health Organization, 2005a). Finland's most used healthcare reporting system is

HaiPro invented by Awanic. The HaiPro reporting system was developed already in 2005 and in the beginning was only meant for adverse events, but quite early also near misses were added to HaiPro. (Kuusisto et al., 2019; Ministry of Social Affairs and Health, 2008) MERs provide a large amount of information on how an organisation has acted, when incidents have occurred and what has been improved after the incidents. (Ruuhielto et al., 2011).

According to Council of Europe's expert group of safe medication practices, MERs should be unpunished, confidential, independent, system-oriented, and responsive. It should also encourage people to report, to rely on expert analysis of incidents and provide health professionals with conditions to report errors. (Council of Europe, 2007) Unfortunately, many studies have shown that only a small number of incidents are reported through voluntary incident reporting systems (Holmström, 2017). Reasons for this in health care was studied in systematic review conducted by Afaya et al. in 2021. They found out different barriers that hindrance nurses to report the medical errors. Those could be categorised as organisation barriers and professional barriers. Organisation barriers were lack of reporting system, lack of consumed time or long forms of reporting. In addition, unclear definition of medical errors, negative response towards nurses who had made the report and no feedback after reporting were mentioned. Professional barriers mentioned were inadequate knowledge on what constitutes errors, fear of reporting due consequences and fear of legal actions. (Afaya et al., 2021)

Different studies have been made regarding different MER systems around the world. The need of increased quality of the reported data was seen in many studies. Also, there were too much focus on individuals' actions and little focus on other contributing factors. Wide variations in severity and lacking information were also seen in the report when evaluating harm to patient and medication error severity. (Holmström, 2017) More focus would also be needed to increase reporting activity in different professional groups. If reporting is based mostly on a single professional group, the data can be inaccurate (Ricci et al., 2004). According to a Finnish registry-based study, when patient safety incidents occurred in home care, mostly practical nurses or registered nurses reported medication errors to HaiPro (Kivimäki et al., 2022).

2.2.1. HaiPro, medication error reporting system

HaiPro reporting system is meant for near misses and adverse events that occurred in the health care units. The purpose is that all professionals report the incidents that they come across to. It is important that the HaiPro report is filled in carefully and all the factors regarding the incident are reported. (Knuuttila et al., 2007; World Health Organization, 2005b)

The reports in HaiPro are divided into fourteen different categories. The highest number of the events reported in HaiPro's early stage were "Medication or infusions, transfusion, contrast agents and marker related". The second highest number of the events were "accidents" and the third highest "information flow and management". (Ruuhilehto et al., 2011)

HaiPro reports are always sent to supervisors and foremen for them to evaluate. They add the events risk class and harm to patient classification in the HaiPro report. The risk classes are divided into four different stages, where the minor level is meaningless risk and the most severe level is a severe risk. (Awanic, 2015; Suomen Potilasturvallisuusyhdistys ry, 2015) In Table 1 is seen how the risk class is being evaluated. Harm to patient must be evaluated every time when an adverse event has occurred. It should be evaluated to response the harm that has actually happened to the patient. (Awanic, 2015) According to Holmström's study, risk class and harm to patient evaluation can vary considerably depending on who has done the evaluation (Holmström et al., 2018).

TABLE I. Risk class evaluating table (Awanic, 2015)

CONSEQUENCES PROBABILITY	MINOR at most discomfort, delay, or prolongation of treatment without a significant health effect	HARMFULL Health effects requiring measures, prolongation of treatment and additional suffering, temporary disability.	SEVERE Death or permanent serious effects, injuries significantly reducing the quality of life, permanent disability
UNLIKELY Accidental hazard, short-term exposure, occurs rarely	I	II	III
POSSIBLE danger and load ratings occurred daily. There were near misses	II	III	IV
PROBABLE there have been frequent and regular incidents. Adverse events have occurred	III	IV	V

I = meaningless risk II= minor risk III = moderate risk IV= major risk V= severe risk

According to Holmström’s analysis of HaiPro’s early days between 2007 and 2009 (n=32 592) (2017), dispensing-, administration-, and documentation errors were the most reported medication errors. The share of administration errors was 24%, and the share of dispensing errors 33%. All the error types summed up, near misses and adverse events were almost equal. The biggest difference in the share of adverse events and near misses was seen in administration errors, of which 87.5% were adverse events and only 12.5% near misses. However, 81% of dispensing errors were near misses and only 19% adverse events. (Holmström, 2017)

In a study conducted 2019 concerning Finland’s reported HaiPro patient safety incidents between 2007 and 2017 (n=312 195), results were slightly different. In this study, adverse events represented 60% and near misses 40% of HaiPro reports. The share of administration errors was 38% of errors and 33% was dispensing errors. Documentation errors were reported as the third highest amount, 13%. (Kuusisto et al., 2019)

In a study conducted by Kivimäki et al. in 2022, where they studied medication errors in Finland's long-term professional homecare between 2009 and 2019 (n= 61,248, where 39,652 were medical errors), the findings were also different. Most of errors related to medication, nearly 45% were related to dispensing, and 25% were administration errors. Documentation errors represented only 2% of HaiPro reports in the long-term professional home care. (Kivimäki et al., 2022)

The data of different studies compared to another is seen in Figure 3. The results vary between studies depending on what data they have used. In Kivimäki's et al. findings, more dispensing errors than in other studies can be seen. However, the number of documentation errors is much smaller compared to other studies.

The home care surrounding varies considerably from hospital or nursing home surroundings. Home settings can be disorganised environments, customers can refuse to take to medication or be under influence of alcohol. There can be more distracting factors from spouses or relatives, and the fact that one is working in someone else's home can itself be a distracting factor. (Härkänen et al., 2020) All of these can be seen as a promoting factor of medical errors.

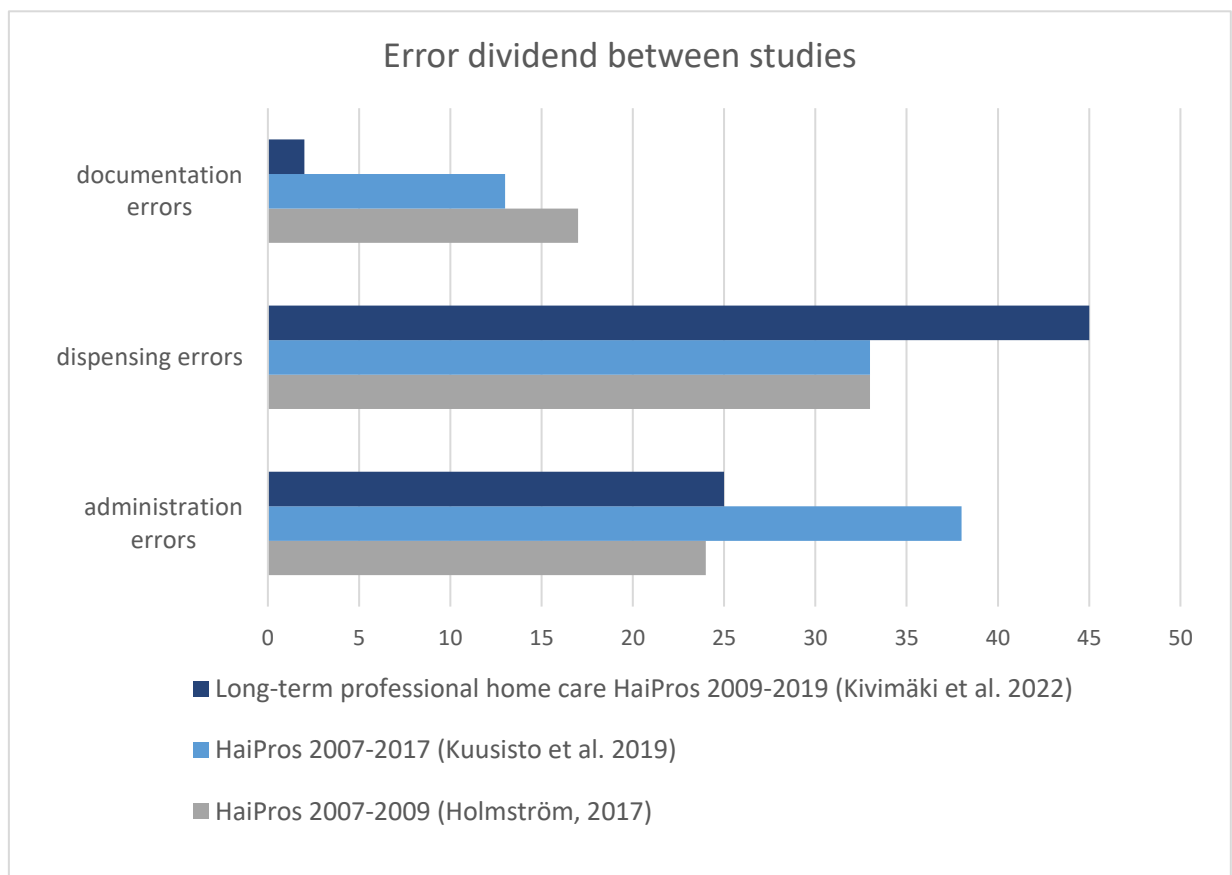


Figure 3. Error divided between HaiPro studies.

2.3. Automated dose dispensing

Automated dose dispensing has been used mostly in Finland, Sweden, Norway, Denmark, and the Netherlands already since the beginning of the 21st century. It is the most common in the Netherlands, with 500,000 users in 2017 and in Sweden, where 230,000 customers are using ADD services (Oriola, 2022; Sinnemäki et al., 2013; Stichting Farmaceutische Kengetallen, 2018). Although the basic concept of the ADD service is similar, there are still some differences between countries. In Norway, one-third of home care patients use ADD. Still, physicians cannot prescribe medicines for ADD electronically; instead, prescriptions are written on paper. The whole medication list is printed and faxed to a pharmacy. According to Josendal's study group's survey, this increased medical errors. Of all errors, 50% that occurred in pharmacies were due to medication being printed on paper. (Josendal et al., 2021) The same kind of response was seen in a study done in Sweden in 2014. Physicians responded to a questionnaire that more patients could be recommended to use ADD, but the prescribing system is too difficult to manage and, therefore, could be seen as a safety risk for the patients (Bardage et al., 2014). In Finland, an electronic prescription has been the only way to prescribe medicines since 2017 (Ahonen et al., 2014). According to studies, electronic prescription promotes the medical safety in many ways. It reduces the possibility to falsify prescriptions, lowers the risk of dispensing errors, promotes better management of the patients' overall medication, and lowers the risk of incorrect interpretation of a prescription (Kauppinen et al., 2017).

The automated dose dispensing started in Finland at the beginning of 2002 (Purasmaa et al., 2002). Since then, ADD has been used in over 600 pharmacies, and over 104,000 patients are using it today. In 2015, the number was only 35 000 patients (Fimea, 2022; Ministry of Social Affairs and Health, 2016). ADD is the most common and used service pharmacies offer. In 2021, 573 of Finland's 632 pharmacies offered ADD to their customers (Fimea, 2022; Suomen Apteekkariliitto, 2022). Automated dose dispensing consists of regularly used medication for two weeks. Medicines are dispensed automatically according to a list of medicines and their dosing times. Therefore, the error percent is very low, only 0.004%. The patient data, dosing date, weekday, and dosing time can be found on every dose bag (Figure 4.) (PharmaService, 2022).



Figure 4. Automated dose dispensing bags (PharmaService, 2022).

ADD consists of an interprofessional collaboration of a health care unit, a pharmacy and a dose dispensing unit. Each of these can be seen as a slice of Reason's Swizz cheese models. Each participant uses its professional skills to prevent medical errors from occurring. According to the Ministry of Social Affairs and Health, the goal of automated dose dispensing is to promote an appropriate medical treatment, and to ensure the patient safety so, that the patient receives the right medication at the right time. The Ministry of Social Affairs and Health conducted a report in 2016, which gathered the good praxis of the automated dose dispensing. The report was made to harmonize the way ADD is done, and to clarify how different health care professionals are responsible for the ADD concept, particularly regarding home care and nursing homes. (Ministry of Social Affairs and Health, 2016)

According to The Ministry of Social Affairs and Health's report, a physician is always the one who starts ADD. Their responsibility is to ensure that the medicines in the patient's medical list are the ones that the patient actually uses, and that the medicines are still needed. By writing new prescriptions with a dose-dispensing label, the physician shows medication being checked. Registered nurses are mostly those that contact a pharmacy when changes are made to the patient's medication. A pharmacist checks the medication lists and if there are any deviations or interactions, they contact nurses or physicians. (Ministry of Social Affairs and

Health, 2016) Overview of different professionals' responsibilities is seen in Table 2. A list of dispensed medicines always comes with every two weeks medication, where it is seen what and when medicines are dispensed (PharmaService, 2022). Finland has four automated dose dispensing units, PharmaService Oy, Pharmac Oy, Pharmados Oy and Yliopiston Apteekki. Three of them are contract-manufacturing ADD to other pharmacies. (Fimea, 2022)

TABLE II. Health care professionals' responsibilities in the ADD process accordingly (Fimea, 2016; Sinnemäki, 2020)

Function	Nurse	Pharmacist	Physician
Monitor effect of the pharmacotherapy	x		x
Medication review (the following aspects needs to be checked):			
• drug doses			
• administration times			
• duplications		x	
• drug-drug interactions			
• harmful medication loads			
• untreated conditions			
• validity of indications			
• drugs avoided for older adults			
Organise the case conference	x		
Participate in the case conference	x	x	x
Final decision of patient's pharmacotherapy			x
Decide when patient enrolls to ADD	x		
Compile the complete medication list	x		
Document the medication review process	x		x

2.4. Legislation behind automated dose dispensing

Fimea published a report in 2022, where they researched the state of automated dose dispensing and its needs of development. According to the report, there are many types of laws and guidelines regarding ADD, but there is still a lack of proper legislation of the whole automated dose dispensing process. The laws and the guidelines concern ADD as a process, how it should be done in ADD units, and how the process should be handled between

pharmacies and ADD units. Mainly the legislation refers to what kinds of agreements and contracts need to be conducted. (Fimea, 2022; FINLEX) Due to this inadequacy, pharmacies have had different approaches, especially regarding the responsibilities of different health care participants and the pricing of ADD (Fimea, 2022; Ministry of Social Affairs and Health, 2016).

