Risk and Event Assessment

A Risk Analysis of Cancer Care in Norway: The Top 16 Patient Safety Hazards

Einar Hannisdal, MD, PhD; Helga Arianson, MD; Geir Sverre Braut, MD; Ellen Schlichting, MD, PhD; Jan Erik Vinnem, Dr.ing

Providing treatment to cancer patients is a process that involves many care providers in various disciplines and health care settings. The care process itself represents a number of potential threats to patient safety,[1] as Lipczak, Knudsen, and Nissen showed in a study of adverse events in cancer care in Denmark. Adverse events in hospitals are a serious problem, annually killing more people than breast cancer or AIDS. For example, de Vries et al., who analyzed findings of eight studies covering 74,485 patient records, found that a median of 9% patients had experienced in-hospital adverse events, 7% of which were lethal and 43% preventable.[2] In outpatient oncology, Walsh et al. reported an average 8% error rate for patient visits.[3] Few studies have addressed medication errors in inpatient oncology,[4] but a study of medication order errors in a general hospital in Israel, for example, showed that of 160 medication order errors detected in a six-month period, anti-infective drugs were the most prevalent class of drugs represented (39%), followed by total parenteral nutrition preparations (22%), antineoplastics (16%) and anticoagulants (11%).[5] To improve patient safety and quality of surgical oncology, France has launched national plans,[6] which include minimum volume thresholds and a mandatory surgical checklist.[7]

Norway has about five million inhabitants distributed over four health regions and 18 counties. All 19 "somatic" (medical)/mental disorders hospital trusts in Norway are owned by the state and governed by the Ministry of Health and Care.* In addition, a few hospitals are privately owned. The Norwegian Board of Health Supervision (NBHS) is an independent supervisory authority with responsibility for general supervision of health, social services, and child welfare. The NBHS has tended to respond reactively to reported adverse events in the health service or has performed system audits of selected services or pro-

* A health trust (*helseforetak*) is a health enterprise owned by one of the four regional health authorities in Norway. Each health trust is led by a board of directors appointed by a regional authority. Most health trusts are responsible for one or more hospitals. Four trusts are solely responsible for pharmacies, and three for drug and alcohol abuse treatment, ambulance services, and rehabilitation.

Article-at-a-Glance

Background: Cancer care processes represents a number of potential threats to patient safety. A national risk analysis of Norwegian cancer care, entailing diagnosis, treatment, follow-up, palliative care, and terminal care, was conducted.

Methods: Literature review and a retrospective analysis of hazards in different national databases were combined with interviews with key health personnel in an attempt to identify 50 possible hazards. A project team from the Norwegian Board of Health Supervision (NBHS) and 23 other persons participated in the workshop in 2009.

Results: In a stepwise, consensus-driven process, the 23 participants discussed the 50 possible hazards and then selected the 16 that they considered most important—clustered into three groups: diagnosis and primary treatment, interactions, and complications. The NBHS distributed the risk analysis report to a variety of stakeholders and asked Norway's hospital trusts to address the hazards. The report generally met a positive reception, albeit with local and interdisciplinary differences in the extent of the perceived applicability of the respective hazards. Two follow-up studies in 2012 and 2013 showed that the hospital trusts lacked the implementation capacity to identify operational solutions to reduce the hazards. At the largest hospital trust in Norway—Oslo University Hospital—the Department of Oncology retested the national risk analysis in in 2011. Four groups, representing different parts of the patient care process. selected 9 of the 16 national hazards and identified 4 new ones. The department has established goals and appropriate activities for 3 of the hazards.

Conclusions: The Ministry of Health and Care determined that hospital trusts must increase their implementation capacity regarding operational solutions to reduce the hazards.

cedures based on assessment of risks.

The NBHS performs risk analyses of different parts of the health services in the 18 counties or in the four health regions. However, this is time-consuming, and important points of failure may be overlooked because of lack of information on national trends and challenges. Furthermore, universal methods for risk assessment in health care have not been defined in Norway. The risk analysis was published in a 2010 report from the NBHS.[8] In this article, we describe this risk analysis and its findings and implications.

