Medication errors in chemotherapy: incidence, types and involvement of patients in prevention. A review of the literature

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Medication errors in chemotherapy occur frequently and have a high potential to cause considerable harm. The objective of this article is to review the literature of medication errors in chemotherapy, their incidences and characteristics, and to report on the growing evidence on involvement of patients in error prevention. Among all medication errors and adverse drug events, administration errors are common. Current developments in oncology, namely, increased outpatient treatment at ambulatory infusion units and the diffusion of oral chemotherapy to the outpatient setting, are likely to increase hazards since the process of preparing and administering the drug is often delegated to patients or their caregivers. While professional activities to error incidence reduction are effective and important, it has been increasingly acknowledged that patients often observe errors in the administration of drugs and can thus be a valuable resource in error prevention. However, patients need appropriate information, motivation and encouragement to act as 'vigilant partners'. Examples of simple strategies to involve patients in their safety are presented. Evidence indicates that high self-efficacy and perceived effectiveness of the specific preventive actions increase likelihood of participation in error prevention. Clinicians play a crucial role in supporting and enabling the chemotherapy patient in approaching errors.

Keywords: chemotherapy, patient safety, medication errors, patient participation.

INTRODUCTION

Adverse events and medical errors pose a serious problem to modern healthcare systems. The incidence of adverse events ranges between 3% and 16% of all hospital admissions (von Laue *et al.* 2003a). For the Canadian healthcare system this translates to roughly 185 000 hospital stays per year that will result in adverse events, of which 70 000 are deemed preventable (Baker *et al.* 2004). A quarter of patients experience adverse events after discharge from hospital (Forster *et al.* 2004). Medication errors are among the most serious single class of errors and cause considerable harm (von Laue *et al.* 2003b; Runciman *et al.* 2003). Kopp *et al.* observed one error resulting in a potential or actual, preventable adverse drug event for every five doses of medication administered in intensive care (Kopp *et al.* 2006). While any class of drugs is susceptible to errors, chemotherapy presents special dangers because: (1) many drugs have a narrow therapeutic index; (2) are toxic even at

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therapeutic dosages; (3) chemotherapy regimens are highly complex; and (4) cancer patients are a vulnerable population with little tolerance (Muller 2003). This suggests that cancer patients may be severely affected by medication errors. Besides professional activities, involvement of patients in error detection and prevention has been widely recommended, for example, by the Institute of Medicine, the American Hospital Association and clinical oncology experts (Institute of Medicine 2000; Kloth 2002; Vincent & Coulter 2002; Coulter 2006). Chemotherapy patients may be particularly qualified to get involved in error prevention as they often experience recurrent procedures and intense episodes of care and thus develop expertise regarding treatment administration.

The main questions are, however, whether cancer patients are willing and able to get involved in error prevention and whether the incidence and nature of medication errors in chemotherapy make them accessible to patients. The purpose of this paper is to better understand the relevance of medication errors for cancer care and the potential role patients can play in their prevention. This paper first reviews international data on types and incidence of medication errors in chemotherapy and their contributing factors. We then report the evidence on patients' participation in chemotherapy error prevention and discuss current developments to engage patients in their safety and act as 'vigilant partners'.

METHODS

We undertook an extensive review of the literature. The databases Medline and Cinahl were searched for articles published in English or German between 1990 and 2008.

The search strategy consisted of MeSH terms related to 'adverse events' ('Iatrogenic Disease/prevention and control' OR 'Medical Errors/prevention and control' OR 'Medical Errors/adverse effects' OR 'safety management'), combined (AND) with MeSH terms related to 'chemotherapy' ('Antineoplastic Agents' OR 'Neoplasms/drug therapy') or the equivalent MeSH terms provided in the databases. This search yielded 112 hits. The reference sections of all retrieved articles and monographs connected to the issue were hand searched for further material. We were also able to draw upon the references gathered in other systematic reviews of closely related topics and extracted the data relevant to cancer patients (von Laue *et al.* 2003a,b; Schwappach & Boluarte 2008; Schwappach 2009). All studies that reported primary data were included in this review. Commentaries, theoretical analyses and papers that focused 'adverse drug reactions' were excluded. The bibliographic data and abstracts of retrieved studies were evaluated for concordance with basic inclusion rules. Studies that violated any criteria were discarded at this stage. The remaining studies were selected for full-text retrieval. After initial review of full-texts, studies were classified according to content a second analysis. The included studies used various methodologies, including qualitative and quantitative surveys, analysis of ordering forms and incident reporting systems, case analysis methodology, as well as prospective cohort studies. The included studies are presented and discussed in detail.