The Parliament's ombudsman stated in his decision in 2013 that dispensing of medicines is a task, which is the municipality's statutory obligation. This statement was made due to a complaint, in which a complainant felt that customers were in an unequal position depending on where they lived, because a service fee charged by pharmacies for ADD varied between municipalities. Customers paid the fee themselves. After the Parliament's ombudsman decision, customers in long-term professional home care did not pay the service fee of ADD themselves. The fee was tendered and paid by the municipalities. The fee of ADD service still varies between pharmacies. (Kuntaliitto, 2014)

The municipality my study focuses on started the ADD to all long-term professional homecare patients at the beginning of 2015 after a tender. Earlier, medicines were dispensed either manually in pharmacies or by nurses or patients themselves.

2.5. Medication reviews and an interprofessional collaboration

A medication review is a method that aims to identify and solve the problems of medication therapy (Bulajeva et al., 2014). Pharmacists have plenty of knowledge of medication and how it should be dispensed. Today, every pharmacist who graduates from a university has a competence to review patients' medication (Apteekkari, 2018).

There are three types of medication reviews done in Finland. The first one, a prescription review, consists of health care professionals' (i.e. physicians' or pharmacists') check of dosage and administration times and correspond to doses that are approved. The second one, a medication adherence review, is a deeper review of a patient's medication. There, a pharmacist who has special training for that checks the need and the rationality of the medication in a pharmacy. The third one, a collaborative medical review (CMR), is a procedure

performed in collaboration with a specially trained pharmacist and other health care professionals. The CMR includes a comprehensive clinical review of medication in use. Its purpose is to reduce drug-related problems and increase medication adherence. (Leikola, 2012; Sinnemäki et al., 2017)

An interprofessional collaboration is a term that is used in many different health care fields. It means a collaboration between different health care professionals. During this collaboration, the knowledge and skills of different professional groups combine to provide extensive and holistic knowledge in decision-making on patient care. (Fimea, 2016) The CMR can be seen as this kind of collaboration.

The medication review most done in pharmacies is the prescription review. According to Sinnemäki et al., if the medication review is properly conducted, it should also lead to qualitative changes in the patient's medication, if there would be potentially inappropriate medications. (Sinnemäki et al., 2017)

According to Toivo's et al. study conducted in Finland's University pharmacies, pharmacists' actions significantly reduce drug-drug interactions (DDI) that otherwise would cause adverse drug events (ADEs) (Toivo et al., 2016). Also, a pragmatic randomised controlled study conducted in the Netherlands concluded that the medication review increased the number of drug changes and also decreased potential drug-related problems by 29% (Kwint et al., 2011).

In a systematic review study conducted by Sinnemäki et al. in 2013, on starting ADD service in pharmacies, aimed at finding out how medication lists were checked and what kinds of changes had been made, when customers start ADD service. They found that only 14% of medication lists were complete as such. Personnel from home care or nursing homes were often needed to assist with the clarification of the medication. The medication review was conducted to 96% of customers starting ADD, and it took on average 38 minutes per customer to have the medication properly checked. Changes were made to 93% of the customers and 22% of changes were related to the medical treatment, which influenced 46% of customers. Other changes were technical due the ADD process. Medication lists, in some cases, were not fully prepared, and the medication was not always appropriate. The review of medication varied considerably between pharmacies. (Sinnemäki et al., 2014) This may be partly due to a lack of precise and uniform guidance from the authority regarding how broad the medication

review should be. For the medication review to be as good as it could be, pharmacists would need better access to the patient information (Bulajeva et al., 2014).

In another study concerning medical reviews, the results were quite similar. During the evaluation of the medical treatment, several potential problems were observed. Problems were mostly DDIs and use of medicines harmful to the elderly. (Lahti, 2017).

The Ministry of Social Affairs and Health published a report in 2017 of an interprofessional medication assessment's effect on home care patients' medication, functional capacity, quality of life and use of health and home care services. A need for this kind of interprofessional medication assessment has arisen from the fact that municipalities do not fulfil their obligation to organise an evaluation of medical treatment for people aged 75 years or over at least once a year. (Ministry of Social Affairs and Health, 2017) According to a systematic review conducted by Fimea, there have been challenges in practical implementation, overall responsibility, and information flow in health care. Therefore, pharmacotherapy evaluation practices are not well established as part of treatment practices. (Fimea, 2016) The report of the Ministry of Social Affairs, unlike the previous studies showed that interprofessional medication assessments did not have much effect on home care patients' functional capacity, quality of life or use of health and home care services. Thus, the pharmacotherapy evaluation could affect the content and reduce risks associated with the medical treatment, but it did not have a significant effect on the number of medication in use. (Ministry of Social Affairs and Health, 2017) A different result, especially CMR's effect towards reduction of medicines in use and effect on quality of life by reduction of side effects, is seen in Leikola's review. According to her review, conducted based on the reports done by the CMR qualified pharmacists, there has been reduction in adverse reactions related to medication and also reduction in number of medicines in use when inappropriate medication has been removed from the patients' medication. (Leikola, 2012b)

2.6. Long-term home care in Finland

The number of people cared for in their homes is increasing. They are more often old, frail and use multiple medications. Home care services support survival at home, and help if needed, due to the customer's illness or reduced ability to cope with everyday chores. (Ministry of Social Affairs and Health, 2022b) In many municipalities, home-help services and home nursing have been combined (Ailasmaa et al., 2006).

Over 115,000 customers in Finland received regular home care services in 2020. The highest number of people receiving services were aged between 85 and 94, approximately 45,000 people. (Saukkonen et al., 2021) In 2021, Finland's long-term home care; professional and private, had in total of 17,000 employees of whom 12,550 were practical nurses and 1,969 registered nurses. Eighty-two per cent of the employees worked in the professional health care and 15% on the private side. (Kehusmaa and Alastalo, 2021)

Even though people live longer, and the number of elderly people is increasing, people are in general more often in a better condition than before. This is one reason why the number of home care customers is increasing more than the number of customers in nursing homes (Turjamaa et al., 2014). The same observation has been made in Norway (Berland and Bentsen, 2017). Still, the number of customers in home care is increasing, and it is expected to increase even more, when the number of elderly people is growing (Kehusmaa et al., 2018; Kehusmaa and Alastalo, 2022). The number of customers having over 60 visits per month is also rising. In 2008, the number of customers was 10,000, when in 2017 the same number was 20,000. This means, that an increasing number of customers living at home need more help than before. Therefore, there is a need of more resources in home care and that is why the number of employees has increased almost in every municipality. (Kehusmaa et al., 2018)

According to a retrospective record review done in Sweden concerning the adverse events of long-term professional homecare, adverse events affected over a third of patients in homecare. Adverse events were mostly preventable and resulted in temporary harm that led to the need of extra healthcare resources. (Schildmeijer et al., 2018)

In a qualitative focus group study published in Norway, municipalities' home care registered nurses' perspectives of medication errors and patient safety in home care were evaluated.

The key findings were lack of information, especially between different health care professionals. The hierarchy between physicians and nurses seemed to have a negative impact on the information flow and, therefore, promoted medical errors. (Berland and Bentsen, 2017) The same type of results concerning hierarchy's effect on the information flow and interprofessional collaboration was also found in Isoherranen's study from 2012 (Isoherranen, 2012). Problems related to information flow, which have led to medical errors, have occurred when a patient has been discharged from hospital (Berland and Bentsen, 2017; Cheung et al., 2014).

2.7. The effect of automated dose dispensing on patient safety

ADD has been suggested to reduce medication errors, increase medical adherence, and decrease the waste of unused medicines (Fimea, 2022). In studies related to ADD and its possibilities to affect patient safety, there have been various results. ADD has been introduced to improve medication safety and treatment adherence, particularly for elderly patients with multiple medications (Cheung et al., 2014). A Swedish cross-sectional nationwide register-based study showed that ADD even increased the amount of potential inappropriate drug use. This could be explained, though, by the fact that users of ADD use a larger number of medicines. The same study also showed that ADD lowers the probability of potentially serious DDIs. (Johnell and Fastbom, 2008)

Some of these studies have been made with questionnaires, where safety is being measured by physicians' or nurses' opinions (Bardage et al., 2014; Fimea, 2022). A study made in Sweden in 2014 (n=1353) deduced that most of the nurses (90%) and practical nurses (82%) felt that ADD reduces duplication of medication and contributes to correct dosage. Only 66% of physicians agreed with this statement. Over half of the physicians and 35% of the registered nurses and practical nurses felt that it is a safety risk if a patient has medicines both in ADD bags and other packages. The biggest difference was in opinions that ADD bags are safer than pill dispenser, where only 8% of physicians agreed, but 89% of nurses agreed to that statement. (Bardage et al., 2014)

In a national register-based study conducted in the Netherlands in 2013, Cheung et al. researched the most typical medication incidents in pharmacies and hospitals related to ADD. They found that most of the errors (~43%) were related to a pharmacist entering prescriptions into pharmacy systems, which resulted in a wrong dose or a wrongly selected patient. (Cheung et al., 2014) In another prospective and observational Dutch study conducted in nursing homes, they found that even though ADD lowers the number of errors, the error frequency is still quite high. Errors were mostly due to incorrect administration, e.g., crushing tablets that are not supposed to be crushed or giving medicines at the wrong time. In addition, a large number of errors were related to antibiotics. They are often dispensed separately from ADD medicines and are not part of long-term medication. This can be a reason for errors in the use of antibiotics. (van den Bemt et al., 2009)

According to Tahvanainen's study of ADD service in home care, a positive impact was seen towards medication risk management, when ADD was introduced into home care (Tahvanainen et al., 2021). Sinnemäki et al. conducted a review about medication safety and adherence of medical care. Their conclusion was that ADD's influence on appropriateness and safety of medication use is still limited. (Sinnemäki et al., 2017) Overall, there are many studies which agree that ADD promotes patient safety, but there are also studies in which safety promotion is being questioned. This is one reason why this study is conducted.

3. AIMS

The aim of this study is to find out what the most common medical errors in this specific municipality's long-term professional home care were, and evaluate whether the common medical errors have changed since ADD started in 2015. To take a systematic approach to this issue, I will review long-term professional home care's HaiPro reports from year 2010 to 2022. I will compare my result to other studies based on HaiPro reports to see what kinds of differences there are between different health care districts. The purpose of this study is to clarify the current state of medical errors in long-term professional home care and to see whether ADD as a dispensing method can help to increase medical safety.

My research questions are:

1. What are the most common medication errors in the municipality's long-term professional home care?
2. Has medical safety improved after the ADD was introduced in 2015 in municipality's long-term professional home care?

4. MATERIAL AND METHODS

4.1. Material

The material in this study is a municipality's long-term professional homecare's HaiPro reports from January 2010 to September 2022. I chose to focus on HaiPro event type 1 "Medication or infusions, transfusion, contrast agents and marker related", because those are the ones where the effect of automated dose dispensing to medical safety incidents can be seen. The total number of HaiPro reports, in event type 1, was 1262. The material consists of HaiPro reports reported in this home care unit during that period. The data included both structured information and free text.

Research approval was granted from the social and health organisation. Then I had access to the register data I needed for my research. The data is categorised as confidential. It does not contain any personal information. The data was printed on paper, which was an idea suggested by the educational planner of the municipality. After my study is completed, I will give the data back to the municipality's educational planner and she will destroy it. This study has been done in such a way that the municipality to which the research applies is not revealed. The data consists of several different kinds of information: when a medication error has occurred, who has reported it, was it a near miss or an adverse event, what was the medicine involved, free text about what has occurred, what was the consequence for the patient and information of the risk class. I also received information about suggested measures that should be taken when the adverse event has occurred. However, they were very brief.

Today there are 399 customers in this municipality's long-term professional home care who receive their medication as ADD and 10 customers, whose medicines are manually dispensed.

4.2. Methods

This study is a quantitative registry-based study. In this study, I collected data about the number and types of adverse events and near misses, and how they have changed over time. I categorised HaiPro reports by the time the medical error has occurred, what kinds of errors there were, and what was the risk class and harm to patient assessment, which is assessed in the report. I also analysed if there are any similarities, which often appear in HaiPro reports. I compared the results to other studies that have been conducted.

I chose to go through all the HaiPro reports related to medication to see all the errors that had occurred. From the free text I could see more detailed information of the report, i.e., whether they concern ADD or manually dispensed medicines, and what kind of administration errors there were.

I categorised every HaiPro report based on the year it had occurred to Microsoft Excel by a report number and the information about the medication error. The information I had was the type of the event (i.e., administration error, dispensing error, communication error), who reported the event, what occurred, was the event related to a tablet dosing or something else, was the event related to ADD, what was the event's risk class and harm to patient assessment. As I had done this categorisation to all the reports, I counted the number of each type of the medication error, analysing different features, that is, what kinds of medicines were related to the event, how many errors were related to ADD, what was the dividend of different types of errors, and if there could be seen any typical types of errors or typical types of medicines that were not dispensed, for example. I also analysed what percentage every error type represented of all the medication errors, and how many cases of different error types there were annually. The results are counted as frequencies, percentages, and the annual numbers of different medication errors. The results are presented as pictures and charts made in Microsoft Excel.

5. RESULTS

In long-term professional homecare, that my study focuses on, a total of 1262 medicine related HaiPro reports had been made between 2010 and September 2022. The average number of HaiPro reports was 97 per year, but for the first four years the average number was only 20. That is probably due to HaiPro not being much used in the early years (Kuusisto et al., 2019). HaiPro reports include medical errors, which are either near misses or adverse events that have occurred to patients. In this long-term professional home care, 94% of the HaiPro reports were adverse events and only 6% were near misses.

Of medical errors, 90% were related to administration (n=1134), whereas 4% of administration errors were near misses and the rest were adverse events (Figures 5 and 6). Dispensing errors were the second highest category, but the number was only 50 HaiPro reports (4%) during these 13 years. Communication, documentation, and storage errors were also reported a few times in a year. Practical nurses reported most of the errors. Only 10% were reported by registered nurses, and in 4% of reports the notifier was not known.