Methods

Preparing the NHBS Risk Analysis

The methodology used in the NHBS risk analysis was adapted from the Preliminary Hazard Analysis described by Aven et al.[9] The risk analysis entailed a literature search and a subsequent workshop.

Literature Search. A search of relevant national and international literature was performed in 2009 (in PubMed and Google) with the search terms *risk factor, risk analysis, risk management, hazard, failure,* and *error,* were combined with *cancer, cancer care* or *oncology* with or without the terms *national* or *regional*. The searches were directed particularly at finding similar national studies, and reports from Denmark and the Netherlands were identified.

The most important Norwegian data sources relating to adverse events were reviewed, including internal reports in the NBHS. These findings were summarized in a short report, in which 50 types of hazards in Norwegian cancer care were defined. This report was sent out to the participants three weeks before the two-day workshop.

Workshop. The hospital trusts, the Norwegian Medical Association, the Norwegian Nurses Organization, and the Norwegian Cancer Society were asked to nominate candidates who could participate in the workshop. After adjusting for specialties and geography, a group of 23 health personnel and administrators was established. The group consisted of patient representatives (3), nurses (3), physicians (10: oncology, surgery, pathology, radiology), medical physicists (3), primary care (2), and hospital trust administrators (2). In addition, 5 NBHS representatives functioned as meeting facilitators, presenters, and reporters.

The first part of the workshop, which took place October 14, 2009, took the form of plenary sessions with introductory lectures about risk analysis and the preliminary findings, including the 50 types of hazards, as described in the report. The rest of the workshop consisted of group work with an iterative approach. In the first round, three different groups were asked to nominate the 5 most important hazards. After plenary discussion, 5 hazards were selected. In the next two rounds, a further 5, and then 6 more, were selected, resulting in a total of 16 hazards, which were plotted by the participants and the chair of the meeting in a risk matrix.

After the workshop, the NBHS prepared a draft report [whose authors included E.H., G.S.B.], which was reviewed by the participants; their comments were reflected in the NBHS final report.[8] The workshop was evaluated through a questionnaire survey distributed to all participants and interviews with five participants after the final report was presented.

Results

The Top 16 Hazards as Identified in the Risk Analysis

Seventeen of the 50 hazards were identified though literature review, and the remaining 33 from national databases and interviews. The 16 most important hazards, as identified by the workshop participants, are summarized in Table 1 (page 513), clustered into three groups: diagnosis and primary treatment, interactions, and complications. The participants also classified the hazards in terms of consequences and likelihood, as shown in the risk analysis matrix (Figure 1, page 514). Of the 19 (83%) participants responding to a questionnaire regarding the hazard identification process, 17 (89%) provided a score of 4 ("good") or 5 ("excellent"). In addition, 18 (95%) advised the NBHS to perform a similar risk analysis for other health services.

Distribution of the Norwegian Board of Health Supervision Report

The NBHS report was distributed to a variety of stakeholders in Norwegian health care, including all hospital trusts, and accompanied by a letter in which the NBHS asked the trusts to address the identified hazards. The report generally met a positive reception, albeit with local and interdisciplinary differences in the extent of the perceived applicability of the respective hazards. For example, bottlenecks in radiology and pathology varied significantly between trusts. In 2011 the Ministry of Health and Care mandated that the regional health care authorities and their hospital trusts carry out specific tasks designed to reduce the major hazards identified in the risk analysis report. The risk analysis significantly contributed to a national debate regarding the causes of the hazards. The Ministry set a national goal—to reduce delays in the diagnostic processes of cancer in Norway, a new 20-working-days' limit was set from reception of referral documents in hospital to the start of cancer treatment. In a follow-up study in 2012, the NBHS reviewed the status of this

