Patient Involvement in Evaluation of Safety in Oral Antineoplastic Treatment: A Failure Mode and Effects Analysis in Patients and Health Care Professionals

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Objectives: To identify risks associated with delivery of treatment with oral antineoplastic agents in an outpatient setting and to evaluate additional value and feasibility of engaging patients in a proactive risk analysis. **Methods:** We conducted 2 separate but parallel failure mode and effects analyses (FMEAs) among patients and health care professionals (HCPs) at a clinical oncology department in Denmark. Comparative analyses were performed using the FMEA process maps and risk priority numbers (RPNs) as main outcome measures. The FMEAs were augmented by semistructured interviews with HCPs and patients on acceptability and feasibility of FMEAs analyzed using systematic text condensation. **Results:** Patients and HCPs found failures in information regarding treatment (cause, aim, and plan) to be of high risk. Also, HCPs found failures in checking for potential interactions to be of high risk. HCPs focused on the in-hospitals procedures, whereas patients identified risks related to both the hospital and the home setting. Both HCPs and patients found participation in the FMEA process meaningful but found the use of RPNs difficult. **Conclusions:** Patient engagement in proactive risk analysis using FMEA is acceptable, meaningful, and feasible, with patients providing a different perspective on the risks associated with oral antineoplastic treatment compared with HCPs.

Key words: chemotherapy, oncology, patient safety

Medication errors involving antineoplastic drugs, that is, drugs with a narrow therapeutic index, complex dosing schedules, and significant toxicities, are a recognized challenge within oncology.[1] While patient safety in the prescribing and administration of intravenous (IV) antineoplastic treatment has received much attention,[1] this is not the case for self-administered oral antineoplastic agents, although this has in recent years become the standard treatment of many cancers.[2-4]

Oral antineoplastics offer numerous advantages to patients and providers, most importantly by allowing administration of treatment outside the hospital, thus enabling the patient to stay at home and engage in daily life activities. Furthermore, reducing costs when reducing admissions and use of IV infusions. Regarding safety, studies have found considerable variation in the prescribing, monitoring of toxicities, extent of information and education delivered to the patient, as well as the methods used in the assessment of safety and treatment adherence for these oral regimens.[3]

One proactive risk assessment tool that can be used to assess safety in medication processes is failure mode and effects analysis (FMEA)[5-7] or the health care modified failure mode and effects analysis (HFMEA), a 6-step process in which a group of health care professionals (HCPs) map a given process and identify potential failure modes to understand where and why failures occur. Appropriate corrective actions are then recommended and prioritized on the basis of severity, probability, and detectability of the failure modes. Although HFMEA is widely recommended as a valuable resource in risk assessment and hence for improvement of safety in organizations, little is known about the validity[8] and reliability of the instrument. Consequently, previous studies concerning the reliability of HFMEA empathize that organizations should not depend solely on FMEA results for identifying safety risks.[9-11]

Patients with cancer are a valuable resource in the detection and prevention of adverse events.[1,12] Yet, evidence on interventions to systematically engage patients in the prevention of errors in antineoplastic treatment is scant.[1] Furthermore, patient involvement in the process of quality improvement and research is currently highly recommended by stakeholders worldwide.[13-15] However, is it unclear how to best do this and the evidence of effect is weak.[16-20] Concerns

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have been expressed that patient involvement in safety may compromise trust of the organization and patient-physician relationship[19,20] or that organizational involvement may become tokenistic.[18,21] Patient engagement in FMEAs has been recommended and is generally considered good practice[22]; yet, to our knowledge, no studies have reported on separate patient FMEAs or the additional value of engaging patients compared with physicians in proactive risk analysis.

This study aimed to explore, from a professional and patient point of view, separately, potential risks when providing treatment with oral antineoplastic agents in an outpatient setting. To this end, we conducted 2 separate FMEA courses to (i) obtain detailed information of risk situations regarding use of oral antineoplastic agents in the outpatient setting, (ii) allow for comparison between the perspectives of the 2 groups, and (iii) evaluate the feasibility of engaging patients in an FMEA process.

METHODS

Setting

The study was conducted at the Department of Clinical Oncology, Odense University Hospital, Denmark, a 1000-bed hospital with all medical specialties represented. The Department of Clinical Oncology is one of 5 highly specialized oncology departments in Denmark. The Department has more than 90 000 outpatient visits and 4000 admissions annually. Patients treated with oral antineoplastic agents are monitored via standard biweekly, triweekly, or monthly visits by a nurse and/or a physician, depending on the patient's health status and the specific oral agent. A standard visit includes evaluation of toxicities through blood tests and physical examination, dose adjustment (if required), information regarding treatment changes, and delivery of medication to the patient to administer at home.

