Immunotherapy Toxilities

A new electronic documentation template to improve patient care

Elizabeth Reimschissel, MSN, RN, CNL, Buenagracia Dela Cruz, BSN, MBA, RN, OCN®, Melissa Gonzalez, BSN, RN, OCN®, Joaquin Buitrago, MS, RN, OCN®, Cary Goodman, BBA, MIS, and Patricia A. Johnston, DNP, RN, OCN®, NEA-BC

BACKGROUND: Emerging immunotherapies are associated with numerous toxicities. Although traditional health records allow nurses to document system-based assessments, few offer immunotherapy-based documentation templates to assess and grade toxicities.

OBJECTIVES: The aim of this article is to present the development of a standardized template for documenting genetically modified cellular product–related toxicities in an electronic health record (EHR).

METHODS: Through interprofessional collaboration, a documentation template for genetically modified cellular product–related toxicities was developed in an EHR, allowing for standardized documentation, data reporting, and tracking of immune-related toxicities.

FINDINGS: The documentation template has enhanced the quality and safety of practice at the authors’ institution and provides a framework for other nursing units when initiating immunotherapy care.

INTEGRATING NEW IMMUNOTHERAPY TREATMENTS INTO CLINICAL CARE requires broad infrastructural adaptations to support safe and effective care, including the training and education of staff on the documentation of treatment-related toxicities and side effects. Traditional health record documentation provides nurses with a place to document assessment findings by system; however, a need was identified for grouping together immunotherapy-related findings, specifically information on genetically modified cellular products, to provide a more cohesive narrative of potential treatment-related toxicities. As electronic health records (EHRs) are implemented across practice settings, unique opportunities exist to develop standardized documentation templates to capture and report integral aspects of patient care. Well-designed and uniformly used patient-care information systems can decrease complexity and support clinicians in their efforts to manage information and its overall flow among nurses, physicians, the rapid-response team, the respiratory team, physical and occupational therapists, social workers, chaplains, and case management workers (Keenan, Yakel, Dunn Lopez, Tschannen, & Ford, 2013). This article presents the collaborative work of one National Cancer Institute (NCI)–designated comprehensive cancer center to design and implement a standardized documentation template for immunotheraphy-related toxicities in the EHR. Current successes and future directions will be shared to provide a template for oncology nurses in the clinical settings that are considering or in the early phases of introducing immunotherapy research and treatment.

Background

The 48-bed inpatient lymphoma/myeloma unit on a 672-bed NCI-designated comprehensive cancer center was one of the first to implement emerging immunotherapy clinical trials. This cancer center serves about 1,700 patients with lymphoma and 500 patients with myeloma each year, including patients with Hodgkin and non-Hodgkin lymphomas. The inpatient unit implemented genetically modified cellular product protocols, which have been delivered to 70 patients to date. These protocols consist of administering a patient’s own cells, primarily in the form of chimeric antigen receptor–modified T cells, which have been genetically altered within a laboratory setting, to activate the body’s own immune system to better detect and kill malignant cells. The introduction
of these protocols in the clinical setting required broad interprofessional collaboration and the development of logistical infrastructure for the education and training of nurses, the safe delivery and management of care, and the documentation of treatment-related toxicities.

Because the genetically modified cellular product protocols were associated with potential neurotoxicity, clinical nurses and their leaders were hypervigilant in enforcing standardized assessment and documentation of findings. Nurses routinely coordinate, deliver, and monitor patient care on behalf of all healthcare disciplines; they are central to ensuring effective information management and flow (Keenan et al., 2013).

In the inpatient lymphoma/myeloma unit, nurses performed enhanced neurotoxicity assessment, including the Mini-Mental State Examination (MMSE), monitoring patients’ handwriting after cell infusion, and closely monitoring patients’ vital signs and laboratory testing as part of the standard of care. However, no one documented the location to aid in efficient and comprehensive monitoring. The ability to document and retrieve documentation of immune-related toxicities in a timely manner was identified as a primary concern. Esper and Walker (2014) have stressed the importance of timely documentation in patient care and how providing staff with tools that can help expedite documentation can improve the quality of information in medical records.

At the unit level, nurse leaders, in collaboration with an interprofessional workgroup, determined the financial effect of new clinical trials and availability of resources, distinguished the roles and responsibilities of the interprofessional team, and developed staff education and technology use. A unit prospective analysis, using the Strengths, Weaknesses, Opportunities, and Threats methodology, was performed to assist in planning and reducing variations in processes during initial implementation (Uhrenfeldt, Lakanmaa, Flinkman, Basto, & Attree, 2012). This work was conducted concurrently with broader institutional initiatives to provide oversight and standardization for the delivery of diverse immunotherapy treatments across the institution.

