Attention to cancer patients' safety after primary treatment is needed

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ABSTRACT

INTRODUCTION: Knowledge about patient safety issues after primary treatment of cancer is sparse.

METHODS: The present article is a retrospective analysis of adverse events (AEs) after primary cancer treatment to characterise the types of AEs and their consequences. A total of 724 AEs reported from 2010 to 2013 were identified via the Danish Patient Safety Database. The International Classification for Patient Safety was used to characterise event types. Consequences were characterised as either psychical harm or delay. We focused on AEs in care transitions.

RESULTS: Common event types were administrative processes (58%), communication and documentation (56%), clinical processes (42%) and medication (27%). 46% of AEs led to physical harm. 4% resulted in severe physical harm or death. 18% resulted in delay in diagnosis of relapse or new cancer, treatment or referral. 50% of all AEs were related to care transitions. The AEs in care transitions carry great potential for prevention as they often relate to inadequate administrative practices, poor communication and documentation, or to unclear transferal of responsibility for the patient.

CONCLUSION: Attention to patient safety after primary cancer treatment is required. The identification of a substantial number of AEs in care transitions stresses a need for increased continuity and clear transfer of responsibility in cancer care after primary treatment. To support learning from AEs, the AE reports should provide more details on the contextual factors.

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The cancer pathway is complex and carries the risk of patients being harmed by the health-care system [1]. One in four Danish cancer patients experience errors related to their treatment or follow-up care [1, 2]. A disease-specific approach to patient safety is uncommon and most literature about safety in cancer care focuses on *primary treatment* at the hospital [1]. Many cancer survivors have complex care needs and require care in multiple settings related to, e.g., rehabilitation and follow-up care [3]. Cancer survivors are said to be lost in the transition from patient to survivor due to fragmented and poorly coordinated cancer care and the absence of a locus of responsibility for follow-up care [4]. Many adverse events (AEs) can be traced back to inadequate care transitions [2, 5, 6], i.e. transfer of professional responsibility for some or all aspects of a patient's diagnosis, treatment or care between two units or organisations on a temporary or permanent basis [7]. AEs are defined as harm – factual or potential – resulting from errors or complications in health-care management [8].

This article focuses on patient safety after primary cancer treatment. The aim is to characterise types of AEs and their consequences. Our hypotheses are 1) that types of AEs differ according to health-care setting, 2) that AEs in care transitions are common and their characteristics differ depending on whether they are intersectoral or not, and 3) that AEs introduce delay in the course after primary treatment.

The study is based on the Danish Patient Safety Database (DPSD) (**Table 1**).

METHODS

5,252 AEs filed in the DPSD from September 2010 to February 2013 were retrieved in text searches using 17 cancer-related search terms, e.g. cancer, tumour, c., terminal, and palliative [3]. A total of 2,385 reports that were either duplicates or not cancer-specific and 2,162 reports related to primary cancer identification/treatment were excluded. Of the remaining 705 reports, 19 referred to two independent AEs; thus, a total of 724 AEs were included in the analysis.

Reporting systems like the DPSD focus on what goes wrong and build on the approach that description of *what happened* (process) and *why did it happen* (problem) creates learning [10, 11]. This study builds on the theoretical framework that causes and contributory factors should be identified and eliminated to enhance safety and that AEs are a result of both active failures and latent conditions, i.e. multiple factors such as the work environment, contextual organisational factors, task-related and team-related factors [10, 11]. These factors are operationalised in the Danish version of the International Classification for Patient Safety (ICPS) [9] (**Table 2**), which we apply to uncover the event types, processes and problems concerned.

The original ICPS classification of event types in the

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TABLE 1

Facts about the Danish Patient Safety Database and reports of adverse events.