Table 1. The 16 Most Important Hazards in Norwegian Cancer Care

Hazards	Examples of Hazards	Addressed by 2013
Diagnosis and primary treatment		
1. Diagnostic delay	Several examples of more than 3 months' delay from referral to start of cancer treatment	Yes
2. Radiology	Insufficient radiological service (due to persistent bottlenecks)	Yes
3. Pathology	Wrong pathological diagnosis or limitations in diagnostic panel (tissue markers)	Yes
4. Surgery	Failure in surgical treatment (performance of procedures)	Yes
5. Volume and quality	Overly low patient volumes in some trusts (< 5–10 patients a year)	Yes
Interactions		
6. Information exchange	Failure in information exchange/coordination between actors in the care process There is no main national information portal which is complete and regularly updated (recommendations, clinical guidelines).	No
7. Referral	Referrals are lost or delayed in all parts of the treatment chain.	Yes
8. Communication	Failure in patient communication and lack of involvement of patients and their relatives	Yes
9. Overtreatment	The limits of treatment are stretched in advanced cancer cases. Difficult talks about stopping treatment are left to another actor in the care chain.	Yes
10. Discontinuity	Failures of continuity in the treatment chain, particularly too many oncologists involved with the same patient over a short time span	Yes
11. Palliation	Failure in palliative care, particularly for patients in terminal stages in the community health care system	Yes
12. Competence	Failure in transferring competence between actors in hospitals and community health care. Limited recruiting and education of oncology health personnel	Yes
13. Working environment	Burnout of health personnel and unsatisfactory working environment reduces the quality/quantity of services delivered.	No
Complications		
14. Complications	Lack of any national overview and surveillance of serious complications	No
15. Infections	Failure in infection prevention and treatment of serious infections	No
16. Radiotherapy	Long-term complications after radiotherapy are underdiagnosed or detected too late.	No

follow-up work. For example, one of the trusts developed a new strategic cancer care plan on the basis of the national risk analysis. Although reporting back to the Ministry was mandatory, none of the four regional health care authorities and only 8 (42%) of the 19 hospital trusts reported as requested in 2011. Most of these hospital trusts reported on the extent of hospitals' compliance with the new 20-day limit for initiation of treatment but not specifically on progress regarding the remaining 15 hazards defined in the national risk analysis. The NBHS reported to the Ministry that it found this follow-up and reporting to be "unacceptable regarding details."

Because of these disappointing results, the NBHS performed another follow-up study in 2013, again finding that the hospital trusts in 2012 had still not addressed most of the hazards identified in the risk analysis. However, one of the four health regions (Helse Vest [The Western Norway Regional Health Authority]) had addressed organizational issues, risk selection, work flow, and bottlenecks issues to fulfill the 20-day referral-to-treatment-start limit. The 2012 and 2013 follow-up studies showed that the hospital trusts were measuring compliance for 9 of the 16 top hazards—all 5 Diagnosis and Primary Treatment hazards and 4 Interactions hazards (Referral, Overtreatment, Palliation, and Competence) (Table 1). The Ministry noted that the hospital trusts lacked the implementation capacity to identify operational solutions to reduce the hazards. In 2013 it released a new National Cancer Strategy, with goals for several of the hazards in the risk analysis (Table 1).

Local Application

At the largest hospital trust in Norway—Oslo University Hospital—the Department of Oncology retested the national risk analysis with 16 hazards in December 2011. This department, with about 1,000 employees, 6,400 hospital stays, and 163,000 outpatient visits annually, primarily provides chemotherapy and radiotherapy services. A total of 24 employees, divided into four groups (wards, outpatients clinic, radiotherapy, and oncologists), participated in three-hour workshops to develop risk matrices. The number of hazards to be identified was limited to a maximum of 5 for each group. In this session, the groups, representing different parts of the patient care process, selected 9 of the 16 national hazards and identified 4 new ones—medical equipment, management, bottlenecks, and patients at wrong place—and then came to consensus regarding a common matrix with 7 hazards (Table 2, page 515). By June 2013, the department had

