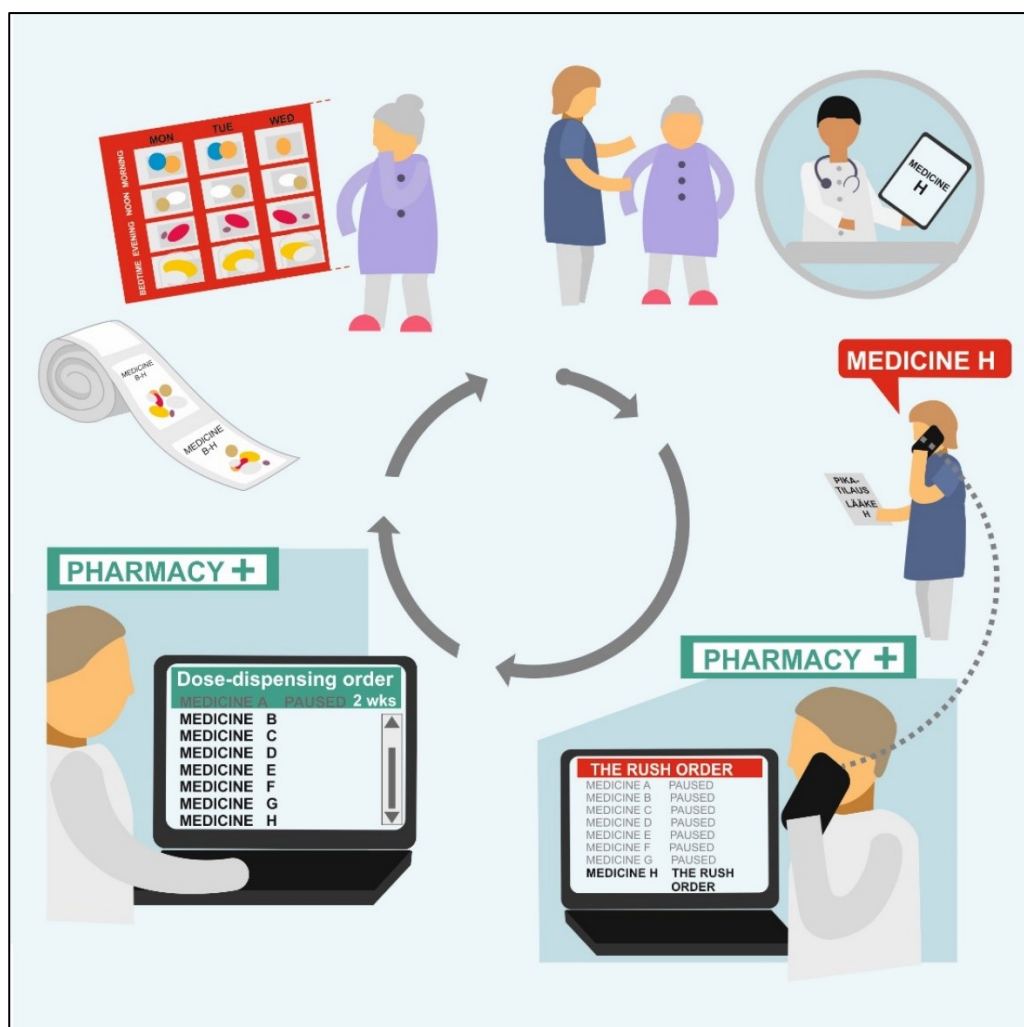




Omission of a dose-dispensed medicine in Satakunta in the spring of 2023



T2023-01

PREFACE

The Safety Investigation Authority, Finland (SIAF) decided, under section 2, subsection 2 of the Safety Investigation Act (525/2011), to conduct an investigation into a medication error that occurred in Satakunta in the spring of 2023, when a dose-dispensed medicine was omitted from a home care patient prescription.

The purpose of a safety investigation is to improve public safety, prevent accidents and hazardous situations, and mitigate the damage caused by accidents. A safety investigation is not conducted in order to allocate legal liability.

The investigation team was led by Alpo Vuorio, MD, PhD, Adjunct Professor, and its other members were Päivi Porkka, MD, PhD, Jari Kotimäki, LLB, LLM and Kari Ylönen, MSocSc. The Investigator-in-Charge was Chief Safety Investigator Hanna Tiirinki.

Petri Pommelin, LicSci (Tech) contributed as an expert in the safety-critical assessment of the pharmaceutical dose-dispensing system.

Krista Laine, MPharm, PharmD acted as a specialist in pharmacy.

A safety investigation examines the course of events, the causes and consequences of the events, the search and rescue actions performed and the actions taken by the authorities. In particular, the investigation determines whether sufficient attention was paid to safety during the activities that led to the accident as well as in the design, manufacture, construction and use of the devices and structures that caused the accident or hazard or were subjected to it. In addition, it is determined whether the management, monitoring and inspection activities were organised and carried out appropriately. If necessary, possible deficiencies in the rules and regulations concerning safety and the authorities must also be investigated.

The investigation report includes an account of the course of the accident, the factors leading to the accident and its consequences, as well as safety recommendations addressed to the appropriate authorities and other instances regarding measures that are necessary in order to promote general safety, prevent further accidents and dangerous situations, prevent damage and improve the effectiveness of the operations of search and rescue and other authorities.

An opportunity to issue a statement on the draft investigation report was reserved for those involved in the accident as well as the authorities in charge of monitoring the sector in which the accident under investigation occurred. Their comments were taken into account when finalising the investigation report. There is a summary of the opinions at the end of this investigation report. In accordance with the Safety Investigation Act, statements by private individuals are not published.

The investigation report has been translated into English by Semantix Oy.

This investigation report and the summary were published on 13 February 2024 on the website of the Safety Investigation Authority, Finland at www.turvallisuustutkinta.fi.

CONTENTS

PREFACE.....	2
1 DESCRIPTION OF THE INCIDENT	5
1.1 Course of events	5
1.2 Alarms and rescue activities.....	6
1.3 Consequences.....	6
2 BACKGROUND	8
2.1 Operating environment, equipment and systems.....	8
2.1.1 The information system used to order dose-dispensed medication.....	8
2.1.2 The dose-dispensing unit and the dose-dispensing machine	9
2.2 Circumstances.....	10
2.3 Recordings.....	10
2.4 Persons and organisations related to the accident as well as safety management	10
2.4.1 The patient.....	10
2.4.2 The home care provider	11
2.4.3 The pharmacy	13
2.4.4 The supplier of the pharmacy management system.....	13
2.4.5 The dose-dispensing unit.....	14
2.5 Preventive measures by the authorities.....	14
2.6 The organisations that participated in the rescue activities and their readiness	16
2.7 Laws, regulations and policies.....	16
2.7.1 Laws and regulations.....	16
2.7.2 The Client and Patient Safety Strategy and Implementation Plan 2022–2026.....	18
2.7.3 The Guide on Good Practices in Patient-specific Dispensing of Medication	18
2.7.4 The Safe Pharmacotherapy Guide.....	20
2.8 Other reports.....	21
2.8.1 The Finnish Medicines Agency’s report on the automated dose dispensing of medicines.....	21
2.8.2 Development of the pharmacy system.....	22
2.8.3 Number of automated dose-dispensing customers	23
2.8.4 Survey for home care operators	24
2.8.5 Automated dose-dispensing survey for pharmacies	26
2.8.6 Patient safety incident reports relating to home care patients’ pharmacotherapy 31	
2.8.7 The National Medication Safety Programme of Community Pharmacies in Finland 32	
2.8.8 Patient safety incidents involving automated dose dispensing at pharmacies.....	32

2.8.9 Safe Pharmacotherapy Toolkit.....	36
2.8.10 National medication lists.....	36
3 ANALYSIS.....	38
3.1 Event analysis	38
3.1.1 The initiation of the dose dispensing of medicines and the first ten months.....	38
3.1.2 The pausing of the medicine	39
3.1.3 The checking of the dose-dispensed medicines at the pharmacy	40
3.1.4 The checking of the dose-dispensed medicines by the home care team	40
3.1.5 The patient not getting his/her medicine and ending up in hospital	40
4 CONCLUSIONS	42
5 SAFETY RECOMMENDATIONS.....	44
5.1 Identification of medication safety requirements for information systems that are used in dose dispensing	44
5.2 Sharing and learning from pharmacies' medication safety incidents.....	44
5.3 Improvements in the self-regulation of pharmacies.....	45
5.4 Revision of national dose-dispensing guidelines	45
5.5 Measures that have been taken.....	46
BIBLIOGRAPHY	47
SUMMARY OF STATEMENTS REGARDING THE DRAFT INVESTIGATION REPORT.....	49

1 DESCRIPTION OF THE INCIDENT

1.1 Course of events

The homecare¹ team of the Wellbeing Services County of Satakunta in south-west Finland had a patient in their 90s who was living in their own home. The patient received most of the medicines that had been prescribed for them in plastic unit-dose bags, prepared using a dose-dispensing² machine. The pharmacy ordered the medicines from the dose-dispensing unit of a pharmacy that had an automated dose-dispensing licence³, for two weeks at a time.⁴ An order based on a medication list supplied by the home care provider was placed with the dose-dispensing unit of the pharmacy that had an automated dose-dispensing licence once a fortnight on a Wednesday. Pouches containing the medicines were delivered by the dose-dispensing unit to the pharmacy on the following Monday, from where a member of the home care team collected them and took them to the home care provider's offices. A registered nurse employed by the home care provider checked the pouches whenever any changes had been made to the patient's medication. A member of the home care team took the pouches to the patient's home and placed the medicines in a dosette box containing a week's worth of medication. The patient took their medication with the home care worker's assistance.

A doctor employed by the home care provider prescribed a new medicine for the patient, which the doctor felt had to be started without delay. The patient was started on the new medicine that same day, dispensed from a regular package. The following Monday, a decision was made to incorporate the new medicine into the patient's automated dose-dispensing regimen. The registered nurse employed by the home care provider called the pharmacy and asked for a rush order on the medicine. The pharmacy put the rush order through the same dose-dispensing information system that it used for the two-week batches of medication. The rush order was made in a way that required all of the patient's existing medications to be paused in the information system before the new medicine could be ordered. The existing medications were paused in the information system, and an order was placed for the new medicine to be supplied in dose-dispensing pouches.

The rush order arrived at the pharmacy, packaged into dose-dispensing pouches, the day after the order was placed, i.e., one day before the start of the next two-week dose-dispensing period. An employee of the home care provider collected the dose-dispensing pouches that same day. The pouches were found to be consistent with the rush order, and they were taken to the patient. As of the start of the new dose-dispensing period that began the following day, the patient was getting all the medicines that had been previously supplied for the two-week period in question as well as the new medicine that had been delivered as a rush order.

Halfway through this new dose-dispensing period, the pharmacy placed an order for the medications needed for the next dose-dispensing period. This involved reactivating the dose dispensing of medicines that had been previously paused in the information system in connection with the rush order. One of the medicines that the patient had been taking regularly was left out during the reactivation process and was consequently left out of the order.

¹ 'Home care' refers to a combination of home-based nursing and other home-based services.

² 'Dose dispensing' refers to pharmacies supplying the tablets or capsules that a patient regularly takes in single doses, usually for two weeks at a time. The sorting of the medication into single doses can be done by a machine or by hand.

³ Automated dose dispensing is subject to a licence and covers the packaging of medicines into single doses, quality control and documentation.

⁴ A timeline of the events is shown in Figure 1.

The ordered pouches arrived at the pharmacy as normal the following Monday. The pouches were checked at the pharmacy and found to be consistent with the list of dispensed medicines⁵ that accompanied the pouches. However, the check-up process concentrated on the new medicine requested as a rush order - no problem related to this medicine was detected. A member of the home care team collected the pouches and took them to the home care provider's offices. As the team knew about the change in the patient's medication that had been put through as a rush order, they focused their checks on this change and on ensuring that all was correct in that respect. The fact that one medicine was missing went unnoticed, and the patient consequently started s/he next dose-dispensing period without that medicine.

Not quite two weeks later, the patient's health deteriorated. The patient used a personal alarm to call for help. A member of the home care team arrived to check on the patient and called emergency services.

1.2 Alarms and rescue activities

The emergency dispatcher sent an ambulance to the patient's home. The ambulance took the patient first to the local health centre and then to hospital. The hospital staff were unaware that the patient had been for almost two weeks without one of the medicines that had been prescribed for her/him. The registered nurse employed by the home care provider compared the medicines that had been given to the patient against the patient's medication list, realised that one medicine was missing and reported this to the hospital. The patient died in the hospital two days after her/his admission.

1.3 Consequences

The patient, who had been a client of home care services, died. The forensic autopsy was unable to establish a connection between the omitted medicine and the patient's death.

⁵ Each dose-dispensed order is delivered with a list of the medicines that are included in the order.

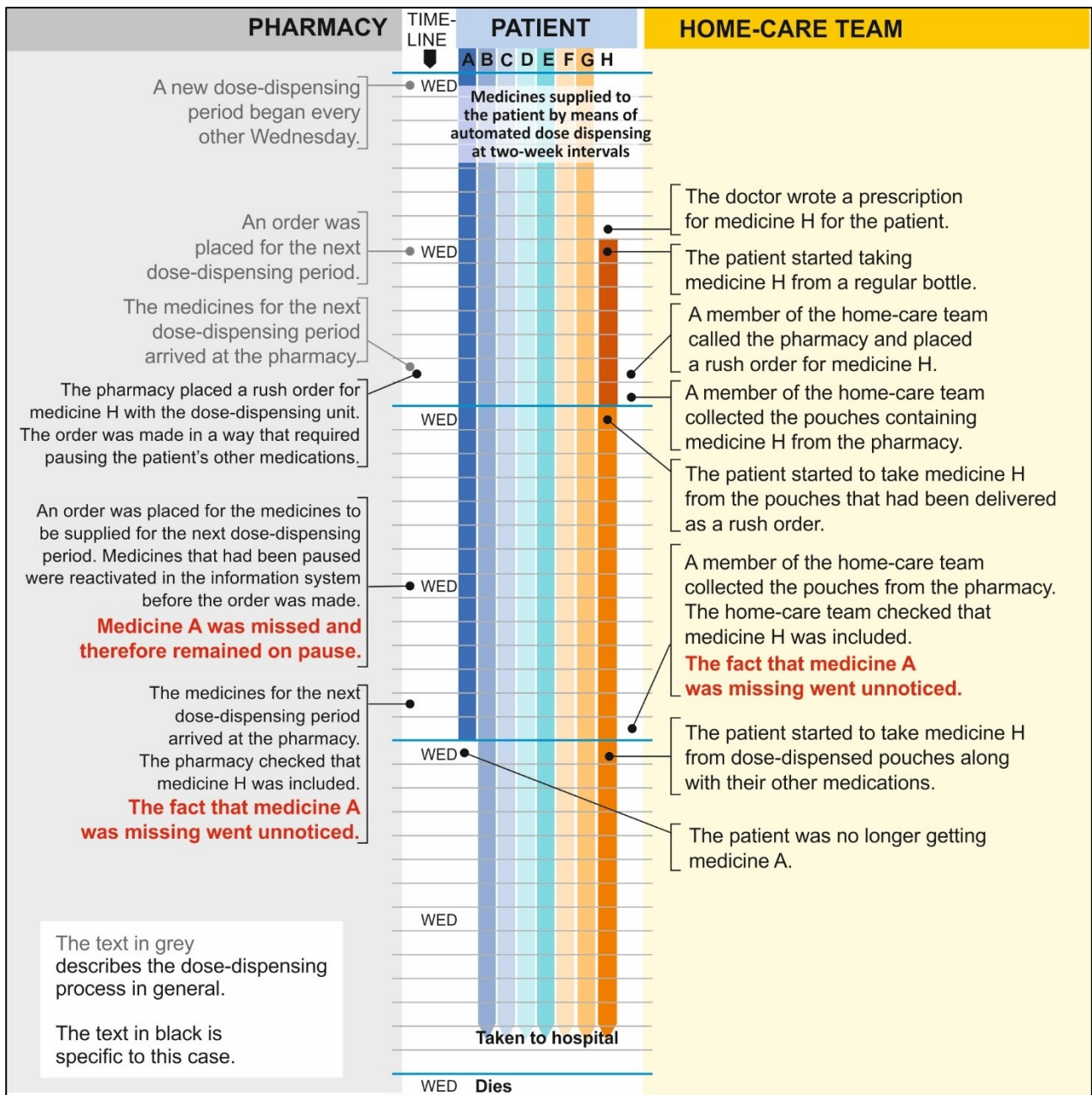


Figure 1. Events relating to the omission of a home-based patient’s dose-dispensed medicine across a six-week timeline covering three two-week dose-dispensing periods. (Image: SIAF)

2 BACKGROUND

2.1 Operating environment, equipment and systems

2.1.1 The information system used to order dose-dispensed medication

The order process for automated dose dispensing begins when the client of the dose-dispensing service, i.e., a home care provider, a nursing home or a private customer, places a dose-dispensing order with a pharmacy that provides a dose-dispensing service. A patient's suitability for automated dose dispensing is always assessed before s/he can be added to the scheme, by examining, for example, the patient's entire medication.

