Chemotherapy Extravasation

Establishing a national benchmark for incidence among cancer centers

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BACKGROUND: Given the high-risk nature and nurse sensitivity of chemotherapy infusion and extravasation prevention, as well as the absence of an industry benchmark, a group of nurses chose to study oncology-specific nursing-sensitive indicators.

OBJECTIVES: The purpose was to establish a benchmark for the incidence of chemotherapy extravasation with vesicants, irritants, and irritants with vesicant potential.

METHODS: Infusions with actual or suspected extravasations of vesicant and irritant chemotherapies were evaluated. Extravasation events were reviewed by type of agent, occurrence by drug category, route of administration, level of harm, follow-up, and patient referrals to surgical consultation.

FINDINGS: A total of 739,812 chemotherapy infusions were evaluated, with 673 extravasation events identified. Incidence for all extravasation events was 0.09%.

KEYWORDS
- chemotherapy
- extravasation
- vesicant
- irritant
- venous access
- cancer program quality

CANCER CARE HAS LARGELY SHAPED OUTPATIENT SETTINGS, but oncology-specific ambulatory quality indicators are lacking. Members from several National Cancer Institute (NCI)–designated cancer centers, consisting of nurses working in hospital quality, safety, chemotherapy infusion practice, and data or decision support, recognized this need and created a nursing consortium, the Cancer Centers Consortium Nursing-Sensitive Indicators (C3NSI) consensus group. The C3NSI group identified chemotherapy infusion practice as a high-risk and nursing-sensitive procedure in ambulatory oncology care and chose to evaluate vesicant chemotherapy extravasation in adult patients with cancer as its first project.

Extravasation, the inadvertent leakage of vesicant chemotherapy outside of the vein and into surrounding tissue, is a significant risk for patients. It can cause pain, swelling, erythema, tissue damage, blistering, sloughing, tissue necrosis, and significant morbidity that may require surgical intervention. Further descriptions of chemotherapy extravasation risk, sequelae, and management can be found in the literature (Ener, Meglathery, & Styler, 2004; Sauerland, Engelking, Wickham, & Corbi, 2006; Schulmeister, 2014; Wickham, Engelking, Sauerland, & Corbi, 2006). Overall incidence of chemotherapy extravasation ranges from 0.1%–6.5% (Ener et al., 2004), with reports of extravasation occurrence via central venous catheters ranging from 0.3%–4.7% (Cassagnol & McBride, 2009) and, in one early report, an incidence of 6.4% (Brothers et al., 1988). No benchmark existed for the incidence of chemotherapy extravasations. For quality assurance, Morris and Holland (2000) recommended that the frequency of chemotherapy extravasation should be significantly less than 1% of the drug administration.

The C3NSI group grew to include 19 cancer centers and met monthly, via teleconference, to determine data elements to be collected by institutions participating in the study. A research protocol was submitted to and approved by the institutional review board at the Roswell Park Cancer Institute, which maintained the data repository. All participating organizations...
obtained approval from their respective institutional review boards.

**Methods**

Defining data elements presented challenges. Incidence was defined as the number of extravasation events (numerator) over the number of drug infusions given for each discreet chemotherapy agent (denominator). The group originally intended to report only drugs that were classified as vesicants. However, each center also gives other chemotherapy agents classified as irritants or vesicants with vesicant potential. Although these agents do not routinely cause tissue sloughing or necrosis, they can cause significant irritation, with burning, pain, tightness, and phlebitis at the IV insertion site and along the peripheral vein, above the administration site. These drugs have different properties than vesicants but can result in significant tissue injury and morbidity. The C3NSI group decided to collect, analyze, and present data on all 24 agents (10 vesicants and 14 irritants and irritants with vesicant potential).

The industry has not reached consensus regarding the classification of these agents in one of the three categories. Table 1 presents two lists of vesicants, irritants, and irritants with vesicant potential agents that represent the consensus of the C3NSI group and those from Polovich, Olsen, and LeFebvre (2014). The predominant difference is that Polovich et al. (2014) included taxanes as non–DNA binding vesicants. Hereafter, vesicants refers to the 10 agents that the C3NSI group categorized as vesicants and irritants refers to the 14 agents that the C3NSI group categorized as irritants or irritants with vesicant potential. The numerator data for each extravasation event were collected by retrospective chart review from each center’s event-reporting system. The drug denominator data were extracted from the electronic health record. The C3NSI group concluded that all actual and suspected events would be included in the numerator. For example, if a patient complained of pain or discomfort at the venous access site or if the patency of the vein was in question, the RN would be highly suspicious of extravasation. In such a case, the nurse would stop the infusion and treat and manage the event as if it were an actual extravasation.