RESULTS

Incidence and types of medication errors in chemotherapy

Few adverse incident studies have been conducted specifically in oncology, including paediatric oncology services, and more recently, in outpatient treatment. In a comparative analysis involving several departments in Israel, the highest medication error rate was found in haemato-oncology (2.48 errors/100 patient days), followed by intensive care (0.82/100 patient days) (Lustig 2000). Anti-infective drugs (38.7%) and antineoplastics (15.6%) were among the most prevalent class of drugs in which errors occurred. Ford *et al.* report the frequency and types of medication administration errors on an oncology ward in a large community hospital in the USA that had already implemented safety guidelines (Ford *et al.* 2006). Medication administration errors were defined as 'preventable mistakes in drug administration due to errors originating in ordering, dispensing, or administering', and included administration of the wrong drug, the wrong dose, wrong route, medication to which the patient had a known allergy, and medication with a known significant interaction with other medications the patient received. During the 2-year prospective study, nurses recorded 141 medication administration errors in 4.752 patient admissions (0.03 medication administration errors/patient admission) or 0.04% of medication administrations. 41% were nurse administration errors (predominantly omitted medications and wrong doses), 21% were errors in order writing or transcription (predominantly pharmacy errors) and 38% were errors in medication dispensing (predominantly nursing dispensing errors such as incorrect dose or wrong medications). The comparably low incidence of medication administration errors may have been due to self-reporting of nurses or due to preinstalled safety guidelines.

Others have reported the positive effects of patient safety actions. For example, Womers *et al.* reported that the chemotherapy medication error rate dropped from 6.2/

1.000 inpatient chemotherapy doses before to 1.0/1.000 doses after the installation of a multidisciplinary systems approach to safety (Womer *et al.* 2002). Electronic prescribing and standardised ordering entry in particular have been shown to be effective in reducing errors (Kloth 2002; Dinning *et al.* 2005; Sano *et al.* 2005). Voeffray *et al.* assessed the effects of computerised physician order entry system on the number of chemotherapy prescription errors in a university hospital (Voeffray *et al.* 2006). Chemotherapy protocols were standardised and transferred to the order entry system and prescription errors were recorded by the centralised chemotherapy unit of the pharmacy 15 months before and 21 months after introduction of the computerised protocol prescription system. During these periods, the prescription error rate declined from 15% before to 5% after the computerised physician order entry system had been introduced.

Medication errors have also been observed in paediatric oncology: Pichon *et al.* analysed transcription errors in a 'paper-based' Swiss paediatric onco-haematology unit and revealed errors to be common (Pichon *et al.* 2002). At the first transcription, 12% of chemotherapy orders had transcription errors. The most common types of errors were missing parenteral formulations (31% of errors) and unreadable transcriptions (25% of errors). At the second transcription, 6.3% of chemotherapy prescriptions included errors, predominantly wrong doses (86%). An analysis of the MEDMARX database, a voluntary error reporting system in the USA, revealed that of the 310 paediatric chemotherapy error reports included in the database, 85% reached the patient and 16% required additional monitoring or intervention (Rinke *et al.* 2007). Nearly half of errors occurred in medication administering (48%), followed by dispensing (30%) and prescribing (10%). While administration errors were common among inpatients, reports relating to outpatients were more likely to involve dispensing and prescribing errors. Improper dose, wrong time, omission and wrong administration route were the most common types of errors. Chemotherapy agents most commonly involved in error reports were methotrexate (15%), cytarabine (12%) and etoposide (8%).

Again, computerised physician order entry system has been shown to reduce medication error incidence also in paediatric chemotherapy: in an US study conducted at a paediatric oncology unit of an academic medical centre, the relative risk for improper dosing in daily chemotherapy orders was 0.26 after introduction of computerised order entry as compared with the observation period before (Kim *et al.* 2006). The likelihood of incorrect dosing calculations (relative risk 0.09), missing cumulative dose calculations (relative risk 0.32) and incomplete nursing checklists (relative risks 0.51) also decreased significantly. However, there is also evidence that medication errors may persist or even be facilitated with computerised order entry (Koppel *et al.* 2005; Nebeker *et al.* 2005). Few studies have assessed medication error incidence in outpatient care settings so far. Gandhi *et al.* investigated medication errors and potential adverse event rates in outpatient chemotherapy in adult and paediatric ambulatory infusion units (Gandhi *et al.* 2005). They report a medication error rate of 3% of all orders in both adult and paediatric patients. 4% of all chemotherapy orders in adults and 1% of chemotherapy orders in children involved errors. Among the medication error subset of potential adverse drug events, 27% were serious (26% in adult and 32% in paediatric patients). The remainder were significant. Chemotherapy-related potential adverse drug events were more likely to be serious.