Licensed health-care professionals in Denmark are required to report AEs to the DPSD
Reporting is confidential and non-punitive [8]
Reports on AEs are filed electronically by frontline personnel, patients, relatives and local risk managers using a combination of categorical and free text data [8]
The frontline personnel or patient/relative reporting the AEs fills in information about
Event location + other providers involved, if any (categorical)
Event description (free text)
Consequence (free text)
Proposed preventive actions (free text)
Profession of the reporter (categorical)
The patient's sex and age (categorical)
A local risk manager from the individual municipalities or regions/hospitals receives, edits and supplements the report with
Harm score based on five categories defined by the physical severity and duration of any harm, and treatment implications that result from an event (categorical
The harm should be scored as the factual harm and not the potential harm[a]
Event type classification using the International Classification for Patient Safety (ICPS) which has 13 event types with subcategories on the details of problem and process concerned (categorical) The event types are not mutually exclusive, and an AE can be classified as more than one event type[b]
The local risk manager forwards the report to The Danish National Agency for Patients' Rights and Complaints and the report is stored in the DPSD

AEs = adverse events; DPSD = Danish Patient Safety Database.
a) Further information in the ICPS manual translated by The Danish National Agency for Patients' Rights and Complaints [9].
b) Further information in Table 2 and in the ICPS manual translated by The Danish National Agency for Patients' Rights and Complaints [9].

TABLE 2

Extraction and description of selected event types in the Danish Patient Safety Database, based on the International Classification for Patient Safety[a].

Event type	Description of selected processes and problems
Administrative process	The AEs usually take place without the patient's presence and is often related to the planning of the patient's stay or pathway, e.g. in the case of handover, transfer of care, referral/consultation, admission or discharge
Communication & documentation	The AEs occur in relation to health professional's verbal, manual or electronic communication/documentation of patients, e.g. missing or wrong information exchange or misinterpretation or misunderstandings regarding document involved in orders/requests, instructions/information or letters/e-mails/records of communication
Clinical process/procedure	The AEs occur in relation to, e.g., diagnosis/assessment, procedure/treatment/intervention or tests/investigations May also include sub-processes closely related to diagnostics and treatment without direct patient contact
Medication	The AEs occur in the processes of ordering, transcribing, dispensing, administering, or monitoring medications, irrespective of the outcome
Individual, team and organisation	The AEs occur in relation to insufficient resources or inappropriate organisation of teams/people The events concerns, e.g., mismatch between tasks and capacity, inadequate staffing or lack of staff with the right skills including professional assessments
Medical device/equipment	The AEs occur in relation to the use of medical devices/equipment for the treatment of patients, e.g., lack of availability of special mattress to avoid pressure ulcers or failure/malfunction of equipment

AEs = adverse events; ICPC = International Classification for Patient Safety.
a) Only the 6 most common event types in this analysis are described. Further descriptions are found in [9]. The other ICPS event types are: Patient accidents, Buildings and infrastructure, Infections, Blood and blood components, Gases and air for medical use, Self-harm, suicide attempts or suicide, Other adverse events.

724 AEs was carried out by many different risk managers across the country. We found that this original classification did not sufficiently describe the multifactorial aspects of the AEs that were described in free text. Also, the original harm scores tended to reflect potential rather than factual harm. Thus, a systematic supplementation of event types (including process and problem) and recoding of harm scores was needed to ensure consistency. Initially, a sample of AEs was classified by the first author and a medical doctor to reach and test for consensus. The following completion of event types and harm scores was conducted by the first author:

1) The original event types were retained. Additional event types were added when relevant according to the ICPS.

2) All harm scores were recoded using the DPSD harm score classification and based on the free text description of consequences [9]. As harm resulting from delay was coded with great inconsistency and reflected that the physical harm often was not known at the time of reporting, the new category *delay* (> 1 week) was added to the existing harm classification.

All AEs were categorised according to the health-care setting represented, e.g. palliative care or follow-up care.