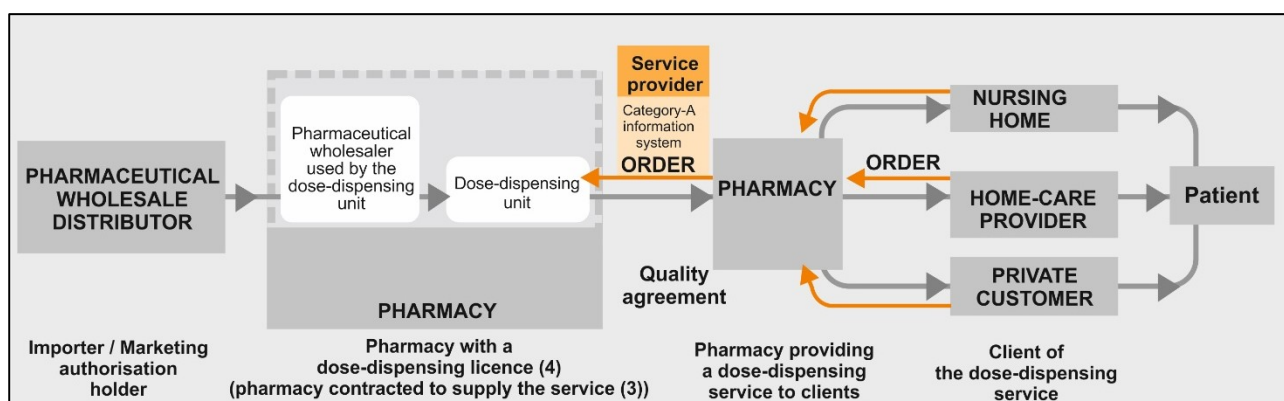


Figure 2. Operators involved in the automated dose dispensing of medicines, shown in the order in which a dose-dispensed medicine makes its way from a pharmaceutical wholesaler to the patient. The steps involved in ordering the medicine are shown in orange. (Image: SIAF. The image is based on an illustration featured in the Finnish Medicines Agency's publication 7/2022: *Current state and development needs of automated dose dispensing of medicines.*)

A client of the dose-dispensing service places an order for medication with a pharmacy that provides a dose-dispensing service as agreed with the pharmacy. The pharmacy may be either given a full list of the patient's medications or just told about any changes in connection with the order. The information can be submitted to the pharmacy, for example, on paper printout or using secure email.

The pharmacy uses a special dose-dispensing information system to send the order through to the information system of the dose-dispensing unit of a pharmacy that has an automated dose-dispensing licence. Orders received from clients cannot be uploaded to the system digitally; the information has to be entered manually.⁶ The information system used to place orders is part of a wider digital information system used by pharmacies. The information system supplier has classified the system as *Category A* pursuant to the relevant regulation⁷ of the Finnish Institute for Health and Welfare.

The information system supplier has its own private online environment that the pharmacy can access. The online environment contains, among other resources, a user manual for the

⁶ The details given here concerning the dose-dispensing process and the information system used by the pharmacy are specific to the dose-dispensing unit and the system of the pharmacy involved in this case. Other operators may have different systems.

⁷ Finnish Institute for Health and Welfare (2021): *Regulation on the classification and certification of information systems in social welfare and health care*, Regulation 4/2021 of the Finnish Institute for Health and Welfare.

system, in addition to which the environment is used to inform clients who use the information system about system maintenance and other updates.

The order process starts by selecting the dose-dispensing client in the information system and then picking the medicines to be dispensed in their pouches from a list. The system checks in real time whether each requested medicine is in stock for dose dispensing, whether the requested dose is possible and whether there is a valid electronic prescription. The medicines that have been added to the order appear as a vertical list in a panel to the left of the screen, arranged in alphabetical order by product name. Approximately eight products are visible at a time, depending on the size of the screen. The others are hidden above or below the visible list and can be viewed by scrolling up or down. The order in which the products are displayed is not affected by any medicines that are included in the dose-dispensing regimen but that have been paused; these products appear in their usual place in the alphabetical list. Dose-dispensed medicines are usually ordered for two weeks at a time⁸.

A rush order refers to a dose-dispensing order placed outside of the usual two-week ordering interval. A rush order makes it possible to request the supply of a new medicine in its own pouch within the same day.

According to the information system supplier's instructions, rush orders for individual medicines should primarily be made anonymously. In practice, this means that the order is placed using the product code and not the patient's personal information. This simplifies and speeds up the order process. The requested medicine is supplied pre-packaged into one or more pouches showing the product code. It is up to the pharmacy to match the medicine to the patient.

Rush orders can also be placed using the patient's information. To do this, however, all the medicines that are included in the patient's regular dose-dispensing order and that the pharmacy does not wish to include in the rush order must be paused in the system. If the medicine added on the medication in a rush order is a new one, it must be added to the list; if the medicine is one that has been previously paused, it must be reactivated in the system. All the medicines on the list that are not on pause when the order is submitted will be included in the order. The option of placing a rush order using the patient's information is designed to be used, for example, if a patient is being discharged from a hospital and is resuming her/his previous pharmacy-supplied dose-dispensed regimen at home. This way, when the order arrives, the medicines to be taken at different times are all in their own pouches and the pouches are labelled with the patient's information.

The information system supplier does not collect statistics on which method is used to place rush orders.

2.1.2 The dose-dispensing unit and the dose-dispensing machine

The information entered into the dose-dispensing unit's information system is sent to the system that controls the dose-dispensing machines. A single dose-dispensing machine can hold up to 400 different pharmaceutical products. The medicines are stored inside cassettes, which are filled manually. The details of the medicines to be placed inside the cassettes are entered into the system using the bar codes and 2D codes recorded on the product packaging. The sorting of the medicines into pouches is an automated process.

⁸ The two-week period is based on the Social Insurance Institution of Finland's guidelines (2021) on the reimbursement of dose-dispensed medicines, which stipulate that a quantity that differs from two weeks' worth of medication can only be authorised for special reasons.

The dose-dispensing machine identifies the cassettes based on an RFID tag⁹ located on the bottom of each cassette. When an order comes in, the machine begins to dispense the medicine into pouches that the machine makes from a roll of plastic using a heat sealer. The number of pouches to be prepared depends on the number of single doses that the patient is to take per day and the length of the period for which medication is being dispensed. A single pouch can contain up to nine different pharmaceutical products. If more doses are needed, the machine prepares multiple pouches. On each pouch, the machine records the patient's personal information, when to take the medication, details of the pharmaceutical products contained in the pouch, as well as a bar code that can be scanned using, for example, a mobile application to identify the contents.

The strip of pouches is then moved into a machine-vision inspection device. The inspection device reads the bar codes on the pouches and takes a picture of the contents of each pouch. The device uses the bar codes to retrieve the order from the system and then compares the pictures against the order and the sample images of medicines that have been taught to the system. If the device is able to establish that a pouch contains the right quantity, based on the order, of the correct pharmaceutical products, corresponding to the sample images, the pouch passes the inspection. If the device detects an error, such as if a pouch contains the wrong medicine or the wrong quantity of medicine, or if the medicine cannot be identified based on the sample images, the pouch is sent to a manual inspection.

A list of dispensed medicines, which itemises the contents of each pouch in the strip of pouches, accompanies each delivery and acts effectively as a despatch note. The dose-dispensing unit cannot access patients' prescriptions and can only check that its deliveries match the orders received from the pharmacy.

The dose-dispensing unit does not collect statistics on which method is used to place rush orders. It is the understanding of the dose-dispensing unit that orders for individual medicines are usually made anonymously, although there are also orders that are made using the patient's information.

2.2 Circumstances

The pharmacy received the rush order on a day when the pharmacist was not scheduled to place dose-dispensing orders. The day on which the pouches were delivered was a regular day at the pharmacy in terms of workload.

The day on which the home care provider received the medicines was a regular day for the home care team in terms of workload.

2.3 Recordings

No recordings were available for the investigators.

2.4 Persons and organisations related to the accident as well as safety management

2.4.1 The patient

The patient was a client of home care services who had multiple chronic health conditions and had been prescribed eight medications that were suitable for dose dispensing. The patient's

⁹ RFID (Radio Frequency IDentification) refers to technology that can be used to read and record information remotely using RFID tags. RFID tags can be attached to products using, for example, stickers.

medication list also included several medicines that were not suitable for dose dispensing or that the patient had been instructed to only take when required. The patient was unable to take his/her medication straight from the pouches, which was why home care workers took the medicines out of the pouches and placed them in a dosette box containing a week's medication at a time. The patient was able to take his/her medication from the dosette box without assistance. The patient lived alone in his/her own home, and home care workers visited the patient daily. The patient also had help from his/her family.

The patient had been registered in the dose-dispensing scheme in March 2022. No record on whether the patient's suitability for the dose dispensing scheme had been assessed or not could be found. The patient records include an entry made by a doctor about the switch to dose dispensing as well as a note about the updating of the patient's electronic prescriptions to make them compatible with dose dispensing. The patient had been admitted to hospital due to a sudden illness in the autumn of 2022. Some of the patient's regular medication had been put on hold at that time, as his/her health had deteriorated. A total of 14 changes had been made to the patient's dose-dispensed medication regimen over a period of less than a year, and half of these changes were related to a single medicine.

2.4.2 The home care provider

The home care provider was the Wellbeing Services County of Satakunta in south-western Finland. The Wellbeing Services Counties were established at the beginning of 2023, when the responsibility for organising health care, social welfare and rescue services was transferred from municipalities and joint municipal authorities to wellbeing services counties. In practice, the provision of services initially continued as before.

The home care organisation was made up of teams. The team responsible for the patient in this case had a total of approximately 40 clients. The team employed one registered nurse, who was responsible, among other things, for administering and monitoring patients' medication together with registered nurses. The registered nurse visited patients as required, at least once a week in most cases. In addition to the home care team's regular clients, the registered nurse had short-term patients who needed, for example, wound dressing or blood tests. In addition to the registered nurse, the team employed ten practical nurses, who visited clients in accordance with their personal treatment, rehabilitation and service plans. Each client had their own registered nurse.

The home care provider had a self-regulation policy¹⁰. The policy included, for example, procedures for dealing with feedback from clients, identifying and addressing risks and non-conformances and organising clients' health care and medical care.

According to the home care pharmacotherapy policy of the Wellbeing Services County of Satakunta, the pharmacotherapy needs of home-based patients must be reviewed by a registered nurse, employed by the home care provider together with the patient's doctor and the pharmacy, before dose dispensing begins and once a year thereafter. According to the policy, the final decision on a patient's suitability for dose dispensing and whether or not to switch him/her to dose dispensing rests with the registered nurse of the relevant home care team.

¹⁰ Social Welfare Act (1301/2014), section 47. The self-regulation policy that was in place at the time of the events discussed in this report had been drawn up by the municipal organisation that had been responsible for home care before the health and social services reform. The policy complied with the National Supervisory Authority for Welfare and Health's regulation (1/2014).

A hospital ward pharmacist was working at the local health centre, who was also available for external consultations. The hospital pharmacist was responsible for coordinating pharmacotherapy policies, drawing up pharmacotherapy guidelines, training staff, as well as reviewing and updating medication lists. The hospital pharmacist carried out pharmacotherapy assessments and reviews for clients of various service providers, such as the health centre's inpatient ward and the home care organisation. The home care organisation had not identified any particular criteria for when the hospital pharmacist should be consulted. When an assessment was considered necessary, the registered nurse employed by the home care provider would send a message to the hospital pharmacist via the Lifecare patient information system¹¹. The pharmacists would record their assessment in the notes section of the Pharmacy (FARM) tab in the Lifecare system and make a note in the medication list in the system to indicate that the patient's medication had been reviewed. Assessments by the hospital pharmacist were typically requested, for example, in the case of patients who were about to be switched to dose dispensing. There was no systematic practice of referring patients who were about to be switched to dose dispensing to the hospital pharmacist, however. Any suggestions that the pharmacist made to the patient's medication were forwarded to the patient's doctor. The hospital pharmacist was not involved in the assessment of patients' suitability for dose dispensing or in monitoring dose dispensing.

According to the Wellbeing Services County's pharmacotherapy policy, the home care organisation has access to a hospital pharmacist, who conducts checks on medication and provides information and advice on pharmacotherapy. The goal is for each home care client to have their medication reviewed by a hospital pharmacist or a community pharmacist once a year.

The Wellbeing Services County, including the home care organisation, uses a web-based tool called HaiPro¹² for reporting patient safety incidents.

The patient's pharmacotherapy was the responsibility of their local home care doctor, who worked closely with the registered nurse employed by the home care provider. The patient's medications were listed in the Lifecare patient information system.

One of the general practitioners employed by the local health care had been designated as a home care doctor, and it was this doctor who mostly dealt with home care consultations. The everyday work of the home care doctor had not been essentially affected by the organisational reform and the establishment of the Wellbeing Services County. The availability of qualified doctors in the area was relatively good. Shopping service doctors had been used for out-of-hours consultations and occasionally to substitute for regular members of staff.

Automated dose dispensing was used by both the local mental health clinic and the home care organisation. Any issues with dose dispensing were referred to the doctor as consultation requests. In most cases the issue related to anomalies in a patient's medication or prescriptions. Whenever a new patient was enrolled in the dose-dispensing scheme, the doctor would review his/her medication list. The doctor also wrote the prescriptions for the medicines that were to be dose dispensed. Issues with the availability of medicines and the consequent need to change prescriptions created considerable extra work for the doctor. The person who most often contacted the doctor was the registered nurse from the home care team. Pharmacy staff rarely called the doctor directly.

¹¹ Lifecare is a patient information system developed by Tietoevry Corporation.

¹² HaiPro is just one of the technological aids used to report client and patient safety incidents. It is designed to promote continuous improvement. The system was developed by Awanic Ltd.

The process of enrolling an individual patient in the dose-dispensing scheme was usually initiated in connection with a needs assessment. Sometimes the suggestion first came from the registered nurse employed by the home care provider and sometimes from the patient's family or their doctor. A note would be made in the medication list in the Lifecare information system to indicate that the patient was enrolled in the dose-dispensing scheme. The regional specialist medical care organisation used the same information system, which meant that any changes made to a patient's medication by a specialist showed up in the information system. If the specialist had written the prescriptions in a way that was compatible with dose dispensing, the change in the patient's medication was not necessarily communicated to the home care doctor but was sent directly to the pharmacy, which would then place the dose-dispensing order.

2.4.3 The pharmacy

The pharmacy involved in the investigated case has been providing an automated dose-dispensing service locally for more than ten years. The pharmacy and the pharmacy contracted to supply the dose-dispensing service had signed a quality agreement.

The pharmacy worker who was responsible for placing and receiving dose-dispensing orders had the appropriate qualifications and was highly experienced. S/he had been trained to handle dose-dispensing orders by his/her predecessor.

The pharmacy had a policy in place for ordering and delivering dose-dispensed medication. According to the policy, all changes to a patient's medication are recorded on a patient-specific form. The policy explains that rush orders can be made both anonymously and by using the patient's information, in which case the patient's other medications need to be paused in the ordering system. The pharmacy had long been following the practice of making rush orders using the patient's information and pausing the patient's other medications. The pharmacy had access to the dose-dispensing unit's private online environment, where the pharmacy could check the contents of orders and whether they had been received.

The pharmacy participates in the National Medication Safety Programme of Community Pharmacies in Finland¹³ and uses the HaiPro system to report medication safety incidents.

2.4.4 The supplier of the pharmacy management system

The supplier of the pharmacy management system is one of the biggest suppliers of pharmacy systems in Finland. All components of the pharmacy system used by the pharmacy involved in this case are certified in accordance with the relevant regulation¹⁴ of the Finnish Institute for Health and Welfare. The certification covers joint testing and an information security assessment, and it was performed by an external certification organisation. The information system supplier has had its information system entered into the National Supervisory Authority for Welfare and Health's information system database and has its own quality management system.

¹³ The National Medication Safety Programme of Community Pharmacies in Finland (VALO) is an initiative launched by the Association of Finnish Pharmacies and the Finnish Centre for Client and Patient Safety in 2022, which aims to improve outpatient medication safety through better cooperation between pharmacies and wellbeing services counties.

¹⁴ Finnish Institute for Health and Welfare (2021): *Regulation on the classification and certification of information systems in social welfare and health care*, Regulation 4/2021 of the Finnish Institute for Health and Welfare.