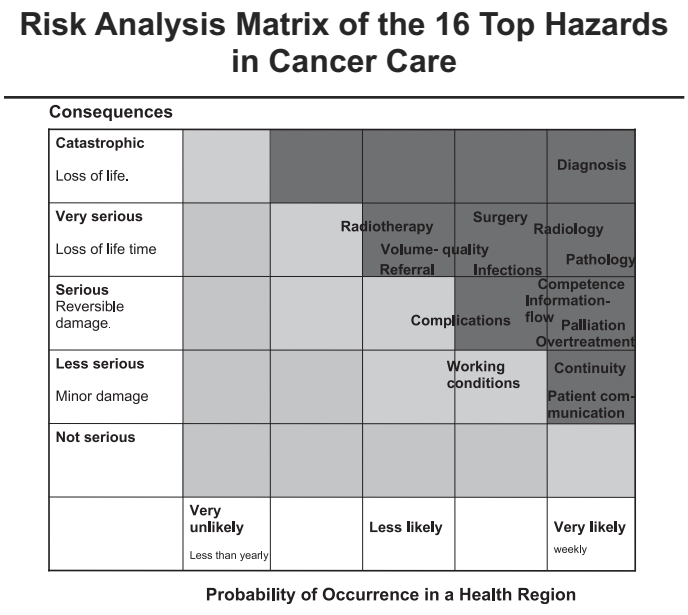


Figure 1. *The workshop participants classified the 16 top hazards in cancer care in terms of consequences and likelihood. The "red" category denotes unacceptably high risk, with intervention mandatory in a short time. "Yellow" connotes medium risk, with intervention needed to avoid escalation to the red category. "Green" connotes partly elevated risk, with intervention not needed. Radiotherapy and complications overlap between yellow and red. (Available in color in online article.)*

established goals and appropriate activities for 3 of the hazards. To reduce discontinuity in the treatment chain, several patient coordinators have been employed, and patients will receive an "individual plan" at first contact. The major bottleneck in the diagnostic phase lies in radiology services, where several additional radiologists have been hired, and an improved booking system is under development. To reduce overtreatment, the department has run several "Enough is Enough" seminars for physicians and nurses, in which case studies are presented and the participants vote online to select treatment strategies.

Discussion

The NBHS performs risk analyses of different parts of the health services in Norway. For example, in a risk analysis for cancer care that it conducted in 2009,[8] the most serious hazard identified was delays in the diagnostic process. The delays occurred at all levels in the treatment chain, from primary care to specialist treatment at university hospitals, reflecting, for example, lost referral papers, unrecorded laboratory results, and waiting time between one care setting and the next. The risk analysis contributed to a national debate, and, in 2011, the Ministry of Health and Care set a national goal of a maximum 20 working days from referral to start of cancer treatment—a goal that most of the country's 19 hospital trusts have failed to meet.

The NHBS risk analysis also identified poor information exchange and discontinuity in the treatment chain as two important hazards, which, like waiting time, were also reported in a Danish study.[1] In a recent investigation, the Dutch Health Care Inspectorate, which examined the entire treatment chain from patient presentation at a referring hospital through treatment at a radiotherapy center and posttreatment follow-up, reported an extremely fragmented care process with many "transfer moments."[10] Such fragmentation placed a heavier reliance on exchange of information and overall coordination of care, which often were not successfully conducted. The report concluded that there was considerable room for improvement and defined several concrete goals for a better oncologic care chain in the Netherlands to be followed up by the relevant services. Patients want better communication, information, and involvement of themselves and their families.[1] Several strategies designed to close the continuity gaps in the treatment chain, such as closer involvement of patients and families, have been developed.[11]

In contrast to the Lipczak, Knudsen, and Nissen study,[1] we did not find chemotherapy to be an important hazard in Norwegian cancer care. One possible explanation of the differences in hazard identification between the two countries may be underreporting in Norway. Alternatively, most hospitals in Norway use a computerized order entry system for chemotherapy, which can help prevent errors.

Radiotherapy treatment was not rated as a major concern in our risk analysis; only the risk of overlooking long-term complications was described. Because of this reported hazard, in 2010 the Norwegian Radiation Protection Authority contributed to an initiative for long-term follow-up after radiotherapy.[12] In addition, a national surveillance system for hazards in radiotherapy has been in operation for the last few years.[12] In the Danish risk analysis, 73 (3%) of 2,429 hazards in cancer care were related to radiotherapy—mainly wrong place (volume) or wrong dose. In a review of patient safety measures in radiotherapy, Shafiq et al. estimated the risk of low or mildly injurious outcome to patients for radiation errors at 1,500 cases per million courses of treatment; death from adverse events in radiotherapy was estimated at 1%.[13]