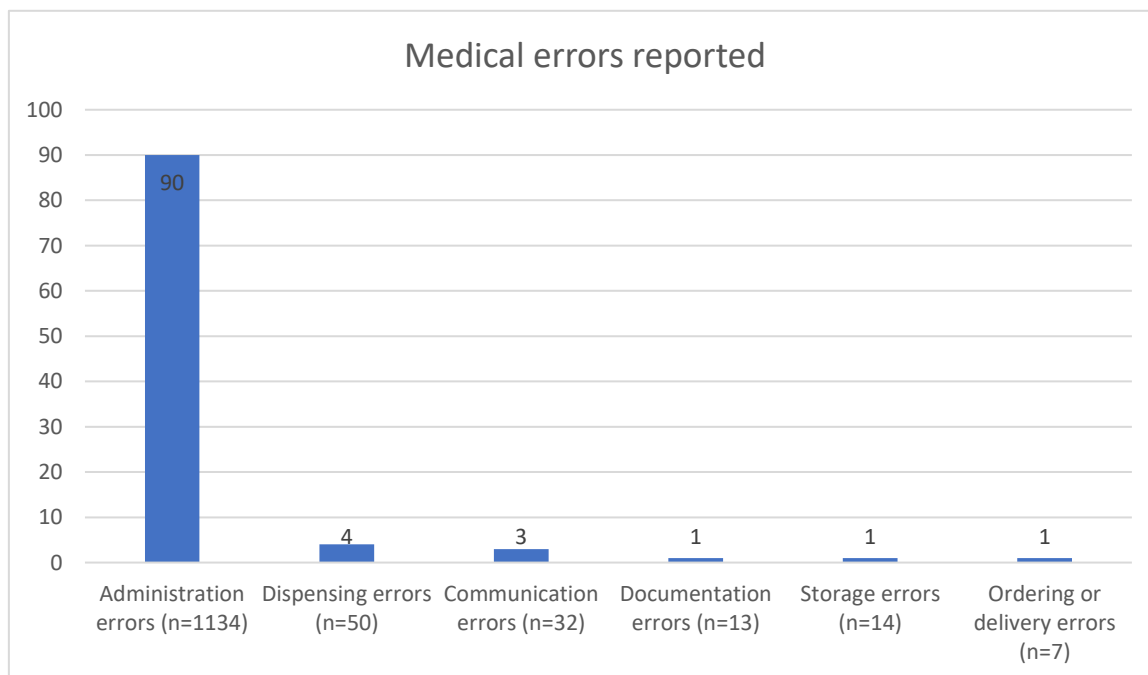


Figure 5. Different medical errors reported.

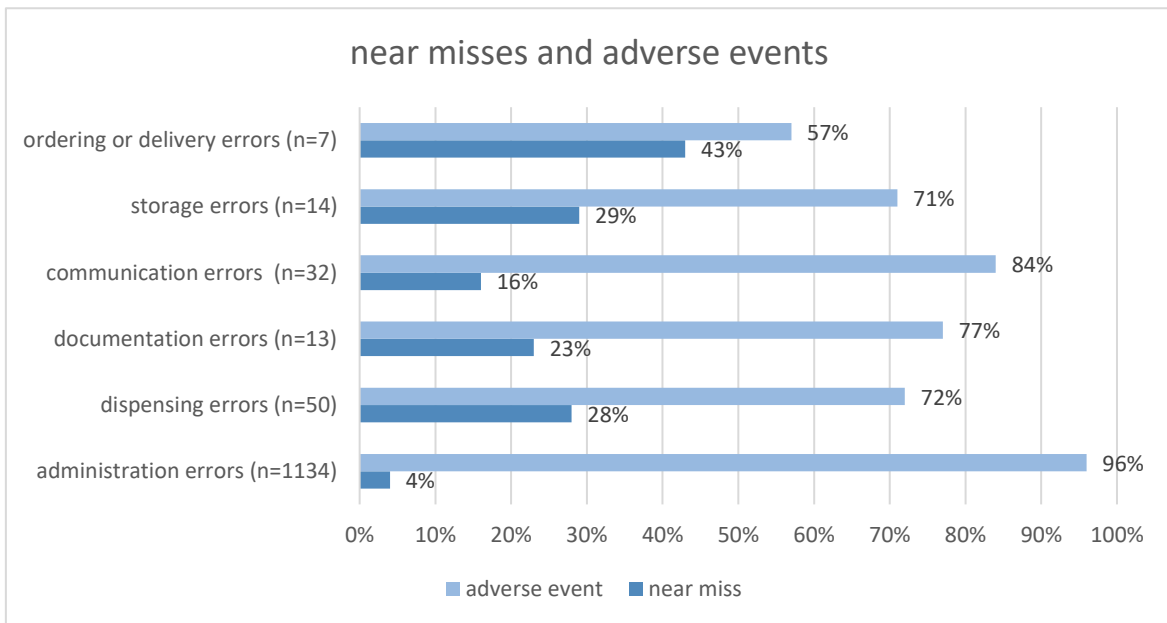


Figure 6. Near misses and adverse events in different categories.

The annual dividend of administration and dispensing errors in percentages is seen in Figure 7. In the beginning, HaiPro reports were not made as frequently as later years, which slightly distorts the charts. However, differences can be seen between the years and most of the dispensing errors have occurred in the early years of the study time. There is also seen the difference between ADD and manually dispensed medicines.

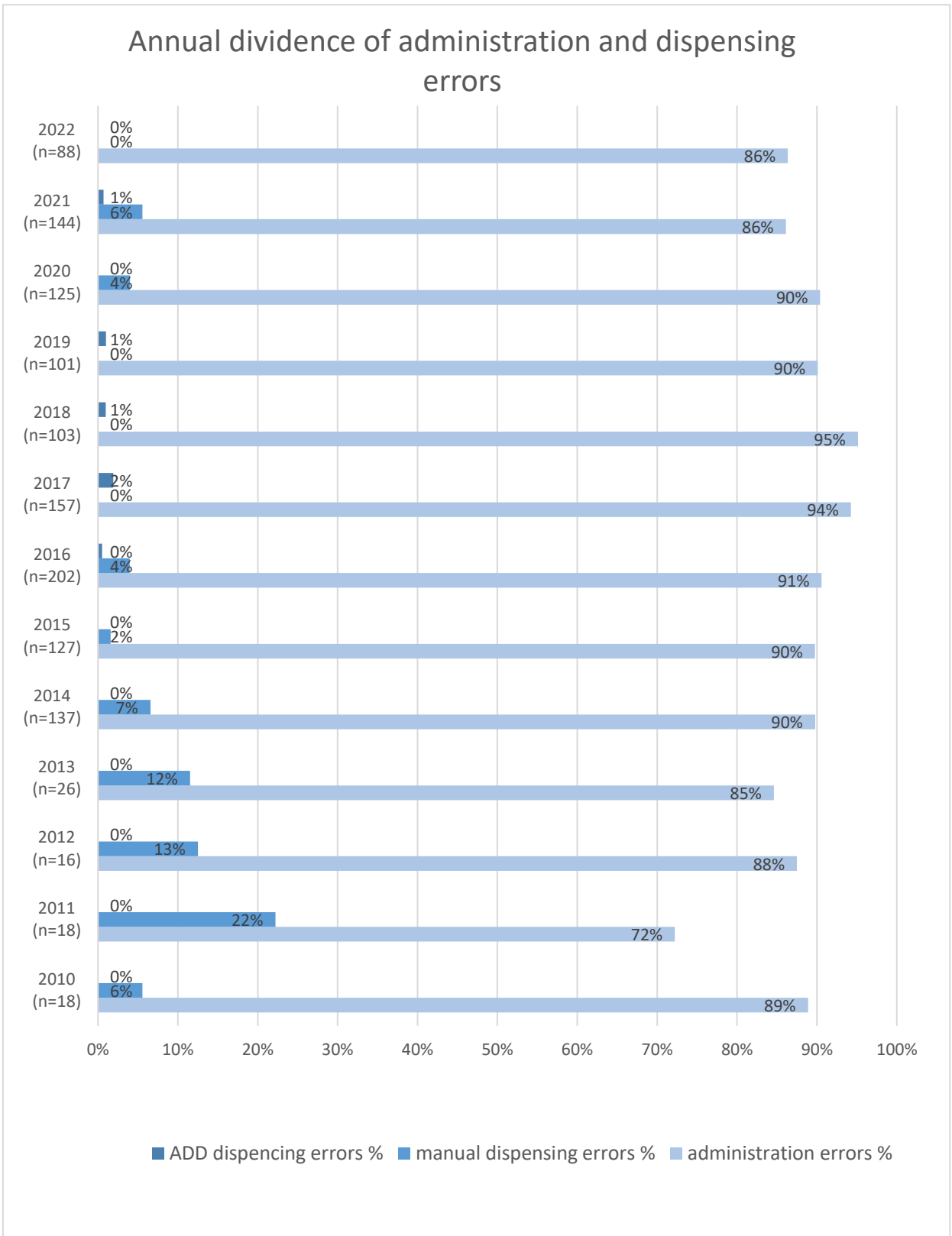


Figure 7. Annual dividend between administration and dispensing errors (n= annual HaiPro reports).

5.1. Administration errors

Administration errors were the biggest error type in this municipality's long-term professional home care. Most of the administration errors documented to HaiPro were related to tablet dosing (Figure 8). HaiPro reports related to injection or parenteral dosing e.g., pain killer patches were also found, but the amount was much smaller. In this study, I am concentrating mostly to tablet dosing since that is related to ADD.

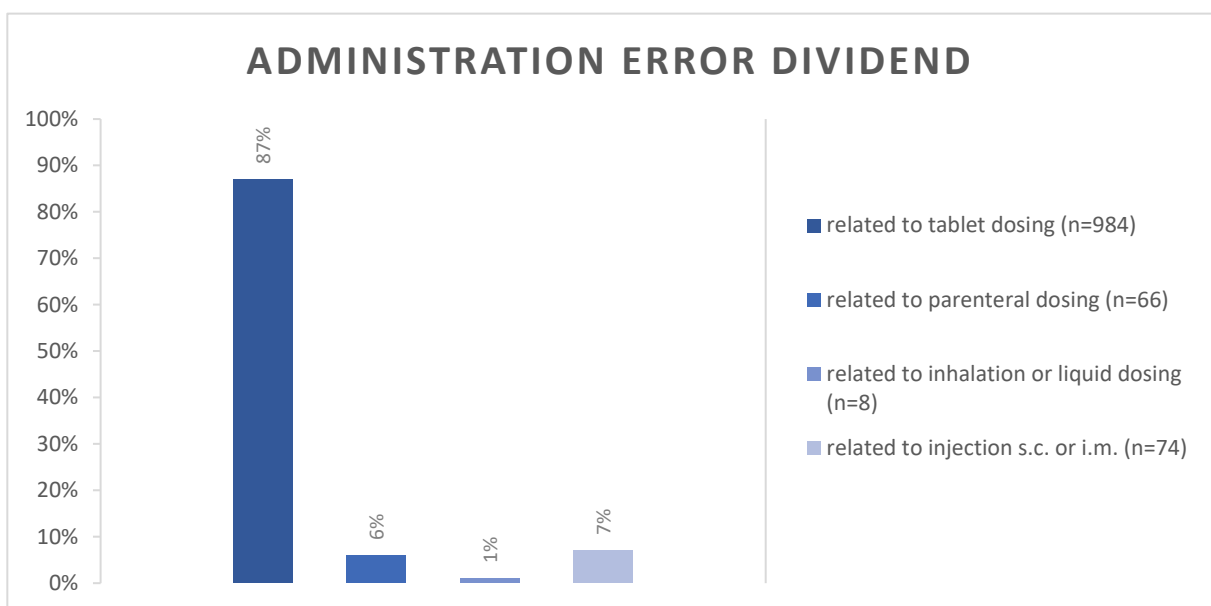


Figure 8. Administration error dividend.

Administration errors are divided into different types of error categories. Clearly the most common type of error is that the medicines are unadministered (n=814) (Figure 9). This group of errors covers 72% of all administration errors. This group consists of errors where practical nurses have not given medication to the customer at all, and errors where medicines have been left for the customer to take, but the customer has not, for some reason taken the medication (Figure 10). The share of practical nurses' errors is 80% of these mistakes and in 20% of these cases the medicine was left to the customer, who did not take the medicine. Nevertheless, those errors have been calculated as one in previous studies due the outcome being the same.

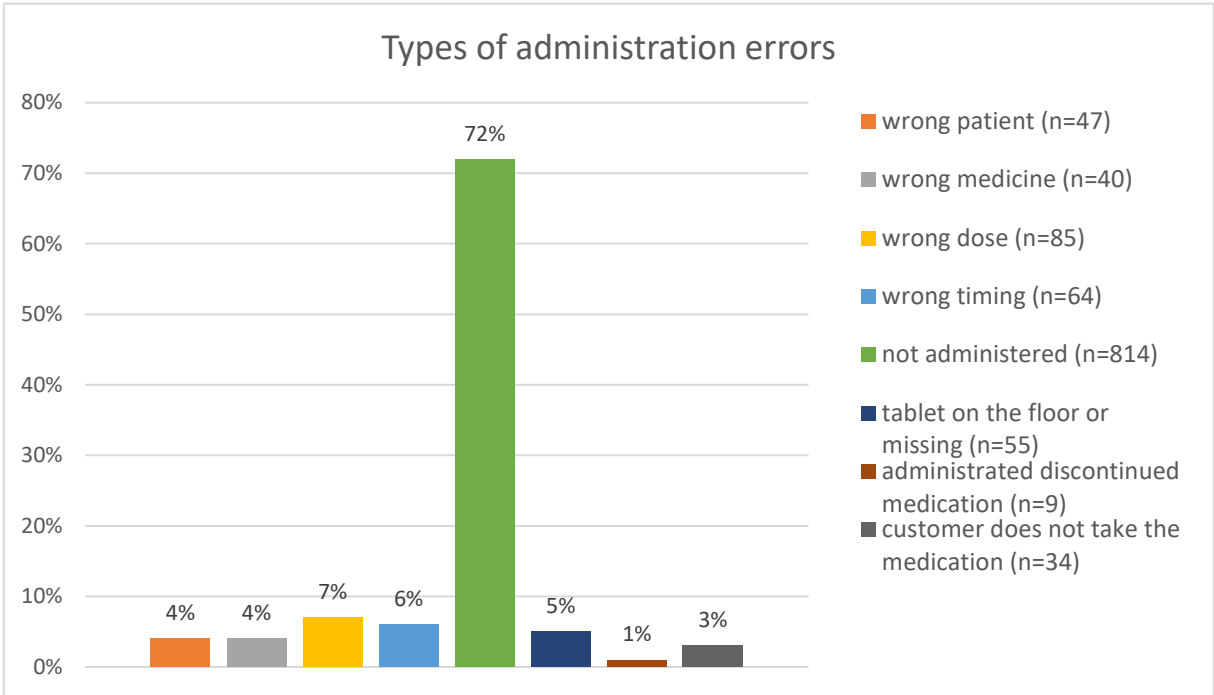


Figure 9. Different types of administration errors and their dividends.

