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Performance of a Trigger Tool for Identifying Adverse Events in Oncology

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QUESTION ASKED: Although patient safety is a priority in oncology, few tools measure adverse events (AEs) beyond treatment-related toxicities. AEs refer to unwarranted outcomes resulting from medical care rather than the patients' underlying disease or condition. A comprehensive understanding of AEs is important to quantify the harm experienced by patients with cancer and to identify opportunities for harm prevention. The study objective was to assemble a set of clinical triggers in the medical record and assess the extent to which triggered events identified AEs.

SUMMARY ANSWER: We identified a large number of triggers and potential AEs in this longitudinal cohort of patients with cancer. Some of these AEs may be targets for prevention or harm reduction. This tool offers a more efficient approach than traditional chart review and may complement the toxicity-oriented tools in routine use (eg, the Common Toxicity Criteria). Our oncology-specific AE screening tool is the first effort, to our knowledge, to develop a medical record–based screening tool that is relevant across inpatient and outpatient oncology settings.

WHAT WE DID: We performed a retrospective cohort study to assess the performance of an oncology medical record screening tool at a comprehensive cancer center. The study cohort included 400 patients age 18 years or older diagnosed with breast (n = 128), colorectal (n = 136), or lung cancer (n = 136), observed as in- and outpatients for up to 1 year. The oncology tool that we developed as part of the Cancer Harm (CHARM) study included 76 distinct triggers, or readily identifiable clinical indicators of potential AEs.

WHAT WE FOUND: We identified 790 triggers, or 1.98 triggers per patient (range, zero to 18 triggers). Three hundred four unique AEs were identified from medical record reviews and existing AE databases. The overall positive predictive value (PPV) of the original tool was 0.40 for total AEs and 0.15 for preventable or mitigable AEs. Examples of high-performing triggers included return to the operating room or interventional radiology within 30 days of surgery (PPV, 0.88 and 0.38 for total and preventable or mitigable AEs, respectively) and elevated blood glucose (> 250 mg/dL; PPV, 0.47 and 0.40 for total and preventable or mitigable AEs, respectively). The final modified tool included 49 triggers, with an overall PPV of 0.48 for total AEs and 0.18 for preventable or mitigable AEs.

BIAS, CONFOUNDING FACTOR(S), REAL-LIFE IMPLICATIONS: A valid medical record screening tool for AEs in oncology could offer a powerful new method for measuring and improving cancer care quality. Future improvements could optimize the tool's efficiency by creating automated electronic triggers for use in real-time AE detection and mitigation algorithms. It can also lead to more structured AE reporting toward this goal. Our oncology tool offers enhanced AE measurement in oncology, a step toward improving patient outcomes. JOP

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Abstract

Purpose

Although patient safety is a priority in oncology, few tools measure adverse events (AEs) beyond treatment-related toxicities. The study objective was to assemble a set of clinical triggers in the medical record and assess the extent to which triggered events identified AEs.

Methods

We performed a retrospective cohort study to assess the performance of an oncology medical record screening tool at a comprehensive cancer center. The study cohort included 400 patients age 18 years or older diagnosed with breast (n = 128), colorectal (n = 136), or lung cancer (n = 136), observed as in- and outpatients for up to 1 year.

Results

We identified 790 triggers, or 1.98 triggers per patient (range, zero to 18 triggers). Three hundred four unique AEs were identified from medical record reviews and existing AE databases. The overall positive predictive value (PPV) of the original tool was 0.40 for total AEs and 0.15 for preventable or mitigable AEs. Examples of high-performing triggers included return to the operating room or interventional radiology within 30 days of surgery (PPV, 0.88 and 0.38 for total and preventable or mitigable AEs, respectively) and elevated blood glucose (> 250 mg/dL; PPV, 0.47 and 0.40 for total and preventable or mitigable AEs, respectively). The final modified tool included 49 triggers, with an overall PPV of 0.48 for total AEs and 0.18 for preventable or mitigable AEs.

Conclusion

A valid medical record screening tool for AEs in oncology could offer a powerful new method for measuring and improving cancer care quality. Future improvements could optimize the tool's efficiency and create automated electronic triggers for use in real-time AE detection and mitigation algorithms.

INTRODUCTION

Although patient safety is a priority in oncology, few tools measure adverse events (AEs) beyond treatment-related toxicities. This information is important to quantify the burden of harm experienced by patients with cancer and to identify opportunities for harm prevention. AEs refer to unwarranted outcomes resulting from medical care rather than the patients' underlying disease or condition.[1,2] Examples of AEs in oncology include lymphedema, anastomotic leak, and sepsis.

