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## Cancer patients' experiences of error and consequences during diagnosis and treatment

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Cover Page Footnote

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### Abstract

The study objective was to investigate patient experienced error during diagnosis and treatment of cancer. The design included a nationwide patient survey on quality and safety in Danish cancer care. Responses regarding patient experienced error were separately analyzed, quantitative responses using descriptive statistics and qualitative responses using systematic text analysis. Study participants included 6,720 adult patients with a first time diagnosis of cancer registered between May 1st and August 31st 2010. The patients received a questionnaire concerning their experiences of care received by general practitioners, specialist practitioners and at the hospital. A response rate of 65% was achieved. 10 – 25% of patients experienced error during diagnosis or treatment. 61% reported that hospital errors had consequences. Unexpected surgical errors/complications (27%), delay due to doctors' assessment errors (24%) and unavailable test results (21%) were the most frequent types of errors identified using closed questions. 819 qualitative responses supplemented this information and revealed errors related to cancer detection, planning & coordination, patient-provider communication, administrative processes and treatment & medication. Physical, psychological, social as well as organizational consequences of the errors were uncovered. Patient experiences of errors suggest that practices related to informed consent, diagnostic reasoning as well as handling of test results, referrals and the medical chart should be further improved. In addition, safety aspects of the patient-provider communication and involvement of patients as an extra safety barrier merit further study.

### Keywords

Patient safety, Patient-centred care, Cancers, Disease categories, Surveys, General Methodology, Medical errors, Patient safety

### Introduction

Cancer patients are at risk of being harmed during their contact with health care services.<sup>1</sup> The disease itself introduces infirmity, but treatment and delivery of care can also pose risks to patients. In Denmark, various providers in complex patient journeys deliver cancer care, with the general practitioner (GP) as a gatekeeper to specialist practitioners outside of hospitals as well as to specialist care at hospitals.

Previous studies on safety and quality in cancer care show that both general risks and risks specific to cancer treatment occur frequently.<sup>1-3</sup> Gathering information from various sources is necessary to complete the understanding of hazards.<sup>4-5</sup> Usually, safety is assessed from a health care perspective and the patients' experiences of errors have only been explored to a limited extent. However, inclusion of patients' experiences of errors is relevant when mapping safety problems.<sup>6</sup> As the patient is the only person

experiencing the entire journey, patients can supplement existing knowledge of safety problems in health care.<sup>7-9</sup>

In 2004, due to an act on Patient Safety, reporting of adverse events to the Danish Patient Safety Database became mandatory for health care professionals. The aim was to support learning and enhance patient safety.<sup>10</sup> Disclosure to patients is not mandatory in relation to the reporting system, but according to the act on patients' rights patients should be informed about the consequences of any errors.

The aim of this study is to examine patient experienced error related to diagnosis and treatment of cancer in the Danish health care sector based on a survey conducted by the Danish Cancer Society.

## Method

This nationwide survey was based on a population of 8.607 cancer patients in Denmark aged 18 years and above registered in the National Patient Registry with a first time cancer diagnosis between May 1st and August 31st 2010. Exclusion criteria were death, emigration, unknown address, research protection, misdiagnosis, a suspected cancer, basal cell carcinoma, and benign or unspecified tumors. A total of 6.720 patients were included. A questionnaire addressing quality and safety in cancer care was mailed to patients in September and October 2010. The questionnaire had 104 items. Five items addressed patient experienced error and consequences (Q15, Q19, Q26, Q56, Q57: see table 2-4) and one item collected 'other comments' (general comments on the last page). Error questions were partly closed, partly open-ended. The closed questions were drafted based on previous studies.<sup>1</sup> They were posed to quantify 'known' types of errors, that is the experience of error at various providers in relation to diagnostics and treatment respectively along with the experience of consequences. A cognitive validation of the questionnaire revealed that patients understood the term error and used it to describe rather serious problems, whereas minor problems in general were not considered errors. Thus, the word 'error' was used in the questionnaire rather than e.g. 'safety problem' and 'adverse event' because it is a word used in everyday spoken Danish. Closed questions were supplemented by open-ended questions in order to qualify both types of errors and types of consequences. Safety information from the item 'general comments' section was identified and included in the analysis.

Two separate analyses were conducted: 1) quantitative analysis of the closed questions and 2) qualitative analysis of the open-ended questions.

