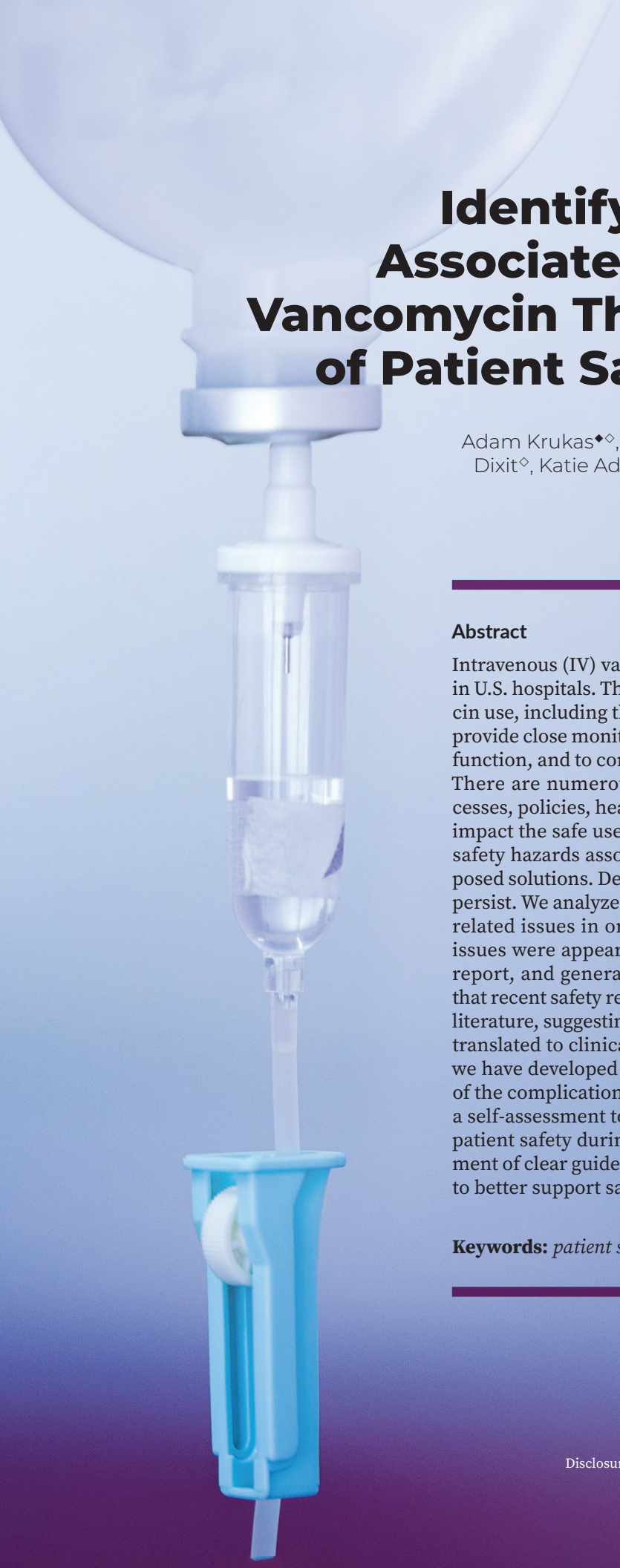


Identifying Safety Hazards Associated With Intravenous Vancomycin Through the Analysis of Patient Safety Event Reports

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Abstract

Intravenous (IV) vancomycin is one of the most commonly used antibiotics in U.S. hospitals. There are several complexities associated with IV vancomycin use, including the need to have an accurate patient weight for dosing, to provide close monitoring to ensure appropriate drug levels, to monitor renal function, and to continue delivery of the medication at prescribed intervals. There are numerous healthcare system factors, including workflow processes, policies, health information technology, and clinical knowledge that impact the safe use of IV vancomycin. Past literature has identified several safety hazards associated with IV vancomycin use and there are some proposed solutions. Despite this literature, IV vancomycin–related safety issues persist. We analyzed patient safety event reports describing IV vancomycin–related issues in order to identify where in the medication process these issues were appearing, the type of medication error associated with each report, and general contributing factor themes. Our results demonstrate that recent safety reports are aligned with the issues already identified in the literature, suggesting that improvements discussed in the literature have not translated to clinical practice. Based on our analysis and current literature, we have developed a shareable infographic to improve clinician awareness of the complications and safety hazards associated with IV vancomycin and a self-assessment tool to support identification of opportunities to improve patient safety during IV vancomycin therapy. We also recommend development of clear guidelines to optimize health information technology systems to better support safe IV vancomycin use.