2.4.5 The dose-dispensing unit

The dose dispensing unit involved in this case is a well-established and experienced provider of dose dispensing services. It is one of the largest units in Finland. The unit has its own quality management system.

According to the dose dispensing unit's statistics, approximately five per cent of the single-dose pouches it prepares are inspected manually. The dose-dispensing machine's inspection device sends a pouch for a manual inspection if the picture of the medicine inside is not a 100% match to the sample image taught to the machine-vision system. Approximately 93% of these are false alarms. The machine vision system cannot read the picture and sends the pouch for a manual inspection if, for example, tablets lie on top of each other in the pouch. The remaining approximately seven per cent of the pouches that are sent for a manual inspection have anomalies. This equates to approximately 0.35% of all pouches.

Mistakes – as in the wrong medicine or too much or too little medicine – are found in one out of a million single-dose pouches supplied by the dose dispensing unit. The dose dispensing unit receives patient safety incident reports concerning these anomalies from the pharmacies to which it delivers the pouches, which check the pouches before handing them over to the buyer. According to the dose dispensing unit, the most common reason for these kinds of anomalies is human error in connection with manual inspection. Incidents in pouches count as product defects, which both the receiving pharmacy and the supplier should report to the Finnish Medicines Agency.

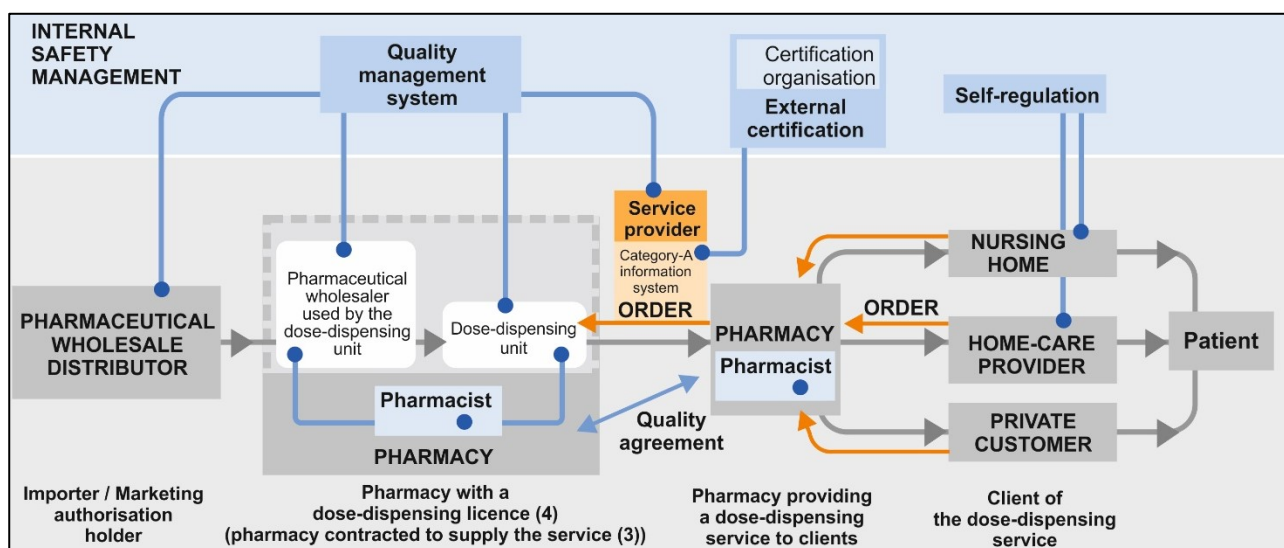


Figure 3. Safety management systems and self-regulation procedures of the operators involved in the automated dose dispensing of medicines are shown in blue. (Image: SIAF. The pharmaceutical supply chain is shown in the image based on an illustration featured in the Finnish Medicines Agency's publication 7/2022.)

2.5 Preventive measures by the authorities

The Ministry of Social Affairs and Health is responsible for the general oversight, organisation, development and supervision of health care and social services. The Ministry is also in charge of drafting healthcare and social welfare legislation.

The Finnish Medicines Agency is responsible for licensing and supervising pharmaceutical wholesalers. Its supervisory duties consist of regular audits and quality control of medicines

that are available on the market. Matters relating to pharmaceutical wholesalers are the responsibility of the *GxP* division¹⁵ of the *Licenses and Inspections* unit, which is part of the *Supervision and Availability* department.

The Finnish Medicines Agency also licenses and supervises pharmacies. Its supervisory duties in this context include providing guidance to operators, licensing and notification procedures, requests for information and pharmacy inspections. Matters relating to pharmacies are the responsibility of the *Pharmacy and Drug Control* division.

The Finnish Medicines Agency conducts regular checks on pharmacies that have an automated dose-dispensing licence. The Finnish Medicines Agency also carries out audits on pharmacies that routinely provide a dose-dispensing service to clients as part of its pharmacy controls.

The Finnish Transport and Communications Agency has oversight of certification organisations that perform certification of healthcare information systems.

The Regional State Administrative Agency oversees the provision of health care and social services on a regional level, ensures the legality of services that the wellbeing services county has a duty to provide and provides guidance on enforcement. Enforcement cases can be opened based on, for example, a whistleblowing report or the Regional State Administrative Agency's own observations. The Regional State Administrative Agency's role in supervising organisations covers organisational issues such as the number and structure of personnel, the standard and scope of care and services as well as practical aspects of pharmacotherapy. Enforcement cases can usually be resolved by means of a documentary inspection, but physical inspections can also be carried out if necessary.

The National Supervisory Authority for Welfare and Health oversees Regional State Administrative Agencies in the implementation, coordination and harmonisation of their enforcement and guidance duties. The National Supervisory Authority for Welfare and Health also oversees the provision of health care and social services on a national level, ensures the legality of services that wellbeing services counties have a duty to provide and provides guidance on enforcement in certain circumstances, such as if a case involves an important matter of principle or has far-reaching implications, or if several Regional State Administrative Agencies or the whole country are affected. The National Supervisory Authority for Welfare and Health also keeps a database of healthcare and social welfare information systems.

¹⁵ The GxP division is responsible for GMP (*Good Manufacturing Practice*), GCP (*Good Clinical Practice*), GLP (*Good Laboratory Practice*) and GDP (*Good Distribution Practices*).

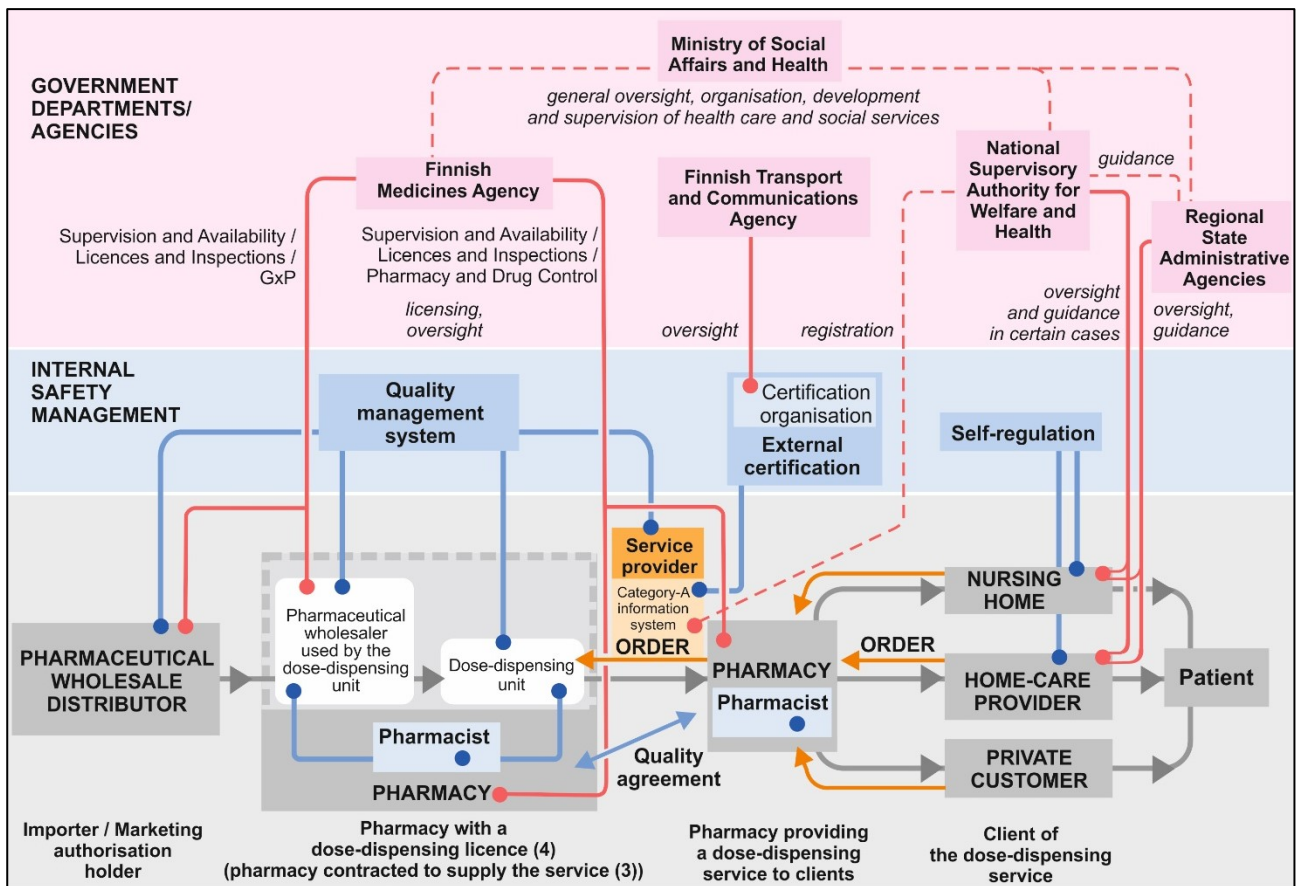


Figure 4. The role of government departments/agencies in providing guidance and oversight of the operators involved in the automated dose dispensing of medicines is shown in red. (Image: SIAF. The pharmaceutical supply chain is shown in the image based on an illustration featured in the Finnish Medicines Agency’s publication 7/2022.)

2.6 The organisations that participated in the rescue activities and their readiness

The local emergency medicine provider was the Wellbeing Services County of Satakunta.

2.7 Laws, regulations and policies

2.7.1 Laws and regulations

The Social Welfare Act¹⁶ defines ‘home care’ as personalised care and nurturing according to the client’s needs, activities that promote and maintain functional capacity and interaction, other activities that help the client to cope as well as home nursing within the meaning of the Health Care Act¹⁷, which the law defines as being part of primary health care. All healthcare providers have a legal obligation to draw up a written quality control and patient safety policy¹⁸. According to the Safe Pharmacotherapy Guide¹⁹, the policy must include a pharmacotherapy plan.

¹⁶ 1301/2014.

¹⁷ 1326/2012.

¹⁸ This legal obligation (section 8, subsection 3) was removed from the law at the end of 2023 when the Act on Supervision in Social and Health Services (741/2023) entered into force.

¹⁹ Ministry of Social Affairs and Health (2021): *Safe Pharmacotherapy – Guide to producing a pharmacotherapy plan*, Publications of the Ministry of Social Affairs and Health 2021:6.

The Medicines Act²⁰ stipulates that automated dose dispensing can only be performed in connection with a pharmacy. A dose-dispensing licence from the Finnish Medicines Agency is required. Pharmacists can outsource automated dose dispensing to another, licensed pharmacy based on a contract. Pharmacies are only permitted to perform automated dose dispensing if their staff are sufficiently familiar with the system and they have the required facilities and equipment. Good pharmaceutical manufacturing practices must be observed as appropriate.

The Finnish Medicines Agency's Regulation²¹ stipulates that a pharmacy employee with either a bachelor's or a master's degree in pharmacy checks all medicines procured by means of automated dose dispensing before they leave the pharmacy. The checks involve making sure that the dose-dispensed medication matches the patient's prescription and that the medicines have been sorted correctly by inspecting, for example, the pouches for the first day. It is the pharmacy's duty to ensure that the medicines have been ordered from the dose-dispensing unit correctly and that no medicines that the patient absolutely needs have been omitted from the order. Any changes that have been made to the patient's medication as a matter of urgency must be given particular attention.

The Finnish Medicines Agency's Regulation²² specifies that the regulations governing contract manufacturing also apply to quality control in the context of any outsourced services relating to pharmaceutical manufacturing. Contract manufacturing in pharmacies requires a licence from the Finnish Medicines Agency. Contract manufacturing is based on a written quality agreement signed between the contracting entity²³ and the manufacturer²⁴, which lays down, in sufficient detail, the specifics of the work and the obligations, responsibilities and rights of the parties.

The Act on the Electronic Processing of Client Data in Healthcare and Social Welfare²⁵ stipulates that all information systems that are used to process client data must satisfy essential interoperability, data protection, information security and functional requirements. Information systems used by service providers must fit the purpose of the service provider's operations and satisfy essential requirements relating to the service provider's operations. Essential functional requirements are deemed to be satisfied if the information system is capable of performing the functions required under the applicable laws and regulations to process client and patient data for the intended purpose of processing. More detailed regulations on essential requirements and which essential requirements must be satisfied by information systems used in the context of different services are issued by the Finnish Institute for Health and Welfare.

A new law, called the Act on the Processing of Client Data in Healthcare and Social Welfare²⁶, entered into force at the start of 2024 and repealed the aforementioned Act. The new Act incorporates the aforementioned provisions of the repealed Act. It also specifies that information systems used by pharmacies must fit the purpose of pharmacies' operations and satisfy essential requirements relating to the operation of pharmacies.

²⁰ 395/1987.

²¹ Finnish Medicines Agency (2016): *Supplying Medicines*, Regulation 2/2016 of the Finnish Medicines Agency.

²² Finnish Medicines Agency (2011): *Manufacturing Medicinal Products in Pharmacies*, Regulation 6/2011 of the Finnish Medicines Agency.

²³ A pharmacy providing a dose-dispensing service to clients.

²⁴ A pharmacy contracted to produce dose-dispensed pouches.

²⁵ 784/2021. The Act was in effect until the end of 2023.

²⁶ 703/2023.

According to the government proposal²⁷, ‘functionality’ also includes the usability of information systems. This means that the individuals who use an information system should be able to use the system or software in the manner intended and instructed by the manufacturer based on the instruction and training given.

2.7.2 The Client and Patient Safety Strategy and Implementation Plan 2022–2026

A Government Decree²⁸ makes the Vaasa Hospital District (now the Wellbeing Services County of Ostrobothnia) responsible for the national coordination of efforts to improve and develop client and patient safety. An organisation called the Patient and Client Safety Development Centre was established in 2019, which changed its name to the Finnish Centre for Client and Patient Safety in 2022. The Ministry of Social Affairs and Health has been financing the organisation since 2020. The Finnish Centre for Client and Patient Safety is responsible for developing, planning, monitoring and evaluating client and patient safety across wellbeing services counties. It also coordinates and promotes the implementation of the national Client and Patient Safety Strategy by the wellbeing services counties.

The Client and Patient Safety Strategy and Implementation Plan²⁹ states that service providers and suppliers play a key role in promoting and monitoring medication safety. The objective of national medication lists is to ensure that the correct medication is provided regardless of the pharmacotherapy provider. Cooperation will be ensured through the development of new operating models. This calls for community pharmacies to also work together with various other operators. According to the Implementation Plan, information systems need to be developed so that they enable seamless information sharing about the pharmacotherapy process and the usability of data across information systems. The implementation of pharmacotherapy policies by service units and providers of outsourced services will be monitored as part of self-regulation. The goal is for service units to introduce predictive risk management techniques for medication safety as well as regular monitoring and transparent reporting of national indicators of pharmacotherapy and medication safety. Another goal is to familiarise professionals with safe pharmacotherapy processes and engage them in complying with harmonised and standardised operating models, and for service units to incorporate their self-regulation or patient safety policy, or their client and patient safety procedures, into the orientation of new employees. Educational institutions are also being urged to harmonise the key contents of pharmacotherapy education in both health care and social welfare degree courses.

2.7.3 The Guide on Good Practices in Patient-specific Dispensing of Medication

The Guide on Good Practices in Patient-specific Dispensing of Medication³⁰ was drawn up in 2016. Prior to this, the dose-dispensing service had been primarily based on locally agreed operating models. The need for a nationwide operating model had grown as dose dispensing had become more widespread and the operating environment was changing thanks to, for example, electronic prescribing. The Guide describes, among other things, a national operating model for dose dispensing, the management of changes in the medication of

²⁷ Government proposal HE 246/2022 for an act on the processing of client data in healthcare and social welfare as well as related acts.

²⁸ 8/2021.