In the quantitative analysis data from the closed questions were summarized using descriptive statistics (PASW statistics 18®).

The qualitative analyses of open questions were conducted to identify categories of patient experienced errors and consequences respectively (figure 1). The patients' descriptions were typed into a database and analyzed in the following steps using Malterud's systematic text condensation:<sup>11</sup>

1. All responses were read in order to provide an overview. Unreadable responses and responses with no relation to patient safety were excluded.
2. Elements concerning patient experienced error and consequences of error were identified. The errors were organized according to provider and to diagnostics/treatment: GP during diagnosis, specialist practitioners during diagnosis, hospital during diagnosis, hospital during treatment. Consequences of

error were analyzed separately. Key points were extracted and categories of types of errors and consequences were created. New categories were created until no more categories emerged. The smallest categories were collapsed into meta-categories to reduce complexity.

3. All responses were deductively coded according to the created categories. Comments that covered multiple errors or consequences were coded in the relevant number of categories. Errors described in the general comments section were grouped with the relevant error items and included in the analysis.
4. The content of the identified categories was summarized and described. By keeping content descriptions against the original responses, data was re-contextualized in order to ensure that content descriptions were loyal to the patients' experiences. Quotes that described the categories were selected.

An expert in patient safety conducted the coding and analysis.

## Results

A total of 4.346 patients returned the questionnaire (response rate 65%). Mean age of respondents was 65 years (19-96 years). Men and women were equally represented in the respondent group (49% vs. 51%). The most frequent cancer diagnoses were breast (23%), gastrointestinal (19%), prostate (17%) and lung (8%). When comparing respondents and non-respondents it appeared that the proportion of women and younger patients was slightly higher among respondents and that the proportion of patients living alone was lower among respondents. The lowest participation rates were observed for patients with 'lung cancer' and 'gastrointestinal cancer besides colon and rectum'. Breast cancer patients had the highest participation rate (Table 1).

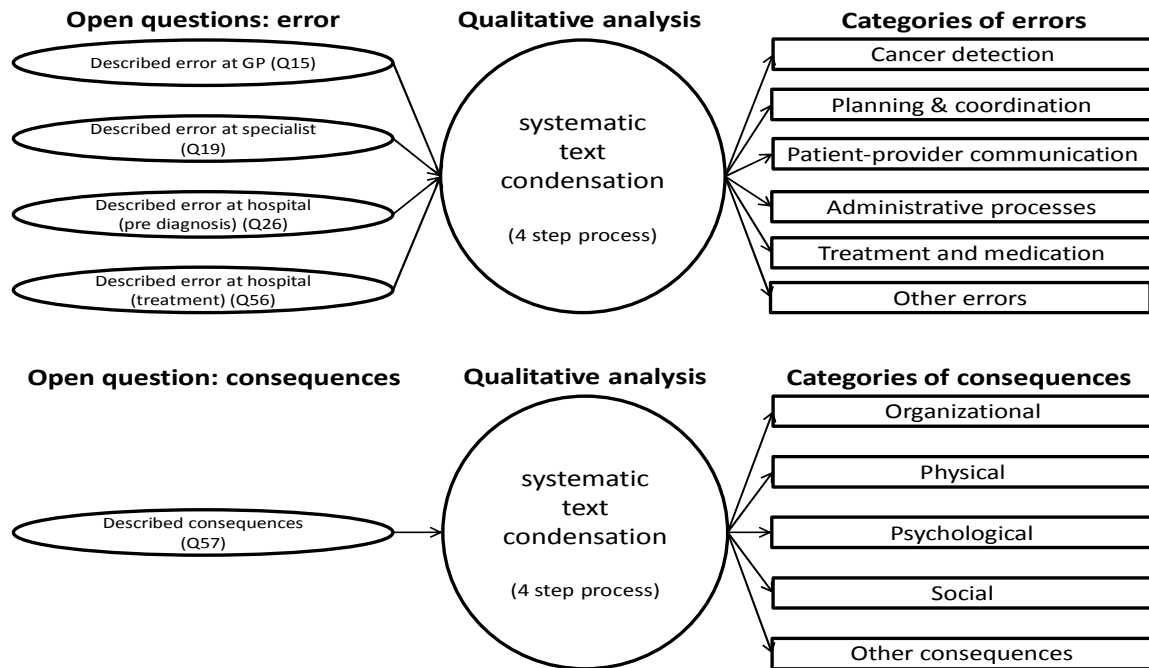
### Quantitative Analysis

During diagnostics 10% of the respondents experienced error at their GP, 11% at the specialist practitioner and 15% at the hospital. During hospital treatment 25% experienced error, with 61% reporting that the error had consequences (table 2). The frequencies of types of errors are shown in table 3 (diagnostics) and table 4 (treatment). Since some patients chose not to respond to all the relevant questions, sample sizes vary across items. Thus, in the tables below the number of responses (sample sizes) are specified for every single question.

