Points of risk and severity of incidents
in cancer medication process

Elina Isokangas
(MSc Pharm, Specialist in Community and Hospital Pharmacy)
Vaasa Central Hospital, Wellbeing Services County of Ostrobothnia, Department of Pharmacology and Pharmacotherapy, Faculty of Pharmacy, University of Helsinki

Tuija Ikonen
(MD, PhD, professor)
The Finnish Centre for Client and Patient Safety, Wellbeing Services County of Ostrobothnia,
Public Health, Faculty of Medicine, University of Turku

Terhi Wilppu
(MSc Pharm, Specialist in Community and Hospital Pharmacy)
Turku University Hospital, Wellbeing Services County of Varsinais-Suomi

Raisa Laaksonen*
(MSc Pharm, PhD, adjunct professor)
Department of Pharmacology and Pharmacotherapy, Faculty of Pharmacy, University of Helsinki,
raisa.laaksonen@helsinki.fi

Correspondence

Isokangas E, Wilppu T, Ikonen T, Laaksonen R: Points of risk and severity of incidents in cancer medication process. Dosis 2025;41(4):498-514.

Abstract

Background
Medication errors are common in healthcare; they may cause harm to patients and costs to the society. Particularly cancer medication process is at high risk for errors. Patient safety incident reporting and learning systems can be used to identify points of risks and improve the medication processes in healthcare organisations. The aims of the study were to identify the points of risks, patient harm, contributing factors, correcting actions and proposed preventative solutions and their follow-up in the cancer medication process from incident reports and to evaluate the severity of patient harm by comparing the initially reported patient harm to the assessment of the harm by expert assessors.

Methods
The data consisted of voluntarily reported incidents (n = 4,196) in cancer treatment units (n = 81) within three healthcare districts between 2019 and 2020. The inter-rater reliability was measured by using Cohen's kappa (κ) to determine the degree of conformity between the assessments of the original data classifiers and expert assessors.

Results
In total, 608 incidents (332 errors, 251 near misses and 25 other identified risk factors) were reported in all phases of the cancer medication process. The original classifiers underestimated the severity of patient harm compared to the assessment of the expert assessors. The inter-rater reliability between the expert assessors and original classifiers was acceptable ($\kappa > 0.41$) only in four of 11 phases of cancer medication process; the comparison of all patient harm assessments showed fair agreement ($\kappa = 0.31$).

Conclusions
Patient safety incidents were reported in all phases of the medication process. There is a need to standardise the assessment of the severity of patient harm. Continuous training to all staff and the engagement of medication safety officers is needed to increase the reliability of reporting and optimise learning from the incidents.

Keywords: Incident reporting, cancer, medication process, inter-rater reliability, medication safety, points of risk

Introduction

Cancer medication treatment comprises cancer and cancer support medication; the patient may also have other diseases, which may require other medications simultaneously (1,2). The pharmacotherapy of a cancer patient and the medication process involved are complex. Many cytostatic drugs are toxic, they have narrow therapeutic ranges and often are administered parenterally (1); errors in cancer medication process are often clinically significant.

However, incidents in the cancer medication process are reported to occur more seldom than in other medication processes (2,3). Yet, incidents may be harmful or even fatal and may cause additional work and extra cost (4,5). Therefore, deviations in cancer treatment should be minimised by making the process as safe as possible.

Guidelines are provided to prevent medication errors in chemotherapy (3). Procedures that are not routine can be assumed to be more liable to incidents (6); people are fallible, and mistakes can happen even in the 'best' organisations (7). The system approach to medication safety is widely used in risk analysis and management in medication processes. Utilising this approach enables learning from medication errors to improve medication safety.

Utilising medication error reporting systems are recommended for learning from errors (8, 9). Voluntary reporting of medication safety incidents allows identifying points of risk in the medication process and developing the processes to be safer for the patient (10). It is estimated that at least 1–3 % of oncology patients are affected by a medication error (an incident that has reached the patient) (2). However, not all incidents, including errors and near-misses (incidents that have been prevented before reaching the patient), are noticed, and not all identified incidents are reported (11).

Incidents in the cancer medication process have mostly been studied in single institution settings with varying methods (2,12–14). Most incidents in cancer treatment have been reported in prescribing, preparation and administration, but due to varying organisational safety practices the results cannot be generalised (2,15). Understanding the potential causes of medication errors and the contributing factors that lead to errors help preventing them (3,16,17). Systematic actions, such as voluntary reporting of correcting actions, proposing of preventative solutions and their follow-up, support organisational learning and can improve patient safety.

In categorisation of patient harm, an accurate incident reporting is needed to achieve the organisational learning from patient safety classification systems (18). Nevertheless, variability has been reported in categorising voluntarily reported incident data (10,18). To our knowledge, studies concerning patient harm categorisations in cancer medication have not been conducted.

The objectives of this study were to:

1. Identify the points of risk in the cancer medication process from voluntary incident reports in the cancer and cancer support medication process.
2. Identify the factors contributing to the incidents, correcting actions and proposed preventative solutions and their follow-up.
3. Identify and evaluate the severity of patient harm caused by the incidents.
4. Compare initially classified patient harm to the assessment of the harm by expert assessors.

Materials and methods

Study design and setting

In this retrospective study, voluntarily and anonymously reported incidents in the cancer and cancer support medication processes between 2019 and 2020 were identified and analysed. The study was conducted in the catchment area of one of the five university hospitals (Turku University Hospital, Satasairaala Central Hospital and Vaasa Central Hospital), providing tertiary care services to 870,000 inhabitants. To identify the oncologic wards or any other units where cancer medication was given to patients, the HaiPro (Awanic Ltd.) software that records all patient care units that have ordered patient-specific parenteral chemotherapy doses from hospital pharmacies was used. Units that might infrequently manage the cancer treatment of single patients, were excluded.

The research approvals were obtained separately from each hospital (Turku University Hospital §2/21; Vaasa Central Hospital §60/21; Satasairaala §36/21). An ethical review was not required as no identifiable patient information is included in the reports.