²⁹ Ministry of Social Affairs and Health (2022): *The Client and Patient Safety Strategy and Implementation Plan 2022–2026*. Publications of the Ministry of Social Affairs and Health 2022:2.

³⁰ Ministry of Social Affairs and Health (2016): *Guide on Good Practices in Patient-specific Dispensing of Medication*, Reports and Memorandums of the Ministry of Social Affairs and Health 2016:1.

patients who are part of the dose-dispensing scheme, the ordering and delivering of dose-dispensed medication by pharmacies and the reception of dose-dispensed medicines by treatment providers.

According to the Guide, patient specific dose dispensing is suitable for patients who regularly take several different medicines by mouth and whose medication regimen is sufficiently well established. If changes are made to the patient's medication more than once a month, the medication regimen is not deemed to be sufficiently well established for dose dispensing.

Doctors are responsible for prescribing. They decide whether a patient should be enrolled in the dose-dispensing scheme on a case-by-case basis and document their decision in the patient information system. These decisions are made together with the patient or his/her loved ones. Doctors perform pharmacotherapy assessments in consultation with other professionals. The pharmacotherapy needs of patients who are part of the dose-dispensing scheme must be reviewed regularly and at least once a year. More regular reviews may be necessary if there are sudden changes in the patient's condition.

Doctors generally write prescriptions for medications that can be dose dispensed for a fixed period of time not exceeding two years once a decision has been made about the medicines to be dose dispensed. It is up to the doctor to make decisions about any changes in the patient's medication and when these changes are to take effect. Ideally, changes in the patient's medication should be implemented so that they coincide with the delivery schedule of the patient's dose-dispensed medicines.

Pharmacists (pharmacy employees with either a bachelor's or a master's degree in pharmacy) contribute to pharmacotherapy assessments of patients who are part of the dose-dispensing scheme as part of the multi-professional team. They place orders with the dose-dispensing unit based on medication lists supplied to the pharmacy, following the pharmacy's own dose-dispensing procedure. It is up to the pharmacist to collect the patient's electronic dose-dispensing prescriptions from the Prescription Centre³¹. The pharmacist checks the dose-dispensed medicines before they leave the pharmacy and ensures that proper instructions for taking the medication are provided. The pharmacist updates the pharmacy system to show that the electronic prescription has been dispensed, and the delivery information gets uploaded to the Prescription Centre.

Registered nurses employed by treatment providers contribute to pharmacotherapy assessments. They are responsible for looking out for any changes in the patient's health condition and for recording their observations in the patient information system. They also report on the effects of pharmacotherapy and any changes in the patient's pharmacotherapy needs to the doctor.

It is important that the registered nurse in charge of the patient has a complete picture of the patient's medication after a decision has been made to enrol the patient in the dose-dispensing scheme. The nurse also decides when the patient should be switched to dose dispensing and carries out an assessment of the patient's functional ability to ensure the practical feasibility of the intended pharmacotherapy. The nurse coordinates any changes in the patient's medication and ensures that such transitions go smoothly, consulting with the doctor as required. The treatment provider's role is to ensure that the medication list they have for the patient matches the medication list that has been uploaded to the patient

³¹ The Prescription Centre is a centralised database of electronic prescriptions, which are uploaded by prescribers, and the associated dispensing events, which are recorded by pharmacies. The Prescription Centre is coordinated by the Social Insurance Institution of Finland.

information system. The treatment provider is also responsible for ensuring that the pharmacy always has the latest medication list for the patient. The registered nurse employed by the treatment provider administers the dose-dispensed medicines to the patient and monitors the effects of the medication. It is up to the nurse to notify the pharmacy if a patient is removed from the dose-dispensing scheme.

2.7.4 The Safe Pharmacotherapy Guide

The Safe Pharmacotherapy guide³² sets out concrete instructions as to how and why a pharmacotherapy policy must be drawn up and by whom. It acts as a set of recommendations that are designed to further improve medication safety practices.

Automated dose-dispensing practices are described in the guide on a general level. According to the guide, patient-specific dose dispensing, the associated practices and procedures for ensuring medication safety should be described in a pharmacotherapy policy. Medicines supplied by means of automated dose dispensing must be checked in accordance with the four-eyes principle in connection with the dose-dispensing process. However, the provider of the medication must always check the medicines before giving them to the client or patient. The Council of Europe's guidelines.

The Council of Europe³³ has published a guide on best practices of automated dose dispensing (ADD) -Guidelines on best practice for the ADD process, and care and safety of patients. The guidelines are designed to help national authorities to ensure the safety and effectiveness of dose dispensing, taking into account local conditions and with special attention to those areas of the dose-dispensing process that carry a high risk in terms of patient safety.

The guidelines include recommendations relating to the *dose-dispensing process*. Dose dispensing is generally performed by pharmacies and more specifically by a designated dose-dispensing pharmacist. This pharmacist, who must have either a bachelor's or a master's degree in pharmacy, is responsible for ensuring, for example, that dose-dispensing prescriptions and orders are appropriately checked and that the patient or the person responsible for the patient's care gets the necessary information about using and storing dose-dispensed medicines. The designated dose-dispensing pharmacist is also responsible for ensuring that the information systems used in the context of dose dispensing work as intended.

The dose-dispensing unit must provide training for all individuals whose actions can affect the dose-dispensing process or its integrity. In-service training must be provided whenever a procedure changes or if the need for more training arises otherwise. The four-eyes principle³⁴ applies to all checks on prescriptions and orders in respect of computerised systems, medications and entries concerning dose-dispensing patients in the patient information system throughout the dose-dispensing process. Checks must be performed at all critical points and in any case at least when the patient's prescriptions are entered into the dose-dispensing information system and when the dose-dispensing unit supplies the medicines to

³² Ministry of Social Affairs and Health (2021): *Safe Pharmacotherapy – Guide to producing a pharmacotherapy plan*, Publications of the Ministry of Social Affairs and Health 2021:6.

³³ European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM) (2018): *Automated dose dispensing (ADD) – Guidelines on best practice for the ADD process, and care and safety of patients*.

³⁴ According to the Ministry of Social Affairs and Health's Guide (2021), the 'four-eyes principle' generally means that two healthcare or social welfare professionals (the person who dispensed the medication plus another person) check whether the medicines have been sorted correctly into patient-specific doses.

the patient, another operator or the pharmacy. All mistakes and incidents relating to dose dispensing must be reported.

In countries where two separate locations are involved in the dose-dispensing process, the patient's prescription must first be converted into a format that is compatible with automated dose dispensing and then forwarded to the dose-dispensing manufacturing unit. If the dose-dispensing process is initiated by placing an order, the dose-dispensing unit must be able to access the patient's original prescription.

The guidelines also include recommendations relating to *patient care* in the context of the dose-dispensing process.

The goal is for everyone involved in the care of patients who receive his/her medication by means of automated dose dispensing to understand the dose-dispensing procedure. It is important to note that some patients who are enrolled in the dose-dispensing scheme take a combination of dose-dispensed and traditionally (manually) dispensed medications. Optimising patient safety requires cooperation and systematic checks on the correctness of the dispensed medication by all care professionals involved in the dispensing process. This is why, and in order to ensure compliance with the applicable laws, it is recommended that procedures or standards be adopted for patient safety in the context of dose dispensing on a national level.

A patient's suitability for automated dose dispensing must always be assessed and documented before they are enrolled in the dose-dispensing scheme. These assessments are performed by a team of healthcare professionals as well as the patient and his/her carer. The outcome of the assessment must be documented. Dose dispensing is not suitable for patients whose medications are constantly changing. The decision to switch a patient to dose dispensing must be based on the patient's needs and consent and not on the treatment provider's interests.

National authorities should identify procedures for receiving and managing requests for switching patients to dose dispensing as well as for converting patients' prescriptions into pharmacotherapy plans before the first dose-dispensing order is sent to the dose-dispensing unit. Healthcare professionals who look after patients enrolled in the dose-dispensing scheme must be specially trained for these duties. The circumstances of patients enrolled in the dose-dispensing scheme must be reviewed at regular intervals to ensure that they are still good candidates for dose dispensing.

2.8 Other reports

2.8.1 The Finnish Medicines Agency's report on the automated dose dispensing of medicines

The Finnish Medicines Agency conducted a study into the current situation with automated dose dispensing and weaknesses in the system in 2022.³⁵ Background information for the study was collected from pharmacies, nursing teams of private care providers, home care teams, pharmaceutical wholesalers, trade organisations, professional associations, dose-dispensing units and government authorities.

According to the findings of the study, dose dispensing is considered useful and is generally thought to improve medication safety. The process appears to work smoothly overall. Nursing

³⁵ Finnish Medicines Agency (2022): *Current state and development needs of automated dose dispensing of medicines*, Fimea Develops, Assesses and Informs 7/2022, Kuopio, Finland.

teams and home care teams felt that the dose dispensing of medicines has improved medication safety and freed nursing staff to focus on other tasks.

The study revealed that there were certain weaknesses in the laws and regulations governing the dose dispensing of medicines. Current laws say nothing about the manufacturing side of dose dispensing, which is why procedures and controls have had to be improvised.

The roles of the various operators involved and the division of responsibilities and obligations could be clearer. Updating the *Guide on Good Practices in Patient-specific Dispensing of Medication* in collaboration with the most important authorities and operators was seen as a high priority.

2.8.2 Development of the pharmacy system

The Ministry of Social Affairs and Health published a report³⁶ on the development of the pharmacy system in early 2023. The report analyses the current situation of the pharmacy system and makes suggestions as to how it could be improved in the future. The report addresses both cooperation between pharmacies and healthcare and social welfare operators and dose dispensing.

Pharmacies and healthcare and social welfare operators work together in, for example, delivering medications, renewing prescriptions and providing a variety of pharmaceutical services. According to the report, several drug policy documents identify pharmacies as being part of the healthcare system. From the perspective of healthcare operators, however, pharmacies are usually seen as a separate entity. Pharmacies and healthcare and social welfare operators already work together in many contexts, but there are pharmacy-specific and regional variations.

The report proposes improving multi-professional cooperation between pharmacies and healthcare and social welfare operators and developing an information sharing tool for this purpose and procedures to promote its use. Going forward, the report recommends performing an assessment on the cooperation needs of pharmacies and healthcare and social welfare operators as well as the prerequisites and barriers to cooperation across wellbeing services counties.

Dose dispensing is, according to the report, currently crippled by inadequate information systems, which make it difficult to manage the totality of a patient's medication in respect to medicines that are not dose dispensed. There are also challenges relating to the interoperability of the information systems that are used to supply dose-dispensed medicines as well as the accessibility and usability of the necessary pharmacotherapy records.

Harmonised procedures need to be developed for checking the totality of dose-dispensing patients' medication and managing medication changes in order to ensure the safety of patients' pharmacotherapy. Existing information systems should be improved to make it easier for pharmacies to process the information needed in the context of dose dispensing and thereby ensure medication safety. The introduction of national "Kanta" medication lists promises to make it easier to get a full picture of a patient's medication, but the compatibility of the new tool with the software applications that are currently used in dose dispensing must be ensured.

³⁶ Ministry of Social Affairs and Health (2023): *Development of the pharmacy system – Assessment of the current situation and proposals for further measures*, Reports and Memorandums of the Ministry of Social Affairs and Health 2023:6.

The report recommends determining minimum requirements for dose-dispensing services, which would include, for example, ensuring medication safety and rational pharmacotherapy as well as pharmacotherapy assessments and reviews. The roles and responsibilities of the operators involved in supplying and dispensing dose-dispensed medicines should also be defined. Going forward, an analysis of the weaknesses of information systems that are currently used in dose dispensing is also needed.

2.8.3 Number of automated dose-dispensing customers

According to the Finnish Medicines Agency’s records, there were 586 pharmacies offering automated dose dispensing and 102,958 customers using dose-dispensing services in the summer of 2023. The number of dose-dispensing customers at the end of the year had grown by 12% on average over the five-year period since the beginning of 2018.

According to the Social Insurance Institution of Finland’s records, a total of 119,424 patients received his/her medication by means of automated dose dispensing in 2022. The number had more than doubled since 2017. The annual growth rate between 2017 and 2022 had been 15% on average.

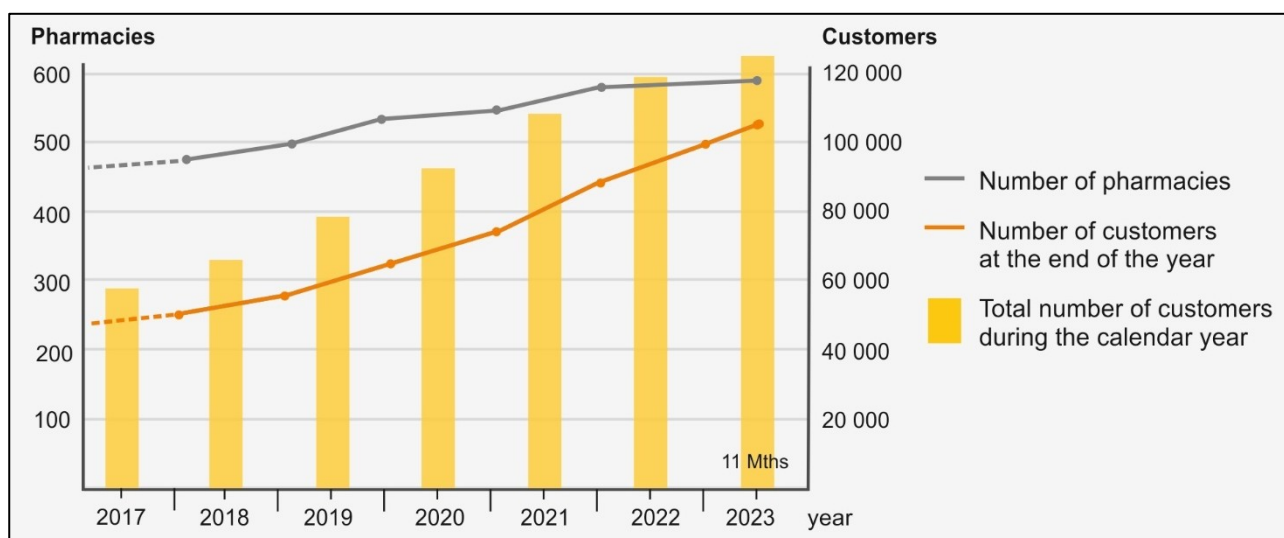


Figure 5. Number of pharmacies offering automated dose dispensing and number of users of automated dose-dispensing services, as well as the total number of dose-dispensing customers during the calendar year. The figures for the number of pharmacies and the number of customers are year-end figures, with the exception of the 2023 figure, which shows the situation in the summer of 2023. (Image: SIAF; number of pharmacies and customer volumes in the summer of 2023: Finnish Medicines Agency; number of customers at the end of the year between 2018 and 2023: dose-dispensing units; total number of customers per year between 2017 and 2023: Social Insurance Institution of Finland.)

According to the Finnish Medicines Agency’s indicator data³⁷, almost 21% of Finns over 75 years of age were being prescribed multiple medications in 2022. The percentage has grown in recent years. According to Statistics Finland’s population records³⁸, there were almost

³⁷ <https://sic.fimea.fi/-/fimean-indikaattoritiedot-iakkaiden-laakehoidoissa-kehittavaa>, 4 December 2023. The indicator measures patients who take ten or more different medications.

³⁸ Official Statistics of Finland: *Population projection* [online publication]. ISSN = 1798-5137. Helsinki, Finland: Statistics Finland [visited on 15 October 2023]. Source: <https://stat.fi/en/statistics/vaenn>.

550,000 people aged 75 years and older in Finland at the end of 2020. Based on the latest population projection, the figure will grow by more than 25% to almost 690,000 by 2025, and the figure in 2030 will be almost 790,000; an increase of more than 43% compared to the year 2020.

Many wellbeing services counties have decided that patients receiving regular home care should, as a rule, be included in the automated dose-dispensing scheme. Even more wellbeing services counties have given their customers service vouchers for automated dose dispensing. It is clear that the number of patients who receive his/her medicines by means of automated dose dispensing will continue to grow in the future.

2.8.4 Survey for home care operators

The investigation team conducted a survey among home care operators in the Wellbeing Services County of Satakunta in August 2023. The objective of the survey was to gauge home care operators' views on the effectiveness of automated dose dispensing in the context of home care. A total of 142 people answered the survey. Four of the respondents were doctors, 28 were registered nurses and 109 were practical nurses. One respondent did not give his/her profession.