### Qualitative Analysis

919 respondents answered one or more of the open-ended questions. Only responses concerning patient safety were included in the analysis, thus the text condensation comprised 752 responses. 67 error descriptions were identified in the general comments section thus 819 responses were included in the qualitative analyses.

Figure 1. Categories of patient experienced errors and consequences



Text condensation led to the formation of six categories of types of errors and five categories of consequences of errors (figure 1). The following sections present data from each of the type of error categories. Within each category, data is organized according to provider and diagnostics/treatment. The nature of errors are described, listed by occurrence in the material (the most frequent first) and followed by quotes for illustration.

### Cancer Detection

At the **GP**, patients experienced inadequate examination of symptoms e.g. patients contacted the doctor repeatedly before referral to further examination (*My GP thought that I was obstipated. I suffered from bowel symptoms for about three years before I was referred to a specialist practitioner*). A substantial number of patients were diagnosed with other diseases than cancer or treated for something else before cancer diagnostics were initiated (*I went to see the GP in January 2009 because of tiredness. The GP thought I suffered from vitamin deficiency. In July 2009, I experienced joint pain, which the GP thought was arthritis. In January 2010, my lymph nodes were swollen which eventually led to my cancer being diagnosed*). At the **specialist practitioner**, patients experienced examinations that did not reveal the cancer, signs or symptoms that were overlooked or situations where the patient was believed to have another disease (*I had my colon examined in February 2009 – everything was OK. According to the operating surgeon, a tumor cannot grow to this size in two years and two months. Another doctor said the same – he said: it has been overlooked*). At the **hospital**, patients reported false negative test results (*I had*

*both mammography and ultrasound in October 2007 and was told that there was no tumor. When I was examined again in June, I was told that the tumor was already present in 2007*). Also, repetition of tests and insufficient examination were experienced (*Bone scan pictures were of low quality. The doctor could not read the pictures properly, so the scan was repeated one week later*).

### Planning & Coordination

At the **GP**, delay was frequently reported and often described as waiting time for medical examination – sometimes related to vacation and sick leave among doctors (*I was to get the test results from the biopsy, but my GP had taken a vacation for 6 weeks. The answer was postponed and later I was acute hospitalized*). At the **specialist practitioner** waiting for medical examination was also frequently experienced. At the **hospital during diagnosis**, delay was the dominant problem and took different forms, e.g. the patient had to wait for examinations, tests, results or diagnosis. During **treatment at hospital** delay was often described as being derived from clinical or administrative processes (*The antibody treatment was forgotten. It was started up three weeks later than first planned*).

### Patient-provider Communication

At the **GP**, patients stated that they were not taken seriously when they consulted their GP (*The GP would not listen and didn't take my symptoms seriously*). Others described that they were 'dismissed' or falsely reassured that their symptoms were not signs of serious illness (*The GP wouldn't admit me to hospital even though the paralysis spread from*

Table 1. Patient characteristics by response status

Variable	Respondents		Non-respondents		Test
	N	%	n	%	p-value
<b>Total</b>	4,346	65	2,374	35	n/a
<b>Gender</b>					
Male	2,138	49	1,323	56	<0,001
Female	2,208	51	1,051	44	
<b>Cancer diagnosis</b>					
Breast	982	23	267	11	<0,001
Prostate	720	17	352	15	
Colon	394	9	207	9	
Rectum	218	5	95	4	
Lung	363	8	323	14	
Malignant melanoma	228	6	129	5	
Uterus	108	3	51	2	
Head and Neck	205	5	117	5	
Gastrointestinal, other than colon and rectum	203	5	204	9	
Female genital organs	123	3	72	3	
Urinary tract	204	5	123	5	
Lymphoid, hematopoietic and related tissue	283	7	186	8	
Other	305	7	248	11	
<b>Age groups</b>					
18-39	132	3	95	4	<0,001
40-49	302	7	140	6	
50-59	767	18	368	16	
60-69	1,520	35	636	27	
70-79	1,099	25	630	27	
80-89	485	11	438	19	
90+	41	1	67	3	