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Attempts to develop methods for measuring errors and AEs in oncology care have been disappointing to date, generally relying on unsuccessful adaptation of approaches developed for general medicine.[3-5] Accordingly, we assembled a set of clinical triggers in the medical record relevant across inpatient and outpatient settings in oncology.[6] Because patients with cancer often receive complex care and are vulnerable to experiencing complications, a better understanding of potentially preventable harm is warranted.

The objective of this study was to assess the performance of our oncology screening tool in practice. We examined the extent to which triggered events identified AEs and preventable or mitigable AEs. A valid medical record screening tool for AEs in oncology could offer a powerful new method for measuring and improving cancer care quality.

METHODS

We performed a retrospective cohort study to assess the performance of an oncology medical record screening tool at Memorial Sloan Kettering Cancer Center, a National Cancer Institute–designated comprehensive cancer center. Medical record screening tools have been developed for different settings and populations to guide the identification of AEs for measurement and possible improvement.[7-10] The oncology tool that we developed as part of the Cancer Harm (CHARM) study included 76 distinct triggers, or readily identifiable clinical indicators of potential AEs.[6,11,12]

The study cohort included 400 patients age $\geq$ 18 years diagnosed with breast (n = 128), colorectal (n = 136), or lung cancer (n = 136). Cohort patients started their first cancer-directed treatment at Memorial Sloan Kettering Cancer Center between January 1 and December 31, 2012, and were observed as in- and outpatients for up to 1 year or until death, whichever came first. We used stratified random sampling. For breast cancer, we stratified patients by stage and chemotherapy use. For colorectal cancer, we stratified patients by stage and cancer type (colon or rectal cancer), and for lung cancer, we also stratified patients by stage and cancer type (non–small-cell lung cancer or small-cell lung cancer).

Five trained nurses completed the chart reviews for the 400 patients. During the training process, a member of the study team reviewed the protocols and logistics. Then, the nurses compared three to five charts with each other that they completed independently to ensure consistency of the process and to discuss their preferred approach.

We allotted 1 hour for each patient chart. The nurses noted if they found any triggers and whether they were associated with an AE according to our study definition. They documented any key details about the patient's case. Then, a nurse presented each case to physician reviewers who made the final determination as to whether the case met the study definition of AE, severity of harm, likelihood of preventability, and likelihood of harm mitigation. Inter-rater agreement was calculated.

We also obtained AE data from existing local safety event-reporting databases (Surgical Secondary Events for surgical complications and RL6:RISQ [RL Solutions, Toronto, Ontario, Canada] system for front-line staff reports). Candidate AEs were reviewed and coded independently by two physicians according to severity, preventability, harm mitigability, and AE type. An event was judged to be preventable if the AE resulted from clinical care that was inconsistent with standard oncology practice or was a treatment-related complication that should have been anticipated. An event was judged mitigable if the severity or the duration of harm could have been lessened had clinicians acted promptly and appropriately.

We calculated the percent agreement between physician pairs with regard to whether the event was an AE (1.0), the level of harm to the patient (categories A to D compared with E to I; 0.8), the likelihood of preventability (definitely or probably preventable, definitely or probably not preventable, or unable to determine; 0.8), and the likelihood of harm mitigation if the event was deemed not preventable (definitely or probably mitigatable, definitely or probably not mitigatable, or unable to determine; 0.8).

We calculated the tool's overall positive predictive value (PPV) for identifying AEs and potentially preventable or mitigable AEs and PPVs of the individual triggers. PPV was defined as the number of times the trigger led to the identification of an AE divided by the total number of times the trigger was identified. We also calculated the sensitivity of the tool, using the combined, confirmed set of AEs from a review of both medical records plus the local reporting databases as the gold standard. On the basis of the PPV results and the research team's expertise and experience, the investigators used a consensus-driven and iterative process to eliminate low-yield triggers and to produce a final set of oncology chart review triggers. Analyses were performed using Microsoft Excel (Microsoft, Redmond, WA) and SAS Software (SAS Institute, Cary, NC). This study was considered exempt research by the Institutional Review Board of Memorial Sloan Kettering Cancer Center.