AEs concerning care transitions were manually identified. This process was guided by the event types and by reading the event descriptions looking for some of the characteristics described in the literature: unclear information (communication or documentation), unclear responsibility or coordination, delayed referrals/bookings/test results [4, 6, 7, 12-14]. The problems in care transition were conceptualised by conducting a content analysis based on Malterud's systematic text condensation [15]. First, all free text descriptions were read in order to provide an overview of what goes wrong in care transitions and why. Categories of problems were created until no more categories emerged. These categories were combined into larger ones. All AEs were deductively coded according to the created categories. Finally, we noted whether one sector (e.g. two or more clinical units at the same hospital) or two sectors (intersectoral) were involved and we noted the specific providers involved.

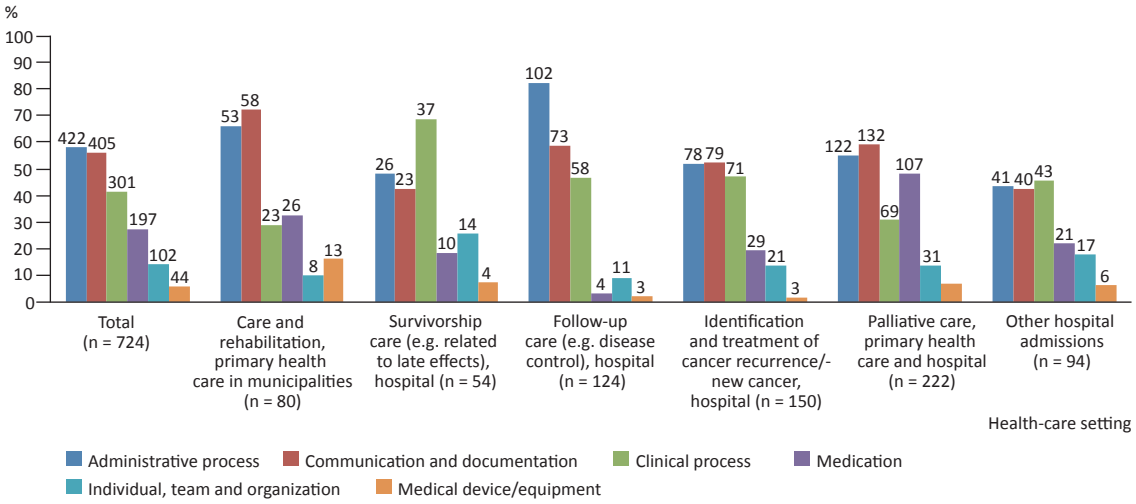
Quantitative analysis was completed in SPSS PASW Statistics 18.

Trial registration: not relevant.

RESULTS

The 724 AEs concerned six *health-care settings* (**Figure 1**). Most AEs (31%) appeared in palliative care. The event location was primarily public hospitals (86%), but often providers in primary health care were involved.

FIGURE 1



The six most frequent types of adverse events (AEs) based on the International Classification for Patient Safety (ICPS) in cancer care after primary treatment across different health-care settings. Percentages are based on the total number of AEs in each setting (N)[a]. Numbers on top of columns refer to numbers of related AEs, e.g., administrative process or medication.

a) Percentages of event types in the individual health-care services add up to more than 100 because each AE is categorised by up to three different ICPS event types.

96% of the AEs were reported by professionals, primarily nurses (46%) and doctors (28%). 4% were reported by patients or relatives.

Types of adverse events

Most AEs were related to administrative process, communication & documentation, clinical process or medication (Figure 1). Types of AEs varied according to health-care setting. Most AEs related to administrative processes were reported in follow-up care, e.g. problems with referrals to follow-up care after primary treatment that were not sent or received were described. Most medication events were reported in palliative care, e.g. problems reported included insufficient medication or lack of continuity in medication regarding pain, treatment or symptom relief.