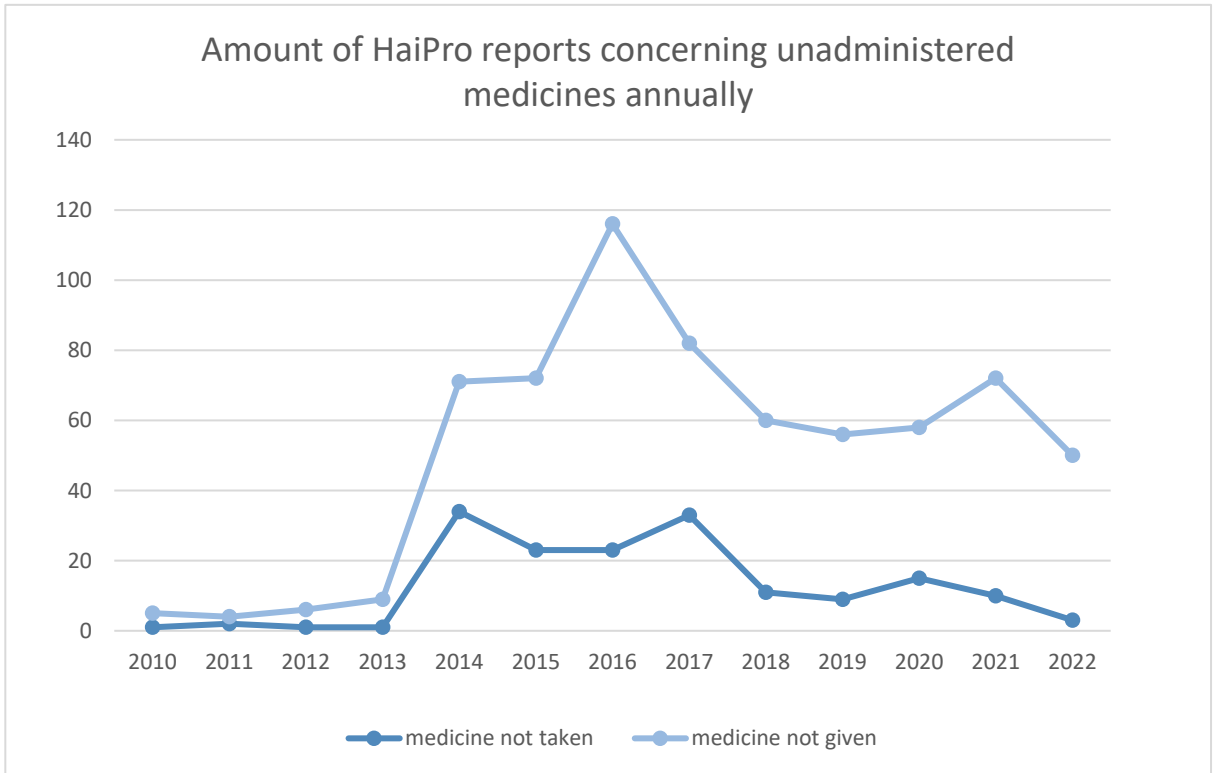


Figure 10. Division of unadministered medicines annually (year 2022 calculated).

Medicines administered at the wrong time or with wrong dose are found 5-7 times a year. In addition, medicines given to the wrong patient, mostly to a spouse, occurred on average 4 times a year. A total of 34 administration errors are documented in the category customer refuses to take the medication.

In the years from 2015 onward, when ADD has been used in this long-term professional home care, there have been 34 documented HaiPro reports, when the customer has not been given either of his/her ADD bags. Two bags, e.g., in the morning, is due to the fact that sometimes all medicines that are meant to be taken at the same time do not fit into one bag, and there are two bags to be taken.

5.2. Dispensing errors

Dispensing errors were the second biggest error group reported to HaiPro. During the whole study period, a total of 50 dispensing errors were reported. Before the year 2015, when ADD has not been widely used in this long-term professional home care, 19 HaiPro reports were made and 4 of them were near misses and 15 were adverse events. All the dispensing errors reported were due to medicines being manually dispensed wrongly into a tablet dispenser by nurses or in a pharmacy.

After 2015, when ADD was more commonly used, errors between manual dispensing and ADD were seen. During those years, there were 19 HaiPro reports related to manual dispensing and seven related to ADD. Eight of the HaiPro reports in manual dispensing were near misses and 11 were adverse events. In ADD, there were two near misses and five adverse events. These dividends are seen in Figure 11.

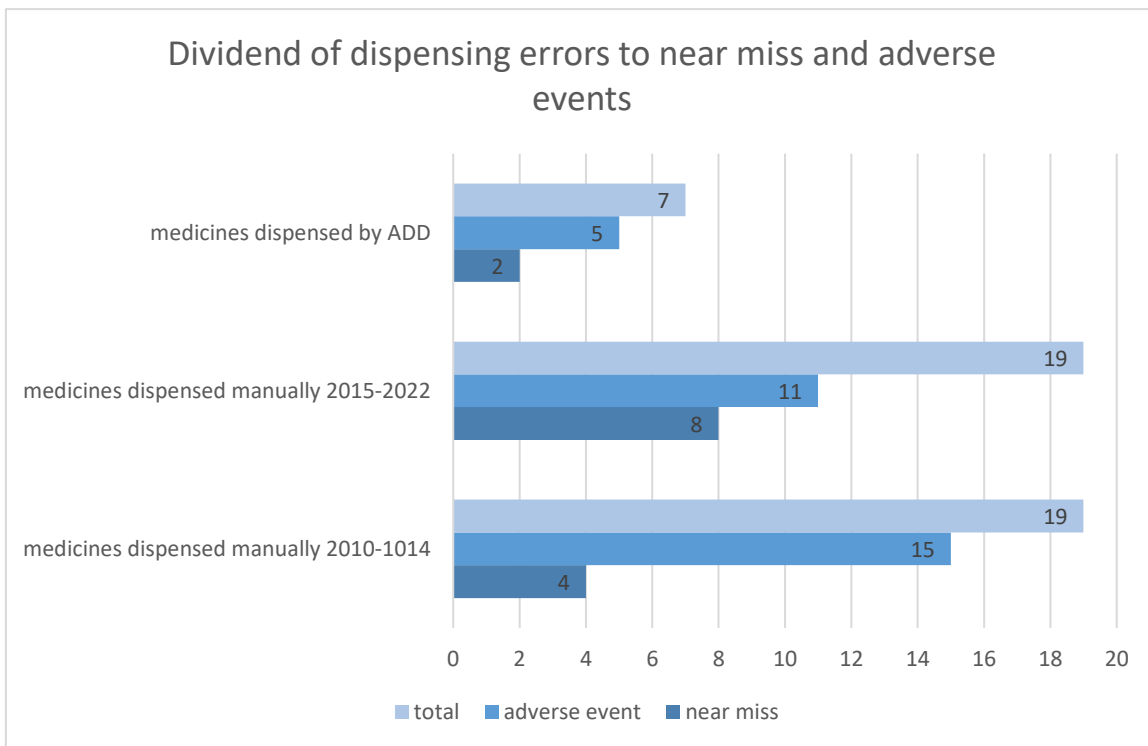


Figure 11. Dispensing error dividends between manual dispensed medicines and ADD.

The most common dispensing error was that medicines are not dispensed (Figure 12). Those errors represent 45% of all dispensing errors. Of errors in which medicines were not dispensed, 14% related to ADD and the rest, 86%, to manually dispensed medicines. The second highest number of HaiPro reported errors were those where the dispensed dose had been wrong. Of those errors, 26% were related to ADD. All other types of errors, e.g., wrong medicine dispensed, or medicines dispensed at the wrong time, were all related to manually dispensed medicines.

There is a clear difference between manually dispensed medicines and ADD. Even though ADD has been introduced to long-term professional home care mostly after 2015, there was still medicines dispensed manually. Today there are 399 customers in this municipality's long-term professional home care who receive their medication as ADD and only 10 customers, whose medicines are manually dispensed. In Figure 11 is seen the dividend where ADD and manually dispensed medicines are being categorised.

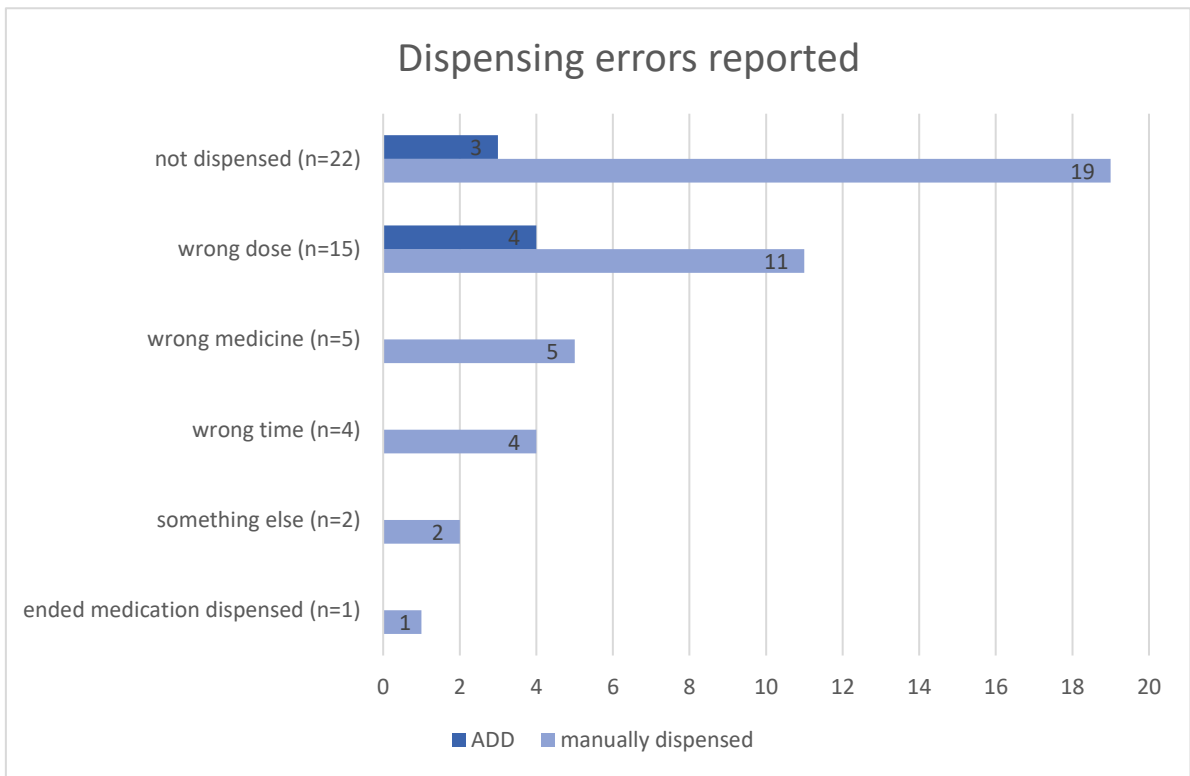


Figure 12. Types of dispensing errors reported.

5.3. Other errors reported

In addition to administration and dispensing errors, communication, documentation, and storage-related errors were reported almost yearly. Especially the number of communication errors seem to be rising (Figure 13).

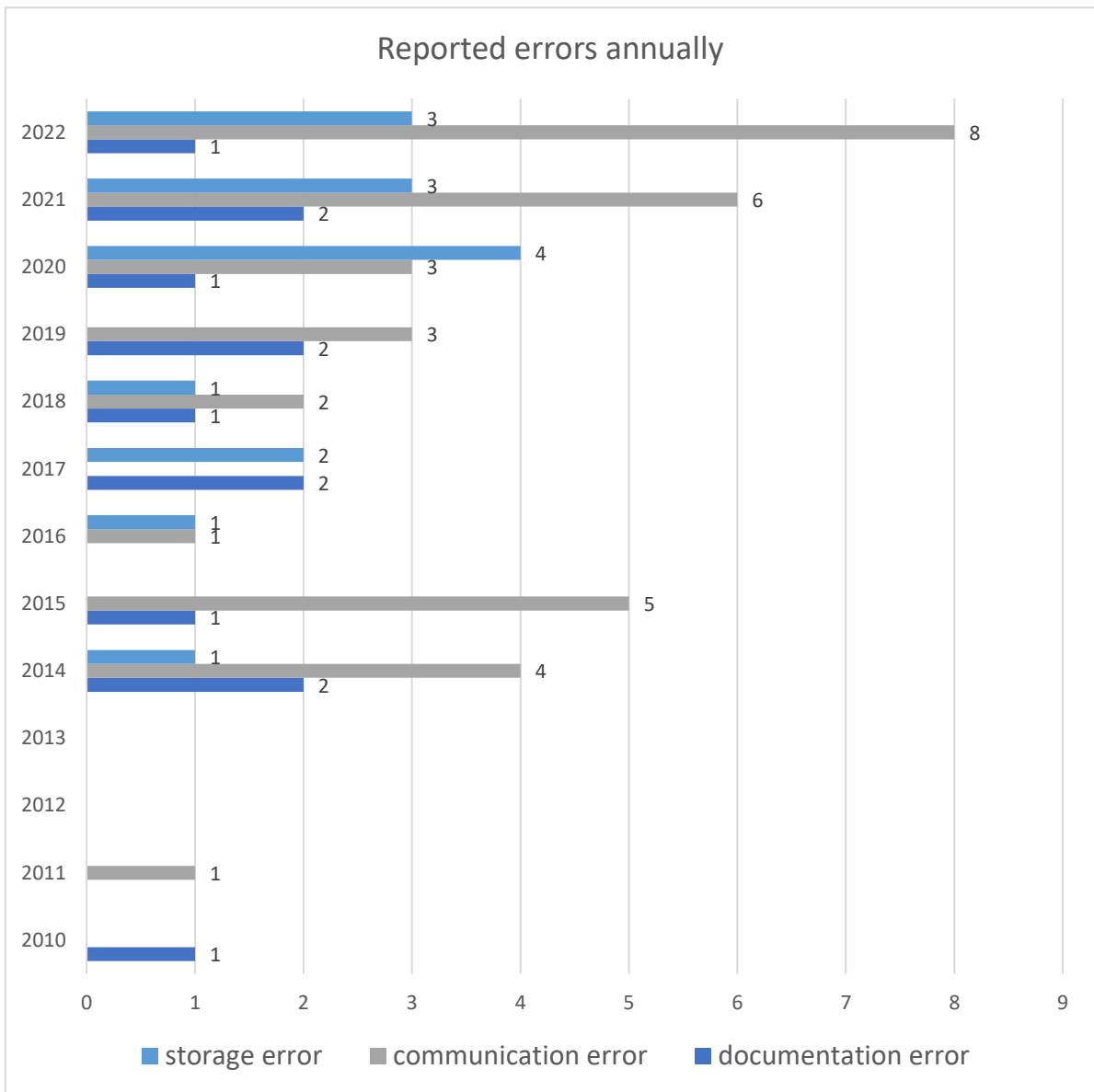


Figure 13. Annual number of storage, communication, and documentation errors.