Data collection and handling

The data were collected from the widely used incident reporting system HaiPro (19). Healthcare professionals (often nurses, but also doctors, pharmacists, and other healthcare professionals), who have identified an incident, i.e. an error or a near-miss, or a risk factor that could contribute to an incident, can report them voluntarily and anonymously by completing an electronic data collection form. The reports are then further processed by classifiers, usually head nurses.

Data were collected from three healthcare districts, providing a more comprehensive material for the analysis of the points of risk of cancer medication process compared to a single institution analysis. All medication-related incident reports, including categorisations (i.e. quantitative data) and narratives (i.e. qualitative data), were provided in Microsoft Excel® (2016) spreadsheets by Awanic Ltd. The following types of events were included: "drug and fluid therapy, blood transfusion and contrast agent"; "flow of information" or "data management"; "medical device"; "asepsis and hygiene"; and "other".

The incident reports contained categorised information (e.g. type of error; name/active substance/ATC classification of drug or product involved; initial assessment of the severity of the patient harm and consequences to the treatment unit) reported by healthcare professionals who had identified the incident. They also contained narrative descriptions of errors/near-misses/other identified risk factors, contributing factors, suggestions for improvement or correcting actions, and follow-up of suggested correcting actions. The "identified risk factor" -option was not used in all hospitals.

The main researcher (EI) identified the cancer and cancer support medication-related incidents and discussed any unclear reports with another researcher (TW) to reach consensus. All reports related to the planning, implementation, or monitoring of cancer medication or cancer support medication were included and reports related to cancer medication in combination with another treatment, e.g., radiotherapy (incidents related to this high-risk treatment should be reported separately). Drugs and fluid products related to cancer and cancer support medication were categorised according to the Anatomical Therapeutic Chemical (ATC) Classification system: antineoplastic agents (ATC: L01); alimentary track preparations (ATC: A02–04); anti-infective agents (ATC: J01–02, J05–06, P01); immunostimulants and immune-suppressants (ATC: L03–04); blood substitutes, perfusion solutions/electrolytes and mineral supplements (ATC: A12, B05, V07); hormonal preparations (ATC: H02, L02); and others (ATC: G04, M04–05, N05, R06, S01, V03). However, reports related to other medication than described above were excluded. Duplicates and inadequate reports were excluded, while reports containing several incidents were separated. Cancer medication protocols were not included in the incident reports.

Analyses

Analyses of both quantitative and qualitative data were performed using Microsoft Excel® (2016). Frequencies and percentages are reported. Furthermore, abductive content analysis was performed on the narrative descriptions (20). The researcher (EI) grouped the reports according to the phases of the medication process (**Table 1**). While there could have been differences in the details of the medication process within, e.g. computerised physician order entry (CPOE) was used in some but not all units in Turku University Hospital, and between the hospitals, e.g., CPOE was in use in Vaasa Central Hospital but not in Satasairaala Central Hospital, the main phases of the medication process could be

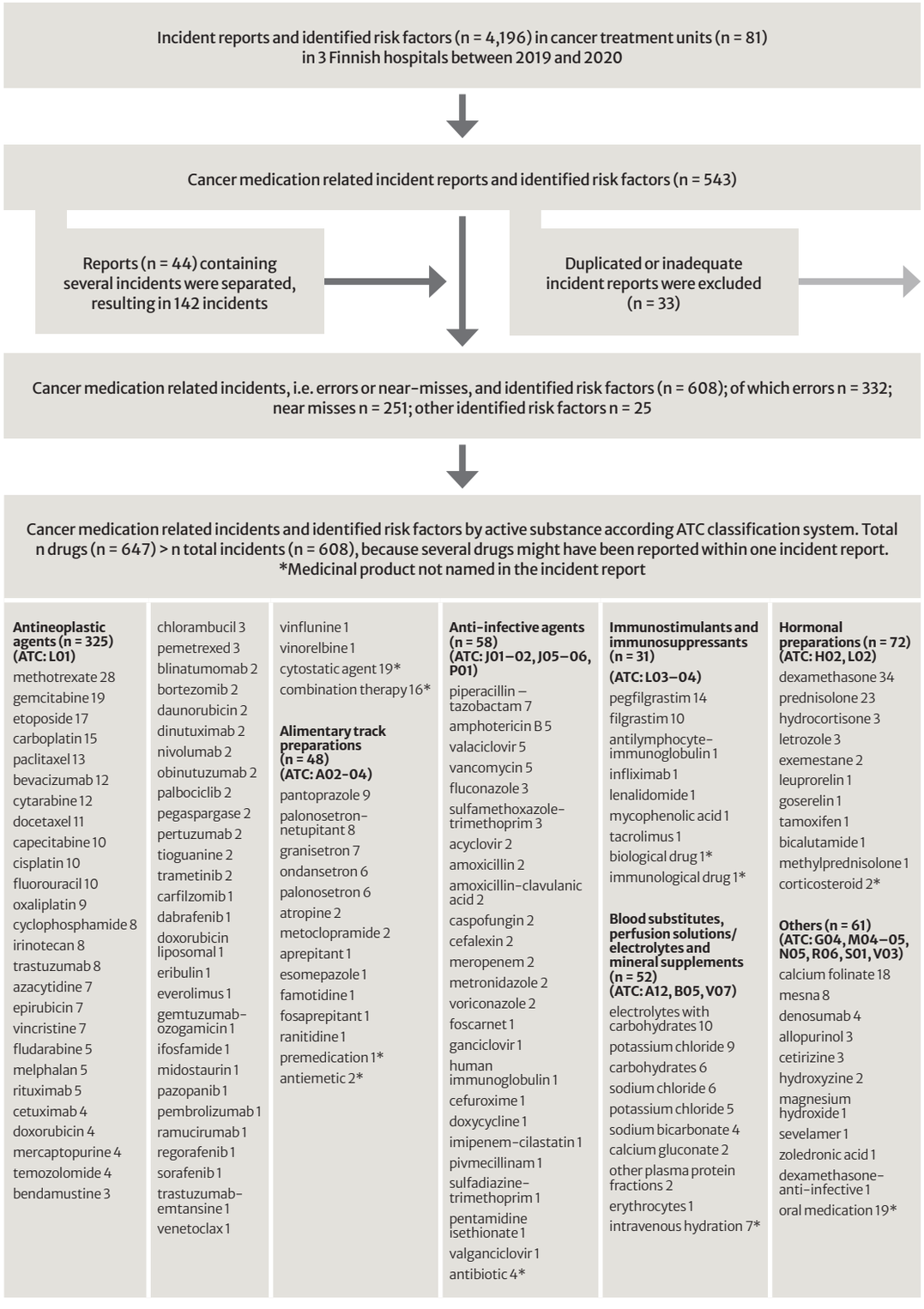

Figure 1. Flowchart of identifying the cancer medication related incidents and identified risk factors (n = 608) and medicinal products involved in the reported incidents or in the identified risk factors.