FMEA in health care

Using the Danish translation of the original HFMEA method,[6] developed and validated by the national Danish Society for Patient Safety, we evaluated the process of prescription, delivery, and self-administration of oral antineoplastic treatment in the outpatient oncology clinic. To obtain both professional and patient perspectives on risks related to this process, 2 parallel FMEAs were conducted; one with a multidisciplinary team of HCPs (HCP FMEA; for characteristics, see Supplementary Digital Content Table 1, available at: http://links.lww.com/QMH/A17) and another with a team of patients receiving oral antineoplastic treatment in the outpatient clinic (patient FMEA; see Supplementary Digital Content Table 2, available at: http://links.lww.com/QMH/A17).

Conducting the FMEA

The first 5 basic steps of an FMEA were conducted; steps 1-2 by the research team prior to the FMEA sessions, and steps 3-5 by the 2 FMEA teams. Because of the scope of the study, step 5 was only partially completed and the sixth FMEA step was considered out of scope and therefore not conducted.

Step 1: *Define the topic.* The topic of the analysis was defined as "the process of prescription, delivery, and self-administration of oral antineoplastic treatment in the outpatient clinic at the Department of Clinical Oncology." This definition was based on clinical experience including patients' comments and questions on the process, as well as data from the department's root-cause analyses and adverse event reports. The process is considered as high risk and high volume, and as a process in which patients engage in their own treatment and care. As such, patients are considered to possess expert knowledge of the process under study.

Step 2: *Assemble a committed team.* According to Danish legislation, the study was approved by the Danish Data Protection Agency and the local department management. An HCP FMEA team was then invited according to predefined recruitment criteria, ensuring representation of nurses and physicians of different age groups and seniority with experience from different diagnostic teams. All members of the HCP team were invited by e-mail by the Principle Investigator (PI). The patient FMEA team was composed to ensure representation of patients of different age, gender, cancer diagnosis, treatment aim, and socioeconomic status assessed by the educational level. The PI invited members of the patient team by personal contact upon their planned visits in the outpatient clinic. Initially, both groups were invited to take part in two 2-hour FMEA sessions.

The PI initiated both of the first 2-hour FMEA sessions with a presentation of the aim of the study and an introduction of the FMEA method.

Step 3: *Describing the process and identifying failures.* The teams were first encouraged to map out the total process and subprocesses starting at "the patient enters the outpatient clinic" and ending with "the patient administers the oral antineoplastic agent." Following this, the teams were asked to identify possible failure modes within the processes, that is, potential failures within the subprocesses and the possible impact of failures on the patient.

Step 4**:** *Identifying severity, probability, and detectability.* The teams were asked to first confirm and supplement the identified failure modes. Then, each failure mode was assigned a score based on a 10-point scale supported by anchor examples for each of the attributes: severity, probability, and detectability. Scores were obtained by group consensus and multiplied by each other to calculate the risk priority number (RPN) scores.[5-7]

Step 5**:** *Making recommendations to decrease or eliminate failure modes.* Both teams were encouraged to "brainstorm" on possible interventions to decrease or eliminate identified failure modes; yet, no structured implementation plan was developed during this

step of the 2 FMEA sessions. Finalizing this step was outside the scope of this study.

Step 6**:** *Monitor, sustain, share, and reevaluate the improvement.* Not included.

The patient FMEA team finished its analysis within the 2 preplanned sessions. The HCP FMEA team had an extra 2-hour FMEA session to complete steps 4-5.

Short semistructured interviews

To evaluate the feasibility of engaging patients in FMEA, short debriefing sessions were conducted immediately after each of the FMEA sessions. Each session included a short semistructured qualitative interview on acceptability, implementation, and practicality of the FMEA method,[20] using open-ended questions. Data from the interviews were analyzed using systematic text condensation.[20]

The 5 FMEA sessions were conducted in parallel on an alternating basis, and no information was shared between groups. The PI facilitated all 5 sessions. All authors participated in the FMEA sessions to ensure both groups were provided with the same information and that the process was facilitated uniformly and neutrally in all sessions. For documentation and analysis purposes, written permission to record sound from all FMEA sessions was obtained prior to initiation of the first session. All patient FMEA team members participated in both patient FMEA sessions. All HCP FMEA team members participated in the 2 first HCP FMEA sessions. In the last session, one HCP participant (nurse specialist) was absent due to acute illness.