5.4. Evaluation of risk class and harm to patient

The HaiPro reports can be used to deduce, what medical errors occurred in a health care unit and how those could be avoided in the future. However, that can only take place when reports are evaluated by supervisors and foremen. They are the ones to assess events risk class and harm to the patient, as well as decide how the organisation reacts to an event. In every adverse event, the risk class and harm to patient evaluation must be added to the report. In

this study, in 5% of the reports the risk class evaluation was missing and 11% of the reports had no harm to patient classification.

The HaiPro reports had the risk class evaluated as II in 44%, referring to the risk being minor. Risk class III was evaluated in 33% of the HaiPro reports, which refers to the risk being moderate (Figure 14).

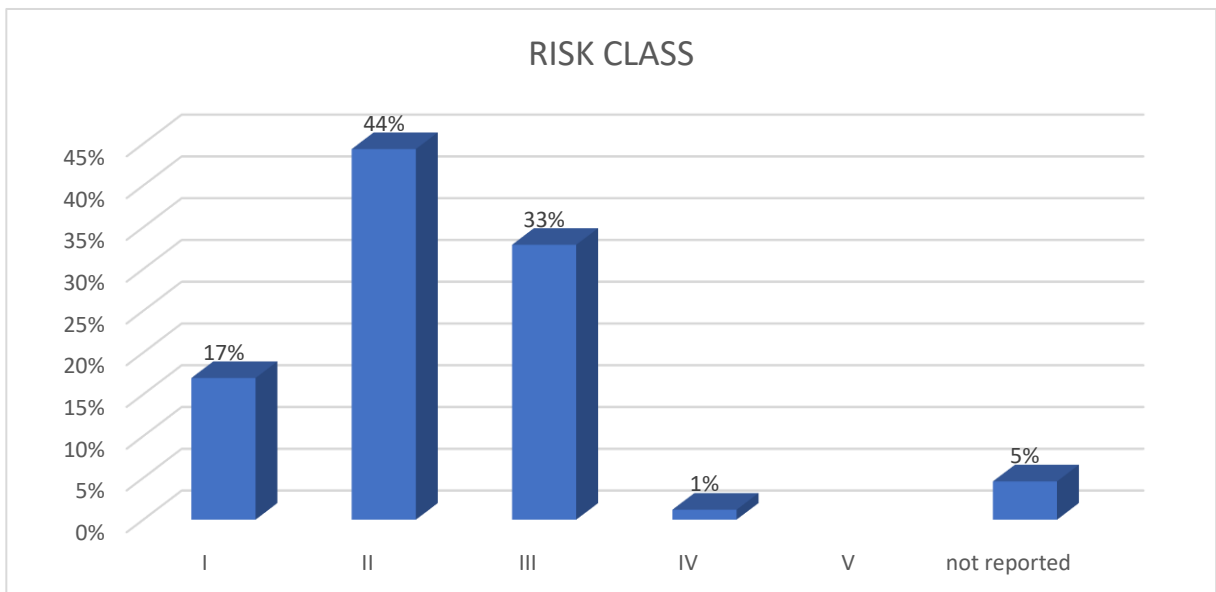


Figure 14. Risk class dividend.

Harm to patient has been evaluated mostly to be mild. Only in 6% of the reports, harm was moderate, and no severe harms were reported (Figure 15). In Figure 16, the harm to patient dividend divided into administration and dispensing errors in per cent is illustrated. A small difference in per cent dividend is observed, even though the number of administration errors is much bigger.

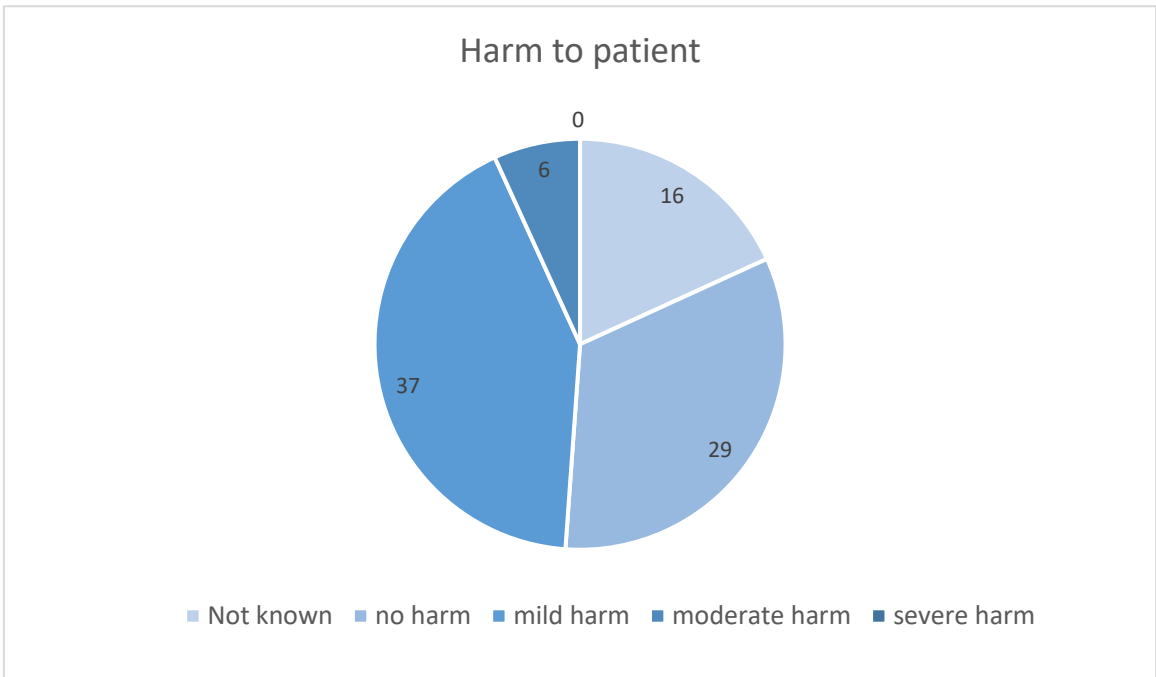


Figure 15. Harm to patient dividend in per cent.

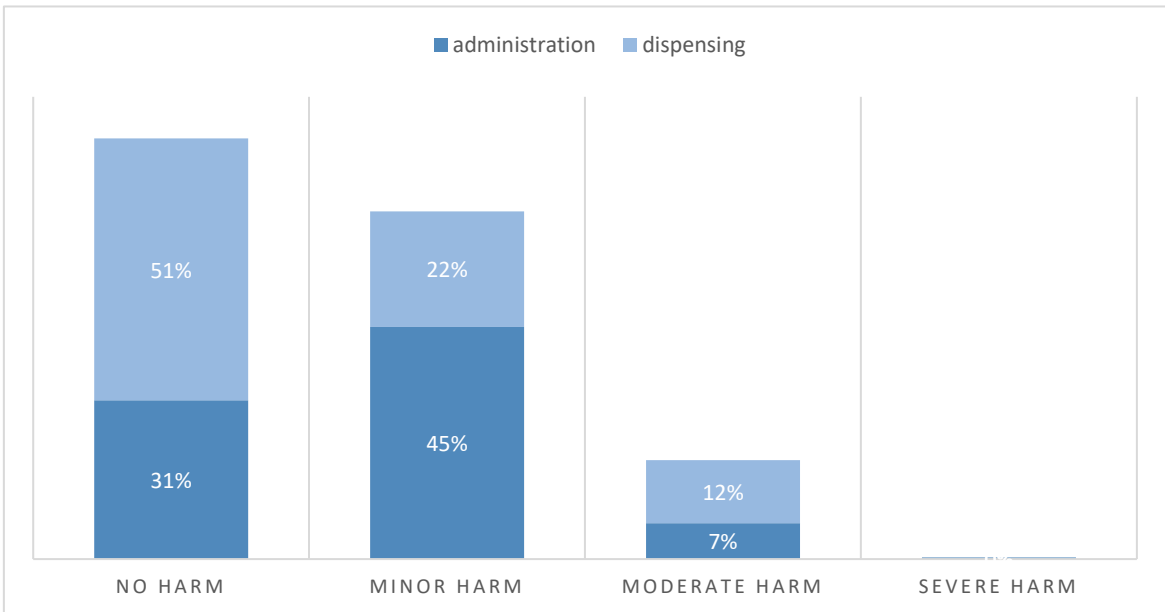


Figure 16. Harm to patient dividend, divided into administration and dispensing errors.

6. DISCUSSION

When analysing my data of medical errors, difference between administration errors and dispensing errors were significant. Also, considerable difference can be observed between adverse events and near misses. When comparing my results to other studies done based on HaiPro reports, the results were remarkably different. In their study of HaiPro reports in Finland's long-term professional home care (n= 61 248 of which medical errors were 36,951) between years 2009 and 2019, Kivimäki et al. found that the number of near misses was much bigger, 20% of all HaiPro reports; as in my study the amount was only 6%. (Kivimäki et al., 2022) In Kuusisto's and her group findings in the study of Finland's HaiPro reports between 2009 and 2019 (n=321 195) near misses were almost 40% and an even bigger difference is seen in Holmström's study from HaiPro's early days, 2007-2009 (n=32 592), where near misses and adverse events were almost even. (Holmström, 2017; Kuusisto et al., 2019)

There can be many reasons for this difference. Near misses are perhaps the ones that are left without reporting, if there is e.g., time pressure within employees. Time pressure is widely reported during studies made in Nordic countries' home cares and in the study conducted by Afaya et al. in 2021 time pressure was one reason why practical nurses did not report medication errors. (Afaya et al., 2021; Martinsen et al., 2018)

According to my data, time pressure and lack of resources are also reported as one of the reasons adverse events occurred. In home care, practical nurses mostly work alone, so there are seldom co-workers double checking if medicines are wrongly administered or not administered at all. This is a significant difference compared to nursing homes or hospitals where registered nurses and practical nurses are more available. However, it would be extremely important to report near misses, because based on those future adverse events may be avoided.

Administration errors in this study cover most of the errors. This is a very different result when compared to other studies (Figure 17). In Kuusisto's et al. study, administration errors covered 38% of all errors and in Kivimäki's et al. and Holmström's studies, there were 25%

administration errors, as in my study the amount was 90% (Holmström, 2017; Kivimäki et al., 2022; Kuusisto et al., 2019).

Since my data is based on the long-term professional home care's HaiPro reports as Kivimäki's, hers just being wider, covering nationally 29 of Finland home care's reports, our dividend should be the most similar. If the number of Kivimäki's study's medication errors is divided by home care units, the average number of medication errors per unit would be 1,274, which correlates to my data's number of reports (1,262). Still, these two studies are the most uneven ones (Figure 17). The reasons for the difference could be that the long-term professional home care my study is based on has more administration errors than in the average of home cares in Finland, or just a very small number of dispensing errors. However, it does not say what dispensing method they have used in other municipalities' long-term professional home cares. The reason could also be that the style or initiative of reporting is different in different home care units.

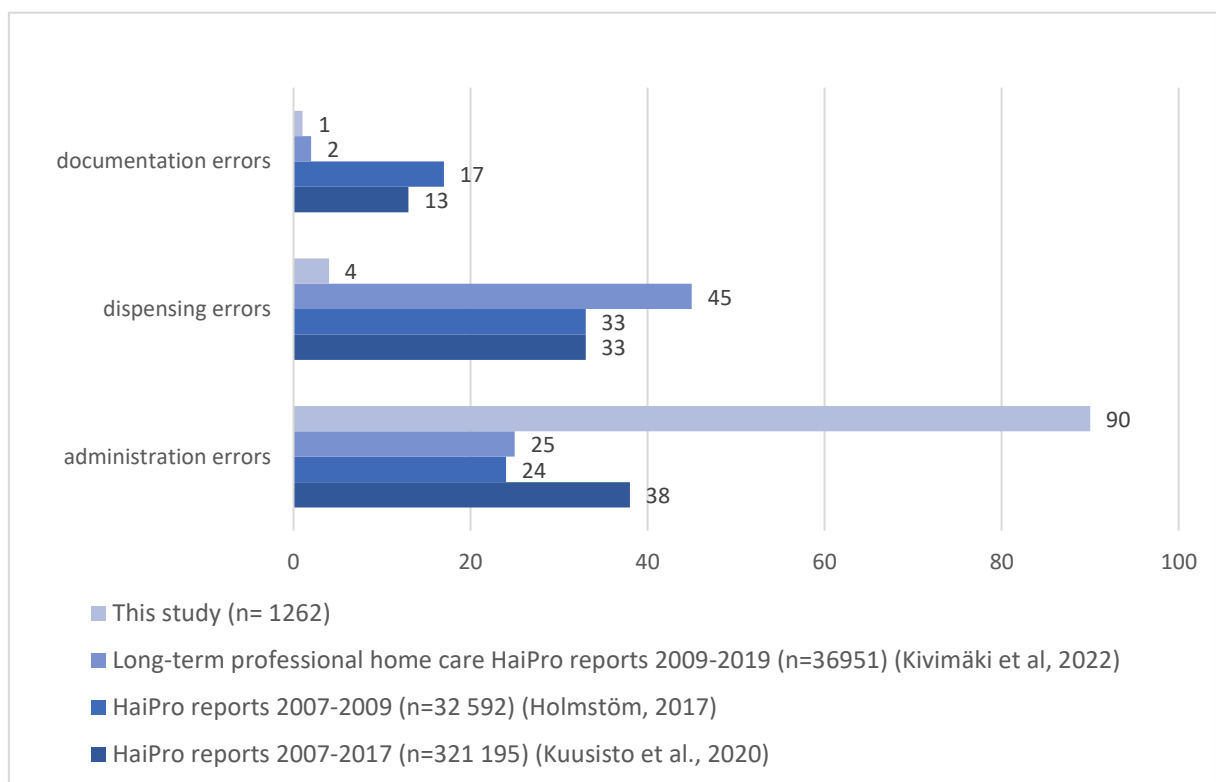


Figure 17. Different types of errors compared to this study.