identified. The phase of the medication process in which the incident occurred was identified from both the categorised information and narrative descriptions. The data concerning incidents during the preparation of a drug or dose in the hospital pharmacy phase may be incomplete since only the hospital pharmacy in Satasairaala used the incident reporting system to report their own manufacturing incidents. Preparing the drug/dose in the unit errors included, e.g. anti-infective agents, azacytidine, biological agents, methotrexate, and cancer support medications (**Table 1**). The researcher (EI) identified factors contributing to the incidents, correcting actions and proposed preventative solutions and their follow-up from the narratives and categorised them. These were confirmed with the other researchers.

The classifiers had categorised the severity of patient harm of the incidents as "no harm", "minor" (mild disadvantage demanding little or no treatment), "moderate" (disadvantage demanding treatment), or "major" (impairing the patient's quality of life or requiring life-sustaining care). Two researchers (EI and TW; pharmacists working within cancer medication safety) comprised an expert assessor team and re-assessed the severity of patient harm based on the narrative descriptions, reaching consensus. The assessment was completed by using the patient harm categorisation in the National Coordinating Council for Medication Error Reporting and Prevention index for categorising medication errors (21) and the Vaasa Central Hospital guidance for categorising the severity of the patient harm (personal communication, 2022).

The severity of patient harm categorised by the classifiers was compared with the assessment of the expert assessors, employing IBM SPSS Statistics (Version 27). The inter-rater reliability was measured by using Cohen's kappa (κ) to determine the degree of conformity between the assessments of the original data classifiers and the researchers (22,23). The variables were coded as: "No consequences/Not known" = 1, "Minor" = 2, "Moderate" = 3, and "Serious" = 4. Interpretation of the kappa-values: 1.00 complete agreement; 0.81–0.99 almost perfect agreement; 0.61–0.80 substantial agreement; 0.41–0.60 moderate agreement; 0.21–0.40 fair agreement; 0.00–0.20 slight agreement, and <0.00 poor agreement or less than agreement by chance (22). The degree of agreement was considered acceptable when resulting in a kappa value of 0.41 or above.

Results

Altogether, 4,196 incidents, including adverse events, errors, near-misses, and other identified risk factors, were reported in 81 cancer treatment units between 2019 and 2020; 543 (12.9%) were related to cancer or cancer support medication. The reports (n = 44) containing multiple incidents were separated, resulting in 142 incidents. Duplicated or inadequate incident reports (n = 33) were excluded. A total of 608 incidents concerning cancer or cancer support medication (332 errors, 251 near-misses and 25 identified risk factors (**Figure 1**) were identified.

Products involved in the incidents

Antineoplastic agents were the most frequently reported drug group involved in 49.2% (n = 299) of the incidents (**Table 1**). Dexamethasone (n = 34) and methotrexate (n = 28) were the drugs most frequently involved in the incidents (**Figure 1**). However, all drug groups included in the study were reported to have been involved in cancer treatment related medication errors, near-misses, or identified risk factors.

Phases of the medication process at which the incident had occurred

Most frequently incidents (**Table 1**) were reported in prescribing (22.2%), administration (19.9%) or dispensing in the unit (14.0%) phases of the medication process that could be deemed points of risk. In the administration, monitoring, or counselling phases, most incidents were errors, and in prescribing and documentation, nearly half of the incidents were errors. However, most incidents related to dispensing in the unit were near-misses. Of the incident types, incorrect dose or missing prescription were the most reported in prescribing, incorrect administration point

Table 1. Reported cancer medication related incidents, i.e. errors or near-misses, and identified risk factors (n = 608) by the phase of the medication process, drug groups involved in the incident, patient harm categorised by the classifiers compared to patient harm identified from narratives by the expert assessors and calculated agreement between the assessors and the original data classifiers.