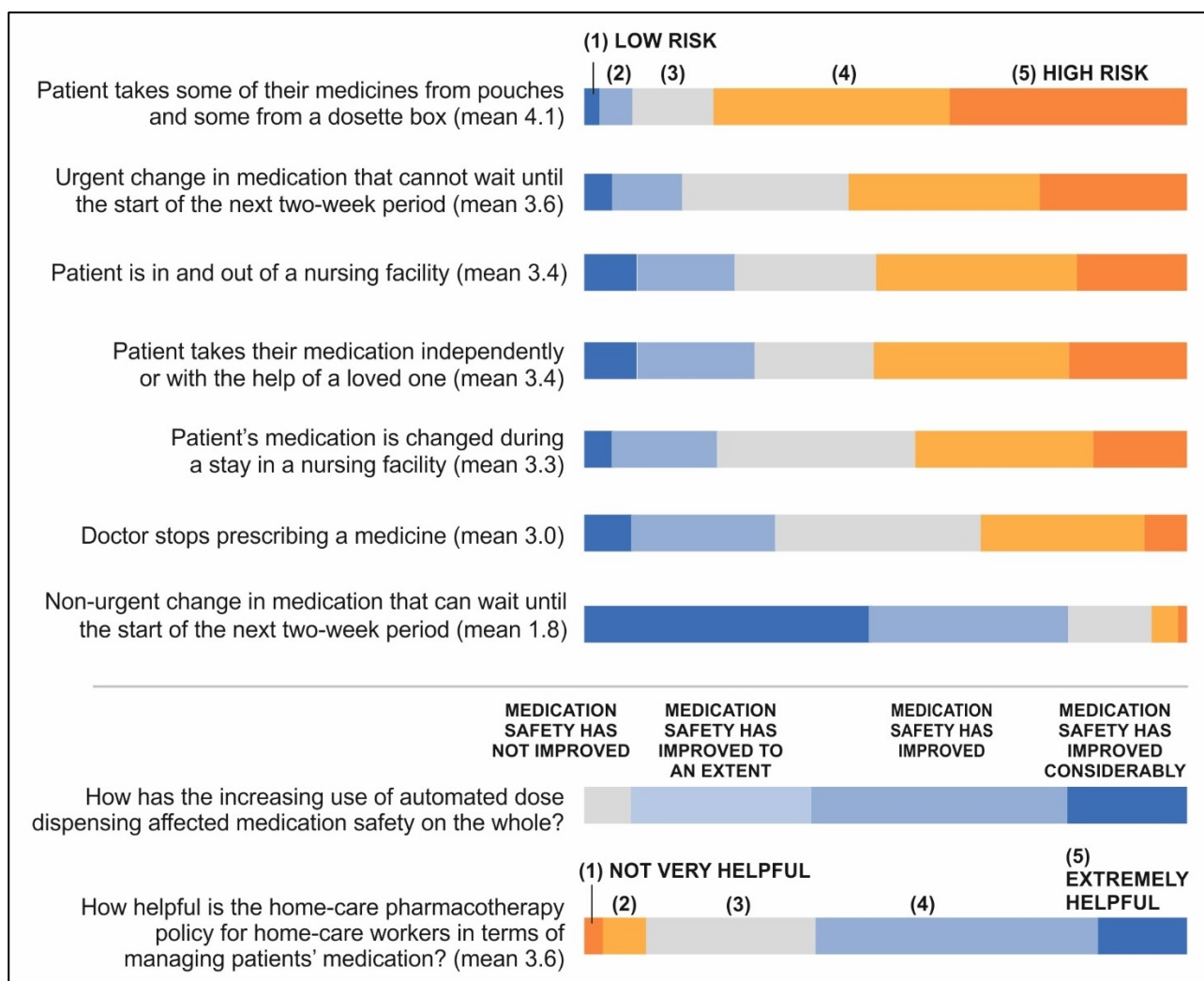


Figure 6. Answers to the survey for home care operators regarding the risk of a medication error in various circumstances. (Image: SIAF)

The risk of a medication error in connection with dose dispensing is, according to the respondents, at its highest in the case of patients who take some of his/her medicines from dose-dispensed pouches and some from a dosette box. The respondents associated a relatively high level of risk with changes in a patient's medication that cannot wait until the start of the next dose-dispensing period. They also felt that there was a risk of a medication error in cases where a patient takes his/her medication independently or with the help of a loved one. According to the responses, the risk of a medication error increases if a patient is in and out of a nursing facility and his/her medication is changed during his/her stay in the facility, which may be indicative of poor communication. Decisions made by doctors to discontinue a medication seem to be communicated more effectively to the dose-dispensing organisation. Non-urgent changes in a patient's medication that can wait until the start of the next dose-dispensing period are seen to carry a low level of risk.

The increasing use of dose dispensing is seen as a positive from the perspective of medication safety by 92% of the respondents.

Pharmacotherapy policies appear to be very helpful for home care workers who manage patients' medication. The survey also included an open-ended question about weaknesses in current pharmacotherapy policies, which was answered by 39% of the respondents. One in four respondents was happy with the current policies. Some found the current pharmacotherapy policy cumbersome, and several felt that it needed updating. There were also calls for the inclusion of concrete best practices for challenging situations in pharmacotherapy policies, and a couple of respondents wanted more discussion about the practical aspects of pharmacotherapy. The answers also reveal that improvements to medication plan are brainstormed together with pharmacies.

Good relationships with pharmacies were mentioned by 70% of the respondents. Many answers talked about a generally good working relationship. Several respondents mentioned that pharmacies liaise actively with the home care organisation in connection with, for example, medication changes. Several respondents also appreciated the ease of communication over the telephone. Dose-dispensing orders have arrived on time, advice has been forthcoming and rush orders have not been a problem either.

Issues with pharmacies were mentioned by 32% of the respondents. Few of the issues relate directly to the operation of pharmacies. Almost half of the respondents mentioned issues with the availability of medicines. Eight respondents talked about issues relating to patients' prescriptions. There had been cases where a doctor had prescribed a medicine that was not available for automated dose dispensing. When the issue was discovered in connection with the dose-dispensing order, the doctor had to be asked to write a new prescription. There have also been times when the expiry of a prescription has only been discovered when the dose-dispensing order was being placed. Prescriptions should be renewed proactively to avoid these kinds of situations.

A few respondents had an issue with the policy of pharmacies to insist on an electronic order. On the other hand, a couple of respondents said that orders are placed by taking a piece of paper to the pharmacy, which they considered to be an outdated practice. There had also been issues with information sharing, for example, when a client had moved to an area that was covered by a different home care team.

Issues with medication lists were mentioned by 65% of the respondents. Almost all felt that medication lists are not always up to date. More than one in three respondents said that it was the doctor who had not recorded the medication they had prescribed in the patient's medication list. According to eight respondents, issues with out-of-date medication lists had

related to a patient's return home after a stay in a nursing facility. Changes made to the patient's medication in the nursing facility had not been communicated to the home care team. Four respondents said that prescriptions written by private doctors had not been added to a patient's medication list.

Patients sometimes have out-of-date medication lists at home, which has caused confusion. One in ten respondents mentioned this issue. According to them, old medication lists should always be removed from clients' homes.

Benefits of automated dose dispensing were mentioned in the open-ended answers of 69% of the respondents. Dose dispensing is seen as quick, straightforward and easy. The pouches are clearly marked, and well-functioning clients are able to take his/her medication from the pouches independently. Pharmacists have been more actively involved in patients' pharmacotherapy since the introduction of dose dispensing. Dose dispensing has freed nurses to focus on other tasks. There have been fewer dispensing errors and less medicine wastage. Rush orders have worked well in connection with medication changes, but more than one in ten respondents mentioned the risk to patient safety in connection with medication changes.

Checks on medicines were the subject of an open-ended question in the survey. A total of 83% of the respondents answered the question. Most of the answers say that the list of dispensed medicines that accompanies dose-dispensed orders is compared against the patient's medication list. Checks are usually limited to the contents of the first day's pouches. Five respondents mentioned that, whenever there is a change in a patient's medication, they compare the new medication list against the patient's previous medication list, which the patient has at home. Almost one in five respondents said that incoming medicines are checked by more than one nurse.

A few respondents suspected that checks are not as thorough as they should be and that there are various practices. There were also respondents who said that the contents of the pouches are checked at the pharmacy and that there is no need for the home care team to check them.

2.8.5 Automated dose-dispensing survey for pharmacies

The investigation team conducted a survey among pharmacies in August 2023. The objective was to gauge pharmacy workers' views on automated dose dispensing. More than 890 people answered the survey.

The number of dose-dispensing customers at the pharmacies where the respondents worked was 100 on average³⁹. The highest number of customers reported by a respondent was more than 1,400.

The number of staff involved in dose dispensing was between two and four pharmacists according to 82% of the respondents. A total of 20 respondents said that they were the only person involved in dose dispensing at their pharmacy.

The number of dose-dispensing orders made by a single person per day varied considerably. The maximum number was 30 according to 23% of the respondents, the median was 60 orders, and 77% of the respondents said that there are up to 100 orders per day. A total of 28 respondents said that the maximum number of orders was more than 200.

Written procedures for the dose-dispensing service were in place at the pharmacy according to more than 93% of the respondents.

³⁹ The average here is the median, which is the middle number in a sorted list of numbers.

The amount of time reserved for making orders was generally considered sufficient. On a scale of one to five, approximately 11% of the respondents chose the two lowest options. The lack of a peaceful working environment in which to make orders was a bigger issue. More than one in four respondents chose one of the two lowest options.

Performing other tasks in between dose-dispensing orders was not required according to 30% of the respondents. A total of 55% of the respondents sometimes had to perform other tasks as well. The remaining 15% of the respondents felt that they are practically always multitasking during periods that are supposed to be reserved for making dose-dispensing orders.

The usability of the information system in terms of placing orders was generally considered relatively good, although 63% of the respondents made suggestions of improvements. The average score given by the respondents to the usability of the information system was 3.7 on a scale of one to five.

The respondents expressed the most dissatisfaction with prescriptions and the second most with the visibility and manageability of medication changes. Other weaknesses mentioned by the respondents related to generic substitution and special orders. Approximately one in ten respondents mentioned that the information system is slow.

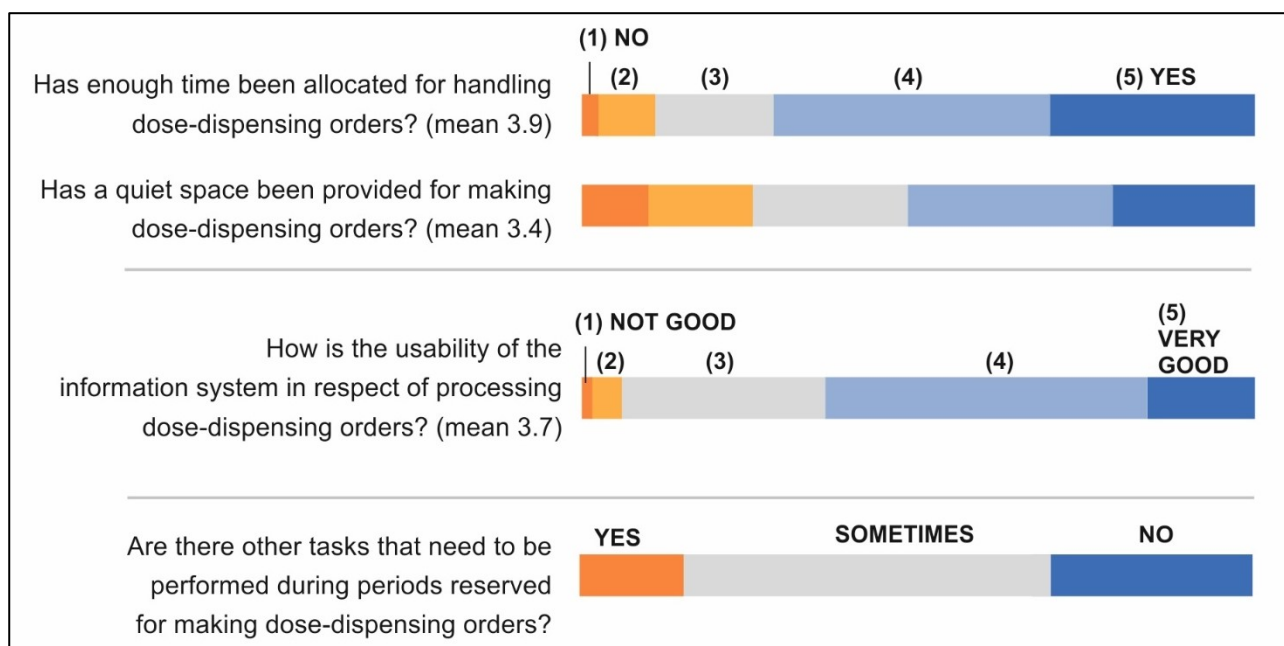


Figure 7. The average score on a scale of one to five is 3.9 in respect of the sufficiency of working hours reserved by the pharmacy for making dose-dispensing, 3.7 in respect of the usability of the information system and 3.4 in respect of the peacefulness of the working environment. More than one in four respondents never have to perform other tasks in between dose-dispensing orders. (Image: SIAF)

Pharmacies get patients' medication lists for the purposes of automated dose dispensing on paper according to 69% of the respondents and via the EasyMedi information system⁴⁰ according to 51% of the respondents. A total of six per cent of the respondents said that medication lists are sent by email, and almost all respondents who gave this answer said that

⁴⁰ EasyMedi is a browser-based digital service that pharmacies use for managing orders and communicating with clients. The service is provided by Pharmadata Oy.

their pharmacy uses encrypted email. Medication lists are communicated over the telephone according to two per cent of the respondents. Fax was also mentioned. There are pharmacies that receive medication lists by various different ways, and the options are therefore not mutually exclusive.

The practices associated with medication lists vary considerably. A total of 13% of the respondents said that their pharmacy gets given an up-to-date medication list whenever there is a change in a patient's medication, while 61% of the respondents said that up-to-date medication lists are only provided if a change concerns a dose-dispensed medicine. A total of 22% of the respondents said that there is no protocol for when a medication list should be supplied, and 17% of the respondents said that their pharmacy never gets medication lists in connection with dose-dispensing orders. Several respondents had answered the question separately for nursing homes and home care providers, and the answers regarding access to medication lists are therefore not mutually exclusive.

More than 120 respondents gave an open-ended answer about practices relating to the sharing of medication lists. The answers are indicative of considerable variation in practices. Many of the answers mentioned that a medication list is supplied when a patient first switches to dose dispensing and at regular intervals thereafter for as long as the patient continues to receive dose-dispensed medicines. Medication changes are often reported initially over the telephone, and the physical medication list is sent to the pharmacy later. Pharmacies therefore have to print out medication lists and record the reported changes manually. The answers also revealed that there had been an instance where a home care provider had refused to send over a medication list for data protection reasons.

Medication lists are always on time according to five per cent of the respondents and usually on time according to 72% of the respondents. A total of 22% of the respondents said that medication lists usually arrive late, and one per cent said that they are always late.

Pharmacies use the telephone to contact the home care provider or nursing home in connection with every dose-dispensing order according to five per cent of the respondents, while 48% said that this happens often, 24% said that it happens sometimes and five per cent said this never happens.

There are issues with prescriptions in connection with every dose-dispensing order according to three per cent of the respondents, while 55% often experience issues and 42% rarely have issues.

The division of labour in respect of checking dose-dispensed medicines has been agreed between the pharmacy and the home care provider or nursing home according to 42% of the respondents. A total of 33% of the respondents said that there was no arrangement in place, and the remaining 25% were unsure.

The responses are indicative of considerable variation in the practices that pharmacies have agreed with home care providers and nursing homes. Among the practices mentioned were that the pharmacy checks the first day's pouches, that the pharmacy checks the pouches whenever there has been a change in the patient's medication and that separate pharmacy workers are responsible for placing dose-dispensing orders and pricing medicines. It is left up to the home care provider or nursing home to check that the list of dispensed medicines that is supplied with the medicines matches the medication list in the patient information system. According to the respondents, there is also a dose-dispensing unit that has assured pharmacies that the delivered medicines are as ordered and that there is no need to routinely

check incoming orders. This has been communicated to home care providers and nursing homes, which have consequently stopped routinely checking the contents of pouches.