How the types of administration errors were divided was opened only in Holmström's study (Figure 18). Therein, unadministered medicines is the biggest medication error type, but the

difference to other error types is much smaller than in my study, as seen in Figure 19. (Holmström, 2017)

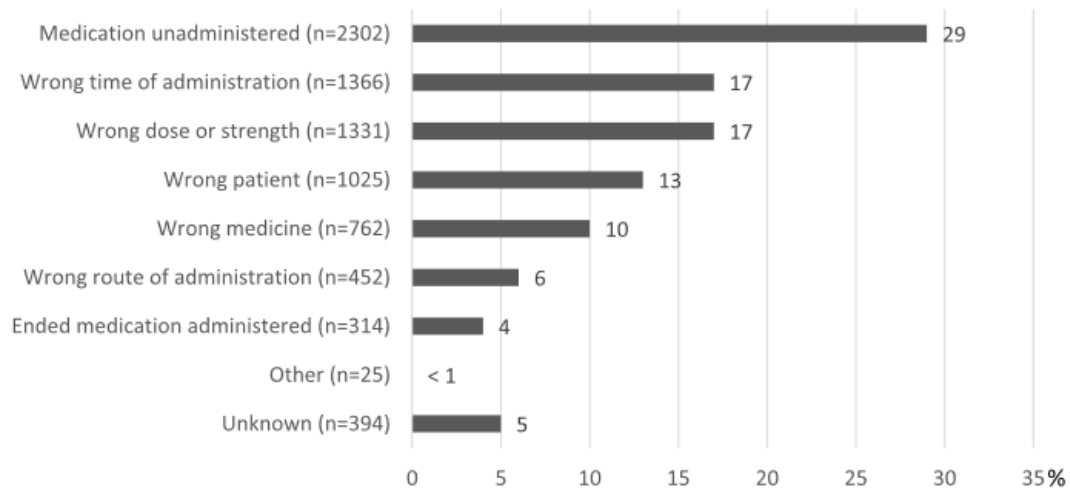


Figure 18. Administration error dividend in a study done on HaiPro reports 2007-2009 (Holmström, 2017).

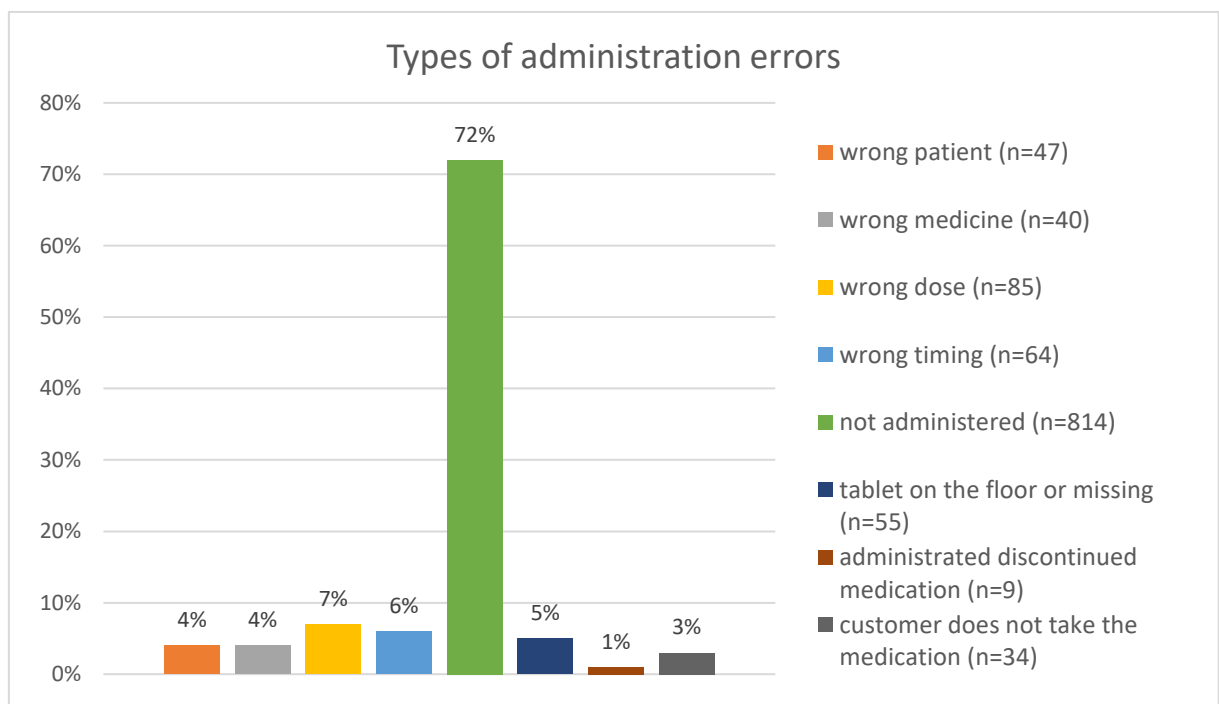


Figure 19. Administration dividend in my study.

Administration errors are clearly the biggest type of medication error in this long-term professional home care. According to Reason's theory of errors, errors are inevitable when human action is involved. Errors in my data are very much due to forgetting to give medicines to customers. Referring on Reason's Swizz cheese model, those types of mistakes are active failures that lead to instant adverse events, if they are not detected in time. Still, considering the number of errors there might also be latent conditions involved, which could be possible to correct. When the reason for the error is seen to be the organisation's systems and not individuals' actions, the instructions can be adjusted and future errors prevented from occurring (Reason, 2000). According to the report by Knuuttila et al., if one type of event is over represented, the process should be further evaluated (Knuuttila et al., 2007). This aspect might be good for this long-term professional home care to think about and evaluate in the future.

Medicines not being administered at all is the biggest medication error in this long-term professional home care. However, as shown in Figure 10, the amount of unadministered medicines is decreasing from the peak year 2016. Adjustments for the instructions can be one reason for the reduction of errors. Also, ADD's effect on administration errors cannot be excluded. Use of ADD can be one reason for reduction of unadministered medicines.

Administration errors related to ADD were also found in my study. A total of 34 HaiPro reports were made, because another bag was not given to the customer to take. The reasons for this can be difficult to identify, but it is possible that practical nurses giving the medicines rely too much on the ADD process and do not check carefully enough if there is another bag to give. This type of reasons have emerged also in Sinnemäki's study. (Sinnemäki, 2020) This could be one development field for ADD units to for example increase the number of tablets that can be dispensed into one bag or label the 1/2 and 2/2 bags clearer, using colours or some other signs that would draw attention to the fact that there are two bags to give.

Five of the administration errors occurred because ADD bags were supposed to be administered for example at 2 pm, but there was no one to give the medicines at that time. Sometimes bags were supposed to be left on the table for the customer to take, or, in some cases, they were meant to be administered at a different time. This was forgotten because the time on the ADD bag was different. Those kinds of errors could be avoided with better communication with the pharmacy. Administration timings could be adjusted to correspond

better with the times the practical nurses visit the customer. A medicine-dispensing robot could also be one solution. Most of the errors occurred without any precise reason but, as mentioned earlier, home care surroundings contain many distracting factors, which can promote medication errors to occur. Those are shown also in my data. This is still an aspect that home care should try to solve beforehand, because the surroundings and its challenges are well-known.

There were also HaiPro reports of situations where, in addition to ADD medicines, the medicine from the original package had not been given, even though it was supposed to. This is sometimes necessary, because not all medications can be dispensed automatically. This is one known lack of ADD, that not all medicines can be dispensed in ADD bags (Ministry of Social Affairs and Health, 2016). This was also mentioned in a Bardage et al. study where over half of physicians and 35% of registered nurses and practical nurses felt that it is a safety risk if a patient has medicines both in ADD bags and other packages (Bardage et al., 2014). This is shown in my data, especially when antibiotics have been administered to a patient. Also, it is not very uncommon that some of the customers' medicines are regularly dispensed manually, even when most of medicines are dispensed by ADD. This can be due to the fact that the customer wants to use the original product, not a generic one or, the customer uses a dose which is so small that it cannot be dispensed in ADD bags. Sometimes registered nurses add manually medicines to ADD bags for reasons mentioned above.

In other studies conducted based on HaiPro reports, dispensing errors are categorised as one, not divided into ADD and manually dispensed medicines. When dispensing errors in my study are calculated as one, they represent only 4% of all the errors, which is much less than in other studies (Figure 17). In my data near misses were mostly represented in dispensing errors; 28% of all dispensing errors. As the near misses can more easily be left unreported, the actual number of dispensing errors may be higher. When dispensing error types are compared to Holmström's study, similarities are seen in my study and in Holmström's study. Medicines not dispensed is the most common type of error, wrong dose being administered the second and wrong medicine the third highest error type (Figures 20 and 21).

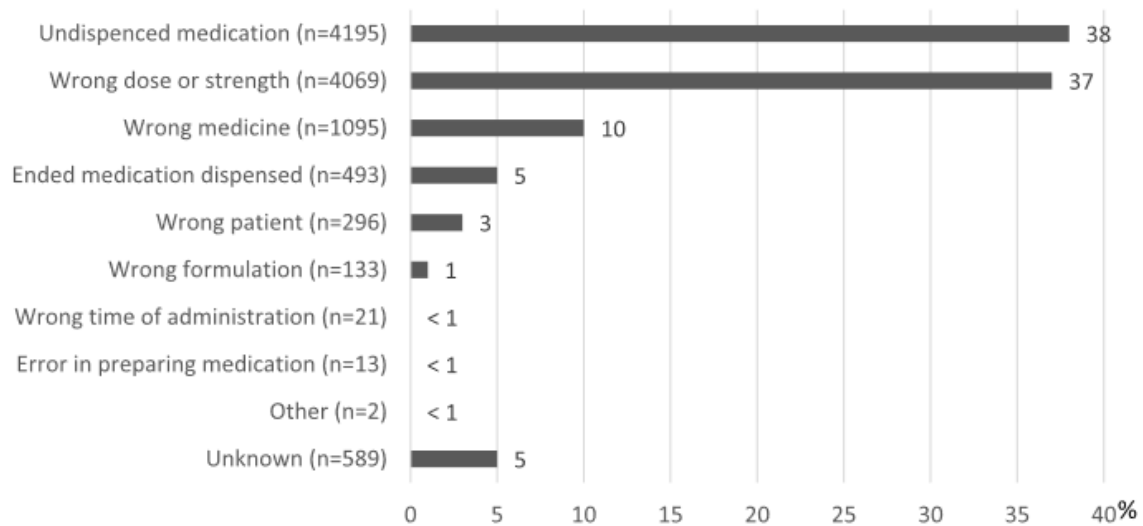


Figure 20. Dispensing errors dividend in study done based on HaiPro reports 2007-2009 (Holmström, 2017).

I have divided dispensing errors in my study into two kinds, depending on whether medicines are dispensed manually or automatically. Differences in number of errors and reasons for errors to occur can be seen (Figure 21).

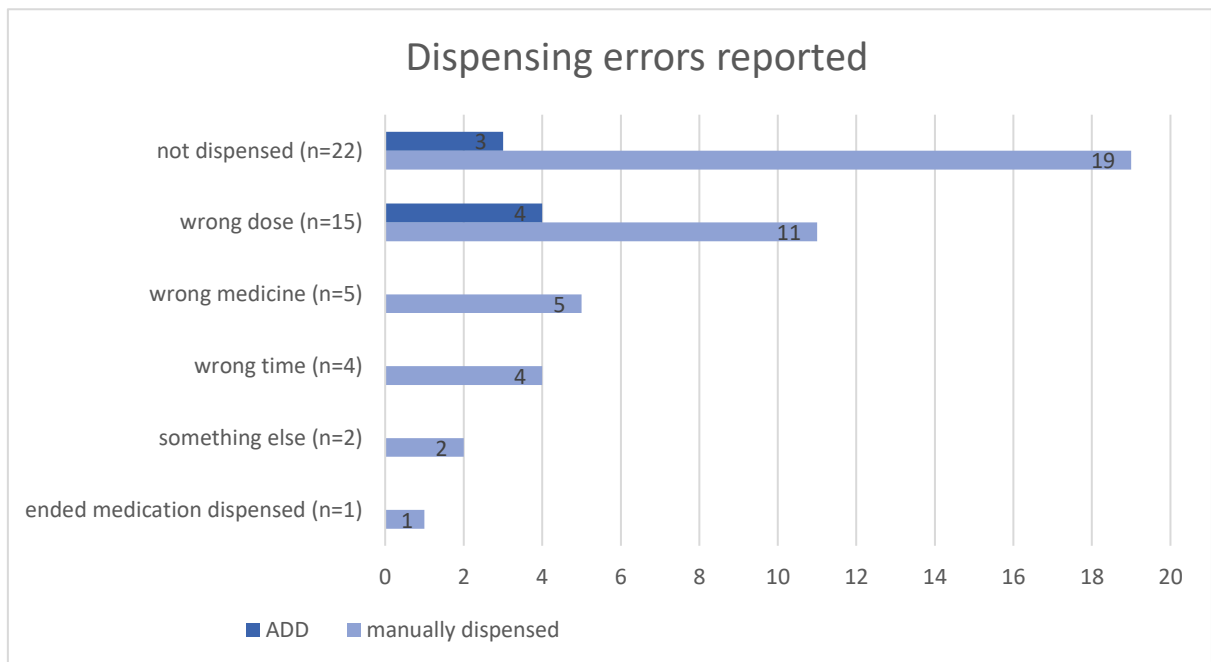


Figure 21. Types of dispensing errors reported in my data.