Analysis of differences in FMEA results between teams

The research group analyzed raw data and calculated the RPN for each failure mode and conducted a descriptive comparative analysis between the processes and failure modes identified by staff and patients.

RESULTS

Process maps and identified failure modes from each team

The patients mapped 5 main process steps (Figure, left side) and 9 subprocesses and identified 28 failure modes (see full table in Supplementary Digital Content Table 3, available at: http://links.lww.com/QMH/A17). The patient team rated 3 failures within the subprocess of information with the highest RPN (Table). The patient team generally rated processes involving HCPs higher in the RPN than processes involving patients.

The HCPs mapped 7 main process steps (Figure, right side) and 17 substeps in the outpatient prescription process and identified 61 failure modes (see full table in Supplementary Digital Content Table 4, available at: http://links.lww.com/QMH/A17). The HCPs rated 2 failures within the subprocess of medication check with the highest RPN, and a failure in the process of information was rated with the third highest RPN (Table).

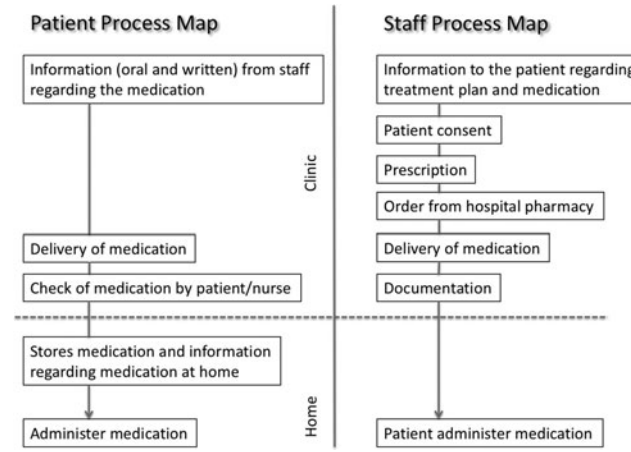

Figure. Comparison of overall FMEA process maps, as described by the patient FMEA team and the HCP team. FMEA indicates failure mode and effects analysis; HCP, health care professional.

Comparison of results from HCP FMEA and patient FMEA

Comparison of the main process steps described by the HCP FMEA team and the patient FMEA team showed that HCPs primarily focused on the in-clinic processes whereas patients had a more equal focus on both the in-clinic and at home processes (Figure). The HCPs had a more detailed process map describing 17 subprocesses with 61 failure modes, whereas the patients mapped 9 subprocesses with 28 failure modes (see Supplementary Digital Content Tables 3 and 4, available at: http://links.lww.com/QMH/A17). For the patients, 13 of the 28 failure modes (46%) were in the home setting compared with 3 of 61 (5%) failure modes among the HCPs.

Feasibility of engaging patients and HCPs in FMEA

The PI recruited patients consecutively during a preplanned ambulatory visit. Nine patients were approached, 3 declined, and the inclusion closed after 6 patients had volunteered. Reasons for declining was long distance travel, fear of further emotional stress, and interference with other appointments at the hospital or a combination hereof. All approached patients found the idea of engaging patients in evaluation of oral medication safety meaningful and expressed willingness to use their own experiences to improve the safety of future patients. One patient participant expressed initial doubt as to whether these experiences were representative of the experiences of others on a larger scale but was willing to "try to help."

The PI recruited HCP members by an e-mail invitation, describing the aim of the study as well as the method and the expected time frame. Two HCP members declined because of nonwillingness to engage in project without financial compensation for "extra hours." All HCP members found the project both interesting and important.

Table. Failures With the Highest RPN Identified by the Patient FMEA Team and the HCP Team

	Top 3 Failure Modes by RPN			
	Patient FMEA Team	RPN	HCP FMEA Team	RPN
1	*Information on treatment aim and treatment plan:* Written information not understood or misunderstood	560	*Check up on existing medical treatment and possible interaction with treatment or supportive care in electronic prescription module:* Lack of time	539
2	*Information on treatment and treatment plan:* Information rushed and limited because of HCPs not having enough time	320	*Check up on existing medical treatment and possible interaction with treatment or supportive care in electronic prescription module:* Lack of attention or responsibility by prescribing doctor	245
3	*Information on treatment and treatment plan:* Information not understood because of patients "state of mind," eg, following delivery of "bad news"	280	*Information to patients and relatives on: Cause of treatment and treatment aim:* Failing to ensure information is both heard and understood by patients and relatives	210

Abbreviations: FMEA, failure mode and effects analysis; HCP, health care professional; RPN, risk priority number.