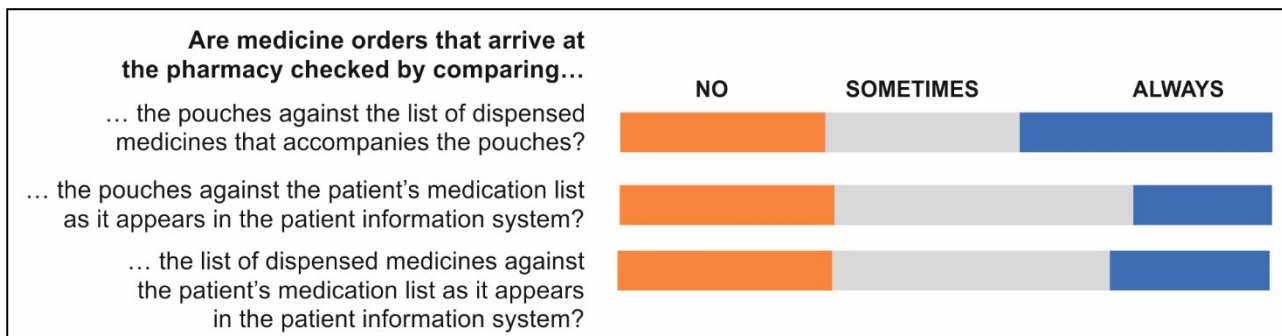


Figure 8. Checks on dose-dispensed medicine orders that arrive at pharmacies from the dose-dispensing unit. (Image: SIAF)

Incoming dose-dispensing pouches are compared against the list of dispensed medicines in connection with every order according to 38% of the respondents. A total of 32% of the respondents said that this is never done, and the remaining 30% said that this check is only performed in special circumstances.

Several respondents said that this check is performed for new customers as well as in connection with medication changes, irregular dosing⁴¹ and other unusual situations, such as if a combination drug is replaced by two separate products. There were also respondents who said that this check is not performed every time but is done at regular intervals. A few respondents mentioned that whether or not the check is performed depends on the employee on duty.

Incoming dose-dispensing pouches are compared against the patient's medication list in connection with every order according to 22% of the respondents. A total of 33% of the respondents said that this is never done, and the remaining 45% said that this check is only performed in special circumstances.

This check is performed if the list of dispensed medicines does not match the patient's medication list or if no list of dispensed medicines has been supplied for some reason, in connection with medication changes, whenever a prescription is renewed and in connection with the first order for a new customer. The answers also revealed that the medication lists that home care providers and nursing homes use are not alphabetical, and the product names are not always the same as those of the dose-dispensed medicines. There are also pharmacies that perform this check at regular intervals, such as twice a year.

The list of dispensed medicines that accompanies incoming orders is compared against the patient's medication list in connection with every order according to 25% of the respondents. A total of 33% of the respondents said that this is never done, and the remaining 42% said that this check is only performed in special circumstances. This check is often performed in similar situations as those mentioned above.

Factors that make checking medication orders more difficult were mentioned by more than 600 respondents. Examples include mistakes in prescriptions, unclear medication records, medication changes, irregular dosing as well as pausing and resuming medications. Running out of time, being interrupted in the middle of the process, having to work in a noisy

⁴¹ If, for example, the daily dose varies.

environment, incompetent stand-ins during holidays and having to work in a cramped space were also mentioned. The respondents also had doubts about the computer literacy of home care workers. Medication lists are not standardised, which can also make it more difficult to check medication orders. Sometimes medicines are listed under product names and sometimes under active ingredients, sometimes in an alphabetical order and sometimes in some other order. A list can include both dose-dispensing medicines and other medicines.

Steps taken in response to dose anomalies were described by more than 800 respondents. The way in which mistakes are dealt with depends on the circumstances. This can mean, for example, documenting and recording the irregularity, filing a patient safety report and making the pharmacy's in-house staff aware of the issue. The goal is to prevent similar mistakes in the future and to learn from the situation. The dose-dispensing unit is alerted if deemed necessary. If the mistake was made by the dose-dispensing unit, the Finnish Medicines Agency also gets told.

The most common reasons for dose-dispensing anomalies are, according to the respondents' answers, issues with prescriptions and medication lists. There may be prescriptions that have not been renewed when the time comes to make the order. There may be mistakes in prescriptions or the doctor may be unfamiliar with dose-dispensing practices. There have also been cases where the patient's medication list was out of date or a medication list supplied on paper was unclear or difficult to read or interpret. Other reasons for anomalies that the respondents mentioned include medication changes, issues with the availability of medicines, irregular dose-dispensing periods, breaks in the patient's regular medication and irregular dosing.

Not having enough time, having to work in a noisy environment, inadequate communication between the various operators involved, properties of the information system and difficulties in getting hold of the doctor were also mentioned in the answers.

Starting a patient on a new medicine in the middle of a dose-dispensing period can be done in two different ways: the medicine can either be purchased from a pharmacy in regular packaging or it can be ordered as a rush order from the dose-dispensing unit. More than one in three respondents said that the usual practice is to purchase the medicine from the pharmacy. In most cases, the smallest available package size is chosen just to get to the start of the next dose-dispensing period. More than one in three respondents said that the usual practice in these situations is to place a rush order with the dose-dispensing unit. The remaining just over one in four respondents said that each case is different and the approach depends on the circumstances.

The survey also asked the respondents what their pharmacy's policy was for placing a rush order for a single medicine. A total of 51% of the respondents who used the same information system as the one involved in the case under investigation and who had indicated that the usual approach in the aforementioned types of situations was a rush order said that they make rush orders anonymously, i.e. not using the patient's information. A total of 49% of the respondents said that they make rush orders using the patient's information, which requires pausing the patient's other medications.

Rush order procedures with home care providers and nursing homes vary considerably. According to the answers, there are many cases in which there is no harmonised procedure. The answers also revealed that rush orders tend to be either avoided or always made in writing. One approach is to order expensive medicines using rush orders and supply less expensive medicines in small package sizes.

Weaknesses in the dose-dispensing system evoked many thoughts in the respondents. There were calls for clear national dose-dispensing procedures that would define the roles, interactions and the division of responsibilities between operators, the four-eyes process and periodic checks. Both doctors and nurses employed by treatment providers should be educated about dose dispensing. Practices relating to the writing of dose-dispensing prescriptions are in need of harmonisation. The introduction of national medication lists is expected to improve the situation in respect of medication lists. Employees whose work involves making dose-dispensing orders and coordinating dose-dispensing deliveries should be allowed to concentrate on the task at hand.

Better communication is needed between pharmacies and treatment providers. Digital channels should be used, and information about medication changes should always be communicated in writing. Treatment providers should have designated doctors and nurses whom pharmacies could call directly. Decisions about enrolling patients in the dose-dispensing scheme need to be made more carefully, and patients whose medication is always changing should not be enrolled in the scheme. Patients' suitability for dose dispensing should be reviewed at regular intervals.

Better information systems are needed. Less of the work should be done manually. It should be possible to compare medication lists against lists of dispensed medicines using bar codes. Information systems should have built-in safeguards against human error. Lists of dispensed medicines could be clearer in respect of, for example, changes.

The number of pharmacy employees who perform dose-dispensing duties should be proportional to the number of customers to ensure the availability of enough human resources for checking dose-dispensing orders. Competitive tendering should be abandoned, and instead the responsibility for dose dispensing should be given to the local pharmacy to maximise local cooperation.

2.8.6 Patient safety incident reports relating to home care patients' pharmacotherapy

The investigation team reviewed patient safety incident reports relating to medication safety that had been filed in the Wellbeing Services County of Satakunta during a 14-month period from the start of 2022 until the end of February 2023. The reports identified 348 incidents, of which 183 involved dose-dispensed medicines.

Of the incidents that involved dose-dispensed medicines, 61% related to a patient's not having received their prescription medication and 21% related to a patient's having been given too much medication. In six per cent of the cases, the patient had been given the wrong medicine. In more than ten per cent of the cases, the medication safety issue was discovered before the patient received the medicine.

Approximately 60% of the incidents that involved dose-dispensed medicines related to the actual taking of the medicine. These cases often involved patients who were responsible for taking his/her own medication and forgot to take it. There were also cases where the person administering the medication had given the patient the wrong medicine or only given them his/her dose-dispensed medicines and forgotten about the medicines in the patient's dosette box.

Almost one in four cases involved patients who had medication in both dose-dispensing pouches and in a dosette box. Almost one in four cases involved a medication change made by the patient's doctor.

A master's thesis in pharmacy that was published in the spring of 2023⁴² studied the effect of dose dispensing on medication safety incidents reported in the context of home care. The study focused on medication safety incident reports relating to home care filed in a single municipality. A total of 1,262 reports had been filed between 2010 and 2022.

According to the thesis, 90% of medication safety incidents involving home care related to the administering of medication. Mistakes in dispensing accounted for four per cent of the incidents. Mistakes in automated dose dispensing accounted for 0.5%.

Of the incidents that related to the administering of medication, the patient had not got his/her medication at all in 72% of the cases, had received the wrong dose in seven per cent of the cases and had been given his/her medication at the wrong time in six per cent of the cases. A medicine had been misplaced in five per cent of the cases, and four per cent of the cases involved the wrong patient or the wrong medicine. Three per cent of the cases involved a patient's refusing to take his/her medication, and in one per cent of the cases a patient was given a medicine that had been taken off his/herr medication list.

According to the conclusions of the thesis, automated dose dispensing appears to improve patient safety in the context of long-term care. However, dose dispensing is not capable of eliminating all anomalies that could be avoided by clearer procedures and instructions. Staff need clear instructions for their work.

2.8.7 The National Medication Safety Programme of Community Pharmacies in Finland

The Association of Finnish Pharmacies and the Finnish Centre for Client and Patient Safety launched an initiative called the National Medication Safety Programme of Community Pharmacies in Finland (VALO)⁴³ at the start of 2021, which aims to improve outpatient medication safety. Pharmacies have been using the HaiPro patient safety incident reporting system to record and deal with incidents involving medication safety since the autumn of 2021.

Sharing patient safety incident reports and closer cooperation between pharmacies and healthcare and social welfare providers were piloted in two regions in the spring of 2022. Sharing patient safety incident reports between different organisations will also be gradually enabled in other regions of Finland as of 2023. Cross-organisational sharing of patient safety incident reports will help to accumulate information about outpatient medication safety and the effectiveness of pharmacotherapy processes in general.

2.8.8 Patient safety incidents involving automated dose dispensing at pharmacies

A total of 1,111 client and patient safety incident reports involving automated dose dispensing were filed in the HaiPro environment for pharmacies between 1 January 2022 and 28 February 2023. Observations relating to pharmacies' own operations are entered as internal reports, which accounted for 87% of all reports. Pharmacies enter incidents in other healthcare and social welfare organisations into the system as external reports, and these accounted for 13% of all reports.

⁴² Jokela, Johanna (2023): *Effect of automated dose dispensing on medication safety incidents in long-term professional home care*, Master's Thesis in Pharmacy, Pharmacy, Faculty of Science and Engineering, Åbo Akademi University, Turku, Finland.

⁴³ The National Medication Safety Programme of Community Pharmacies in Finland (VALO), <https://valo.apteekki.fi/information-in-english/>, 4 December 2023.

Table 1. Client and patient safety incident reports involving automated dose dispensing filed in the HaiPro environment for pharmacies between 1 January 2022 and 28 February 2023. The classification is based on the assessment of the person who reported or dealt with the incident.

Nature of incident	External	Internal	Total
Close call	69	499	568
Other observation / suggested improvement	11	28	39
Incident involving a client/patient	64	440	504
In total	144	967	1,111

The data were sorted by theme using a risk management tool developed by the Association of Finnish Pharmacies for home care operators as well as the bow-tie method⁴⁴.

⁴⁴ The bow-tie method involves drawing a diagram to visualise different risk management scenarios. The method is named after the shape of the diagram, which resembles a bow-tie. In the middle of the diagram is an unintended event with the potential to escalate to undesired consequences. The credible initiating causes of the event are shown on the left. The path from the initiators to the event can be severed by means of preventive barriers. The ultimate outcomes of the event are shown on the right and can be prevented or mitigated by means of anticipatory barriers.

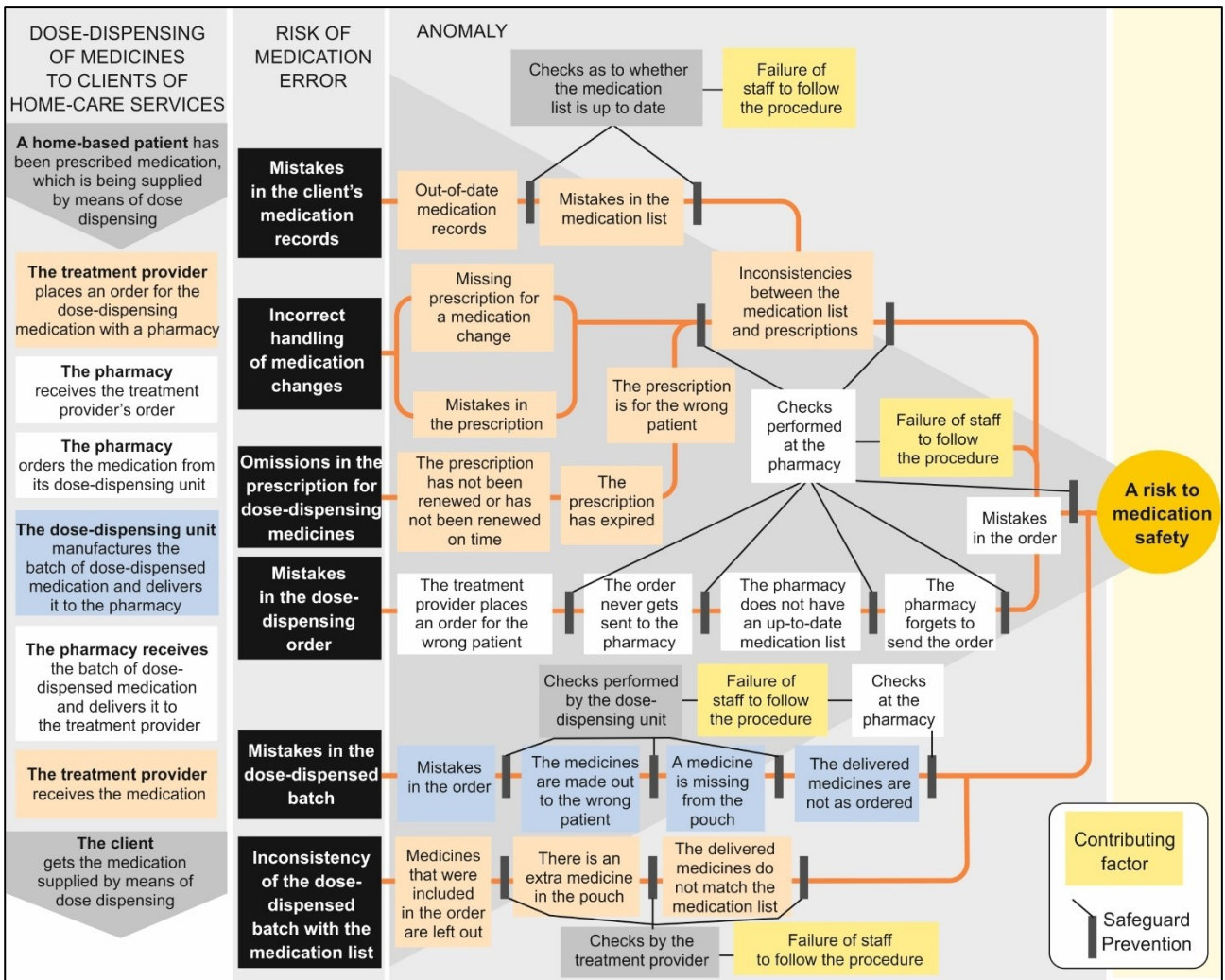


Figure 9. Incidents relating to the automated dose dispensing of medicines and their causes, which can, according to the patient safety incident reports filed in the HaiPro environment for pharmacies, compromise medication safety. The most important causes of the events have been grouped into categories, and control measures are described in the illustration on a general level. (Image: SIAF)