To address the growth of genetically modified cellular product protocols at the authors’ institution, an institutional interprofessional initiatives committee, led by the institution’s provost, was developed. Colleagues from various institutional departments, including hematology, medical oncology, surgical oncology, critical care, nursing, pharmacy, and information services, met weekly to create a comprehensive program for the care of patients receiving therapy. The team implemented a number of initiatives, including developing standardized clinical effectiveness guidelines; revising the grading toxicity scales based on the Common Terminology Criteria for Adverse Events (CTCAE), version 4.0 (U.S. Department of Health and Human Services, 2009); creating a comprehensive computer-based training module for the medical providers and nursing staff; and forming detailed order sets for consistent order-

“Using a standard documentation process can enhance the trending and reporting of toxicities for clinical and research purposes.”

ing workflows. To promote consistent, standardized documentation, new EHR flowsheets were developed, which contributed to the development of documentation checklists and workflows to properly reflect nursing critical thinking skills and confirmation of appropriate interventions to ensure patient safety and quality of care (Blair & Smith, 2012). These workflows were essential in ensuring timely assessment and management of toxicities related to treatment, escalation of care needs, and the reduction of potential missed care and adverse events. Ensuring consistent documentation of assessment and toxicities related to genetically modified cellular product protocols is important in clinical and research documentation and in standardized tracking of complications as they emerge.

Methods
Design of Documentation Template
The institutional committee identified data and assessment points that were recommended to be captured within the EHR, specifically vital signs, symptoms of cytokine release syndrome, symptoms of neurotoxicity, and notification of the provider (see Figure 1). In collaboration with the institutionally employed EHR analyst, the committee developed a symptom toxicity flowsheet with capabilities to expand data entry if additional information was needed; to calculate the SpO2 and FiO2 ratio and neurotoxicity grading; and to autopopulate pertinent information, such as vital signs and laboratory values, from other flowsheets. The resulting flowsheet provides a standardized location to document findings and allows nurses to communicate assessment findings, based on the CTCAE grading criteria, to the medical team in a timely manner. The flowsheet also allows nurses to generate reports to track various outcomes. By collaborating with the flowsheet build team, clinicians and researchers generated specialized reports to track a multitude of data during and after patient treatment with genetically modified cellular products.
**Integration Into Nursing Practice**

Integrating a seamless approach to nursing documentation of patients receiving genetically modified cellular products can present challenges to any organization, regardless of the type of documentation system used. Whether formulating new flowsheets within an EHR or combining pertinent assessment findings with advanced clinical judgments to grade toxicities, nurses can look for opportunities to standardize documentation to ensure patient safety and proper monitoring of the effects of genetically modified cellular products. This flowsheet, although the first designed in this organization, was further optimized to be modified for application to diverse and expanding immunotherapy protocols. This modification capacity helped respond to the growing number of approved and investigational immunotherapy-based agents used in cancer care.

Nursing documentation is an essential component of interdisciplinary communication in health care (Chand & Sarin, 2014). Along with the standardized documentation template, a complementary educational plan regarding template use was developed for nurses. Adult learning theories have suggested that learning is enhanced when participants perceive information to be realistic and useful to their personal and professional needs (Vandeveer, 2009). To promote engagement from clinical nurses, a collaborative education initiative was deployed among the healthcare professionals caring for patients receiving immunotherapies. This education consisted of simulation training and practice documenting with the template, which allowed nurses to gain confidence with the documentation flowsheet items before using them with patients, complementing the printed educational tip sheets created to reinforce the active learning content.