Acceptability and relevance of the FMEA method

Both the patient and HCP teams were asked, at the end of the interview sessions, to openly share thoughts on their experience with their participation in this FMEA, including pros and cons.

Patients expressed joy and "a sense of value and meaning" in the opportunity to improve the experience and safety of future patients with cancer. However, they also highlighted "a certain stress of focusing on failures in the process of health care." This could lead to both an increased awareness of "what could go wrong" in future medication processes, as well as in other processes, and "a sense of luck" in past processes. Nevertheless, all patients agreed that they would not hesitate to take part in future FMEAs or recommend participation to others. The patients found that taking part in the FMEA method was relatively easy and that the time frame of 2 sessions of each 2 hours was reasonable and within their emotional and physical limits. During FMEA process step 4—identifying probability, severity, and detectability, several patients expressed difficulties in deciding on probability and detectability scores, especially in the processes within the hospital. Furthermore, a patient raised the question of reproducibility, stating he might answer differently had he been asked tomorrow; this led to other patients expressing a feeling of randomness in attributing scores.

The HCPs expressed that taking part in the FMEA was meaningful and described an increased daily focus and reflection on own communication, patients' compliance, and acceptance of treatment both during and following participation in the FMEA process. The HCPs further stated that mapping the medication process had increased their awareness of the process and opportunities for future improvement. In particular, differences between nurses and doctors in workflow and detectability of failures became clear. The HCPs had noticed that processes involving nurses contain numerous checks and double-checks (of which some may be unnecessary), whereas processes involving doctors may lack checks and hence possibilities of detecting failures. When asked to comment on future FMEA use on other medical processes, the HCPs were generally positive yet expressed concerns regarding reproducibility and validity of the RPN scores. They noted that failures in cancer treatment are always potentially very severe or even deadly, making it difficult to address differences in severity and therefore distinguish between the risks associated with the individual failures. One HCP informant suggested to refrain from mapping the failures that are not very severe and easily detected. Another suggested changing RPNs to only graduate scores 1 through 3 instead of 1 through 10. Also, an HCP member expressed concern in time consumption of the FMEA in means of "value for money."

Cost and time

Six patients engaged in two 2-hour sessions, a total of 24 *patient-hours* excluding time spent on transportation to and from the hospital. Five HCP members engaged in the initially planned two 2-hour sessions; an additional third 2-hour session was held to ensure a complete HCP-mapped FMEA process. This comprised 28 *HCP-hours*. Time, by the PI, on planning, conducting the FMEAs, and analyzing data is estimated to at least 37 hours. Costs of materials were limited to use of existing office facilities, computers, and whiteboards.

DISCUSSION

We conducted 2 separate FMEA courses, engaging HCPs and patients, providing 2 detailed risk maps of the process of prescribing, delivering, and self-administering oral antineoplastic agents in an outpatient setting. While the HCPs focused on the in-hospitals procedures, the patients identified risks related to both the hospital and the home setting. The patients found participation in the FMEA process meaningful and supplemented insights into risks present among HCPs. Both the HCPs and patients found the use of RPNs difficult and questioned validity hereof.

Process maps

Comparison of the 2 process maps show patients and HCPs map the process from different perspectives—the HCPs focus on processes within the hospital, whereas the patients have a more even distribution of process steps between hospital and home. Furthermore, HCPs generally describe the process in more detail, in particular regarding in-hospital subprocesses,

whereas patients provide substantially more detail in describing the subprocesses of self-administering the medicine and possible failures hereof. This highlights that patients can provide knowledge on possible failures in the medication process that is unknown to the HCPs. As such, involving patients as well as HCPs in an FMEA process will provide a broader perspective on the related risks. This is in full accordance with previous studies, showing that patients with cancer serve as a valuable resource in the detection and prevention of medication errors.[1,12]

Identified failure modes

The study shows that providing and ensuring clear, valid, and comprehensive information regarding treatment aim and plan is a high-risk process that is identified by both patients and HCPs when using an FMEA (Table). Patients found that failure to understand written information regarding treatment aim and plan, as well as how and when to react when experiencing possible side effects, is potentially highly severe. Failures in these processes are likely to result in nonadherence to the regimen (eg, wrong time, self-modified timing, forgotten dose, interactions with food or other drugs) and considered to have a low possibility of being detected, as well as a high occurrence rate. This is all in line with results from prior studies addressing medication errors involving oral antineoplastic agents.[23,24] Also, failure to deliver information in small amounts allowing patients time to question information, as well as delivering information in a timely manner to ensure information is understood, was related to similar risks and rated with a high RPN by the patients and HCPs.