Phase of the medication process at which the incident had occurred	Nature of incident, n				Drug group (ATC) involved in the incident, n (n ≠ 608, because drug names are not mentioned in all incident reports, and, on the other hand, several drug groups might be involved in one incident)							Severity of the patient harm categorised by the classifiers compared to severity of the patient harm identified from the narratives and categorised by the researchers, n								Cohen`s kappa (κ) describes the agreement of categorised patient harm between the expert assessors and the original data classifiers by the phase of the medication process for which the kappa (κ) was possible to calculate
												Categorised by classifiers				Identified and categorised by expert assessors				
	Total (%)	Errors (%)	Near misses (%)	Identified risk factors (%)	Antineoplastic agent	Alimentary track preparation	Anti-infective agent	Immunostimulant / Immunosuppressant	Blood substitute, perfusion solution /electrolyte or mineral supplement	Hormonal preparation	Other	Serious, n	Moderate, n	Minor, n	No consequences/Not known, n	Serious, n	Moderate, n	Minor, n	No consequences/Not known, n	Severity rating changed by researchers, n (%)	kappa (k) Acceptable agreement rates (κ ≥ 0.41) are in bold
Planning therapy	**49 (8)**	28 (57)	14 (29)	7 (14)	32	3	2	3	0	0	4	0	3	10	36	1	5	22	21	20 (41)	0.305
Prescribing	**135 (22)**	62 (46)	66 (49)	7 (5)	66	11	10	9	4	22	11	0	2	5	128	1	25	35	74	55 (41)	0.109
Ordering the drug / dose from the pharmacy	**34 (6)**	11 (32)	21 (62)	2 (6)	32	0	0	0	0	2	2	0	0	7	27	0	0	14	20	7 (21)	**0.541**
Preparing the parenteral drug / dose in the pharmacy*	**14 (2)**	4 (29)	10 (71)	0 (0)	14	0	0	0	0	0	0	0	0	1	13	0	0	5	9	4 (29)	0.243
Dispensing or delivery of the drug from the pharmacy to the unit	**7 (1)**	5 (71)	1 (14)	1 (14)	7	0	0	0	0	0	0	0	0	3	4	0	0	5	2	2 (29)	**0.462**
Storage	**10 (2)**	4 (40)	6 (60)	0 (0)	5	0	1	1	3	0	0	0	0	3	7	0	0	3	7	0 (0)	**1.000**
Preparing the drug / dose in the unit**	**9 (2)**	6 (67)	2 (22)	1 (11)	3	1	3	1	1	0	0	0	0	0	9	0	0	5	4	5 (56)	- (#)
Dispensing in the unit	**85 (14)**	4 (5)	81 (95)	0 (0)	5	13	9	2	4	27	22	0	0	4	81	0	1	9	75	7 (8)	**0.466**
Administration	**121 (20)**	112 (93)	9 (7)	0 (0)	64	8	17	5	11	7	12	0	9	47	65	1	34	71	15	72 (60)	0.139
Monitoring or counselling	**62 (10)**	52 (84)	8 (13)	2 (3)	36	2	1	2	9	3	4	0	3	21	38	1	13	39	9	37 (60)	0.132
Documentation ***	**82 (13)**	44 (54)	33 (40)	5 (6)	35	5	8	10	8	11	5	0	1	11	70	0	7	25	50	24 (29)	0.331
Total	**608 (100)**	332 (55)	251 (41)	25 (4)	299	43	51	33	40	72	60	0	18	112	478	4	85	233	286	233 (38)	0.307

* Preparing the parenteral drug / dose in the pharmacy errors may be incomplete as these were only reported to the incident reporting system in Satasairaala.
** Preparing the drug / dose in the unit errors included, e.g. anti-infective agents, azacytidine, biological agents, methotrexate, and cancer support medications.
*** Documentation errors may be linked to any phase of the medication process.
# No measures of association could be computed as at least one variable was computed as a constant.

or duration of the treatment in administration, and incorrect drug/dose/dosage form in dispensing in the unit (**Figure 2**). Incidents involving antineoplastic agents, the drug group most frequently involved in the incidents (**Table 1**), were reported in all phases.

Contributing factors, correcting actions, and follow-up of correcting actions

Deficiencies related to communication and information, and working patterns, work environment or working tools were frequently reported as contributing factors (**Figure 2**). Several contributing factors were usually identified in a single report. However, some reports did not include any suggestions for improvement or correcting actions, or follow-up of these correcting actions.

Severity of the patient harm

The classifiers had most often categorised the severity of patient harm of the incidents as "No consequences/Not known" (n = 478, 78.6%); none had been categorised as "Serious" (**Table 1**). The researchers identified the patient harm from the narrative descriptions and considered them more serious: the severity of the patient harm was changed for 233 (38.3%) reported incidents (**Table 1**).

Inter-rater reliability between the original classifiers and the researcher

The agreement of patient harm in the reported incidents was considered acceptable (κ ≥ 0.41) in only four phases of the medication process (**Table 1**). The kappa value for all patient harm assessments was fair (κ = 0.307).

Contributing factors to incidents in cancer medication process*

Communication, information, teamwork
Lack of oral communication
Lack of written communication
Unclear information
Dictation delayed
Medication list without reconciliation
Shift change, break or nightshift
Patient monitoring incomplete

Competence of personnel
Inadequate training
New staff
Deviation from the instructions
Complicated treatment protocol
Incompatibility
Unusual hydration protocol

Work environment and tools
Distractions
Patient transfer between units
New department
New patient information system or challenges of using the system
Insufficient access to the patient information system
New patient group in the unit

Drugs
Rarely used drug
Same drug dispensed to several patients at the same time

Devices or instruments
Malfunction of the medical device

Working patterns
Insufficient methods or practices
Documentation on paper instead of patient information system
Documentation to multiple locations
Oral prescription or rarely prescribed drug
Atypical time for prescription or drug administration
Outpatient care
Incorrect documentation
Drug paused incorrectly
Results of the laboratory tests uninterpreted
Inadequate double checking
Sampling in the middle of treatment
Drug/dose not ordered from the pharmacy

Human factors
Calculation or typing error
Hurry or fatigue
Negligence
Oblivion
Patient factors

Organisation and leadership
Process planning incomplete
Different treatment practices between units
Unclear sharing of responsibilities
Out of date instructions
Shift arrangements
Insufficient human resources

Incidents or identified risk factors (n = 608)

Planning therapy (n = 49)
Appointment or referral incomplete or incorrect (n = 24)
Non-transmitted or incorrect information (n = 15)
Challenges to carry out the treatment protocol (n = 10)

Prescribing (n = 135)
Incorrect dose (n = 46)
Missing prescription (n = 32)
Unclear or incorrect prescription (n = 28)
Overlapping or unnecessary prescription (n = 19)
Incorrect drug or unrevised prescription (n = 10)

Ordering the drug / dose from the pharmacy (n = 34)
Incorrect order (n = 23)
Order forgotten to complete or cancel (n = 11)

Preparing the drug / dose (n = 23)
Incorrect preparing in the pharmacy (n = 14)
Incorrect preparing in the unit (n = 9)

Delivery (n = 7)
Delivery error (n = 7)

Storage (n = 10)
Incorrect storage (n = 10)

Dispensing (n = 85)
Incorrect drug, dose or dosage form dispensed (n = 45)
Undispensed drug (n = 33)
Incorrect dispensing point (n = 7)