Overtreatment of cancer patients was ranked among the 16 most important hazards in our study. The costs of cancer care in the last six months of a patient's life are considerable.[14] Overtreatment becomes a hazard because it puts additional stress on a treatment chain that is already under considerable strain, resulting in more outpatient visits, more admissions, and more inpatients under treatment. Furthermore, the risk of complications

Table 2. The 16 Most Important Hazards in Norwegian Cancer Care Retested in an Oncology Department as Defined by Four Personnel Groups*

Hazards	Personnel Groups				
	Outpatient Clinic, Nurses	Ward, Nurses	Radiotherapy†	Oncologists	Common Matrix
Diagnosis			+	(+)	
Radiology	+		(+)	+	
Pathology					
Surgery					
Volume and quality					
Information exchange	+	(+)	+	+	+
Referral	(+)	(+)	+	(+)	
Communication	(+)	(+)			
Overtreatment	+	+	(+)	(+)	+
Discontinuity	+				+
Palliation					
Competence					
Working environment	+	+			+
Complications					
Infections					
Radiotherapy				+	
New Hazards Defined					
Medical equipment			+		+
Management				+	+
Bottlenecks	(+)	+	+	+	+
Patients at wrong place		+			

* The groups were asked to select the five most important hazards, indicated by "+"; "related" hazards are indicated by (+).
† Medical physicists, radiotherapists.

increases, given the fragile condition of patients with terminal cancer. Palliative care outside hospitals was also rated as an important hazard—as was "competence," that is, transfer of competence "between actors in hospitals and community health care." These three hazards together argue for a shift of resources from tumor-specific treatment to a broader focus on palliation.

Information exchange was considered to be a hazard in our risk analysis, which refers to both "failure in information exchange/coordination" and the lack of a "main national information portal that is complete and regularly updated." (At least seven different national portals contain information about cancer and clinical guidelines.) For several cancer types, no portals are completely updated, and hospitals may also have internal recommendations that differ in some respects from those available for patients and other health personnel in the public portals. To address this confusing hazard, the NBHS recommended that the Norwegian information portal structure provide guidelines for different cancer types and that all information be updated more consistently.

As stated earlier, we adapted the risk analysis from Preliminary Hazard Analysis.[9] Bonnabry et al., who used failure modes, effects, and criticality analysis to prospectively study the chemotherapy process, reported that strong improvement was associated with centralization in the pharmacy and increased use of information technologies.[15] Kessels-Habraken et al. combined retrospective analyses of incident reports with prospective analyses for employees' identification and assessment of possible hazards in a Dutch hospital, an integrated approach that may improve the efficiency of the analysis.[16] Our own risk analysis also represents a combination of a retrospective and prospective approach. We first conducted a literature review and a retrospective survey describing 50 possible hazards in Norwegian cancer care. Preparation of this risk analysis showed that hazards in Norwegian cancer care are clearly underreported, much as has been shown in Sweden.[17] We then asked the workshop participants to assess the prospective risk picture, which led to the identification of the top 16 hazards. The four-month period included the preparatory phase (data collection and introductory report), the three-hour workshop, and the participants' subsequent review of the final report. It may be tempting to speed up the process, but we do not recommend this on a national level because of the difficulty of reconciling participants' schedules. On the other hand, Oslo University Hospital performed the risk analysis as an "express" process (about one week from workshop to report) without major problems.

We considered the broad involvement of health personnel, as

we achieved in the national risk analysis, to be an important success factor. The NBHS received no major critical feedback regarding the report of the identified 16 hazards, although in the subsequent public debate, some people expressed the view that "Norwegian cancer care is not so bad."

The risk matrix that we developed in this work was intended for application at a national level. One limitation might be that a new workshop with other participants could well result in a wholly different risk matrix. Risk matrices will naturally vary between types of institutions, clinical specialties, departments, and wards. Yet when we retested the 16-hazard risk matrix at the University of Oslo Hospital in 2011, the participants proceeded to selected 9 of the 16 original hazards and define 4 new ones. We believe that this second workshop confirmed the usefulness of the input provided by such consensus-driven approaches, with the identified hazards forming the basis for a more focused and measurable management of cancer care.