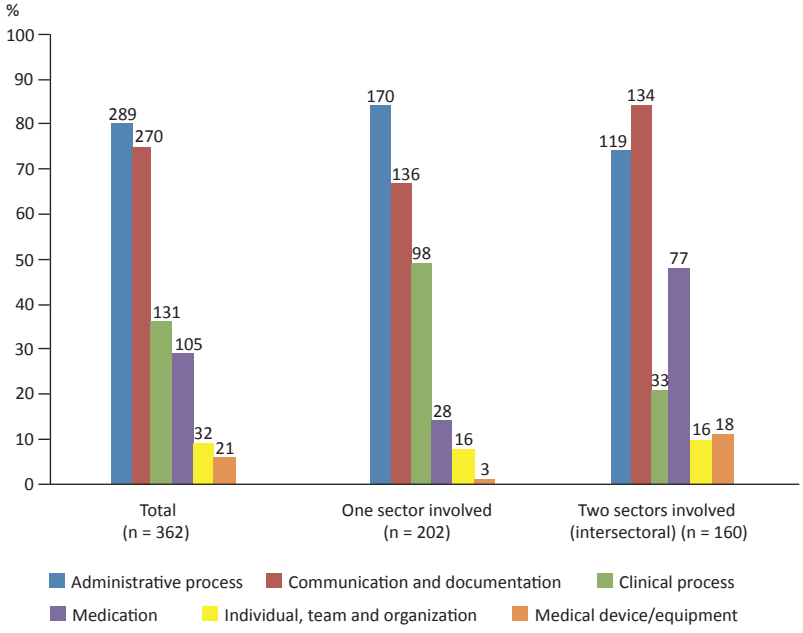
Safety issues in care transitions

A total of 362 (50%) AEs were related to care transitions. In all, 202 (56%) care transitions involved one sector and 160 (44%) were intersectoral (**Figure 2**). The AEs involving one sector mostly addressed transitions between two clinical units at the same hospital (78%), e.g. problems with test results that were overlooked or not passed on to the clinical unit requesting the test. The intersectoral AEs primarily addressed transitions between a public hospital and primary health care (81%) at hospital discharge (77%) or admission (23%), e.g. problems with changes in medication that was not shared or updated, or incomplete discharge summaries were described.

Care transitions were commonly related to administrative processes and/or communication and documentation. Types of AEs involving one sector differed from the intersectoral AEs (Figure 2), e.g. by showing more

FIGURE 2

The six most frequent types of adverse events (AEs) in care transitions after primary cancer treatment based on the International Classification for Patient Safety (ICPS). Percentages are based on the number of AEs involving one sector and two sectors, respectively[a]. Numbers on top of columns refer to numbers of related AEs.



a) Percentages of event types in care transitions add up to more than 100 because each AE is categorised by up to three different ICPS event types.

medication events in transitions between sectors (48% versus 14%).

Content analysis identified four categories of problems in care transitions (n = 362):

- Unclear, missing or delayed access to information regarding the patient (57%, n = 203)
- Unclear coordination, planning and responsibility for the patient pathway (48%, n = 175)
- Delayed or missing referral/booking (23%, n = 73)
- Delayed or missing test results or identification of recurrent cancer (11%, n = 39).

Consequences

A total of 265 (37%) of the AEs resulted in no physical harm, 201 (28%) in mild physical harm, 101 (14%) in moderate physical harm, 19 (3%) in severe physical harm and five (1%) in death. The consequence in the remaining 133 AEs (18%) was *delay* of the processes of follow-up on abnormal results, referral to planned follow-up care, treatment of cancer recurrence, new cancer or palliative needs. Delay ranged from one week to several years.

DISCUSSION

To our knowledge, this is the only study using a national reporting system to analyse AEs in cancer care after primary treatment and in care transitions.

This disease-specific approach contributes to the understanding of the nature of AEs, but it does not produce generalisable incidence rates as underreporting is inherent in most reporting systems. Differences in safety focus between the reporters may also affect both reporting and results. Thus, reporting of AEs must be complemented through other measures of patient safety [10].

Cancer-related AEs in DPSD were identified manually. This poses the risk that not all relevant AEs were identified and thus a risk of underestimation. Event types were supplemented and harm scores recoded as we believe that this gives the most complete and reliable picture of the reported AEs.