Administration (n = 121)
Incorrect administration point or duration of the treatment (n = 23)
Extravasation or allergic reaction (n = 19)
Incorrect drug, fluid or blood product administered (n = 16)
Unadministered drug, fluid or blood product (n = 16)
Incorrect dose or strength (n = 11)
Incorrect dosage form or route of administration (n = 4)
Other (n = 32)

Follow-up or counselling (n = 62)
Insufficient patient monitoring (n = 33)
Laboratory tests unperformed or uninterpreted (n = 16)
Non-transmitted or incorrect information (n = 13)

Documentation # (n = 82)
Incomplete, unclear, or incorrect patient information (n = 20)
Drug administration or discontinuation not documented (n = 19)
Information documented in wrong place (n = 4)
Medication list not updated (n = 4)
Data not checked/printed from electronic system (n = 3)
Patient information ignored (n = 1)
Other incidents in drug documentation (n = 24)
Other misunderstood information in documentation (n = 7)

(#documentation might be linked to any phase of the medication process)

Correcting actions**

Communication, information, teamwork, working patterns
Common procedures for documentation
Common treatment protocols for units
At least two nurses present with a demanding chemotherapy patient
Using electronic procedures
Drug programming as close as possible to the administration time to avoid confusion
Use of highlighting with the important information in the batch document to make it more visible
Oral prescriptions shall be repeated if they are necessary to be used
Performing the drug dispensing during the day instead of the night shift

Competence of personnel
Training
Update the student guidance process
Compile checklists for example to the introduction of chemotherapy work
Preparing a newsletter for staff

Work environment, tools and resources
Actions to minimize noise and interruptions
Optimization of time used for chemotherapy orders
Developing the electronic patient information system
Shortening the response time for medical devise maintenance

Drugs
Double-checking
Use of a barcode scanner or mobile recording
Agreeing common procedures to ensure the right medicine (e.g. identification of the Vnr-number)
Enclosing the label and the batch document if the patient receives more than one IV-administered drug
Printed patient label in use instead of a handwritten label
Clearer shelf markings for storage
Updating the dilution fluids of chemotherapy courses

Organisation and leadership
Occupational well-being development plan to tackle overlapping work tasks
Development of the patient scheduling
Harmonising patient guidance
Development of the nurse's job description
Need for clinical pharmacist identified
Correction of incomplete instructions
More accurate determination of liabilities
Evaluation of policies

Follow-up of correcting actions***

Communication, information, teamwork, working patterns
Prepared guidance for cold deliveries and delivery practices
Errors related to the patient information system are reported by e-mail to the responsible person
Established the job description for the coordinating nurse
Additional pharmacist resources received to the unit
Double-check of the hydration protocol by two nurses and additional confirmation of the doctor
Drugs to be dispensed by two nurses
The guidelines for patient's own medicines defined

Competence of personnel
Internal training initiated for the treatment of a new group of patients
Check-list form for the administration of drug
Written instructions prepared
Additional training arranged

Work environment, tools and resources
Mobile recording adopted
Complaint for the manufacturer
Software developed
Electronic cancer drug treatment instructions introduced at the hospital

Drugs
Standard doses introduced

Organisation and leadership
Agreed consistent policy, which has been sent a newsletter by e-mail to personnel
Convened a multi professional team to develop the process
Process revised and new guidelines prepared
Multi professional guidelines compiled

* Less than one or more than one contributing factor could have been identified and reported per one incident.
**Less than one or more than one correcting action could have been suggested and reported per one incident.
*** Less than one or more than one correcting action could have been implemented and reported per one incident.

Figure 2. Reported cancer medication contributing factors, incidents, i.e. errors or near-misses, or identified risk factors (n = 608), correcting actions and follow-up of correcting actions described in the incident reports. Several contributing factors were usually identified in a single report. However, some reports did not include any suggestions for improvement or correcting actions, or follow-up of these correcting actions.

Discussion

The widely used patient safety incident reporting and learning system, and reports from one university hospital catchment area, enabled the detection of, and learning from, potential systemic points of risk in the cancer medication process. More than half of the reported incidents had occurred in three phases of the medication process: prescribing; administration; and dispensing in the unit. However, incidents were reported in all phases of the medication process, and all drug groups involved in cancer or cancer support treatment were reported to have been involved in the incidents. The reporters had been able to identify some contributing factors but might not have been able to identify or report all potential factors (24) or had time to do so. The classifiers might not have been able to identify all potential correcting actions or safeguards or had the time to report the follow-up of correcting actions, and they had originally estimated the severity of patient harm less severe than the expert assessors.

Products involved in the incidents and phases of the medication process at which the incident had occurred

Both antineoplastic agents such as methotrexate, but also supportive drugs such as dexamethasone, were involved in the incidents. Incidents were reported to have occurred in the use of all drug groups and in all phases of the medication process, as also suggested previously (2,6). Prescribing, administration and dispensing in the unit were the phases in which the incidents were most frequently reported as in other studies (2,14). On the contrary to prescribing and administration, most reports related to dispensing in the unit in this study were near misses, which might reflect the functionality of the recommendations on double-checking (3).

In this study, the proportion of prescribing errors was similarly high as in another study in which the effect of the implementation of an electronic health record system on the reported medication errors was studied in another university hospital (25), and higher than in a previous study using all data gathered in the national patient safety incident reporting and learning system between 2007 and 2009 (10). This might reflect improvement in the identification and reporting of prescribing errors. However, complex treatment protocols such as methotrexate treatment were frequently reported also in prescribing and, therefore, need to be studied further, since the cumulative risk of adverse events has been reported over a course of a treatment (2). While, in 2022, 8,227 parenteral cancer treatments were administered to patients in outpatient cancer clinic of Turku University Hospital (26), voluntary incident reports should not be used to draw conclusions about quantitative differences between medications used and errors occurred, between error types, or between hospitals or their units, but to identify points of risk as extensively as possible.