Table 1. Outcome of Triggers Sorted by Overall PPV

Trigger	No. (%) of Unique Patients With ≥ 1 Trigger	No. of Triggers Detected*	No. of Overall AEs	No. of Preventable or Mitigable AEs†	PPV for Overall AEs (%)‡	PPV for Preventable or Mitigable AEs (%)‡
Total (N = 400)	236 (59)	790	316	119	40	15
Neutropenic fever (except in patients with leukemia or bone marrow transplantation)	5 (1.25)	6	6	1	100	17
Pressure ulcer	3 (0.75)	3	3	3	100	100
Abnormal serum potassium (> 6, < 2.5 mEq/L)	3 (0.75)	3	3	1	100	33
Contact precautions/order for isolation	2 (0.5)	2	3	0	100	0
Abnormal serum bicarbonate (< 18, > 36 mEq/L)	1 (0.25)	1	1	0	100	0
Return to the OR or IR within 30 days of surgery	8 (2)	8	7	3	88	38
Clostridium difficile toxin positive	7 (1.75)	7	6	2	86	29
Oral anesthetics (eg, Magic Mouth Wash, viscous lidocaine)	25 (6.25)	30	23	4	77	13
Noncontrast chest CT after radiation to the chest	4 (1)	4	3	1	75	25
Initiation of therapeutic anticoagulation	21 (5.25)	21	15	2	71	10
Percutaneous drain placement	6 (1.5)	8	5	1	63	13
Nasogastric tube (not in OR)	13 (3.25)	13	8	1	62	8
Low oximetry results (SaO_2 < 88%)	10 (2.5)	10	6	4	60	40
Positive blood culture without contaminant (eg, *Staphylococcus epidermidis*)	5 (1.25)	5	3	1	60	20
Blood transfusion	46 (11.5)	68	40	12	59	18
Nephrology consultation	11 (2.75)	11	6	2	55	18
Elevated Cr > 1 mg/dL and 50% greater than baseline	24 (6)	28	15	11	54	39
Bladder catheter and positive urine culture	10 (2.5)	12	6	4	50	33
Lymphedema consult	8 (2)	8	4	3	50	38
Positive upper extremity ultrasound	4 (1)	4	2	0	50	0
Kayexalate	2 (0.5)	2	1	1	50	50
Total parental nutrition	2 (0.5)	2	1	1	50	50

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Table 1. Outcome of Triggers Sorted by Overall PPV (continued)

Trigger	No. (%) of Unique Patients With ≥ 1 Trigger	No. of Triggers Detected*	No. of Overall AEs	No. of Preventable or Mitigable AEs†	PPV for Overall AEs (%)‡	PPV for Preventable or Mitigable AEs (%)‡
Use of IV glucose or dextrose	2 (0.5)	2	1	0	50	0
Elevated blood glucose (> 250 mg/dL)	11 (2.75)	15	7	6	47	40
Abnormal serum bilirubin (> 2 mg/dL)	8 (2)	11	5	1	45	9
Positive lower extremity ultrasound	8 (2)	9	4	0	44	0
Elevated AST (> 300 units/L) or ALT (> 300 units/L)	12 (3)	14	6	0	43	0
Inpatient gastroenterology consult	10 (2.5)	12	5	1	42	8
Abnormal serum magnesium (> 4, < 1.5 mg/dL)	34 (8.5)	83	33	22	40	27
Pain score (≥ 7)	39 (9.75)	50	20	6	40	12
Fall	9 (2.25)	10	4	2	40	20
Low urine output (< 30 mL/h)	5 (1.25)	5	2	0	40	0
Abnormal phosphate (> 5, < 1.5 mg/dL)	8 (2)	8	3	3	38	38
Arterial blood gas (not in PACU/ICU)	8 (2)	8	3	1	38	13
Inpatient cardiology consult	16 (4)	19	7	2	37	11
Abnormal serum calcium (> 12, < 7 mg/dL)	11 (2.75)	12	4	0	33	0
Extravasation	3 (0.75)	3	1	0	33	0
Epinephrine	3 (0.75)	3	1	0	33	0
Flumazenil, glucagon, naloxone, protamine	3 (0.75)	3	1	1	33	33
Platelet transfusion (except in patients with leukemia or bone marrow transplantation)	3 (0.75)	3	1	1	33	33
Rapid response team	3 (0.75)	3	1	0	33	0
Death in hospital	7 (1.75)	7	2	2	29	29
ICU transfer from floor	7 (1.75)	7	2	0	29	0
Hospital readmission/urgent care visit within 72 hours of hospital discharge or ambulatory surgery	10 (2.5)	12	3	2	25	17
Chest x-ray in inpatient or UCC	50 (12.5)	68	14	3	21	4
Inpatient or outpatient IR consult (excluding referral for port placement)	53 (13.25)	62	12	6	19	10