Manually dispensed medicines were sometimes dispensed very confusingly. For example, two weeks' medication was dispensed into one tablet dispenser, so that neither the practical nurse nor the customer knew what medicines were supposed to be taken. When comparing this to ADD, those kinds of confusions could not take place, because the bags of medicines are always labelled with the date and time the medicines are meant to be taken. Errors related to manually dispensed medicines were usually due to forgetting to dispense the medicine or dispensing it wrongly. Mostly errors were due to a lack of precise methods of dispense medicines and, therefore, caused confusion, whether some of the medicines should also be taken from an original packaging. Instructions for dispensing of medicines were often set to costumers' home, and when changes to medication were made, those instructions had not been changed, which led to an adverse event. There have been situations when a practical nurse is visiting a customer for the first time, and due to inaccurate instructions has given medicines incorrectly.

Errors in ADD bags were related to two factors: a medicine is not dispensed, or the medicine is dispensed with the wrong dose. If medicine was not dispensed, it was due to the fact that, in a pharmacy, when ordering the ADD medication, a pharmacist had not chosen a medicine to be dispensed. This could be due to a mistake a pharmacist has made, by not choosing the medicine to be dispensed, or communication error when nurses inform the changes to the pharmacy. Also, in four of the errors medicines were dispensed in the wrong dose. The reasons for this type of error are similar to those mentioned above. Some of these errors had been detected when nurses checked the similarities of the list of dispensed medicines to the customers' medication list. This is categorised as their responsibility by the Ministry of Social Affairs and Health. (Ministry of Social Affairs and Health, 2016) This promotes ADD as dispensing method, due to multiple checks by different professionals. None of the errors in my study was related to ADD units' errors.

The difference in the errors before and after ADD was introduced can be seen in Figure 22. The total number of dispensing errors has not decreased, but when analysing more thoroughly the errors related to ADD are fewer than 40% of the manually dispensed errors occur in the same time period. Remembering that only 2.5% of customers in this municipality's long-term professional home care are having their medicines dispensed manually. This promotes ADD as a dispensing method. Also, there is no reported error in this study related to the ADD unit

which correlates with the earlier findings which suggest that the error rate of ADD is small. The errors related to ADD are mostly due to the pharmacist placing the order incorrectly. It is good to remember, that ADD has many different middlemen, which in itself can lead to medication errors if the process of ADD is not carefully thought through. Therefore, it is essential to have good communication with everyone related to the ADD process and to make them aware of their responsibilities.

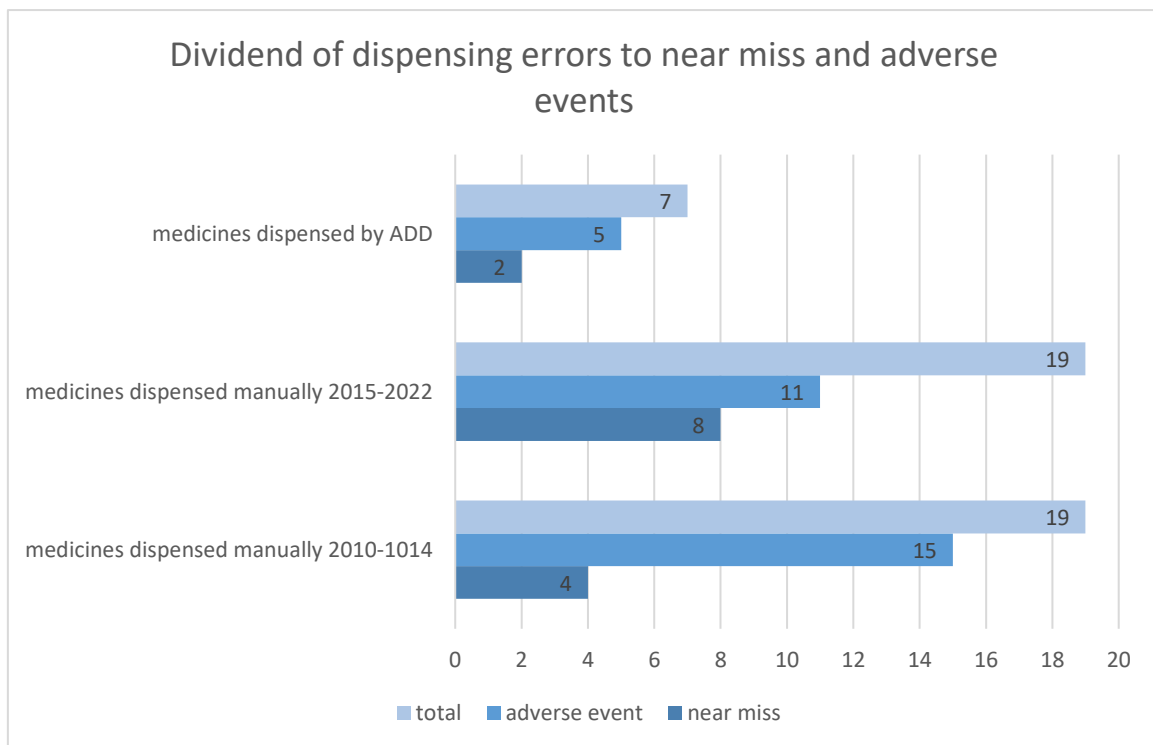


Figure 22. Dispensing error dividends between manual dispensed medicines and ADD.

Administration errors have also been decreasing as ADD has been more widely used (Fig. 9) It cannot be said from the data what has been the reason, but possibly ADD could be seen as one reason for that.

Most of the errors were reported by practical nurses, which can result in one-sided results, especially when reporting the reasons for the error to occur. It is still obvious that practical nurses are the most common professional group to report errors, since they are the ones giving the medicines.

The risk class and harm to patient evaluation can vary considerably depending on who has done the evaluation (Holmström et al., 2018). This was seen also in my data where a deviation between years varies, even if the error reports would have been similarly written. Holmström et al. requested in their study that one of the future requests might be for reporting systems to be more accurate and precise, so that the data would be more comparable (Holmström et al., 2018).

The meaning of every HaiPro report is that medical errors are known and, therefore, prevented in the future. The risk class and harm to patient evaluation are important, but the most important part is how the organisation responds to the errors. According to the World Health Organisation's World alliance for patient safety programme, 2005:

*"It is important to note that reporting in itself does not improve safety.
It is the response to reports that leads to change. - "*

Responses to reports in my data vary from "we will discuss this" to "we will do something about this". Since my data does not tell what the actual responses or actions to errors have been, I cannot analyse the outcome thoroughly. However, in responses are seen also person approach and system approach regarding the response of the errors.

When comparing this study to Fimea's report of ADD, I think this study correlates to those findings. ADD can be seen as a promotive factor to the medical safety, and in my study, this can be seen in the difference of errors related to manually dispensed medicines and in errors related to ADD. Administration errors are seen to decrease and ADD could also be one reason for that. Also, none of the errors were related to the ADD unit, which tells that the ADD unit perform their part very well.

ADD is a process requiring different health care professionals to participate in the medical care. Referring to Sinnemäki's et al. (2014) findings about starting the ADD process, where changes had to be made in 46% of the customers' medical lists due to their inaccuracy, there is clearly a need for interprofessional collaboration and medical reviews widely in patient care.

Today, when medical reviews are still not conducted for everyone, customers using ADD can be seen as privileged in this case.

7. CONCLUSIONS

Patient safety incidents are a challenge that health care must conquer to be able to offer safer medical care to patients. Automated dose dispensing is often promoted to be one solution to patient safety incidents. However, as seen in this study, safety incidents are not black and white. Based on the results I obtained, automated dose dispensing in the long-term professional home care seems to increase patient safety, as it reduces dispensing errors; but it does not solve all the error types. Administration errors are the biggest error type, and mostly they occur due to forgetting to give the medicines to customers, but in some cases, ADD can be the reason for reduction also in these. Since administration errors represent an enormous part of the errors, latent conditions can be assumed to be involved. Administration errors might be avoidable, if the organisation made the working environment and procedures clearer and the instructions easy to follow. This way the employees would have clear instructions to follow and there would probably be less medication errors. If ADD is seen as the only tool to enhance patient safety in home care, it does not fill that requirement. As James Reason said about his Swizz Cheese model, every slice of cheese represents one defence against the potential error and, thus, ADD can be seen as one slice. It does not solve everything, but it helps on the way towards safer medical care.

For future research in this field, it would be interesting to see how administration- and dispensing errors have changed in other health care units when ADD has been introduced, and what kind of dividends between the error types are seen in nursing homes where the surrounding compared to home care is very different.

8. SUMMARY IN SWEDISH, SAMMANFATTNING PÅ SVENSKA

EFFEKTEN AV AUTOMATISERADE DOSDISPENSERING PÅ LÄKEMEDELESSÄKERHETINCIDENTER INOM HEMVÅRDEN

8.1. Introduktion

Patientsäkerhet är en del av kvaliteten och säkerheten i vården, och den kan delas in i vårdsäkerhet och läkemedelssäkerhet. Läkemedelsäkerhet kan delas vidare in i läkemedelssäkerhet och medicineringsäkerhet. Medicineringsäkerhet inkluderar åtgärder för att förebygga, undvika och korrigera avvikelser relaterade till användningen av läkemedel. (Stakes ja lääkehoidon kehittämiskeskus Rohto, 2006; Wittich et al., 2014)

Finland har en patientsäkerhetsstrategi som har skapats för att främja patientsäkerheten. Ett syfte med denna strategi under 2009 var att samla ihop alla avvikelser inom hälsovården och således förbättra patientsäkerheten genom att utreda dessa avvikelser och utveckla sjukvårdens arbetssätt. (Ministry of Social Affairs and Health, 2009)

Medicineringsavvikelser kan vara antingen tillbud eller negativa händelser. Ett tillbud är en incident som kunde ha lett till negativa händelser och som kunde ha orsakat patienten skada. (Stakes ja lääkehoidon kehittämiskeskus Rohto, 2006) WHO definierar en negativ händelse som en incident som resulterar i skada hos en patient och som orsakats av en medicinsk behandling, i motsats till en sjukdom eller komplikation av en sjukdom (World Health Organisation, 2021).

Enligt James Reason och hans teori om avvikelser är avvikelser oundvikliga när mänskliga handlingar är inblandade i processen. Han kategoriserar olika förhållningssätt till avvikelser som personansats och som systemansats. Det personliga förhållningssättet fokuserar på personen som har gjort en avvikelse, och skyller på personen. I systemansatsen ses avvikelser

som konsekvenser och man förstår att de sker även inom de bästa organisationerna. Systemansatsen fokuserar på att hitta orsakerna till avvikelser i organisationens system och ta reda på varför deras skyddsmekanismerna har misslyckats. Reason hävdar att om ett systematiskt tillvägagångssätt är det ledande sättet att hantera avvikelser, kan vi lära oss av misstag och planera säkrare arbetsmetoder. (Reason, 2000)

Reasons schweizerostmodell är ett välkänt exempel på hur avvikelser uppstår (Bild 21). Varje ostskiva representerar en person som gör sitt arbete eller ett försvar mot potentiella fel som påverkar resultatet. Hålen kan orsakas av aktivitetsfel eller förhållanden. En person eller ett misstag leder inte till avvikelser, utan det krävs en kombination av flera avvikelser. Reason hävdar att hålen uppstår i och med aktiva fel och latenta fel. Aktiva fel är riskfyllda handlingar som läkare, vårdare eller farmaceuter har gjort. Några exempel på aktiva fel är att glömma en del av sina arbetsuppgifter, att utföra dem på ett felaktigt sätt, eller att inte följa instruktioner. Aktiva fel har vanligtvis direkt och kortvarig påverkan. Latenta fel uppstår från beslut som har fastställts av ledningen och är relaterade till organisationens sätt att arbeta. Exempel på detta är brist på instruktioner, eller brist på noggrannhet inom organisationen. (Reason, 2000)

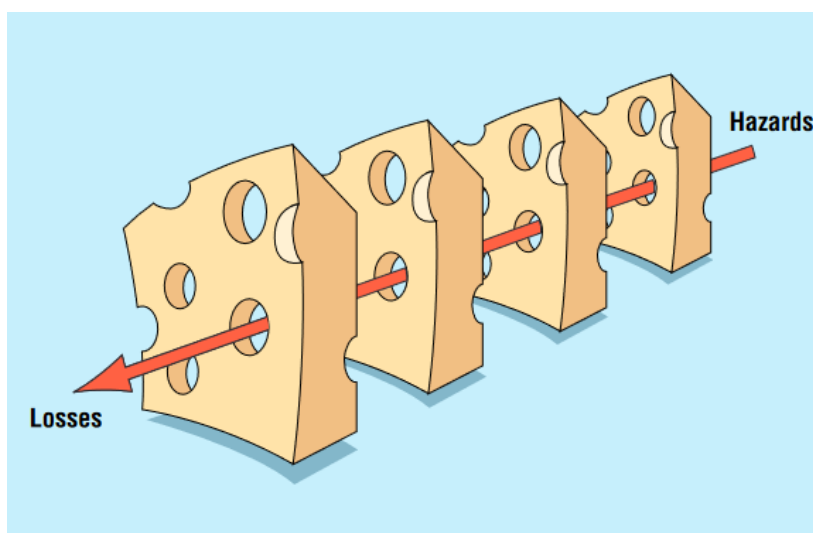


Bild 21. Schweizerostmodellen beskriver hur avvikelser kan uppstå (Reason, 2000).

Medicineringsavvikelser som har förekommit inom hälsovårdsenheter ska rapporteras i HaiPro. HaiPro-rapporter är avsedda för tillbud och negativa händelser som har inträffat på vårdenheter. HaiPro-rapporter bör alltid skickas till arbetsledaren för att hen ska kunna

utvärdera dem. Ledaren lägger till en riskklass och en allvarlighetsgrad som patienten utsattes för.