Contributing factors, correcting actions, and follow-up of correcting actions

In this study, the reporters had identified some contributing factors but might not have been able to identify or report all potential factors. Moreover, the classifiers might not have been able to identify all potential correcting actions or safeguards, since suggestions for improvement or correcting actions and follow-up of correcting actions were not reported in all reports. Lack of competence in incident reporting has previously been considered as a barrier to reporting problems (24); educational interventions have been reported to have improved awareness (27). However, many correcting actions were proposed, for example, actions to minimise noise and interruptions were frequently mentioned in the reports; distractions are observed to increase the risk for medication errors (2,28).

Deficiencies in communication and information were frequently reported to have contributed to medication errors in this and previous studies (3,6). Weiss et al. (2017) reported that multidisciplinary teamwork, such as a daily chemotherapy huddle, could prevent medication errors related to poor communication (28). Pharmacists are recommended to participate in cancer medication process in multidisciplinary teams (3); their role e.g. in medication reviews, prescription or order verification (29,30) and information could prevent deficiencies in communication and thus errors.

Creating or improving procedures for documentation, such as computerised provider order entries (CPOEs), were suggested as corrective actions to standardise cancer treatment and to improve medication safety; at the time of the study, CPOE was being used in cancer care in Vaasa Central Hospital, in some but not all units in Turku University Hospital, and not in Satasairaala Central Hospital. Other suggestions for improvement reported previously and in this study were, e.g., double checking, training of staff, barcode technology and developing the patient information system (2,3). Indeed, it might be possible to prevent many cancer medication prescribing errors by software engineering (e.g. implementing CPOEs), but it might also create new points of risk to the medication process, e.g., if cancer medication order templates are used without checking dose or patient details carefully (3,17). However, there is a need for co-operative patient information systems between different organisations, since software engineering may play an even more important role in the future in preventing medication errors, as the use of outpatient oral cancer medication increases, and different health and social care providers are being integrated to cancer treatment (30,31).

Inter-rater reliability and the severity of the patient harm

The classifiers of the incident reports might not have the expertise in medication safety to categorise the severity of patient harm (10). Indeed, the classifiers had tended to underestimate the severity of patient harm compared with the assessment of an expert assessors, particularly in the rating of patient harm related to errors reported in the prescribing and administration phases.

Learning from incident reporting and improving medication safety

The reporters of the incidents might not have been able to identify or report all potential contributing factors, and the classifiers might not have been able to identify all potential correcting actions or safeguards or had the time to report the follow-up of correcting actions as also reported previously (24). Moreover, the classifiers had not been able to identify or categorise the severity of patient harm. There is need for improvement so that most, if not all, contributing factors, potential correcting actions and follow-up of correcting actions are identified and reported, and that patient harm is correctly identified to improve medication safety. It is crucial to have continuous training to all staff and classifiers to increase their understanding of the system approach to medication safety to optimise the reliability and accuracy of incident reporting, and most importantly, to learn from incidents (7). More detailed instructions for incident reporting in organisations might be useful to improve the reporting, but standardising practices might be even more useful (24). Furthermore, the expertise of medication safety officers could be utilised more to implement the learning from incident reporting at organisational (32) and even national level through the Finnish Centre for Client and Patient Safety.

There is a need for national consensus on how patient safety incident reporting and learning systems should be developed, e.g., in addition to harmonising assessment of the severity of patient harm, adding further information on the cancer medication protocol could be considered. International guidelines for incident reporting already exist (3,8,9,21). These guidelines and learning from incident reporting can be utilised to improve medication safety also in the cancer medication process (3). In the future, data mining and artificial intelligence could be utilised to supplement incident reporting data to identify patient safety incidents, which could also enable quantitative analysis of incidents and comparisons of e.g. hospitals, enhancing safety.

Strengths and limitations

This study pooled incident reports from 81 units within three hospitals in the catchment area of one of the five university hospitals: a major strength. The purpose of using voluntary incident reporting data is to iden-

tify points of risk in the medication process as extensively as possible, not to evaluate their incidences, or to compare differences in reported incidents in different medication processes or between hospitals. Thus, combining data from different hospitals and their medication processes is a strength as the points of risks identified from the pooled data may be more transferable to other hospitals and may be utilised to prevent similar incidents.

However, not all incidents are noticed or reported (11) due to voluntary incident reporting system. Further, incident reports from the units that are not cancer treatment units, but that might infrequently manage cancer treatment were excluded. These units have no routine in cancer treatment; therefore, cancer patients in these units might have even a greater risk to experience a cancer or cancer support medication related incident. The data concerning incidents during the preparation of a drug/dose in the hospital pharmacy phase were incomplete since only hospital pharmacy in Satasairaala used the incident reporting system to report their own manufacturing incidents. The incident reports from these units and the pharmacies should be studied in the future. The severity of patient harm was assessed by expert assessors, i.e. researchers, which minimises the variation in patient harm assessment (10), providing a more truthful picture to support learning from errors.

Conclusions

The results can be transferable to the cancer medication processes of other organisations. There is a need for improvement actions and national consensus on how the patient safety incident reporting and learning systems need to be developed. Continuous training to all classifiers is needed to standardise the reporting practices. This would increase the reliability and optimise the benefits of incident reporting. Moreover, involvement of medication safety coordinators in the classification might improve the reliability of incident reporting. In Vaasa central hospital, a new practice has already been implemented: not only the patient safety coordinators but also the medication safety coordinator participates in processing incident reports. Future studies are needed to observe the impact of patient safety specialists on the reliability in incident reporting. Incidents might still happen in all phases of cancer medication process, but the more the organisations learn from incident reporting, the more benefits they will obtain to improve medication safety, since they are able to build more safeguards to their processes.