The C3NSI group defined and ascribed three levels of harm. Level 1 was no harm, an event that reached the patient but caused no harm. In these events, no overt evidence of an extravasation was found (e.g., pain or discomfort at the infusion site). Level 2 was temporary or minor harm, an event that resulted in any swelling, skin discoloration, burning, or loss of blood return. Level 3 was an event resulting in injury requiring an increased level of care. If a patient received an antidote, topical or systemic antibiotic, and/or was referred to consultation with plastics and reconstructive surgery (PRS), level 3 was assigned. If the extravasation worsened during follow-up, the severity level was increased to reflect the higher harm. The route of administration was assigned as peripheral IV access or central venous access device (CVAD).

For patients who experienced extravasation, the C3NSI group agreed to follow up by telephone or in person on days 1, 7, and 14 after the day of occurrence (day 0). For the purposes of the study and the referral nature of many of the centers, two weeks of follow-up was the most to which some centers could commit. Extravasations can sometimes evolve over several days or weeks. If a patient had no occurrence on the day of treatment but presented later with signs of an extravasation, the day of presentation was considered day 0 (except where institutional practice dictated otherwise), and follow-up ensued from there. If the patient was receiving combination chemotherapy that included more than one vesicant or irritant drug (e.g., gemcitabine [Gemzar®] and cisplatin [Platinol®]), the extravasation was attributed to the drug given at the time of the extravasation (according to the RN’s documentation). In combined infusions containing more than one vesicant (e.g., vincristine [Oncovin®], doxorubicin [Adriamycin®], dexamethasone [Decadron®]), the agent with the most potential for tissue damage, based on the concentration of drug, was considered to be the extravasate.

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**TABLE 1.**

| VESICANTS, IRRITANTS, AND IRRITANTS WITH VESICANT POTENTIAL BY PUBLICATION |
|-----------------|-----------------|-----------------|
| AGENT           | CONSORTIUM®     | CHEMOTHERAPY GUIDELINES® |
| Dactinomycin    | Albumin-bound paclitaxel    | Daunorubicin |
| Daunorubicin    | Daclomycin         | Docetaxel     |
| Doxorubicin     | Daunorubicin       | Doxorubicin   |
| Epirubicin      | Epirubicin         | Idarubicin    |
| Idarubicin      | Idarubicin         | Mechlorethamine |
| Mechlorethamine | Mechlorethamine    | Mitomycin     |
| Mitomycin       | Mitomycin          | Vinblastine   |
| Vinblastine     | Mitoxantrone       | Vincristine   |
| Vincristine     | Paclitaxel         | Vinorelbine   |
| Vinorelbine     | Paclitaxel         | Vinorelbine   |
| $^*$            | $^*$              | $^*$          |

*Based on information from Cancer Centers Consortium Nursing-Sensitive Indicators consensus group (Jackson-Rose et al., 2015).

*Based on information from Polovich et al., 2014.
From October 2011 through December 2015, 11 participating centers provided data that were collected via a tool designed by the C3NSI group and included the data points described previously (numerator, denominator, route of administration [peripheral/central], level of harm, and follow-up). Strict definitions for each data element were provided to each reporting center. Quarterly data reports were compiled by C3NSI nurses and submitted to Roswell Park Cancer Institute. Data were reviewed by the primary investigators and any needed clarifications were made. Data were aggregated and presented at regular intervals to the C3NSI membership. Each participating center’s data were kept de-identified, and the center was represented by a letter of the alphabet.

**Results**

A total of 739,812 doses of vesicant and irritant chemotherapy infusions were included in the evaluation. For vesicants and irritants, the incidence of extravasation events was 0.07% and 0.09%, respectively (see Table 2). These rates were consistently stable during the 17-quarter reporting period. Of the participating centers, the range for vesicants and irritants was 0.00%–0.18% and 0.03%–0.18%, respectively. In the 673 total extravasation events in the study, events that occurred via peripheral IV account for 87.7% of the total vesicant extravasations and 96.7% of the total irritant extravasations.

To estimate the overall prevalence of the use of peripheral IV versus CVAD IV for the administration of all chemotherapies, including nonirritants and nonvesicants, four of the centers provided an aggregate record of 21,922 doses of chemotherapy administration from 2014–2016. Of those doses, 51% were given by CVAD and 49% by peripheral IV, which was significantly different (p < 0.001). The three agents docetaxel (Taxotere®), etoposide (Etopophos®), and paclitaxel (Taxol®) accounted for 33.8% of the doses (n = 250,245). However, these three agents accounted for 59.3% of the extravasation events (n = 399). The vast majority of these events (n = 392, 98%) occurred with peripheral IV access.