Exact information regarding the individual patient's treatment aim and plan is complex and highly personal with different schedules and therapy combinations depending on numerous factors such as cancer type, tumor biology, prior treatment, current treatment aim, patient's comorbidities, and current physical state. Furthermore, treatment is often adjusted continuously. Hence, providing valid and detailed information on the individual level is complex. It is therefore not surprising that both the HCP and patient teams, in this study, as in previous studies,[1,25] rate failures in providing and understanding oral and written information as high risk.

The HCPs rated failures in the prescription process, specifically checking for possible interactions between the antineoplastic treatment and other prescribed medications, to be of high risk. All prescriptions for patients treated within the Danish national health care system are processed through a common electronic prescription system. Interactions and side effects of new oral antineoplastic treatments such as targeted and immunotherapy drugs are increasingly being described as they are discovered.[26] For HCPs to stay updated, they require vast attention and time. Patients did not include this step of the process, which may be explained in lack of knowledge of the process and/or sheer trust in the doctors "to do the right thing."

The patient and HCP teams took on and completed the task of assigning RPNs. Yet, both teams struggled with step 4 "Identifying severity, probability, and detectability," with team members expressing doubt in both the general and their own reproducibility of the scores, due to difficulties in judging probability and detectability. Both the HCP and patient teams discussed consistency between prior judgments and current judgment when working through their process maps and assigning the RPN scores. The PI and the research team observed several cases where judgments on severity were argued with low probability, and vice versa, supporting the fact that teams struggled not to let individual scores interfere prior to calculation of RPNs. Concerns regarding the reliability and validity of RPN scores have been raised in prior studies,[10,27] also questioning the mathematical limitations of the RPN scores and showing RPN values may be identical, although their risk implications may be different.[28] Furthermore, these studies state that multiplication of an ordinal scale violates standard mathematical principles.[11,28] A specific HFMEA has been developed both limiting RPN scores and number of failures to be assigned to RPNs; yet, validity hereof remains uncertain.[29] Until further evaluation of their validity, we cannot recommend using RPNs to prioritize suggested interventions.

Feasibility of FMEA and patient engagement

The general acceptability of engaging in the FMEA was high, inclusion of patients relatively easy, and both patients and HCPs expressed that participation was indeed meaningful. Patients gained energy from using own experience to improve safety for future patients, and all agreed that they would participate in future FMEAs if asked. Face validity of the FMEA was initially high in both groups. Implementation of FMEA with engagement of patients in the process is considered practically possible, with an acceptable time frame, as well as acceptable physical and emotional stress. Patients did report an increased awareness of "what could have gone wrong," as well as a concern of "what might go wrong in the future." This could cause both negative and positive effects. Negative effects could relate to anxiety and increased emotional stress. Positive effects could stem from increased awareness of potential failures leading to increased safety as well as a sense of control and responsibility of one's own disease. It is considered important that future FMEAs involving patients address this and discuss this aspect with the participants.

We conducted parallel FMEA sessions to study differences between perspectives, but the authors find it likely that both patients and HCPs may gain a broader perspective from discussing with each other the process map and the identified failures as well as possible solutions hereof. This should not replace the separate analysis since these facilitate an open and free discussion between equals—reducing the risk of patient involvement becoming tokenistic.

The limitations of the study include the inherent limitations of the FMEA with little knowledge of the true validity of the instrument,[8,10,11] as well as questions

regarding reliability. Also, our study included only 2 FMEA teams with 11 members. Results from this study may therefore not be generalizable to other FMEA processes and organizations.

CONCLUSION

Using FMEAs to proactively obtain detailed information on situations, with a risk of patient harm related to the use of oral antineoplastic agents, is possible and meaningful. We identified several failures—the most severe concerning failures in information transfer from physicians to patients. Yet, quantitative prioritization of identified process failures is not recommended because of concerns regarding reliability and validity.

Patients can provide knowledge on failure modes of clinical relevance in the self-medication process that is unknown to the HCPs, and it seems appropriate to engage patients in future processes of proactively mapping out possible failure modes in order to improve patient safety. However, research is needed to identify the best way of converting this into improvements.

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