Tiivistelmä

Syöpälääkehoitoprosessin riskikohtia ja vaaratapahtumien vakavuus

Elina Isokangas
erikoisproviisori (apteekki- ja sairaalafarmasia), Vaasan keskussairaala, Pohjanmaan hyvinvointialue; Farmakologian ja lääkehoidon osasto, Farmasian tiedekunta, Helsingin yliopisto

Terhi Wilppu
erikoisproviisori (apteekki- ja sairaalafarmasia), Turun yliopistollinen keskussairaala, Varsinais-Suomen hyvinvointialue

Tuija Ikonen
potilasturvallisuuden professori, Potilas- ja asiakasturvallisuuskeskus, Pohjanmaan hyvinvointialue; Kansanterveystiede, Lääketieteellinen tiedekunta, Turun yliopisto

Raisa Laaksonen*
kliinisen farmasian dosentti, Farmakologian ja lääkehoidon osasto, Farmasian tiedekunta, Helsingin yliopisto, raisa.laaksonen@helsinki.fi

Kirjeenvaihto

Johdanto

Lääkityspoikkeamat ovat yleisiä terveydenhuollossa. Niistä koituu haittoja potilaille ja kustannuksia yhteiskunnalle. Erityisesti syövän lääkehoitoprosessi on altis lääkityspoikkeamille. Potilas- ja asiakasturvallisuutta vaarantavien tapahtumien raportointiin ja niistä oppimiseen tarkoitettuja järjestelmiä voidaan hyödyntää lääkehoitoprosessien riskikohtien tunnistamisessa ja prosessin parantamisessa terveydenhuollon organisaatioissa. Tavoitteena oli vaaratapahtumaraporttien avulla tunnistaa syövän lääkehoitoprosessin riskikohtia, lääkityspoikkeamien haittaa potilaille, niihin myötävaikuttaneita tekijöitä, niiden takia tehtyjä toimenpiteitä ja niiden estämiseksi tehtyjä suojausehdotuksia sekä arvioida vaaratapahtumien potilaille aiheuttaman haitan vakavuutta vertaamalla raportoitua haittaa asiantuntijatiimin määrittämään haittaan.

Aineisto ja menetelmät

Aineisto koostui kolmen sairaanhoitopiirin syöpähoitoyksiköissä (n = 81) vapaaehtoisesti raportoiduista vaaratapahtumista (n = 4 196) vuosina 2019 ja 2020. Asiantuntijatiimin ja syöpähoitoyksiköiden vaaratapahtumien luokittelijoiden määrittelemien potilashaittojen vakavuuden arviointien välistä yhdenmukaisuutta mitattiin laskemalla Cohenin kappa (κ).

Tulokset

Syövän lääkehoitoprosessissa raportoitiin 608 vaaratapahtumaa (332 poikkeamaa, 251 läheltä piti -tapahtumaa ja 25 muuta tunnistettua riskitekijää) kaikissa prosessin eri vaiheissa. Alkuperäisissä luokitteluissa potilaalle aiheutuneen haitan vakavuutta oli aliarvioitu verrattuna asiantuntijatiimin arvioon. Asiantuntijatiimin ja yksiköiden luokittelijoiden arviointien välinen yhdenmukaisuus oli hyväksyttävä (κ > 0.41) vain neljässä yhdestätoista syövän lääkehoitoprosessin vaiheessa; kaikkien potilashaittojen vakavuuden arviointien vertailujen luotettavuus oli kohtalaista (κ = 0.31).

Johtopäätökset

Syövän lääkehoitoprosessin kaikissa vaiheissa raportoitiin vaaratapahtumia. Potilaalle aiheutuneen haitan arviointia on yhdenmukaistettava. Henkilökunnalle on tarjottava jatkuvaa koulutusta ja lääkitysturvallisuuskoordinaattoreiden asiantuntemusta on hyödynnettävä, jotta voidaan lisätä raportoinnin luotettavuutta ja vaaratapahtumista oppimista.

Avainsanat: vaaratapahtumaraportointi, syöpä, lääkehoitoprosessi, arvioitsijaluotettavuus, lääkitysturvallisuus, riskikohta

Conflict of interest

The authors declare no competing interests.

Funding and acknowledgements

This work was completed as part of hospital pharmacy specialisation. The work was supported by Vaasa Central Hospital research funding (EI). We also thank Mr. Jarkko Wallenius from Awanic Ltd. for providing the HaiPro-material.

References

1. Fyhr A, Akselsson R. Characteristics of medication errors with parenteral cytotoxic drugs. Eur J Cancer Care. 2012; 21(5):606–13. https://doi.org/10.1111/j.1365-2354.2012.01331.x

2. Weingart SN, Zhang L, Sweeney M, Hassett M. Chemotherapy medication errors. Lancet Oncol. 2018;19(4):e191–9. https://doi.org/10.1016/S1470-2045(18)30094-9

3. Goldspiel B, Hoffman J, Griffith N, Goodin S, DeChristoforo R, Montello CM et al. ASHP guidelines on preventing medication errors with chemotherapy and biotherapy. Am J Health Syst Pharm. 2015;72: e6–35. https://doi.org/10.2146/sp150001

4. Ranchon F, Salles G, Späth HM, Schwiertz V, Vantard N, Parat S et al. Chemotherapeutic errors in hospitalised cancer patients: attributable damage and extra costs. BMC Cancer. 2011;11(8):478–87. http://www.biomedcentral.com/1471-2407/11/478

5. Valtiontarkastusvirasto. Tuloksellisuustarkastuskertomus: Potilas- ja asiakasturvallisuuden ohjaus ja seuranta. Valtiontalouden tarkastusviraston tarkastuskertomukset 7/2021. [Internet] (referred to 27.11.2024). https://www.vtv.fi/app/uploads/2021/06/VTV-Tarkastus-7-2021-Potilas-ja-asiakasturvallisuuden-ohjaus-ja-seuranta.pdf

6. McDowell S, Ferner H, Ferner R. The pathophysiology of medication errors: how and where they arise. Br J Clin Pharmacol. 2009;67(6):605–13. https://doi.org/10.1111/j.1365-2125.2009.03416.x

7. Reason J. Human error: models and management. BMJ. 2000;320:768–70.

8. World Health Organization. WHO draft guidelines for adverse event reporting and learning systems. [Internet] 2005. (referred to 15.10.2024). http://apps.who.int/iris/handle/10665/69797

9. World Health Organization. Patient safety incident reporting and learning systems: technical report and guidance. [Internet] 2020. (referred to 15.10.2024). www.who.int/publications/i/item/9789240010338

10. Holmström A-R, Järvinen R, Laaksonen R, Keistinen T, Doupi P, Airaksinen M. Inter-rater reliability of medication error classification in a voluntary patient safety incident reporting system HaiPro in Finland. Res Social Adm Pharm. 2019;15 (7):864–72. https://doi.org/10.1016/j.sapharm.2018.11.013

11. Rauhala A, Kinnunen M, Kuosmanen A, Liukka M, Olin K, Sahlström M et al. Mitä vapaaehtoiset vaaratapahtumailmoitukset kertovat? Suomen Lääkärilehti. 2018;73(46):2716–20.