Automatiserad dosdispensering (ADD) togs i bruk i Finland i början av 2002 (Purasmaa et al., 2002). ADD är den vanligaste och mest använda tjänsten som apoteken erbjuder. Idén bakom den automatiserade dosdispenseringen är att beställa kundens regelbundna medicinering i dospåsar enligt den individuella läkemedelslistan. Dosdispenseringen sker automatiskt och läkemedel beställs för två veckors behov på en gång. ADD bygger på interprofessionellt samarbete mellan sjukvårdsenheter, apotek och dosdispenseringsenheten. Var och en av hälsovårdspersonalen kan ses som en skiva i Reasons schweizerostmodell, som genom professionell skicklighet förhindrar att medicinska avvikelser sker. Enligt Social- och hälsovårdsministeriet är målet med automatiserad dosdispensering att befrämja en lämplig medicinsk behandling och säkerställa patientsäkerheten så att patienten får rätta mediciner vid rätt tidpunkt. (Ministry of Social Affairs and Health, 2016)

Mitt syfte är att undersöka vilka typer av rapporterade avvikelser det finns inom en viss kommuns hemvård och om ADD påverkar dem på något sätt. Denna kommuns hemvård började använda ADD år 2015 och antalet kunder som får sina läkemedel i ADD-påsar har stadigt ökat. Idag finns det 399 kunder som får sina mediciner i ADD-påsar och 10 kunder vars mediciner fortfarande dispenserar i en dosett.

8.2. Resultat

Datan jag använt hade totalt 1262 HaiPro-rapporter rapporterats mellan 2010 och september 2022. I dessa HaiPro-rapporter var 94 % negativa händelser och endast 6 % var tillbud. Största delen, 90 % av avvikelserna var relaterade till administrering (n=1134). Av dessa avvikelser var 4 % tillbud och 96 % negativa händelser. Dispenseringsavvikelser var den näst största kategorin, men kategorin omfattade endast 50 HaiPro-rapporter (4 %) under de senaste 13 åren. Några fall av kommunikations-, dokumentations- och lagringsavvikelser har också rapporterats per år.

Den vanligaste typen av administrationsavvikelser var att mediciner inte överhuvudtaget hade administrerats (n=814). Denna grupp av avvikelser täcker 72 % av alla administrationsavvikelser. Under dessa år från 2015 då ADD har använts inom hemvården har det dessutom varit 34 dokumenterade HaiPro-rapporter där kunden inte har fått båda sina ADD-påsar.

Dispenseringsavvikelser var den näst högsta avvikelseklassen som rapporterades till HaiPro under denna studieperiod. Det finns totalt 50 HaiPro-rapporter. Före 2015, då ADD inte användes så mycket inom hemvården, har alla rapporterade avvikelser berott på att mediciner manuellt har dispenserats felaktigt till en dosett. Efter 2015 då ADD har använts mera, finns det fortfarande avvikelser som gäller manuell dispenserering och ADD. Under dessa år fanns det 19 HaiPro-rapporter relaterade till manuell dispenserering och 7 relaterade till ADD (Bild 22).

Den vanligaste dispenseringsavvikelsen var att läkemedlet inte hade dispenserats. Denna avvikelse representerar 45 % av alla dispenseringsavvikelser. 14 % av dessa fel relaterade till ADD och 86 % till manuellt dispenserade läkemedel. Den näst vanligaste orsaken till HaiPro-rapporter var att den dispenserade dosen var fel. 26 % av dessa avvikelser var relaterade till ADD. Andra typer av avvikelser, till exempel att fel läkemedel har dispenserats eller läkemedel har dispenserats vid fel tidpunkt, var alla relaterade till manuellt dispenserade mediciner. Även om ADD har introducerats till hemvården efter 2015, finns det fortfarande mediciner som bör dispensereras manuellt.

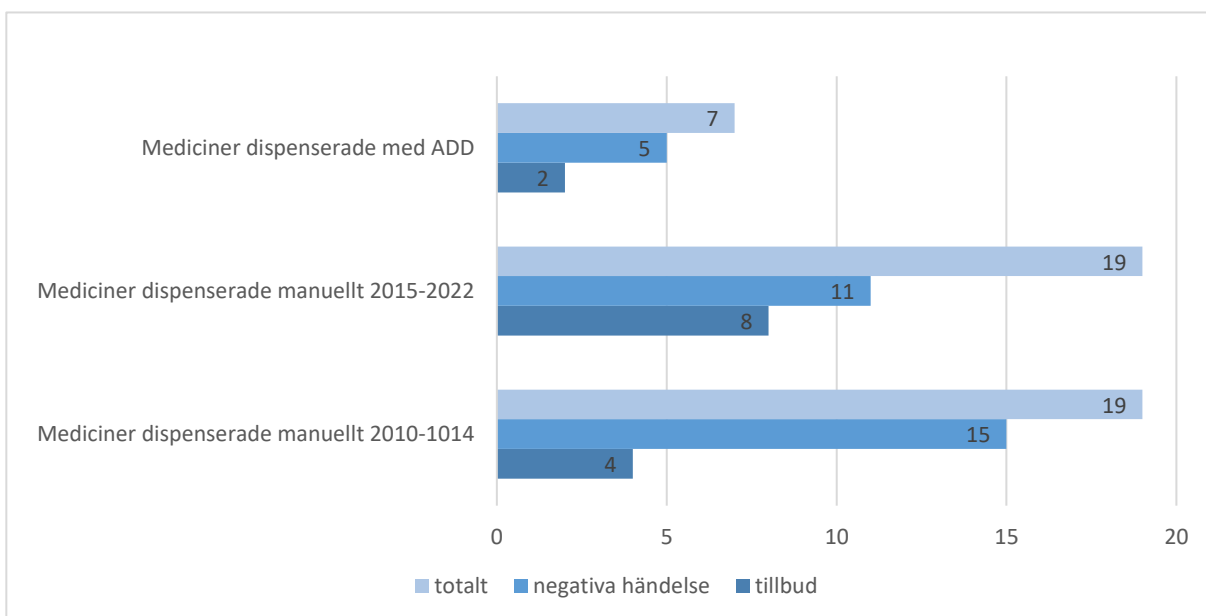


Bild 22. Dispenseringsavvikelser fördelade i tillbud och negativa händelser.

8.3. Diskussion

Resultatet som jag fick skilde sig relativt mycket från tidigare studier om HaiPro-rapporter (Bild 23). Kivimäki upptäckte i sin studie av HaiPro-rapporter i Finlands hemvård (n=61 248) mellan åren 2009–2019 att andelen av tillbud var mycket större, 20 % av alla HaiPro-rapporter, när andelen av tillbud i min studie var endast 6 %. (Kivimäki et al., 2021) I Kuusistos och hennes grupps resultat i studien av Finlands HaiPro-rapporter mellan 2009–2019 (n=321 195) var andelen av tillbud nästan 40 %. Ännu större skillnad ses i Holmströms studie om HaiPro-rapporter mellan 2007–2009 (n=32 592), där andelen av tillbud och negativa händelser var nästan samma. (Holmström, 2017; Kuusisto et al., 2019)

Det kan finnas många anledningar till dessa skillnader. Tillbud lämnas lätt bort från rapporter på grund av till exempel tidsbrist. Tidspressen har rapporterats som en stor utmaning i studier gjorda av de nordiska ländernas hemvård (Martinsen et al., 2018). Det syns också i mitt data som en orsak till avvikelser.

Administrationsavvikelser i denna studie täcker de flesta av alla avvikelser. Det finns ganska olika resultat då man jämför olika studier som har gjorts. I Kuusistos studie omfattade administrationsavvikelser 38 % av alla avvikelser och i Kivimäkis och Holmströms studier fanns det 25 % administrationsavvikelser, då antalet i min studie var 90 % (Holmström, 2017; Kivimäki et al., 2021; Kuusisto et al., 2019).

Läkemedel som inte administrerats alls är den största orsaken till avvikelser i denna kommuns hemvård, dock har antalet läkemedel som inte administrerats minskat från toppåret 2016. Enligt Reasons teori, är avvikelser oundvikliga när mänskliga handlingar är inblandade. Men om orsaken till avvikelse anses komma från organisationens system och inte från enskilda arbetares handlingar, kan instruktionerna justeras och på så sätt minska antalet avvikelser i framtiden. (Reason, 2000)

Det fanns också HaiPro-rapporter om situationer där, förutom ADD, medicin från originalförpackningen inte hade administrerats. Detta är ibland nödvändigt eftersom alla mediciner inte kan dispenserats automatiskt, vilket är en välkänd nackdel med ADD (Ministry of Social Affairs and Health, 2016). Det kan orsaka att närvårdaren inte kommer ihåg att

administrera både en ADD-påse och läkemedel från förpackningar för att de litar för mycket på ADD-processen och inte fokuserar tillräckligt på instruktionerna (Sinnemäki, 2020).

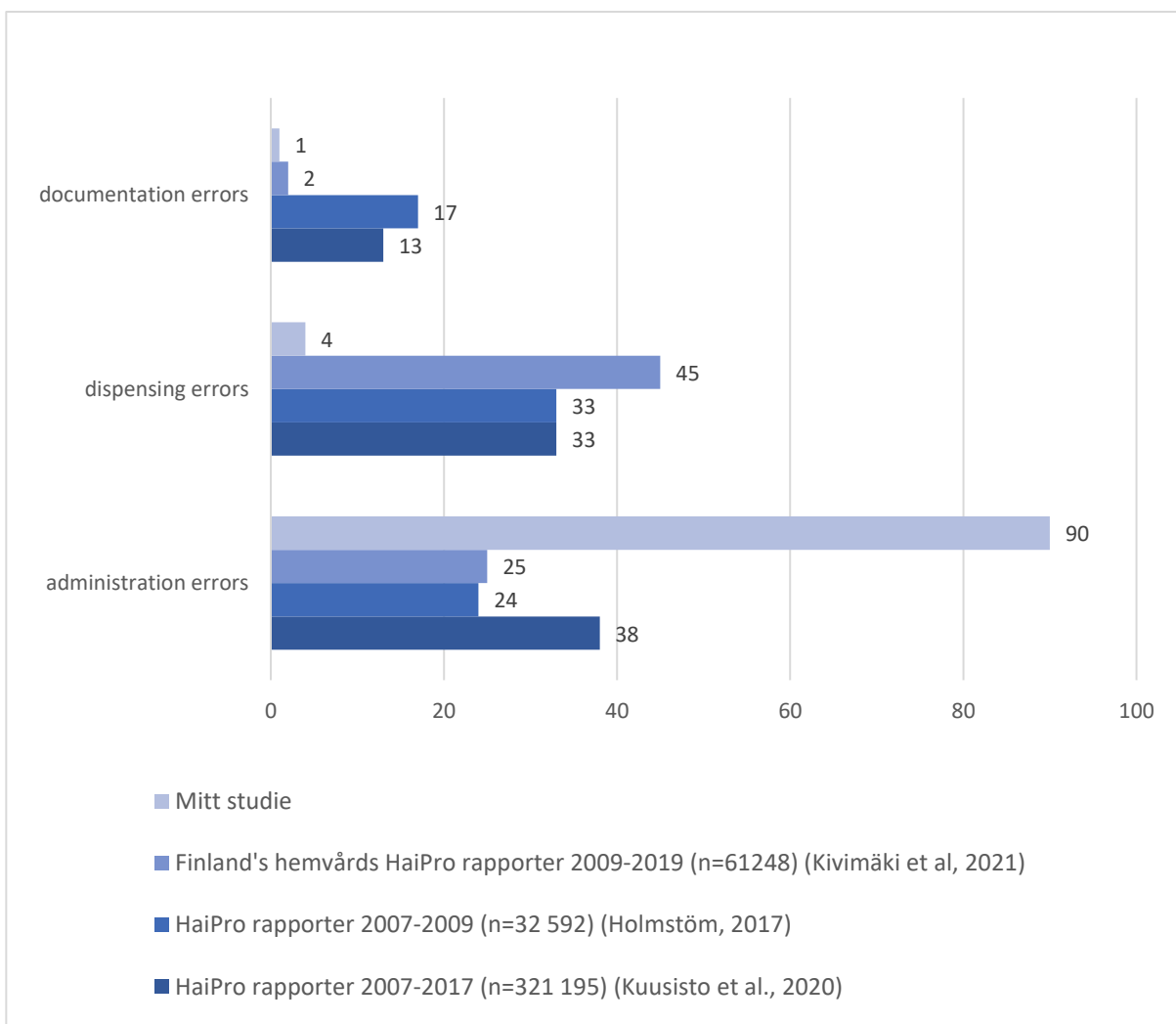


Bild 23. Jämförelse med andra studier.

Dispenseringavvikelser i min studie representerade endast 4 % av alla avvikelser, vilket är en mycket mindre andel än i andra studier (Bild 23). Jag har delat dispenseringsavvikelser i min studie i två skilda delar, beroende på om läkemedel dispenserades manuellt eller automatiskt. Det finns skillnader i antalet avvikelser och orsaker till att fel uppstår. Manuellt dispenserade läkemedel dispenserades ibland på ett mycket komplicerat sätt. Till exempel, hade två veckors mediciner dispenserats i en dosett, så att varken närvårdaren eller kunden visste vilka mediciner som skulle tas. Då man jämför detta med ADD skulle sådana avvikelser inte hända,

för påsar är alltid märkta med ett datum och en tid då medicinerna ska tas. Avvikelse gällande ADD-påsarna berodde mest på att farmaceuten inte hade valt alla läkemedel som skulle dispensereras eller att fel dos har dispenserats. Dessa fel kunde också ha upptäckts om vårdarna jämförde kundens läkemedelslista med ADD-påsarna (Ministry of Social Affairs and Health, 2016). Några av avvikelserna relaterade till ADD hade upptäckts i dessa kontroller. Ingen avvikelse i min studie var relaterad till en ADD-enhet.

8.4. Slutsats

Automatisk dosdispensering rekommenderas oftast för att den kan vara en möjlig lösning för att undvika patientsäkerhetsincidenter. Automatiserad dosdispensering inom hemvården verkar öka patientsäkerheten eftersom det minskar antalet dispenseringsavvikelse. Men som denna studie visar är säkerhetsincidenter ändå inte så enkla. Administrationsavvikelse är det största problemet och i vissa fall kan ADD hjälpa till även i dessa, men oftast beror de på att närvårdaren glömmer att ge mediciner till kunden. Sådana avvikelser kan undvikas om organisationen skapar en anständig arbetsmiljö och rutiner som är lätta att följa. ADD kan inte ses som det enda verktyget för att förbättra patientsäkerheten inom hemvården. Som James Reason visar med sin schweizerostmodell, representerar varje ostskiva ett försvar mot den potentiella avvikelsen, där ADD kan ses som en skiva. Automatisk dosdispensering löser inte alla problem, men den hjälper på vägen till en säkrare medicinsk vård.

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