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Table 1. Outcome of Triggers Sorted by Overall PPV (continued)

Trigger	No. (%) of Unique Patients With ≥ 1 Trigger	No. of Triggers Detected*	No. of Overall AEs	No. of Preventable or Mitigable AEs†	PPV for Overall AEs (%)‡	PPV for Preventable or Mitigable AEs (%)‡
Intravascular thrombolytic therapy	6 (1.5)	6	1	0	17	0
Inpatient surgery consult for nonsurgical patients	5 (1.25)	6	1	0	17	0
Blood pressure (> 200/100 mm Hg)	6 (1.5)	8	1	1	13	13
Use of > 3 doses of antiemetics within 24 hours	39 (9.75)	44	3	1	7	2
Neurology consult and noncontrast head CT	14 (3.5)	17	1	0	6	0
Sitter and inpatient psychiatric consult	8 (2)	9	0	0	0	0
Abnormal serum sodium (> 150, < 130 mEq/L)	5 (1.25)	6	0	0	0	0
Positive bone imaging test (plain films, CTs)	4 (1)	5	0	0	0	0
Temperature (< 35°C perioperatively)	1 (0.25)	1	0	0	0	0
Methylnaltrexone	1 (0.25)	1	0	0	0	0
Vitamin K	1 (0.25)	1	0	0	0	0
Elevated troponin (> 0.64 ng/mL)	1 (0.25)	1	0	0	0	0

Abbreviations: AE, adverse event; CT, computed tomography; ICU, intensive care unit; IR, interventional radiology; IV, intravenous; OR, operating room; PACU, postanesthesia care unit; PPV, positive predictive value; SaO_2, arterial oxygen saturation; UCC, urgent care clinic.

*The following 18 triggers were not identified through the medical record review: octreotide; sodium thiosulfate, hyaluronidase, topical dimethyl sulfoxide, dexrazoxane, or phentolamine; adrenal function studies; B-type natiuretic peptide (> 400 pg/mL); elevated international normalized ratio (> 8); elevated lipase (> 160 U/L); elevated serum uric acid (> 10 mg/dL); elevated thyroid-stimulating hormone (> 10 mcU/mL); low fibrinogen (< 100 mg/dL); platelet count < 20,000 (except in patients with leukemia or bone marrow transplantation); acetaminophen blood level; adrenal function studies; cardiac defibrillator; fistulogram or sinogram; high-dose IV proton pump inhibitor (omeprazole, esomeprazole, or pantoprazole 80 mg bolus followed by 8 mg/h infusion); reintubation; steroid enema; and use of pressors.

†A trigger could identify more than one AE. AEs deemed definitely or probably preventable or mitigable by physician reviewers.

‡PPV is the number of times the trigger led to the identification of an AE divided by the total number of times the trigger was identified.

RESULTS

Of the 400 patients, 32% were male, 19% were nonwhite, and 6% were Hispanic or Latino. Patients' median age was 61 years (range, 26 to 92 years). We identified 790 triggers, or 1.98 triggers per patient (range, zero to 18 triggers). A total of 304 unique AEs were identified from all sources; 316 AEs, including repeat AEs, were identified from specific triggers. Examples of AEs included hypokalemia, mucositis, and *Clostridium difficile*. Thirty-six AEs were identified in the medical record without a specific trigger, and 14 were included in the hospital reporting systems alone. Thirty-three AEs were identified in both the hospital reporting system and the medical records. Thirty-six percent of patients (95% CI, 31% to 40%) had at least one AE.