Our follow-up studies showed that 11 of the 16 hazards were addressed by June 2013 (Table 1). However, "addressed" does not mean "mission completed." For example, only one hospital trust reported some initiatives on overtreatment, which remains an unresolved national problem. Resources related to overtreatment can be transferred to the diagnostic phase to reduce the known hazards of delays. We find it disappointing that the hospital trusts reporting back to national authorities continue to show little capacity to implement operational solutions to reduce the hazards. It may be useful for hospitals to redefine the national risk matrix at the organizationwide, department, and ward levels and proceed to develop solutions. J

Funding for the work described in this article was provided by the Norwegian Board of Health Supervision, Oslo. The authors thank Dr. Anne-Berit Gunbjørud, for facilitating the process and workshop; the workshop participants, for their important contributions; and Professor Kjell M. Tveit, Oslo University Hospital, for kindly providing access to the results of the workshop and adapted risk matrix.

Einar Hannisdal, MD, PhD, is Consultant in Oncology, Department of Oncology, Akershus University Hospital, Lørenskog, Norway. **Helga Arianson, MD,** is Chief County Medical Officer, Norwegian Board of Health Supervision, Hordaland/Bergen, Bergen, Norway. **Geir Sverre Braut, MD,** is Deputy General Director, Norwegian Board of Health Supervision, Speciality in Community Medicine, Oslo. **Ellen Schlichting, MD, PhD,** is Consultant in Surgery, Department of Oncology, Oslo University Hospital. **Jan Erik Vinnem, Dr. ing,** is Professor, Risk Management, University of Stavanger; and Special Advisor in Risk Management, Preventor AS, Stavanger, Norway. Please address correspondence to Einar Hannisdal, einh@ahus.no.

Online-Only Content

See the online version of this article for

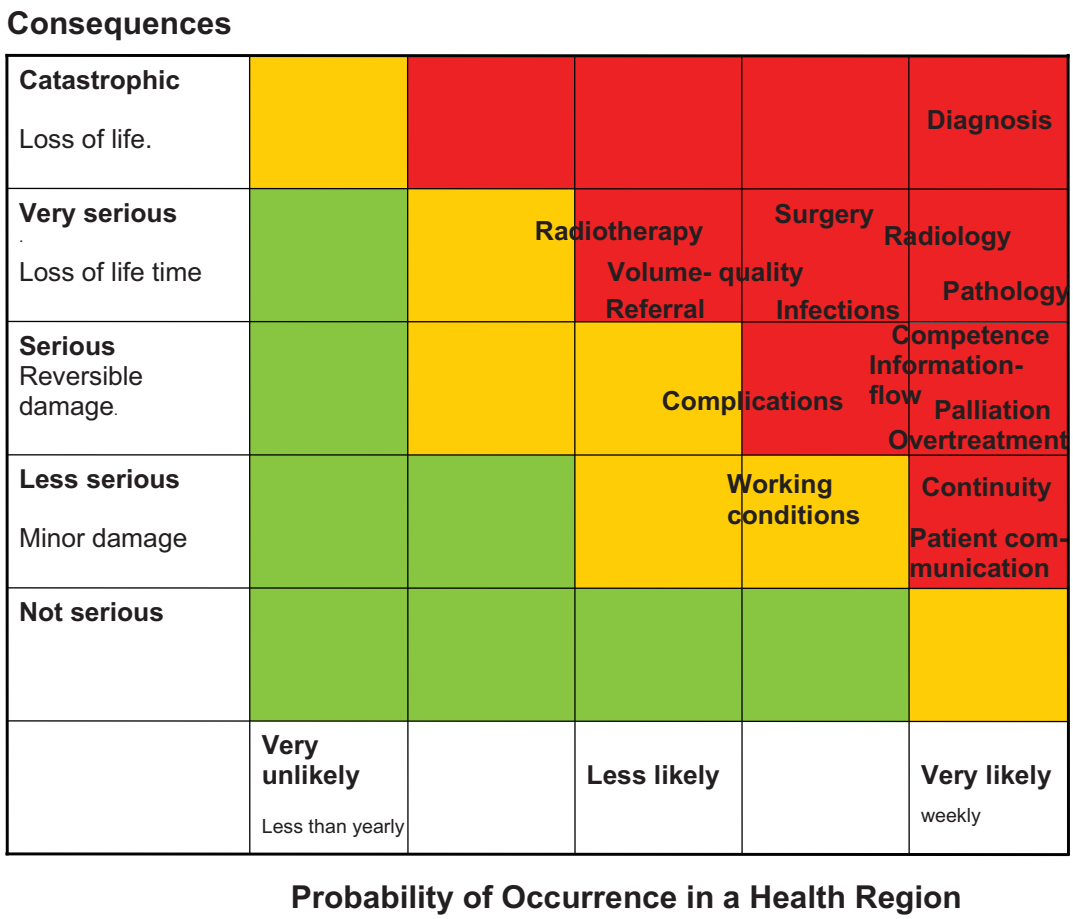
Figure 1. Risk Analysis Matrix of the 16 Top Hazards in Cancer Care (color version)