Compliance with follow-up on day 1 was 74.9%, day 7 was 71.3%, and day 14 was 62.9%. About 8%–9% of patients were not able to be reached on the follow-up day, and 1.6% refused follow-up. Twenty-five patients (3.7%) had a referral to PRS (vesicants [n = 6], irritants [n = 19]), and 16 patients (2.4%) had a change in severity level (vesicants [n = 6], irritants [n = 10]).

**Discussion**

The C3NSI group has established a stable national benchmark for the extravasation of vesicant and irritant chemotherapy agents in 11 NCI-designated cancer centers. This benchmark provides a threshold for all chemotherapy infusion practices to target as best practice.

The benchmark emanates from significant volumes of chemotherapy given by infusion nurses at centers where the administration of cytotoxic agents is routine. The infusion nurses work in state-of-the-art facilities with a well-trained workforce of oncology nurses, oncologists, pharmacists, and advanced practice professionals. The centers have well-developed competency validation processes, policies and procedures, structured guidelines for the management of actual and suspected chemotherapy extravasations, immediate access to antidote therapies, and immediate referral access to PRS services. However, only 19% of cancer care is delivered in NCI-designated cancer centers; the remaining care is delivered in private office practices and community and non–NCI-designated hospital-based practices (NCI Office of Cancer Centers, 2013). In those sites, resources may not be as rich and readily available. No literature describes the assessment, evaluation, and management of vesicant chemotherapy extravasations in community cancer practices. However, the

**TABLE 2.**

INCIDENCE OF EXTRAVASATIONS: VESICANTS, IRITANTS, AND IRITANTS WITH VESICANT POTENTIAL

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>DOSES</th>
<th>CVAD IV</th>
<th>PERIPHERAL IV</th>
<th>TOTAL</th>
<th>%</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vesicants</td>
<td>123,993</td>
<td>11</td>
<td>79</td>
<td>90</td>
<td>0.07</td>
<td>[0.07%, 0.08%]</td>
</tr>
<tr>
<td>Irritants and irritants with vesicant potential</td>
<td>615,819</td>
<td>19</td>
<td>564</td>
<td>583</td>
<td>0.09</td>
<td>[0.09%, 0.10%]</td>
</tr>
<tr>
<td>Total</td>
<td>739,812</td>
<td>30</td>
<td>643</td>
<td>673</td>
<td>0.09</td>
<td>[0.09%, 0.09%]</td>
</tr>
</tbody>
</table>

CI—confidence interval; CVAD—central venous access device
Association of Community Cancer Centers (2016) recommended that oncology nurses subscribe to the Oncology Nursing Society standards and guidelines for all aspects of patient care and professional practice. Infusion nurses can use the information from the current study to benchmark their own practices, no matter the setting.

The data regarding extravasations that occurred via peripheral versus central venous catheter routes have led to a recommendation of increased use of central venous access for vesicant or irritant administration and vigilant assessment for risk of peripheral venous extravasation. Ener et al. (2004) recommended that vesicant agents be administered via CVAD when possible, particularly for continuous infusions. Others have also recommended CVADs (Al-Benna, O’Boyle, & Holley, 2013; Hoff et al., 2012; Pérez Fidalgo et al., 2012; Sauerland et al., 2006).

As noted previously, the incidence for extravasations of CVAD catheters ranges from 0.3%–4.7% (Sauerland et al., 2006). As such, the risk of CVAD extravasation has historically been considered equivalent to peripheral IV risk. However, in the 673 total events in the current study, 95.5% of the events occurred via peripheral IV compared to 4.5% via CVAD (p < 0.001).

### Complications

Catheter-related infection and occlusion are serious complications of central venous access and occur with more frequency than immediate complications (Nakazawa, 2010). When advising patients to obtain central venous access, practitioners must provide informed consent about the risks and benefits of such access.

Immediate complications are rare but can be life-threatening. They include air embolism, cardiac tamponade, carotid artery puncture, hemothorax, pneumothorax, catheter migration, subclavian artery damage, and bleeding. Mechanical complications can also occur, such as pinch-off syndrome, accidental dislodgegment, improper needle access, thrombosis, and fibrin sheath formation (Sauerland et al., 2006). Some potential risk exists through kinking, bending, or breakage of the lumen.