The diffusion of oral versus infusion chemotherapy to the outpatient setting may be associated with even increased hazards since the process of preparing and administering the drug is often delegated to patients or their relatives. A recent study in oral outpatient chemotherapy in children with acute lymphoblastic leukaemia showed that parents have major difficulties in preparing, dispensing and administering the medication to their children (Taylor *et al.* 2006). Prescribing and administration errors occurred in nearly 10% of all medications (7% administration, 3% prescribing errors, 0% pharmacy dispensing errors). In 19% of patients at least one medication error occurred. All errors were due to incorrect dosing or failure to administer an indicated medication. Children in the maintenance phase of treatment were at highest risk for experiencing medication errors.

Professionals involved in administration of chemotherapy seem to be well aware of the occurrence of mistakes and errors. For example, Schulmeister surveyed oncology nurses involved in patient care and chemotherapy administration in the USA about their personal experience with errors (Schulmeister 1999). Chemotherapy medication errors were reported to have occurred in the workplace of 63% of the respondents in the previous year, and 140 errors were described in total. Common errors include under- and overdosing (39% of errors), schedule and timing errors (21%), wrong drugs (18%), chemotherapy given to the wrong patients (14%) and other incidents, such as infusion-rate errors, omission of drugs or hydration, improper preparation of drugs. 10% of errors required medical intervention and prolonged hospital stays.

Across the various research approaches, patient groups and drug formulations studied, the results of the reviewed studies show that errors in administration in chemotherapy contribute a significant fraction to all medication errors in chemotherapy. A systematic analysis of accidental iatrogenic intoxications by cytotoxic drugs also confirmed that most cases with a fatal outcome involved erroneous drug administration (Zernikow *et al.* 1999).

Patients' involvement in detection and prevention of error

There is increasing evidence from survey studies that patients frequently observe, detect and report errors and adverse events (Fränneby *et al.* 2008; Schwappach 2008; Weissman *et al.* 2008). Schulmeister's analysis of errors described by oncology nurses also includes a number of examples in which patients identified and intercepted the error (Schulmeister 1999). For example, patients recognise – rather by accident – that wrong drugs or doses of the right drug are being given ('Why is that bag so big? I'll be here all day'), or that devices such as infusion pumps malfunction (Muller 2003). Weingart *et al.* conducted interview studies including adult oncology patients treated on a chemotherapy infusion unit and investigated recognition of serious events by patients (Weingart *et al.* 2005; 2007). In this study, patients were asked to report experiences of adverse events and recognition of safety practices, such as double checking of identity. Patients' reports were analysed and classified by trained clinicians. 1% of patients reported adverse events, 2% reported close calls, 7% reported medical error without risk of harm and 52% of patients reported events that were classified as quality problems such as waits and delays and poor communication and information. While patients' recognition of application of safe practices was high (96%), 22% reported to have experienced situations they would characterise as unsafe episodes of care.

As patients are the only individuals physically present during every treatment and consultation, patients are a valuable resource for safe and effective cancer treatment systems and carry with them important contextualised information as they move through a distributed system of care. Unruh und Pratt used Rasmussen's taxonomy of human performance and observed in a qualitative study among cancer patients how much of patients' work revolves around coordinating care between different organisational units, detecting error and intervening (Unruh & Pratt 2006). Typical case notes depict patients that identify wrong infusion intervals, a patient that intervenes to interrupt attempts to remove a portocath prematurely, and a patient that ensures proper treatment by communicating individual care needs to discontinuous staff.

Preliminary results of an ongoing study into chemotherapy patients' perceptions of administration errors by the authors confirm these data. In this study, both, patients and oncology nurses, reported various occurrences of patients that intervened to intercept errors including patients that detect omitted doses of premedication, wrong infusion intervals, leaking infusions and wrong doses of oral chemotherapeutic agents.

A central and crucial element for patients' ability and effectiveness to participate in error identification is information. As described in the study by Unruh and Pratt, cancer patients with recurring episodes of care commonly identify errors by checking concordance of prior experiences and information, more or less randomly obtained, to formulate rules, for example, 'this infusion requires 20 minutes', and to check reality against these rules (Unruh & Pratt 2006). However, the available data also suggest that information provision, recognition and possibly interception of medication errors occur largely unsystematically 'at random'. Correspondingly, clinics at large have usually no defined mechanisms for storing important rules about individual patients' preferences or customised care needs and this knowledge is much too often backupped by individual staff members, again, more or less at random, and in reliance on the individual clinician's performance and with the potential to get lost.