left to right arm and leg and I couldn't control gas or stool'). At the **specialist practitioner**, patients experienced the communication to be insufficient, unclear or containing contradictory information ('the dermatologist looked at the skin spot with a dermatoscope and said 'it is nothing, but have a plastic surgeon remove it so it will look better than if I do it'. She did not leave me with the impression that I should hurry to make an appointment'). At the **hospital during diagnosis**, the communication often was presented as 'poor' e.g. having the diagnosis delivered over the phone, language problems, lack of empathy and insufficient preparation for bad news. At **hospital during treatment**, many patients described lack of information and contradictory information ('at the first consultation I was told to stop taking a certain kind of pills. At the next I was told that I should take the pills and that the first instruction was a misinformation').

#### Administrative Processes

At the **GP**, patients described referrals that were not sent or received as expected ('the first electronic referral from my GP was never received at the hospital. It was discovered when I contacted my GP'). At the **specialist practitioner**, errors primarily related to test results that were overlooked, delayed, not sent or received as expected ('the hospital never received the test results the medical specialist said he would send'). **During diagnosis at the hospital**, errors related to handling of test results (results not seen, not analyzed, delayed or unavailable) and to the medical chart ('I was referred from Hospital X to Hospital Y. My medical chart was sent from X to Y but when I was referred back, they forget to send my chart to X. This was discovered when I contacted Hospital Y'). **During treatment at the hospital**, patients experienced error related to test results (unavailable, not read, unknown, delayed, lost) and the medical chart (e.g. missing chart, wrong information)

**Table 2. Frequency of experienced consequences of errors during hospital treatment (n = number of responses)**

Consequences of error				
Question		Yes	No	Do not know
Q57	If you experienced any errors, did the errors affect you (e.g. increased length of hospital stay, insecurity)? (n=451)	275 (61%)	126 (28%)	50 (11%)

**Table 3. Frequency of experienced errors in relation to cancer diagnostics (n = number of responses)**

Question		Yes	No	Don't know
Q15	Did you experience any errors at your GP's? (n=3,336)	334 (10%)	2736 (82%)	267 (8%)
Q19	Did you experience any errors at the specialist practitioner? (n=1,737)	191 (11%)	1442 (83%)	104 (7%)
Q26	Did you experience any errors at the hospital? (n=3,514)	527 (15%)	2987 (85%)	-
Sub question		Number of errors* (% of total number of errors)		
Have you experienced one or more of the following types of errors at the hospital before you were diagnosed?				
Q26a	My treatment was delayed because the doctors thought I had some other disease than cancer	168 (24%)		
Q26b	The hospital did not call me in for examinations my GP/specialist practitioner had referred me to	69 (10%)		
Q26c	Test results were not available as expected (delayed or mislaid)	146 (21%)		
Q26d	My medical record was not available when needed	62 (9%)		
Q26e	Other errors	256 (36%)		
<i>Total number of experienced errors (Q26a-e)</i>		701 (100%)*		

\*The total number of experienced errors exceeds the number of patients who have experienced errors because each patient may experience more than one error.

(*The test result revealing if the cancer had been removed was not available when I met at the hospital 14 days after discharge to receive the result*).

### Treatment & Medication Processes

At the **hospital during diagnosis and treatment** patients experienced errors related to surgical/invasive procedures especially biopsies (unusable sample, complications, lost sample) (*Due to bleeding the biopsy material couldn't be used*). In addition, imaging errors were frequently described (inadequate preparation, not performed, repeated or poor quality images) (*When I was referred to a PET scan I wasn't told to be fasting, so I waited an additional 6 hours*). During the treatment phase, experienced errors related to surgery, to chemotherapy, radiotherapy as well as other cancer specific clinical procedures. The patient experienced surgical errors included infections and wound problems (dehiscence/herniation) (*a small part of the wound wouldn't heal and developed into a deep wound. The plasti*

*c surgeons had to perform revision surgery*). A few patients experienced medication errors in terms of wrong drug, dose, duration or timing.

### Other Errors

Few patients only described a minor proportion of the errors. They were all pooled in the category 'other errors' (*the doctor didn't find out anything at all, so I had to demand a second opinion. Only then something happened*).