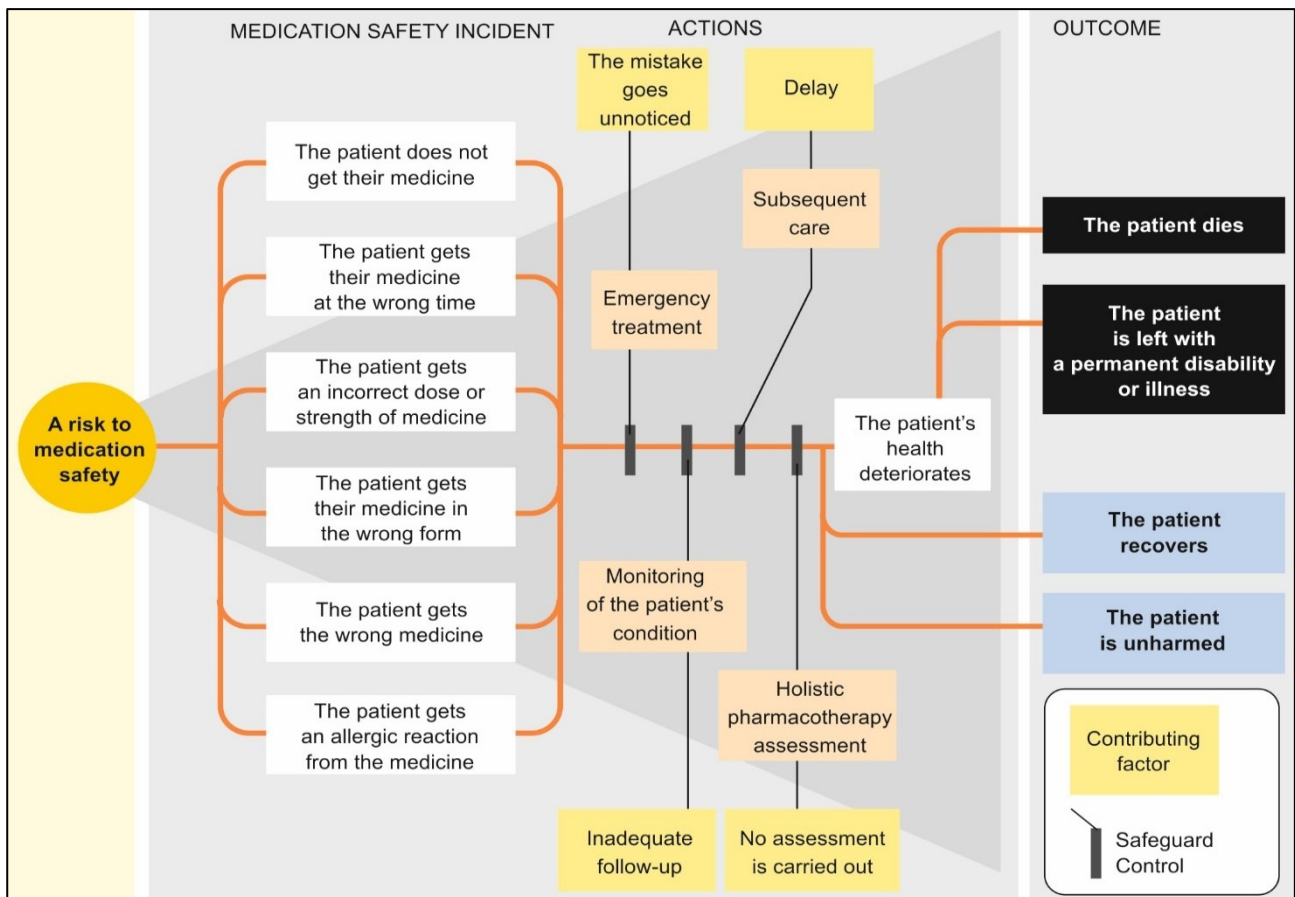


Figure 10. Consequences of patient safety incidents relating to the dose dispensing of medicines that have been reported by pharmacies via the HaiPro system, assuming that the medication safety risk associated with the process of automated dose dispensing is realised and medication safety is compromised. The ultimate outcomes of the event from the perspective of the patient and ways to control them are described in the illustration on a general level (Image: SIAF)

Table 2. Patient safety incident reports relating to automated dose dispensing, grouped by nature of incident. The classification is based on the assessment of the person who reported or dealt with the incident.

Nature of incident	External	Internal	Total
Related to pharmacotherapy	115	785	900
Prescription error	54	30	84
Out-of-date medication records	29	42	71
Mistake in an order	17	245	262
Mistake in dispensing	12	192	204
Mistake in the delivery	1	270	271
Mistake in storing or manufacturing medication	0	2	2
Mistake related to transport	1	3	4
Mistake in advising/instructing a patient on their medication or in pharmacotherapy oversight	1	1	2
Related to information sharing and information management	23	76	99
Related to an information system, device, tools or their use	3	61	64
Other	3	45	48

A total of 81% of the patient safety incident reports that involved dose dispensing related to pharmacotherapy and nine per cent related to information sharing or information management. Approximately six percent of all reports related to an information system, device, tools or their use.

2.8.9 Safe Pharmacotherapy Toolkit

The Association of Finnish Pharmacies has developed a *Safe Pharmacotherapy Toolkit*, which is a consultancy service provided by pharmacies to treatment providers and which aims to incorporate pharmacotherapy assessment and risk identification into treatment providers' self-regulation procedures. The objective of the service is to improve the safety and standard of pharmacotherapy. Pharmacies price the service independently, and the service can be provided separately or as part of the pharmacy's dose-dispensing service. The service has been available since the spring of 2018.

There are separate versions of the toolkit for home care and for assisted living. The toolkit consists of four risk management tools: safe automated dose dispensing, medicine cabinet inspections and safe pharmaceutical logistics, safe pharmacotherapy practice and prerequisites of safe pharmacotherapy.

The tool developed for safe automated dose dispensing focuses on routine procedures, pharmacotherapy assessment, the start of dose dispensing in the case of individual patients, electronic prescriptions, ordering dose-dispensed medicines from a pharmacy, managing medication changes, treatment providers' procedures for receiving dose-dispensing orders, the use and storing of lists of dispensed medicines, the storing of dose-dispensed medicines, safe handling and administering of dose-dispensed medicines, sources of pharmaceutical information, disposal of dose-dispensed medicines and reporting of medication safety incidents. Success in these areas is measured through multi-professional talks between representatives of the pharmacy and the treatment provider. The most critical weaknesses and ways to address them are identified together.

According to the Association of Finnish Pharmacies, the service is not yet widely known and its use has not been optimised. Approximately 10% of pharmacies have said that they offer the service. According to the Association of Finnish Pharmacies' 2019 survey, the biggest obstacle to using the service is the cost. The high turnover of treatment providers' staff, lack of time, staff shortages and service providers' not having recognised a need for the service and its benefits were also mentioned as barriers to using the service.

2.8.10 National medication lists

Once Kanta medication lists⁴⁵ are deployed, all healthcare professionals who are involved in a patient's pharmacotherapy will be able to see the same, simply presented, up-to-date medication list of anyone with a Finnish identity code in all client and patient information systems that are linked to the Prescription Centre, regardless of where they work. Citizens will be able to view their own records in MyKanta⁴⁶.

Kanta medication lists will make it easier to keep track of patients' latest medication. The new approach to managing pharmacotherapy information will be medicine-based instead of prescription-based. Each individual's medications will be compiled into a list at the

⁴⁵ <https://www.kanta.fi/en/professionals/kanta-medication-list>, 4 December 2023.

⁴⁶ MyKanta is an online service for citizens where they can browse their own client and patient data and medication records as they appear in healthcare and social welfare information systems.

Prescription Centre. Kanta medication lists will be based on nationwide information systems that make it possible to record and save data in a harmonised format.

Kanta medication lists are being deployed in five phases: prescription development, deployment of national medication lists, medication lists at treatment interfaces, inpatient medication and citizens' entries as well as comprehensive and holistic pharmacotherapy data.

The first phase began on 1 May 2022 and covers, for example, structured dosage. Everyone must have adopted structured dosage by 2025. Information system suppliers can begin to test their systems in the summer of 2024.

The second phase involves deploying Kanta medication lists in stages starting in the autumn of 2025. At that point, medication lists will include not only prescriptions but also information about dose changes and the discontinuation of medicines. The deadline for deployment is 1 October 2027. The dose-dispensing functionality will be as before in the deployment-phase Kanta medication lists.

The third phase involves improving the functioning of medication lists at treatment interfaces, adding information about pharmacotherapy checks, enabling messaging between pharmacies and healthcare providers and incorporating over-the-counter medication. The plan is to make the changes relating to dose dispensing during this phase.

The fourth and fifth phases involve incorporating citizens' own entries and enabling messaging between citizens and their pharmacy or healthcare provider. More detail will also be added to patients' pharmacotherapy data by incorporating natural remedies and dietary supplements as well as special circumstances.

The project has been slowed down by, for example, legislative challenges, delays in the deployment of patient information systems, the multitude of information systems involved and the Finnish health and social services reform. Future challenges are expected to relate to the learning of new procedures and the cancelling of outdated prescriptions at the Prescription Centre.

Automated dose dispensing of medicines is widely believed to improve medication safety, but medication safety incidents related to dose dispensing still occur. It is clear that the number of incidents will grow as more patients are added to the dose-dispensing scheme while there are no harmonised procedures.

Patients' medication changes are recorded in both the patient information system and the pharmacy system. According to the national guidelines, patients' suitability for dose dispensing must be reviewed at least once a year. If a patient's medication changes more than once a month, his/her medication is not sufficiently well established for dose dispensing. According to the Council of Europe's guidelines, a patient's suitability for dose dispensing must be assessed on a case-by-case basis and reviewed, for example, whenever changes are made to the patient's medication. The records of medication changes that accumulate in information systems do not support the assessment of patients' suitability. It appears that the threshold for removing patients from the dose-dispensing scheme is high.

3.1.2 The pausing of the medicine

A new medicine was prescribed for the patient, which s/he needed to start taking immediately. A decision was made to have the medicine supplied by means of automated dose dispensing. The new prescription was the 14th change in the medication that the patient was getting by means of automated dose dispensing within less than a year. The pharmacy placed a rush order for automated dose dispensing in a way that required the patient's existing medications to be paused in the automated dose-dispensing system. The plan was to reactivate all of the patient's previous medicines in the system when the next regular two-week dose-dispensing order was made. However, one medicine was not returned during the reactivation process.

The information system displays the ordered medicines as a vertical list. Older patients often have multiple medications, which means that not all of their medicines necessarily appear on the screen at the same time. The information system does not clearly show whether a medicine is on pause.

The information system supplier recommends making rush orders for individual medicines 'anonymously', in which case all the medicines are supplied in one or several pouches. The pouches will not be labelled with the patient's name, however, and it is up to the pharmacy to match the pouches to the patient. This recommended method does not require pausing the patient's other medications. Homecare workers take the medicines out of the pouches and place them manually in the patient's dosette box. The benefit of having medicines supplied in pouches according to when the patient is meant to take them is therefore lost. The information system should enable making a rush order using the patient's information without pausing their other medications.

The pharmacy employee who made the order had learned the method s/he used from his/her predecessor as part of their orientation. The advantage of this method was that the medicines would be supplied in single-dose pouches according to when the patient was meant to take them and the pouches would be labelled with the patient's name.

Pharmacies have adopted practices that are not the best from the perspective of medication safety. How widespread these practices are could be studied based on statistics compiled by dose-dispensing units, however no such statistics currently exist.

3.1.3 The checking of the dose-dispensed medicines at the pharmacy

The pharmacy checked the medicines that had arrived from the dose-dispensing unit against the dose-dispensing order. Particular attention was given to ensuring that the newly prescribed medicine had been dispensed as ordered and was included in the delivered batch of medicines. The contents of the order were not checked against the patient's up-to-date medication list, contrary to the Finnish Medicines Agency's regulation.

Pharmacies do not always have access to patients' latest medication lists. One of the objectives of the introduction of national Kanta medication lists is to make it easier for pharmacies to find each patient's most recent medication list.

The ways in which dose-dispensed medicines are checked at pharmacies vary. The current system of pharmacy oversight and supervision is not equipped to stop irregular and unsafe practices.

3.1.4 The checking of the dose-dispensed medicines by the home care team

The home care team checked the medicines that they had received against the dose-dispensing order. The batch of dose-dispensed medicines that had arrived was not checked against the patient's most recent medication list. The checks focused on making sure that the recent medication change was included and that the medicines were as ordered. This was the home care provider's established procedure. The home care team relied on the pharmacy to ensure the correctness of dose-dispensed orders.

Neither the home care organisation's self-regulation procedures nor the current system of oversight by the service provider and the authorities are equipped to stop irregular and unsafe practices and prevent anomalies.

Both pharmacies and home care providers collect information about incidents to improve their own operations. There have been a lot of anomalies. It appears that information about these anomalies has been shared between the organisations to an extent, but there has been no systematic procedure.

The National Medication Safety Programme of Community Pharmacies in Finland, launched by the Association of Finnish Pharmacies and the Finnish Centre for Client and Patient Safety, will enable the sharing of patient safety incident reports between organisations in the future. Analysing incidents is one way to identify weaknesses in existing procedures.

The current national guidelines are not always very effective in factoring in all the medication safety aspects associated with dose dispensing. More detailed guidance is needed on the assessment of patients' suitability in connection with medication changes.

Good information sharing practices need to be identified and decisions made about how the sharing of information about patient safety incidents between organisations should be taken into account as a measure of quality.

3.1.5 The patient not getting his/her medicine and ending up in hospital

The patient was left without one of his/her medicines when the next two-week dose-dispensing period began. The patient's health took a turn for the worse towards the end of the dose-dispensing period, a little less than two weeks later. The patient was admitted to hospital.

The doctors at the hospital did not initially know that the patient had not received one of his/her medicines for two weeks. The registered nurse employed by the homecare provider

took the initiative to look into the case, noticed the omission and notified the hospital. The patient died in hospital two days after his/her admission.

4 CONCLUSIONS

The conclusions include the causes of the accident or incident. A cause means the various factors behind the incident and the direct and indirect circumstances affecting it.

1. The medication that the patient was being supplied by means of automated dose dispensing had changed a total of 14 times in the within of ten months, and this information would have been available in the information systems. The patient's medication regimen was not sufficiently well established for dose dispensing.

Conclusion: *The patient's suitability for automated dose dispensing had not been reviewed, even though there were reasons to discontinue dose dispensing. The existing information systems do not promote suitability assessment as well as they should. The threshold for removing a patient from the dose-dispensing scheme is high.*

2. The pharmacy chose to make a rush order for automated dose dispensing in a way that required the patient's other medications to be paused in the information system. There are also other pharmacies that follow this procedure. The information system supplier recommends that rush orders be made anonymously, without using the patient's information, in which case the patient's existing medications do not need to be paused in the system. When this method is used, the home care provider receives all of the patient's medication in a single pouch, which means that the medicines have to be dispensed to the patient manually and some of the medication safety benefit is lost.

Conclusion: *Some pharmacies have adopted a practice whereby they execute rush orders in a way that does not comply with the information system supplier's instructions, which creates a risk of a medication error.*

3. The medicines that had arrived from the dose-dispensing unit were checked against the order at the pharmacy. The checks focused on the medication change that had been put through as a rush order. According to the Finnish Medicines Agency's regulation, the correctness of dose-dispensed medication must be checked by comparing the medicines received from the dose-dispensing unit against the patient's most recent medication list. This was not done in the case at hand. The second phase of the deployment of national Kanta medication lists is scheduled to run from 2025 to 2027.

Conclusion: *The current system of pharmacy oversight and supervision is not equipped to stop irregular, high-risk practices. One of the objectives of the introduction of national Kanta medication lists is to make it easier for pharmacies to find each patient's most recent medication list.*

4. The home care team checked the medicines that had been received against the order. The checks focused on the medication change that had been put through as a rush order. The home care team did not check the medicines against the patient's up-to-date medication list.

Conclusion: *The current system of home care oversight and supervision failed to stop this high-risk practice.*

5. Both pharmacies and home care providers collect information about patient safety incidents to improve their own operations. There has been no systematic sharing of patient safety incident reports between organisations.

Conclusion: *The National Medication Safety Programme of Community Pharmacies in Finland, launched by the Association of Finnish Pharmacies and the Finnish Centre for*

Client and Patient Safety, will enable the sharing of patient safety incident reports between organisations in the future.

5 SAFETY RECOMMENDATIONS

5.1 Identification of medication safety requirements for information systems that are used in dose dispensing

Medication safety in the context of dose dispensing is made up of multiple elements, including information systems. The overall picture is fragmented. The current information systems are not always conducive to ensuring medication safety. The systems do not issue prompts or warnings when a patient is no longer a good candidate for dose dispensing or when a review of a patient's suitability for dose dispensing is overdue. The frequency of a patient's medication changes is not tracked in real time, even though this is critical from the perspective of safe pharmacotherapy.

The Safety Investigation Authority recommends that:

The Ministry of Social Affairs and Health investigate weaknesses in the information systems that are currently used in dose dispensing and any legislation that may be needed for the competent authorities to be able to issue more detailed regulations regarding essential information system requirements. [2024-S1]

The goal is to have information systems actively encourage users to access all the information that is needed for dose dispensing and thereby promote medication safety. Information systems should issue prompts, for example, if the user does something that contradicts the user manual. The systems themselves would therefore contribute to controlling the risk associated with using information systems. Information systems are not currently certified from the perspective of medication safety.

5.2 Sharing and learning from pharmacies' medication safety incidents

The pharmacotherapy process consists of multiple steps, and medication safety requires everyone involved in the process to work together. Older patients in particular are often prescribed multiple medications, which increases the risks. Medication safety incidents involving dose dispensing still happen. There is no systematic sharing of patient safety incident reports between pharmacies and wellbeing services counties, and no lessons are being learned from the incidents. The National Medication Safety Programme of Community Pharmacies in Finland (VALO) launched by the Association of Finnish Pharmacies and the Finnish Centre for Client and Patient Safety should be deployed across all wellbeing services counties. Collecting information about patient safety incidents, reporting incidents and learning from incidents all contribute to the safety of dose dispensing. The valuable information that can be gleaned from the VALO initiative must be leveraged to promote medication safety management.