The observation that patients frequently engage in their own safety but commonly face suboptimal conditions to be effective in doing so has recently led to considerations to systematically support and strengthen patients' awareness and to tap their potential in approaching errors by providing information and motivation. Patients may be particularly able to detect errors in administration of medications, a frequent class of error, as has been described above.

Engaging patients in error prevention

Rule-based information provided by clinicians is often the crucial element to enable the chemotherapy patient to identify that something goes wrong. In theory, providing patients with all necessary 'rules' together with a customised and personalised medication information, for example, a check-card including pictograms of drugs, would permit patients to prevent drug dispensing and administration errors by verifying their own identity, confirming the name of the medication, and ensuring correct dosing, drug form, route and administration time, and by

speaking up if they observe or experience anything that violates these rules. It has been suggested that tracking of therapy not only makes patients more aware of what medications they are supposed to be on but also act as a check against what is in their medical records. Keeping track of medications is especially important in oncology, where patients often receive multiple drugs both as part of their therapy and to mitigate side effects. As response some US cancer centres now provide patients a card listing their medications, which they can update as they receive treatment at different sites and physicians are instructed to ask for medications at every visit (Finkelstein 2006). Basch *et al.* investigated the value of an Internet-based monitoring system for cancer patients' reports of medication side effects (Basch *et al.* 2005; 2007). Chemotherapy patients' continuous reporting of toxicity symptoms has recently been shown a feasible and successful approach well-accepted by patients.

However, still little is known about patients' attitudes, willingness and effectiveness to engage as 'vigilant partners' in general, and in cancer patients in particular (Davis *et al.* 2007). Some studies surveyed patients or members of the general public about their attitudes and willingness to engage in clearly described error prevention activities (Hibbard *et al.* 2005; Nau & Erickson 2005; Waterman *et al.* 2006; Davis *et al.* 2008). The available evidence suggests that while a vast majority of responders agreed that patients could help prevent errors and recommended actions are viewed as effective, patients' comfortability with taking action themselves is often much lower and varies very much by specific action: for example, most patients feel comfortable with actions that conform to more traditional patient roles, for example, asking a medication's purpose or confirming their identity, but much smaller fractions would participate in error prevention actions that are perceived as questioning medical authority, for example, asking staff whether they had washed their hands. Davis *et al.* report from a survey study among surgery patients that patients were more likely to engage in new, unfamiliar actions if they would be instructed by clinicians to do so (Davis *et al.* 2008). This study highlights the important role of clinical staff in motivating patients to engage in their safety. Evidence also suggests that patient safety partnerships do not negatively affect the patient–provider relationship (Weingart *et al.* 2004).

The study by Hibbard *et al.* also investigated predictors for actively participating in error prevention (Hibbard *et al.* 2005): they show that an individual's perceived self-efficacy, that is, how efficacious one feels in the ability to prevent errors, is strongly related to the reported likelihood of taking preventive actions. Self-efficacy is a particularly strong predictor of taking preventive actions that are newer and unfamiliar and ones that require questioning medical authority, such as confirming the right medication and dose. Notably, neither gender, age, education nor self-rated health status were predictors of self-efficacy. However, having heard about medical errors in the past were significant correlates of self-efficacy. The important role of risk perception and worry about errors for engagement in safety actions has also been confirmed by Peters *et al.* (Peters *et al.* 2006). However, perceptions of risk of treatment clearly need to be sensitively counterbalanced with trust in the patient–provider relation, in particular in cancer treatment. Hibbard *et al.* also observed that perceived self-efficacy significantly increased during their study, that is, simply by working through examples of medical errors and responding to the survey questions. The mean response to the initial self-efficacy question in the survey was significantly lower as compared with the mean response at the end of the interview study. These results suggest that exposure to specific information and communication about errors increases self-perceived efficacy. A path analyses indicated that high self-efficacy and perceived effectiveness of the specific preventive actions are two distinct patterns that additively increase participation in error prevention. Those subjects with both high self-efficacy and who perceived the actions as more effective were 50% more likely to engage in preventive actions as compared to those low on both dimensions. The key to both dimensions – self-efficacy and perceived effectiveness – is education, information and encouragement.