Infection risk varies according to type of central catheter and treatment site. Centers for Disease Control and Prevention Guidelines (O’Grady et al., 2011) note that peripherally inserted central catheters (PICCs) have a lower incidence of infection than non-tunneled central venous catheters. Non-tunneled catheters account for the majority of bloodstream infections. Totally implantable ports have the lowest incidence of bloodstream infection. With tunneled central venous catheters, the cuff mitigates the movement of organisms into the catheter tract and has a lower infection rate than non-tunneled central venous catheter (O’Grady et al., 2011).

Chopra, O’Horo, Rogers, Maki, and Safdar (2013) published a meta-analysis of 23 studies involving 57,250 patients. Twenty of the studies included central line-associated bloodstream infections (CLABSI) in patients with PICC access. For hospital-ized patients, the unweighted incidence for PICC was 5.2% (76 of 1,473) and for central venous catheters, it was 5.8% (76 of 1,302). However, among outpatients, the incidence was 0.5% for PICC (117 of 25,822) and 2.1% for central venous catheters (418 of 19,715). PICCs were associated with lower relative risk (RR) of CLABSI than central venous catheters (RR = 0.62, confidence interval [CI] [0.4, 0.94]). The risk was least for outpatients with PICC versus central venous catheters (RR = 0.22, CI [0.18, 0.27]). However, in the 13 studies that presented CLABSI per catheter day, PICC and central venous catheter CLABSI occurred with the same frequency (RR = 0.91, CI [0.46, 1.79]).

Maki, Kluger, and Crnich (2006) reviewed 200 prospective studies published from 1966–2005. Their analysis provided the following bloodstream infection pooled mean rates:

- Cuffed and tunneled central venous catheters = 1.6 bloodstream infections per 1,000 catheter days
- Non-cuffed, non-tunneled central venous catheters = 2.7 bloodstream infections per 1,000 catheter days
- Inpatient PICC = 2.1 per 1,000 catheter days
- Outpatient PICC = 1.0 per 1,000 catheter days
- Implantable port = 0.1 per 1,000 catheter days

### Recommendations

In the context of extravasation risk, given the current study’s data and the infectious risk data, support is adequate to recommend that patients who receive any of the 24 agents identified by the C2NSI group should consider having a CVAD placed to receive therapy.

In review of the 673 events, patient movement is a common theme (e.g., going to the bathroom, complaining of pain and burning after returning to the infusion chair). Those events were most frequent in patients with peripheral IV access. Many instances of extravasations, most often with peripheral IV access, occurred in administrations with large volumes and longer infusion duration, such as etoposide (98% peripheral events), taxanes (98% peripheral events), and oxaliplatin (Eloxatin™) (98% peripheral events) (see Tables 3 and 4). Those agents also warrant recommendations for central venous access or vigilant peripheral IV site assessment.

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“Given the high risk, a suspected extravasation must be treated as an actual extravasation event.”
Nurse and provider follow-up of patients with an actual or suspected extravasation is an essential part of care. Processes must be in place to follow up, either by telephone or in person, on day 1 after the event and, at a minimum, weekly (and more frequently as required). Follow-up should continue for a minimum of three weeks and a maximum of six weeks, or until complete resolution of the extravasation (or referral to a PRS consult).

Given the high risk, a suspected extravasation must be treated as an actual extravasation event. Level 2 and level 3 harm events (n = 613) accounted for 91.1% of the extravasation events. Only 8.9% (n = 60) of the events were level 1 harm. Because of the potential consequences of an extravasation, chemotherapy infusion RNs must maintain a high level of suspicion for any sign of an impending event and treat the event in the same manner as an actual event.

The group identified two additional best practices and considerations. Although gemcitabine is considered an irritant and does burn on peripheral administration, significant tissue damage rarely occurs. Regarding administration of fosaprepitant via peripheral administration for delayed emesis, some centers have changed their practice to give the highly emetogenic chemotherapy agent first, followed by fosaprepitant (Emend® injection). By doing so, adverse events to the infusion site associated with administering the fosprepitant first (e.g., pain, erythema, swelling, phlebitis) are lessened (Tsuda et al., 2016). The delayed emesis effect is preserved because of the mechanism of action of fosaprepitant (Merck, 2016).

**Limitations and Future Directions**
The current study was intended only to determine the incidence of vesicant and irritant chemotherapy extravasation at NCI-designated cancer centers. It did not consider the patient, nurse, treatment, and center-related variables that can influence chemotherapy infusion practice. Patient-related considerations may include the number of venipuncture attempts, history of receiving multiple vesicant and irritant agents, treatment duration, age, performance status, body mass index, and exposure to nonchemotherapeutic agents that are irritants (e.g., potassium chloride, TABLE 3.