12. Lennes I, Bohlen N, Park ER, Mort E, Burke D, Ryan DP. Chemotherapy Errors: A call for a standardized approach to measurement and reporting. J Oncol Pract. 2016;12(4):e495–501. https://doi.org/10.1200/JOP.2015.008995

13. Lichtner V, Baysari M, Gates P, Dalla-Pozza L, Westbrook JI. Medication safety incidents in paediatric oncology after electronic medication management system implementation. Eur J Cancer Care. 2019;28 (6). https://doi.org/10.1111/ecc.13152

14. Cottell M, Wätterbjörk M and Hälleberg N. Medication-related incidents at 19 hospitals: A retrospective study using incident reports. Nursing Open. 2020;7(5):1526–35. https://doi.org/10.1002/nop2.534

15. Kahangi LS, Toghian Chaharsough N. Chemotherapy medication errors in patients with cancer: A narrative review. J Multidiscip Care. 2021;10(3):126–131. https://doi.org/10.34172/jmdc.2021.25

16. Billstein-Leber M, Carrillo C, Cassano A, Moline K, Robertson JJ. ASHP Guidelines on Preventing Medication Errors in Hospitals. Am J Health Syst Pharm. 2018;75(19):1493–1517. https://doi.org/10.2146/ajhp170811

17. Reinhardt H, Otte P, Eggleton A, Ruch M, Wöhrl S, Ajayi S et al. Avoiding chemotherapy prescribing errors: Analysis and innovative strategies. Cancer. 2019;125(9):1547–57. https://doi.org/10.1002/cncr.31950

18. Lee K, Yoon K, Yoon B, Shin E. Differences in the perception of harm assessment among nurses in the patient safety classification system. PloS One. 2020;15(12). https://doi.org/10.1371/journal.pone.0243583

19. Awanic Ltd. HaiPro: Sosiaali- ja terveydenhuollon vaaratapahtumien raportointijärjestelmä. [Internet] (referred to 15.10.2024). https://awanic.fi/

20. Miles MB, Huberman AM, Saldaña J. Qualitative Data Analysis: A methods sourcebook and the coding manual for qualitative researchers. Thousand Oaks, CA: SAGE; 2014.

21. National Coordinating Council for Medication Error Reporting and Prevention: NCC MERP Index for Categorizing Medication Errors. [Internet] 2001 (referred to 15.10.2024). http://www.nccmerp.org/sites/default/files/indexColor2001-06-12.pdf

22. Landis, JR and Koch, GG. The measurement of observer agreement for categorical data. Biometrics. 1977;33:159–74.

23. Kunac DL, Reith DM, Kennedy J, Austin NC, Williams SM. Inter- and intra-rater reliability for classification of medication related events in paediatric inpatients. Qual Saf Health Care. 2006;15(3):196–201. https://doi.org/10.1136/qshc.2005.014407

24. Lambrinos A: Patient learning systems: A systematic review and qualitative synthesis. Ont Health Technol Assess Ser. 2017;17(3):1–23.

25. Lindén-Lahti C, Kivivuori S-M, Lehtonen L, Schepel L. Implementing a new electronic health record system in a university hospital: the effect on reported medication errors. Healthcare 2022;10:1020. https://doi.org/10.3390/healthcare10061020

26. Rautakorpi L, Väliaho V, Alanne E. Akuutti reaktio lääkeaineinfuusioista – syöpälääkehoitopoliklinikan arkea. Lääketieteellinen Aikakauskirja Duodecim. 2023;139(22):1841–7.

27. Kunwor P, Basyal B, Pathak N, Vaidya P, Shrestha S. Study to evaluate awareness about medication errors and impact of an educational intervention among healthcare personnel in a cancer hospital. J Oncol Pharm Pract. 2025;31(3):347–54. https://doi.org/10.1177/10781552241235898

28. Weiss B, Scott M, Demmel K, Kotagal UR, Perentesis JP, Walsh KE. Significant and sustained reduction in chemotherapy errors through improvement science. J Oncol Pract. 2017;13(4):e329–36. https://doi.org/10.1200/JOP.2017.020842

29. Wat SK, Wesolowski B, Cierniak K, Roberts P. Assessing the impact of an electronic chemotherapy order verification checklist on pharmacist reported errors in oncology infusion centers of a health-system. J Oncol Pharm Pract. 2025;31(1):65–71. https://doi.org/10.1177/10781552231223511

30. Salman BM, Ayaad O, Ibrahim R, AlHatrushi MS, Majed M, Al Zadjali R et al. Enhancing Medication Safety: Reducing Administration Errors in Oncology Setting. Asian Pac J Cancer Prev. 2025;26(1):269-77. https://doi.org/10.31557/APJCP.2025.26.1.269 PMID: 39874010.

31. Greenall J, Shastay A, Vaida A, U D, Johnson PE, O'Leary J et al. Establishing an international baseline for medication safety in oncology: Findings from the 2012 ISMP International Medication Safety Self Assessment® for Oncology. J Oncol Pharm Pract. 2015;21(1):26–35. https://doi.org/10.1177/1078155214556522

32. Kurttila M, Saano S, Laaksonen R: Describing voluntary reported fluid therapy incidents in the care of critically ill patients: Identifying, and learning from, points on risk at the national level. Expl Res Clin Social Pharm. 2021;2. https://doi.org/10.1016/j.rcsop.2021.100012

Isokangas E, Wilppu T, Ikonen T, Laaksonen R: Points of risk and severity of incidents in cancer medication process. Dosis 2025;41(4):498–514.