It is important to note that these studies were conducted among members of the general public and patients with a one-time hospitalisation. Thus, transferability to chemotherapy patients remains unclear: most importantly, surveyed individuals had only single hospital stays prior to the survey, obtained only little information about medical errors and had little incentive to currently engage in their own safety. Contrary, chemotherapy patients have usually a higher number of episodes of intense care, and thus more opportunities to learn and to participate in error prevention. The fact that chemotherapy administration involves highly specific and rather homogeneous processes of care leaves also room to design very specific activities for patients to get involved and check *with* their healthcare provider rather than checking *up on them* (Entwistle 2007). In summary, chemotherapy patients seem to be a qualified population for participation in error prevention on theoretical grounds. The available evidence also suggests that cancer patients usually work hard to ensure safety and the quality of care they receive, often develop expert knowledge regarding their disease and

Table 1. Examples of strategies to involve patients in their safety

Involvement of patients	Example
Perform double-checks on medications (i.e. IV bags) together with patients, e.g. ask them to read their name, birth date and medication name.	'I'm bringing your today's medication. Let's read together what the labels say. Please give me your name and birthdates first.' (Patient provides name and birthdates) 'Ok, thank you. What does the label say then? (Reading label information together with patients) So, this is correct, right?'
Provide patients with as much rule-based information as possible naturally during medication administration, e.g. tell them duration of IV interval while administering the IV bag, communicate easy observable characteristics of drugs, e.g. the number of tablets they receive or the colour of IV fluids, and treatment intervals. Try to use clear, rule-based language.	'This infusion takes 30 minutes.' 'You get one of these blue tablets as premedication every time prior to an infusion.' 'The IV fluid of your medication is red.' 'You get these infusions every Wednesday during a course of four weeks.'
When checking on the performance of devices (e.g. IV lines, pumps or portocaths), explain what you are checking, how and why.	'See, I'm now controlling whether the clamps are all switched open. This is how an open clamp looks like. All need to be open for the fluid to run properly.'
Repeatedly teach patients to observe any signs of adverse events or side effects. Use teach-back methods to ensure they understand what to watch for and why (Garcia & Brach 2008).	'I want to make sure we have the same understanding. Can you tell me, in your own words, the (three) signs you should watch out for?' 'It is my job to explain things clearly. To make sure I did this, can you tell me what to do if you experience aching around the cannula?'
Encourage patients to ask questions and to speak up if they feel something goes wrong or deviates from the routines. Motivation needs to be communicated repeatedly.	'What questions do you have?' (rather than 'Do you have any questions?') 'It is important and of high value that you speak up whenever you are concerned about a procedure or medicine. If you note something that seems to be wrong, please ask so we can check this with you.'
Strengthen patients' feelings of self-efficacy, e.g. confirm their ability to observe processes of care, acknowledge the importance of their contribution and compliment them on communicating their observations	'We are very careful in preparing your medications. But it is of high value to us that you also watch out that everything is ok.' 'It is very good that you noticed that and called me. I just confirmed that this is the correct medication intended for you. If you again notice something that bothers you, please do not hesitate to speak up again.'
In case patients observe any errors or close-calls, it is sometimes valuable to offer them to get care by another staff member.	'It is very fortunate that you observed that mistake (and helped us to intercept it). I could understand if your trust in me has been affected. I can offer you that my colleague will take over your care.'

treatment, and frequently prefer to be involved in the processes of care. On the other side, oncology patients are burdened by severe illness, anxiety, fear and medication side effects. It is therefore crucial to ensure that patients do not feel overburdened by activities to engage them in their safety or that responsibility for safety is shifted from staff to patients. It is also likely that perceptions of self-efficacy and preferences for involvement in error prevention change over time and with the course of treatment (Davis *et al.* 2007). It is a sensitive and demanding task for clinicians to 'diagnose' patients' current preparedness and adjust communication and involvement accordingly.

The crucial element is not to push all patients to engage in all aspects of safety, but to provide those able and willing to participate with the necessary information and support to do so. Table 1 provides some practical examples of activities to engage patients in their safety. It is important that these steps are conducted in an appropriate atmosphere that acknowledges the value of patients' work, are integrated into the natural course of communication and that activities are repetitive to provide opportunities for training. It needs also be continuously ensured that activities to involve patients leave no room for shifting responsibility for safety from providers to patients. An ongoing study by the authors currently addresses the feasibility of strategies to involve patients both from the patient's and the professional's perspective.

CONCLUSION

Medication errors in chemotherapy occur frequently, many of which are administration errors and thereby frequently observable by patients. Besides professional activities to error incidence reduction, such as computerised order entry systems or critical incident reporting, patients are a valuable resource to detect and intercept administration errors and to identify risky routines. Data confirm that patients commonly identify deviations from routines and then act to intercept potentially errant administration of medication. However, evidence on interventions to systematically engage patients in the prevention of errors in chemotherapy is scant. Clinical staff plays a vital role in the information, motivation and encouragement of patients to engage in their safety.

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