### Consequences of Errors

Patients who experienced that hospital errors had consequences reported one or more of the following impacts: 1) organizational consequences as increased length of stay, readmission or prolongation of the patient journey (*I had too much chemotherapy so I was admitted with diarrhea and was hospitalized for almost a month*), 2) physical consequences (*My urethra was not sutured properly so urine and blood leaked into the abdominal cavity. It was so serious that I thought I would die*), 3) psychological consequences

(Insecurity, doubt – what would be the consequences? Especially my family was affected) or 4) social consequences (I have not been able to work – I’m an independent hairdresser).

**Discussion**

Overall, 10-25% of the cancer patients experienced error. The prevalence was higher during treatment than diagnostics. Compared to other studies of patient experienced error the estimates are on a par.<sup>9,12</sup> Compared to international health professional estimates of error, the prevalence is high.<sup>13-14</sup> This may be because patients and healthcare professionals have different perspectives on errors.<sup>1,5,8</sup>

Sample sizes vary across items in the questionnaire. This reflects certain selectivity in patient responses because no two patient journeys are quite alike. The questionnaire was designed to reflect a ‘standard journey’. Thus, it was expected that not all items were relevant to all patients and that sample sizes would vary from question to question. We do not know if the layout of the questionnaire contributes to the sample size variation but in the future, the survey will be developed into an electronic adaptive questionnaire design. Hopefully, this will support the

patients further in answering all the items that are relevant to them.

**Quantitative Analysis**

More than a quarter of those who experienced errors indicated that errors/complications occurred that they were not informed of prior to surgery. This reflects the problems summarized by the National Quality Forum almost a decade ago.<sup>15-17</sup> Our data does not determine whether information was not provided or not perceived. Either way the findings call for a focus on practices concerning informed consent.

**Qualitative Analysis**

In relation to *cancer detection* about a quarter of those who experienced an error reported that their treatment was delayed because the doctors thought they suffered from some other disease than cancer. The described diagnostic errors revolve around this clinician assessment theme but also outline how symptoms were overlooked/not investigated and how examinations did not reveal the cancer or had to be repeated. Missed and delayed diagnosis of cancer is known to be common and harmful<sup>18-22</sup> and can be attributed to factors related to both patients and providers e.g. patients not contacting the GP when

**Table 4. Frequency of experienced errors in relation to treatment (n = number of responses)**

Question		Yes	No
Q 56	Did you experience any errors at the hospital during treatment? (n=2,206)	553 (25%)	1653 (75%)
<b>Sub question</b> Have you experienced one or more of the following types of errors in connection with your hospital treatment?		<b>Number of errors* (% of total number of errors)</b>	
Q56a	<i>Surgery</i> Errors/complications occurred, the risk of which I had not been informed about beforehand (e.g. damage to an organ, infection)	220 (27%)*	
Q56b	<i>Chemotherapy</i> I was given wrong medication	10 (1%)*	
	I was given a wrong dose of medicine	29 (4%)*	
	I was given my chemotherapy with a delay or not at all	42 (5%)*	
	I was given chemotherapy that ran outside the vein	16 (2%)*	
Q56c	<i>Radiation therapy</i> I received radiation on a wrong part of the body	4 (1%)*	
	I received a wrong radiation dose	6 (1%)*	
Q56d	<i>Coordination</i> Important information about my treatment (e.g. records and letters) were missing when I reported to a new ward/hospital	70 (9%)*	
	Test results were not available as expected (delayed or mislaid)	118 (15%)*	
Q56e	<i>Other errors</i>	292 (36%)*	
<i>Total number of experienced errors (Q56a-e)</i>		807 (100%)*	

\*The total number of experienced errors exceeds the number of patients who have experienced errors because each patient may experience more than one error.



experiencing cancer suspect symptoms or errors in clinical reasoning/cognitive errors.<sup>20,22-25</sup>

The safety challenges related to *planning & coordination* refer to delay in the patient journey. In 2007, standardised cancer patient pathways to ensure fast diagnosis of patients suspected of having cancer were introduced in Denmark in order to reduce waiting times from referral to treatment. The pathways have reduced waiting times and the improvement efforts are now expanded with the implementation of diagnostic centres for evaluation of patients with nonspecific, serious symptoms and with 'No-Yes-Clinics' for cancer investigations when the patient presents with common symptoms. The initiatives all apply to the time until primary treatment, but will not affect the delay during or after treatment, which is described by some patients in this study.