The Safety Investigation Authority recommends that:

The Ministry of Social and Affairs ensure that patient safety incident reports concerning medication errors and lessons to be learned from such incidents are communicated effectively between pharmacies and wellbeing services counties and that clear, established procedures for sharing information are put in place. [2024-S2]

5.3 Improvements in the self-regulation of pharmacies

Pharmacies follow a variety of procedures relating to dose-dispensing services, which the current system of oversight and supervision has not been able to prevent. The Finnish Medicines Agency supervises pharmacies through licensing and by imposing notification obligations as well as by means of auditing pharmacy inspections. Unlike other service providers in the healthcare and social welfare sector, pharmacies have no legal obligation to have a self-regulation policy in place. The objective of self-regulation is to ensure a high standard of customer service and safety. Above all, self-regulation prevents weaknesses in service provision and reduces the need for the supervisory authorities to intervene by means of retrospective enforcement.

The Safety Investigation Authority recommends that:

The Finnish Medicines Agency ensure that pharmacies adopt better self-regulation procedures to promote medication safety. [2024-S3]

Implementing the recommendation would bring pharmacies closer to the rest of the healthcare and social welfare system and harmonise medication safety practices between healthcare and social welfare providers.

5.4 Revision of national dose-dispensing guidelines

The Finnish Medicines Agency found in its 2022 report that the roles of the various operators involved in dose dispensing and the division of responsibilities and obligations could be clearer. The report saw updating the national *Guide on Good Practices in Patient-specific Dispensing of Medication* in collaboration with the most important authorities and operators as a high priority.

The investigation team agrees that the Guide is in need of updating. A procedure for assessing the suitability of patients in connection with medication changes and a description of how information systems can encourage these assessments need to be added to the Guide. The Guide also needs to include a description of the standard of cooperation between dose-dispensing clients and pharmacies as well as of the division of responsibilities. This will ensure systematic sharing of information about medication safety incidents between different organisations and the provision of support by pharmacies to clients.

The Safety Investigation Authority recommends that:

The Ministry of Social Affairs and Health ensure that the Guide on Good Practices in Patient-specific Dispensing of Medication is updated in collaboration with the relevant authorities and operators. [2024-S4]

Procedures relating to automated dose dispensing are also described in the Safe Pharmacotherapy guide, which healthcare and social welfare providers have adopted as the recommended standard of safe pharmacotherapy. The need to also update this guide must be evaluated in connection with the updating of dose-dispensing procedures.

5.5 Measures that have been taken

The pharmacy has changed its order procedure so that rush orders for a single medicine are now always made anonymously.

The supplier of the pharmacy management system has added a new feature to the ordering system that now requires a time limit to be specified whenever a medicine is put on pause in connection with an order. This feature had already been in the works before the incident described in this report. The new feature was added in connection with a software update in August 2023.

BIBLIOGRAPHY

Written sources

- European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM) (2018): *Automated dose dispensing (ADD) – Guidelines on best practice for the ADD process, and care and safety of patients*. Strasbourg, France.
- Jokela, Johanna (2023): *Effect of automated dose dispensing on medication safety incidents in long-term professional home care*. Master's Thesis in Pharmacy, Pharmacy, Faculty of Science and Engineering, Åbo Akademi University, Turku, Finland.
- Social Insurance Institution of Finland (2021): *Dose dispensing*. <https://www.kela.fi/yhteistyokumppanit-laakekorvaukset-apteekit-annosjakelu>, 4 December 2023.
- Social Insurance Institution of Finland (2023): *Kanta medication list*. <https://www.kanta.fi/en/professionals/kanta-medication-list>, 4 December 2023.
- Finnish Medicines Agency (2011): *Manufacturing Medicinal Products in Pharmacies*. Regulation 6/2011 of the Finnish Medicines Agency. Helsinki, Finland.
- Finnish Medicines Agency (2016): *Supplying Medicines*. Regulation 2/2016 of the Finnish Medicines Agency. Helsinki, Finland.
- Finnish Medicines Agency (2022): *Current state and development needs of automated dose dispensing of medicines*. Fimea Develops, Assesses and Informs 7/2022. Kuopio, Finland.
- Finnish Medicines Agency (2023): *Finnish Medicines Agency's indicator data: Weaknesses in the Pharmacotherapy of Elderly People*. Sic! newsletter. <https://sic.fimea.fi/-/fimean-indikaattoritiedot-iakkaiden-laakehoidoissa-kehittavaa>, 4 December 2023.
- Rasmussen, J & Svedung, I (2000): *Proactive Risk Management in a Dynamic Society*. Karlstad, Sweden: Swedish Rescue Services Agency.
- National Supervisory Authority for Welfare and Health (2014): *Regulation on the content, drawing up and monitoring of self-regulation plans for private social services and public services for older people*. Regulation 1/2014. Helsinki, Finland.
- Ministry of Social Affairs and Health (2016): *Guide on Good Practices in Patient-specific Dispensing of Medication*. Reports and Memorandums of the Ministry of Social Affairs and Health 2016:1. Helsinki, Finland.
- Ministry of Social Affairs and Health (2021): *Safe Pharmacotherapy – Guide to producing a pharmacotherapy plan*. Publications of the Ministry of Social Affairs and Health 2021:6. Helsinki, Finland.
- Ministry of Social Affairs and Health (2022): *The Client and Patient Safety Strategy and Implementation Plan 2022–2026*. Publications of the Ministry of Social Affairs and Health 2022:2. Helsinki, Finland.
- Ministry of Social Affairs and Health (2023): *Development of the pharmacy system – Assessment of the current situation and proposals for further measures*. Reports and Memorandums of the Ministry of Social Affairs and Health 2023:6. Helsinki, Finland.
- Association of Finnish Pharmacies (2018): *Safe Pharmacotherapy Toolkit*. Service for health-care and social welfare operators. <https://www.apteekki.fi/apteekki-palvelut/sote-toimijoille.html>, 4 December 2023.
- Official Statistics of Finland (OSF): *Population projection* [online publication]. ISSN = 1798-5137. Helsinki, Finland: Statistics Finland <https://stat.fi/en/statistics/vaenn>, 15 October 2023.
- Finnish Institute for Health and Welfare (2021): *Regulation on the classification and certification of information systems in social welfare and health care*. Regulation 4/2021 of the Finnish Institute for Health and Welfare. Helsinki, Finland.

Investigation materials

- 1) Internal procedures of the pharmacy
- 2) Patient safety incident reports involving home care

- 3) Patient safety incident reports involving pharmacies
- 4) Survey for home care operators
- 5) Survey for pharmacies
- 6) Interviews
- 7) Client and patient records and policies of the Wellbeing Services County
- 8) Records and documents of the authorities
- 9) Forensic medical data

SUMMARY OF STATEMENTS REGARDING THE DRAFT INVESTIGATION REPORT

The draft version of the investigation report has been sent for comments to the Ministry of Social Affairs and Health, the Finnish Institute for Health and Welfare, the Finnish Medicines Agency, the National Supervisory Authority for Welfare and Health, the Regional State Administrative Agency for Southwestern Finland, the Wellbeing Services County of Satakunta, the Association of Finnish Pharmacies, the Finnish Centre for Client and Patient Safety, the pharmacy involved in the case, the parties involved in the case, the information system supplier, the dose-dispensing unit and the patient's family. In accordance with the Safety Investigation Act, statements by private individuals are not published.

According to the statement of the **Ministry of Social Affairs and Health**, the draft version of the investigation report clearly describes the course of events and the contributing factors. The reports that were consulted in the course of the work have been described comprehensively. The information provided by the Ministry to the investigation team in the course of the investigation has also been factored in comprehensively.

The Ministry considers the recommendations addressed at the Ministry of Social Affairs and Health in the draft version of the investigation report to be appropriate. The Ministry is aware of the identified weaknesses, and some improvements are already being planned. The current Government Programme also recognises the need to further improve dose dispensing to increase medication safety and efficient use of human resources. The Ministry of Social Affairs and Health intends to examine the regulations governing dose dispensing and any weaknesses in those regulations as part of its Medicines and Pharmaceutical Economy project.

Regarding the recommendation to identify medication safety requirements for information systems that are used in dose dispensing, the Ministry of Social Affairs and Health points out that the law already lays down essential functional requirements for information systems. The prompts mentioned in the draft version of the investigation report that information systems should issue at various points of the process to ensure medication safety could be incorporated into these essential requirements. This should be worked into the wording of the recommendation.

The Ministry of Social Affairs and Health supports the recommendation to share and learn from pharmacies' medication safety incidents. The Client and Patient Safety Strategy and Implementation Plan identify the need to review the procedures for reporting adverse reactions, patient safety incidents and non-compliances in general as well as to learn from these incidents and to openly share the lessons learned.

The Ministry of Social Affairs and Health also supports the recommendation to update national dose-dispensing guidelines. The Ministry's view is that the feasibility of regulating about requirements and operators' responsibilities should be assessed before the procedural guidelines are revised.

The Ministry of Social Affairs and Health also proposes certain changes to the terminology used in the draft version of the investigation report.

According to the **Finnish Medicines Agency**, the draft version of the investigation report is clear and well written on the whole. The operators and procedures involved in automated dose dispensing are described comprehensively and in detail, and the critical points from the perspective of medication safety are explained clearly. The Finnish Medicines Agency has no issue with any of the safety recommendations made in the report. All the recommendations are justified and supportable. The safety recommendations are concrete and practical. The

Finnish Medicines Agency believes that implementing the recommendations will improve medication safety in the case of patients who rely on automated dose dispensing.

The Finnish Medicines Agency calls attention to the practice described in the draft version of the report according to which medicines supplied in pouches are placed in patients' dosette boxes by home care workers. Placing medicines that have been supplied by means of automated dose dispensing into dosette boxes can potentially compromise medication safety, as redistributing the medicines involves a risk of medicines getting lost or the patient ending up taking medicines at the wrong time if they are placed in the dosette box incorrectly. Moreover, when medicines are administered from dosette boxes, verifying the name of the patient and the names and strengths of the medicinal products is not as straightforward as when medicines are supplied by means of automated dose dispensing and the information is printed on the pouches. If placing medicines in a dosette box is the only way to ensure that the patient gets his/her medication, this must be done with extra care and avoiding risk whenever possible.

The Finnish Medicines Agency has emphasised in its guidance and supervision of pharmacies the importance of supplying dose-dispensed medicines in accordance with the Finnish Medicines Agency's regulation. Final checks before medicines are deemed ready to deliver must be made against the patient's prescriptions or up-to-date medication list. Any pharmacies that auditors have found to be checking outgoing medicines against, for example, the list of dispensed medicines provided by the dose-dispensing unit have been given a warning and instructed to change their practice.

The Finnish Medicines Agency intends to further emphasise in its guidance the importance of checking outgoing medicines that have been supplied by means of automated dose dispensing against the patient's most recent medication list. The Finnish Medicines Agency is committed to start promoting the self-regulation of pharmacies in the context of automated dose dispensing and educating pharmacies on best practices in this respect.

The Finnish Medicines Agency also proposes a few minor changes to the draft version of the investigation report.

According to the **Regional State Administrative Agency for Southwestern Finland**, the draft version of the investigation report is comprehensive and detailed. The Regional State Administrative Agency points out that home care is regulated by the Social Welfare Act. Home care encompasses, for example, personalised care and nurturing according to the client's needs as well as home nursing within the meaning of the Health Care Act. The home care organisation is not a health-care provider.

The Regional State Administrative Agency for Southwestern Finland suggests adding the updating of the Ministry of Social Affairs and Health's Safe Pharmacotherapy guide (Publications of the Ministry of Social Affairs and Health 2021:6) to the safety recommendations made in the draft version of the investigation report. Health-care and social welfare providers have adopted the guide as the recommended standard of safe pharmacotherapy. Due to the increasing use of automated dose dispensing, it would be good for the Safe Pharmacotherapy guide to include more detailed guidance on risk management in the context of automated dose dispensing regarding, for example, the identity of the employee of the health-care or social welfare provider who should inspect the dose-dispensing pouches that arrive from pharmacies as well as how and when the checks should be performed. Special attention should be given to social welfare providers that employ not just health-care and social welfare professionals but also other staff (such as care assistants) who may sometimes be involved in administering medication. The Regional State Administrative Agency for

Southwestern Finland considers it important that the Safe Pharmacotherapy guide and the Guide on Good Practices in Patient-specific Dispensing of Medication not contradict each other.

The **Wellbeing Services County of Satakunta** considers the investigation report relatively comprehensive. The Wellbeing Services County believes that they will be able to use the investigation as a springboard for further improvements in their internal medication safety efforts especially in respect of dose dispensing. The Wellbeing Services County also proposes a few minor changes to the draft version of the investigation report.

The **Association of Finnish Pharmacies** appreciates how thoroughly the incident has been investigated and the clear and necessary practical actions recommended by the investigation team for improving the safety of automated dose dispensing. The Association of Finnish Pharmacies considers the draft version of the investigation report to provide a very clear and comprehensive description of the complex process involved in dose dispensing. The fact that the practices and views of all those involved in the dose-dispensing process as well as cooperation between these operators, including information systems, have been examined is important.

The Association of Finnish Pharmacies considers it of the utmost importance to promptly implement the safety recommendations made in the draft version of the investigation report. Regarding the recommendation to share and learn from pharmacies' medication safety incidents, the Association of Finnish Pharmacies considers it important that a plan be put in place at this stage as to who will be responsible for using the information to promote national and regional medication safety after the VALO initiative. The majority of prescribed pharmacotherapies are administered in the context of outpatient care and supplied by community pharmacies. Cooperation with pharmacies should be turned into an efficient and systematic element of the constantly evolving coordination of medication safety in wellbeing services counties. The Association of Finnish Pharmacies proposes that the Ministry of Social Affairs and Health make the Finnish Centre for Client and Patient Safety responsible for this and give them the necessary resources.

Ordering individual medicines as rush orders from dose-dispensing units has been challenging from pharmacies' perspective. It is important to improve information systems so as to enable making a rush order using the patient's information without pausing his/her other medications. The dose dispensing of medicines is also hampered by staff shortages in the healthcare sector, as the process relies on the pharmacy having up-to-date information on the patient's medication and the associated prescriptions before the dose-dispensing order can be placed.

The process could be made smoother and safety improved, for example, by giving pharmacies broader authorisations to make generic substitutions and by updating information systems and communication channels to improve the exchange of information. Pharmacies must be given appropriate and sufficient access and editing privileges in respect of national Kanta medication lists.

The Association of Finnish Pharmacies emphasises that the increasingly widespread issues with the availability of medicines are making it necessary to make more and more frequent changes to patients' dose-dispensed medication. The above was also one of the contributing factors in this case. Multiple medication changes increase the risk of a medication error at various stages of the dose-dispensing process, and dose dispensing is not suitable for patients whose medication is constantly changing, as is stated in the draft version of the investigation report.

The Association of Finnish Pharmacies also proposes certain minor changes to the draft version of the investigation report.

The **Finnish Centre for Client and Patient Safety** considers the draft version of the investigation report to be clear and comprehensive on the whole and agrees with the safety recommendations. In respect of the recommendation to identify medication safety requirements for information systems that are used in dose dispensing, it would be good to explore the possibility of synchronising the Prescription Centre's data with the dose-dispensing system. Regarding the recommendation to improve the self-regulation of pharmacies, attention should be given to the possibility of imposing a legal obligation on pharmacies to systematically measure quality or introduce similar self-regulation procedures as healthcare and social welfare organisations have an obligation to have in place under the Act on Supervision in Social and Health Services.

The Finnish Centre for Client and Patient Safety would add to the recommendations the efficient implementation across wellbeing services counties of the Act on Supervision in Social and Health Services that entered into force at the start of 2024. The objective of the Act is to encourage greater self-regulation by service providers. When implemented correctly, self-regulation effectively prevents and rectifies weaknesses in service provision. The Finnish Centre for Client and Patient Safety also considers it important that pharmacies and wellbeing services counties ensure not just the orientation of new employees but also that their existing staff understand the dose-dispensing process of pharmacies and the home care provision of wellbeing services counties.

The Finnish Centre for Client and Patient Safety also proposes a few changes to the sections of the draft version of the investigation report that concern the Client and Patient Safety Strategy.

According to the **dose-dispensing unit**, the background information given in the draft version of the investigation report and the course of events are a good match to the dose-dispensing unit's internal documentation and understanding. The dose-dispensing unit has nothing to add to the content of the report or the recommendations. The dose-dispensing unit nevertheless proposes a few minor changes to the descriptions of the dose-dispensing unit's procedures.