Despite inherent limitations, the DPSD has been highlighted as a tool that if used may help improve patient safety in Denmark - even though there is no scientific evidence of the effect of reporting systems on patient safety [10]. We found that it is difficult to translate knowledge from the DPSD into recommendations and safety-enhancing actions to prevent future AEs because the reporters' event descriptions of contextual and contributing factors are often insufficient to describe especially the latent conditions in the organisation. Thus, our results mainly contribute to knowledge about *what went wrong* (process), whereas the learning regarding *why did it happen* (problem) is sparse.

Reporting of AEs is the only Danish safety activity based on regulation. It builds on the idea that safety can be enhanced by retrospective analysis and learning from things that have gone wrong. However, it is suggested that safety cannot be managed by focusing only on what goes wrong, but must also look ahead to ensure that things go right [10].

AEs related to care transitions were surprisingly frequent representing half of the AEs in this material. Due to inconsistencies in definitions of care transitions [7], comparisons with the number of AEs in care transitions are difficult. However, the problems reported in this study and in the literature are similar. Many problems in care transitions relate to a lack of clarity about who is responsible for the patient [7]. Care transitions are described as unstructured, informal and prone to error [7] and with substantial deficits in communication and information transfer across the different health-care settings and sectors [3, 5, 7, 9]. The problems related to communication failure in transitions are related to, e.g., lack of understanding of roles, lack of coordination and not giving discharge planning priority [5, 7]. Furthermore, discharge summaries often fail to provide important information [6, 16]. This supports our findings.

The identified medication events frequently stressed risks relating to treatment discontinuity, especially regarding palliative care (pain relief and symptom relief) at admission and discharge. Discrepancies in the patients' medication lists at admission and discharge are well-known safety issues [5, 6, 14, 17]. A review showed that 54% of patients experienced at least one unintended medication discrepancy on admission [6] and 14% when going home from the hospital [17].

Our findings on harm are similar to those found in both cancer-specific and non-cancer-specific analyses of DPSD data [1, 18]. However, it is surprising that the extent of psychical harm after primary treatment is at the same level as during treatment since the latter is considered a high-risk area.

Our study documents that delay is not just an issue of major concern during primary cancer treatment, but also afterwards as delay often has a serious impact, including several missed cancer recurrences. Delay is an intermediary consequence that could lead to severe physical harm [12, 19], but it is difficult to assess the overall contribution of delay to factual harm. Delayed referrals and unrecorded test results are frequent in our study. The scope of failure to follow-up on test results was shown to be 7-62% for laboratory tests and 1-36% for radiology [13].

Nearly half of all AEs are considered preventable [20]. However, the results of our study indicate that more AEs may be preventable, as especially the AEs in care transitions relate to inadequate administrative

practices, poor communication and documentation or to unclear division of responsibility for the patient between providers. This is supported by others who found that approximately 70% of AEs after discharge could be prevented or ameliorated with simple strategies [5].

To avoid suboptimal care and delay in, e.g., identification and treatment of cancer recurrence or palliative needs, responsibility for the patient should be clearly located. Also, it must always be visible when and to whom the responsibility is transferred. This applies to both the responsibility for a patient, a referral and a test result. Interventions to improve care transitions and tools to monitor these are needed.

There is no widespread agreement on definitions of AEs in care transitions. Adding categories of care transitions in the DPSD may probably improve analyses and comparisons in future studies. Furthermore, mandatory disease categorisation would be a valuable adjunct to disease-specific analyses. However, if the DPSD is to be used as a tool to improve learning (at a national level), there is a need to enhance the quality of the reports, i.e. they must provide more details of why the AE happened.

CONCLUSION

Attention to patient safety after primary cancer treatment is required to avoid delay in identification/treatment of cancer recurrence and suboptimal palliative care. To enhance safety in care transitions, a dedicated focus on continuity and transfer of responsibility after primary cancer treatment is needed. To support learning from AEs, the AE reports to the DPSD should provide more details on the contextual factors, both active failures and latent conditions. Patient safety issues identified in the DPSD should be combined with other data and ways of thinking to reflect all relevant safety dimensions and provide a solid basis for improvement.

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