References

1. Lipczak H, Knudsen JL, Nissen A. Safety hazards in cancer care: Findings using three different methods. *BMJ Qual Saf.* 2011;20(12):1052–1056.
2. de Vries EN, et al. The incidence and nature of in-hospital adverse events: A systematic review. *Qual Saf Health Care.* 2008;17(3):216–223.
3. Walsh KE, et al. Medication errors among adults and children with cancer in the outpatient setting. *J Clin Oncol.* 2009 Feb 20;27(6):891–896.
4. Schwappach DL, Wernli M. Medication errors in chemotherapy: Incidence, types and involvement of patients in prevention. A review of the literature. *Eur J Cancer Care (Engl).* 2010;19(3):285–292.
5. Lustig A. Medication error prevention by pharmacists—An Israeli solution. *Pharm World Sci.* 2000;22(1):21–25.
6. Evrard S. Enhancing patient safety and quality of surgical cancer care: The French National Cancer Plans. *Eur J Surg Oncol.* 2010;36 Suppl 1:S14–17.
7. Haynes AB, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med.* 2009 Jan 29;360(5):491–499.
8. Norwegian Board of Health Supervision. Risk Profile of Treatment of Cancer in Norway: Summary of Report of the Norwegian Board of Health Supervision 4/2010 [summary in English]. May 27, 2010 Accessed Sep 25, 2013.
9. Aven T, et al. *Societal Safety* [in Norwegian]. Oslo: Universitetsforlaget, 2004.
10. Dutch Health Care Inspectorate. Management of and Oversight of Care for Cancer Patients Is Insufficient [in Dutch]. Mar 11, 2009. Accessed Sep 25, 2013.
11. Weingart SN, et al. The You CAN campaign: Teamwork training for patients and families in ambulatory oncology. Jt Comm J Qual Patient Saf. 2009;35(2):63–71.
12. Hellebust TP, et al. Quality assurance in radiotherapy on a national level; experience from Norway: The KVIST initiative. *J Radiother Pract.* 2013, forthcoming.
13. Shafiq J, et al. An international review of patient safety measures in radiotherapy practice. *Radiother Oncol.* 2009;92(1):15–21.
14. Gielen B, Remacle A, Mertens R. Patterns of health care use and expenditure during the last 6 months of life in Belgium: Differences between age categories in cancer and non-cancer patients. *Health Policy.* 2010;97(1):53–61.
15. Bonnabry P, et al. Use of a prospective risk analysis method to improve the safety of the cancer chemotherapy process. *Int J Qual Health Care.* 2006;18(1):9–16.
16. Kessels-Habraken M, et al. Integration of prospective and retrospective methods for risk analysis in hospitals. *Int J Qual Health Care.* 2009;21(6):427–432.
17. Ohrn A, et al. Reporting of sentinel events in Swedish hospitals: A comparison of severe adverse events reported by patients and providers. *Jt Comm J Qual Patient Saf.* 2011;37(11):495–501.

Online-Only Content

Figure 1. Risk Analysis Matrix of the 16 Top Hazards in Cancer Care



The workshop participants classified the 16 top hazards in cancer care in terms of consequences and likelihood. The "red" category denotes unacceptably high risk, with intervention mandatory in a short time. "Yellow" connotes medium risk, with intervention needed to avoid escalation to the red category. "Green" connotes partly elevated risk, with intervention not needed. Radiotherapy and complications overlap between yellow and red.