Other patient safety aspects related to *patient-provider communication* arise from the descriptions of doctors not listening to or taking patients seriously or from patients feeling rejected. This adds a new dimension to patient safety in the period from onset of symptoms to diagnosis. Safety aspects of patient-provider communication are not as well described in the literature as inter-professional communication, but it is well known that multiple factors affect patient-provider communication, e.g. time limitations, patient's fear of cancer or of embarrassment.<sup>18-20,26</sup> Further studies of 'lack of listening' and the doctors' 'risk perception' (probability of cancer) is needed.

Of the experienced errors at hospital until time of diagnosis, more than a fifth addressed test results that were not made available as expected (delayed or mislaid).

*Administrative processes* are not always visible to patients, but many patients in this study report on errors involving referrals, test results or the medical chart. The patients also describe how they often identify these errors themselves. Other studies demonstrate similar types of errors and suggest that systems improvement is needed.<sup>22,27,28</sup> A fragmented health care system has an inherent risk of these administrative errors going unnoticed and patients may play a vital role in bridging these gaps. Despite their limited insight into the core processes of health care patients, at most stages of care, can contribute by speaking up when things do not seem right, e.g. when care plans are not followed, test results are not received etc. However, a prerequisite for this is that the patient is encouraged to participate, and the health care professionals are supported in and prepared for patient involvement.

Patients also reported errors related to *treatment & medication processes*. As is the case with provider reported errors, these types of errors stimulate reflection on how to distinguish error from complication.<sup>1,29</sup> Assessing preventability is key to differentiation, but is not an exact science and based on the relatively short descriptions in

the survey pose a significant challenge.<sup>30</sup> In this study no efforts were made to exclude experienced errors according to a distinction between error and complication.

The *consequences of error* are not limited to physical injury. The patients' psychological wellbeing as well as social function can also be affected. The reported organizational impact – e.g. increased length of stay – indicates the potential cost savings related to safety improvement but does not allow for quantification hereof.

### Methodological Limitations

This study has some methodological limitations. First, the discovery that 67 patients described errors in the final generic comment box without stating these experiences in the error section of the questionnaire stresses the challenges of safety terminology. Due to the lack of a better alternative, the word 'error' was used in the questionnaire. The initial cognitive validation showed that the patients consider errors to be rather serious problems, and not – as one might speculate – more trivial issues. This was confirmed in the responses to the open-ended questions. Based on prior experience with provider reported safety issues apparently patients and providers to some extent share their understanding of the term error<sup>1</sup>. Nevertheless, both parties are in a position to identify errors that are invisible to the other part (e.g. providers more easily detect errors related to clinical and administrative processes, whereas patients more easily detect errors related to e.g. continuity of care). Unfortunately, the results of this study do not help us to refine our terminology prospectively.

Second, one person carried out coding of types of errors only. This eliminates the challenges related to inter rater reliability, but at the expense of support to intersubjectivity. As the coder was an expert in patient safety, the approach introduced a bias according to the coder's knowledge of existing error classifications. At the outset of the analysis, a co-author independently categorized a random sample of 250 responses. In order to minimize the 'expert bias' divergent coding was discussed by the two coders in an informal consensus process, (e.g. the understanding of waiting time as either an error or a consequences category was debated). Furthermore, the consensus process was used to explore and clarify the understanding of the various categories.

Third, due to the numerous responses to open questions, this study provides detailed insight into patient's perception of errors in the cancer journey. The descriptions complement the quantitative responses, thus provide details on 'new' types of error, causes, contributing factors or context. Since a survey does not allow for clarification if comments are imprecise or unclear, sometimes comments are difficult to understand and use.

Fourth, our study is disease specific with only cancer patients being included. The results reveal patient experienced errors that also appear in other patient populations. Despite the generic types of some errors the disease may be of importance, e.g. the prevalence of some types of errors may be higher in the complex cancer patient journey or the consequences may be more severe for cancer patients. This may affect generalization of the results.

Our findings confirm that patients can supplement health care's knowledge on patient safety issues. The results suggest that greater attention to the patient-provider communication is needed, with a specific focus on information on surgical complications. Also, measures aiming at mitigating administrative errors should be taken. The fact that patients identify errors that are not necessarily recognized by the health care system sets the stage for the involvement of patients as an extra safety barrier.

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