The overall PPV of the original screening tool was 0.40 for total AEs and 0.15 for preventable or mitigable AEs. Examples of high-performing triggers for identifying AEs and preventable or mitigable AEs included return to the operating room or interventional radiology within 30 days of surgery (PPV, 0.88 and 0.38, respectively) and elevated blood glucose (> 250 mg/dL; PPV, 0.47 and 0.40, respectively). Poor-performing triggers included use of more than three doses

Table 2. Final Memorial Sloan Kettering Cancer Center Oncology Adverse Event Trigger Tool

Adverse Event
General care
Death in hospital
Extravasation
Fall
Hospital readmission/urgent care visit within 72 hours of hospital discharge or ambulatory surgery
Low urine output (< 30 mL/h)
Pressure ulcer
Return to the OR or IR within 30 days of surgery
Vital signs
Low oximetry results (SaO_2 < 88%)
Pain score (≥ 7)
Fever (> 38.2°C)
Temperature (< 35°C perioperatively)
Orders
Blood transfusion
Cardiac arrest
Chest x-ray in inpatient or UCC
Contact precautions/order for isolation
ICU transfer from floor
Nasogastric tube (not in OR)
Noncontrast chest CT after radiation to the chest
Percutaneous drain placement
Platelet transfusion (except in patients with leukemia or bone marrow transplantation)
Positive lower extremity ultrasound
Positive upper extremity ultrasound
Rapid response team
Reintubation
Laboratories
Abnormal phosphate (> 5, < 1.5 mg/dL)
Abnormal serum bicarbonate (< 18, > 36 mEq/L)
Abnormal serum bilirubin (> 2 mg/dL)
Abnormal serum calcium (> 12, < 7 mg/dL)
Abnormal serum magnesium (> 4, < 1.5 mg/dL)
Abnormal serum potassium (> 6, < 2.5 mEqL)
Arterial blood gas (not in PACU/ICU)
Bladder catheter and positive urine culture
Clostridium difficile toxin positive
Elevated AST (> 300 units/L) or ALT (> 300 units/L)
Elevated blood glucose (> 250 mg/dL)
Elevated Cr > 1 mg/dL and 50% greater than baseline
Elevated INR (> 8)
Positive blood culture without contaminant (eg, *Staphylococcus epidermidis*)
Medication related
Epinephrine
Flumazenil, glucagon, naloxone, protamine
Initiation of therapeutic anticoagulation
Kayexalate
Oral anesthetics (eg, Magic Mouth Wash, viscous lidocaine)
Total parental nutrition
Use of IV glucose or dextrose
Consults
Inpatient cardiology consult
Inpatient gastroenterology consult
Lymphedema consult
Nephrology consultation

NOTE. Triggers that did not identify an adverse event or had a positive predictive value less than 0.020 were dropped. Other triggers were modified or combined based on expert opinion of the investigators.

Abbreviations: CT, computed tomography; ICU, intensive care unit; INR, international normalized ratio; IR, interventional radiology; IV, intravenous; OR, operating room; PACU, postanesthesia care unit; SaO_2, arterial oxygen saturation; UCC, urgent care clinic.

of antiemetics within 24 hours (PPV, 0.07 and 0.02 for total AEs and preventable or mitigable AEs, respectively) and neurology consult and noncontrast head computed tomography (PPV, 0.06 and 0.00 for otal AEs and preventable or mitigable AEs, respectively; Table 1). The sensitivity of the medical record review was 92% compared with the gold standard.

Of the 76 triggers in the tool, 18 were not identified through our study. The final modified screening tool included 49 triggers (Table 2). The PPV of the modified tool for identifying AEs was 0.48, and the PPV for identifying preventable or mitigable AEs was 0.18.

DISCUSSION

Our oncology-specific AE screening tool is the first effort, to our knowledge, to develop a medical record–based screening tool that is relevant across inpatient and outpatient oncology settings. We identified a large number of triggers and potential AEs in this longitudinal cohort of patients with cancer. Some of these AEs may be targets for prevention or harm reduction. This tool offers a more efficient approach than traditional chart review and may complement the toxicity-oriented tools in routine use (eg, the Common Toxicity Criteria).[13]

Our oncology tool's performance is in line with that of tools in other clinical settings.[7,14,15] It is important to note that it can be difficult to distinguish expected toxicities from unnecessary harm in oncology, which could influence our assessment of the tool's performance for identifying preventable or mitigable AEs. We used best practice and required consensus by two physician reviewers but recognize the inherent subjectivity. The setting of this study was a single academic institution with a broad referral population and extensive clinical trials program. The institution's focus on patient safety and quality may increase detection of AEs or reduce their incidence compared with other institutions. Further testing of the modified tool is required to generalize our results to other cancer care settings.

Future improvements could optimize the tool's efficiency by creating automated electronic triggers for use in real-time AE detection and mitigation algorithms. It can also lead to more structured AE reporting toward this goal. Our oncology tool offers enhanced AE measurement in oncology, a step toward improving patient outcomes. JOP

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Authors' Disclosures of Potential Conflicts of Interest

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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