<table>
<thead>
<tr>
<th>VESICANT</th>
<th>DOSES ADMINISTERED</th>
<th>EXTRAVASATIONS BY TYPE</th>
<th>EXTRAVASATION RATE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>CVAD IV</td>
<td>PERIPHERAL IV</td>
</tr>
<tr>
<td>Dactinomycin</td>
<td>826</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Daunorubicin</td>
<td>1,167</td>
<td>1</td>
<td>–</td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>55,182</td>
<td>6</td>
<td>41</td>
</tr>
<tr>
<td>Epirubicin</td>
<td>1,758</td>
<td>–</td>
<td>4</td>
</tr>
<tr>
<td>Idarubicin</td>
<td>414</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Mechlorethamine</td>
<td>59</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Mitomycin</td>
<td>3,445</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Vinblastine</td>
<td>12,120</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Vincristine</td>
<td>29,759</td>
<td>–</td>
<td>3</td>
</tr>
<tr>
<td>Vinorelbine</td>
<td>19,263</td>
<td>3</td>
<td>27</td>
</tr>
<tr>
<td>Total vesicants</td>
<td>123,993</td>
<td>11</td>
<td>79</td>
</tr>
</tbody>
</table>

CI—confidence interval; CVAD—central venous access device
Calcium chloride, dextrose > 10%). RN characteristics may include age, years of experience, education, and certification. Most contributing centers were general medical oncology infusion centers, with all types of adult patients with cancer receiving care. However, some centers had higher patient volumes and varied disease-specific infusion centers. The study did not account for differences in types of patients, underlying diagnoses, disease stage, geographical differences, or patient referral patterns among centers.

In the years since the study began, drugs have come to market or have been reclassified as vesicants (e.g., liposomal vincristine [Marqibo®], trabectedin [Yondelis®]), irritants (e.g., ado-trastuzumab emtansine [Kadcyla®], carboplatin [Paraplatin®]), and irritants with vesicant potential (e.g., bendamustine [Treanda®]). Chemotherapy agents must be continually evaluated and updated regarding drug classification and potential for tissue damage.

Future efforts may evaluate patient or other risk factors associated with peripheral IV access that may predispose extravasation. One consideration may be the development and validation of a peripheral IV risk assessment tool. Current efforts by the C3NSI group address standardizing patient and staff education regarding chemotherapy extravasation. In addition, ongoing work by the Oncology Nursing Society addresses standardization of nursing documentation, including chemotherapy, surgery, radiation therapy, bone marrow transplantation, and venous access devices. These efforts will also include standardizing documentation for chemotherapy extravasation.

**Conclusion**

This study has provided a stable benchmark incidence for vesicant and irritant chemotherapy extravasation. That benchmark can inform chemotherapy infusion nursing practice. The observations and recommendations for best practice may also improve the quality and safety of the care provided to patients who receive chemotherapy treatments and their families.
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The authors gratefully acknowledge the contributions of Kathleen Wolf, MBA, RN, NEA-BC. The authors also gratefully acknowledge the members of the participating centers in the consortium who were not able to provide data but who contributed to concept and protocol development, and review of the data. These are Norris Cotton Cancer Center at Dartmouth-Hitchcock in Lebanon, NH; Duke Cancer Institute in Durham, NC; Sylvester Comprehensive Cancer Center, University of Miami in Florida; City of Hope in Duarte, CA; Dana-Farber Cancer Institute in Boston, MA; Barbara Ann Karmanos Cancer Institute in Detroit, MI; MD Anderson Cancer Center in Houston, TX; and Moffitt Cancer Center in Tampa, FL. The authors also gratefully acknowledge the support, encouragement, and resources provided by the chief nurse executives of the 19 cancer centers in the Cancer Centers Consortium Nursing-Sensitive Indicators group. The authors also gratefully acknowledge the constructive input and data review of the following members of the Oncology Nursing Society leadership team: Brenda Nevidjon, RN, MSN, FAAN; Gail Mallory, PhD, RN, NEA-BC; Michele Galjota, RN, MSN; Deborah Struth, MSN, RN; Kathleen Wiley, RN, MSN, AOCN®, and Susan Schneider, PhD, RN, AOCN®, FAAN. This article honors the life, work, and memory of Elizabeth Wertz Evans.

The authors take full responsibility for this content. Three of the authors were or are Memorial Sloan Kettering Cancer Center employees. This research was funded, in part, through the National Institutes of Health/National Cancer Institute Cancer Center Support Grant P30 CA008748. The article has been reviewed by independent peer reviewers to ensure that it is objective and free from bias. Mention of specific products and opinions related to those products do not indicate or imply endorsement by the Oncology Nursing Society.

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