**Discussion**

The standardized documentation template has been successfully integrated into the EHR at this institution and is consistently used by clinical nurses to assess toxicity in patients receiving genetically modified cellular products. Standardized documentation allows the use of data from EHRs to learn about health care, preventive actions, and outcomes of nursing interventions (Lj & Korniewicz, 2013). This standardized workflow is easily translated across diverse clinical settings with different EHRs and written documentation templates. Using a standard documentation process of

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**FIGURE 1.**

**IMMUNOTHERAPY DOCUMENTATION FLOWSHEET CONTENTS**

**VITAL SIGNS AND LABORATORY VALUES**

- Vital signs (autopopulate)
  - Temperature
  - Blood pressure
  - Peripheral capillary oxygen saturation
- Laboratory (autopopulate)
  - Aspartate aminotransferase (AST) or alanine aminotransferase (ALT)
  - Creatinine
  - Bilirubin total
  - Ferritin level
  - C-reactive protein

**CYTOKINE RELEASE SYNDROME**

- Respiratory
  - Pleural effusion
  - Pulmonary edema
- Cardiac
  - Tachycardia
  - Arrhythmia or heart block
  - Ejection fraction decrease
- Hepatic
  - AST or ALT
  - Total bilirubin
- Renal
  - Urine output decreased
  - Acute kidney injury
- Coagulopathy
  - Disseminated intravascular coagulation
- Gastrointestinal
  - Nausea
  - Vomiting
  - Diarrhea
- Neurotoxicity
  - The following are entered into the flowsheet to calculate a neurotoxicity score:
    - Level of consciousness
    - Activities of daily living
    - Encephalopathy
    - Speech
    - Seizure
    - Incontinent or motor weakness
    - Orientation
    - Ability to write, name three objects, and count to 10 backwards
- Cytokine
  - Reason for communication
  - Provider name
  - Provider role
  - Method of communication
  - Response
  - Notification time

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genetically modified cellular product administration and toxicities can enhance the trending and reporting of toxicities for clinical and research purposes. This ultimately contributes to the enhancement of safe and effective clinical care for this patient population.

Interprofessional collaboration is the cornerstone of successful implementation of new clinical therapies (D’Amour, Ferrada-Videla, San Martin Rodriguez, & Beaulieu, 2005). The efficacy of this practice improvement initiative was derived from unit and institutional-based interprofessional collaboration. An institutional committee provided oversight of the immunotherapy implementation, allowing for standardizing and tracking of best practices as new immunotherapy trials and standard of care agents emerged. The committee at the institution continues to meet weekly to review new protocols either approved or awaiting approval from the institutional review board. In addition, all current patients on active inpatient treatment are reviewed to assess the quality and continuity of care they receive.

Financial and logistical concerns, including the cost to build, maintain, and update documentation templates, and identifying who has the access and expertise to make such modifications are important considerations when evaluating the feasibility of this work within an organization. Financial and logistical implications may vary between institutions, depending on available resources. The documentation flow sheet at the comprehensive cancer center took about 100–120 hours to complete and cost about $4,800. This did not account for the numerous hours healthcare providers spent providing feedback on the creation and optimization of the flow sheet. In addition, the use of internal resources versus outsourced EHR build teams may dramatically affect the cost of such an endeavor.

Logistically, access to certain EHR elements for building and expanding within templates is predicated on the software package purchased by the institution. The flow sheet at the current institution was populated by information drawn from clinical and research documentation modules. In addition, the ability to build and customize the flow sheet is dependent on the modules purchased by each institution. At the institution, a full-time EHR application analyst worked with clinicians to electronically build and program the flow sheet. This seamless collaboration helped ensure that the flow sheet was technologically effective and clinically relevant. However, each institution will employ different individuals with different jobs and specializations to complete the work. The interprofessional collaboration of people with EHR build knowledge and clinical expertise is invaluable.

**Conclusion**

Ultimately, nurses are ideally situated to identify changes in patient status. Providing a standardized mechanism for the assessment and documentation of immunotherapy toxicities allows for continuity of care across shifts and providers and promotes seamless communication between nurses and interprofessional providers. Using patient health records to organize the capture their progress on immunotherapies is a universally accessible approach to enhancing the quality, safety, and efficacy of nursing care.

Elizabeth Reimischissel, MSN, RN, CNE, is a nurse educator. Buenagracia Dela Cruz, BSN, MBA, RN, OCN®, is an associate director, Melissa Gonzalez, BSN, RN, OCN®, is a nurse manager, Joaquin Buitrago, MS, RN, OCN®, is a nurse educator. Cary Goodman, BBA, MIS, is an electronic health record application analyst, and Patricia A. Johnston, DNP, RN, OCN®, NEA-BC, is the executive director of Clinical Nursing Practice, all at the University of Texas MD Anderson Cancer Center in Houston. Reimischissel can be reached at em clockwise@mdanderson.org, with copy to editor at CJONEditor@ons.org. (Submitted November 2016. Accepted January 11, 2017.)

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**REFERENCES**