Keywords: *patient safety event, medication safety, vancomycin, human factors*

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Vancomycin is one of the most commonly used broad-spectrum antibiotics prescribed to treat many different types of infections. For example, from 2006 to 2012, vancomycin use in U.S. hospitals increased by 32%, with intravenous (IV) vancomycin being the most common administration route.[1] While this drug can be effective when prescribed for the appropriate clinical conditions and administered properly, there are unique complexities to using IV vancomycin. If these complexities are not well understood and appropriate processes are not implemented, there can be serious patient safety consequences that result in patient harm or death. Understanding the complexity of delivering treatments like IV vancomycin, including healthcare system factors such as the clinicians involved in the care process, technology, and workflow processes and policies, is critical to improve patient safety.

Physicians, nurses, pharmacists, phlebotomists, dialysis technicians, and laboratory technicians all have important roles in the delivery of IV vancomycin, whether for a critically ill patient, routine preoperative prophylaxis, or scheduling therapy around dialysis.[2] IV vancomycin therapy requires an accurate patient weight for dosing, monitoring of drug levels, attention to renal function, and the ongoing delivery of doses at scheduled intervals. Most IV vancomycin doses are initially calculated from a patient's total body weight and kidney function. Once an initial dose of vancomycin is administered to a patient, clinicians must continuously monitor vancomycin levels in the patient's blood. This is typically called a trough and is done by measuring serum concentrations.[2,3] The trough level is obtained by drawing blood 30 minutes prior to a patient's third or fourth dose of vancomycin, once the medication has reached a steady state.[4] The trough is the best current method we have to monitor and guide adjustment of vancomycin dosing.

These complexities create opportunities for numerous patient safety hazards. In this paper we (1) identify many of these hazards and proposed solutions developed to mitigate some of the risks from previous literature, (2) analyze recent patient safety event (PSE) reports in the context of this existing literature to determine where gaps between research and clinical practice exist, and (3) propose and develop solutions to address some of these gaps in the form of a safety assessment tool (**Appendix A**).

Recognized Safety Hazards Associated with IV Vancomycin and Current Improvement Efforts

Dosing. Challenges with vancomycin dosing are a well-recognized safety issue. Several case studies described unintentional overdoses of vancomycin and the use of hemodialysis to quickly remove excess drug.[5,6] At the other extreme, groups with the highest frequency of subtherapeutic drug levels included critically ill patients and patients receiving hemodialysis.[7,8] To address these issues, some hospitals have implemented therapeutic drug monitoring (TDM) programs. These programs are managed by clinical pharmacists and have demonstrated improvement in effective vancomycin therapy.[9–11]

> While IV vancomycin can be effective when prescribed and administered appropriately, this drug has unique complexities.

Monitoring. Monitoring the circulating concentration of vancomycin and kidney function is essential for effective treatment and prevention of renal complications. An individual's severity of illness and comorbid conditions affect the metabolism of IV vancomycin. Therefore, a vancomycin trough is necessary to measure the remaining serum concentration of vancomycin after an individual metabolizes several doses of the drug. Trough levels guide adjustments of future doses to prevent under or overdosing. Underdosing may not effectively treat the target infection while overdosage may impair renal function. Monitoring of serum creatinine trends provides an indication of renal response to therapy. Processes that support the timely collection, processing, and reporting of both the trough level and serum creatinine have been the focus of improvement efforts. Pharmacist participation in physician rounds has been found to reduce preventable adverse drug events by up to 78% and computer physician order entry (CPOE) with guided order sets has significantly increased appropriate vancomycin dosing and monitoring.[12,13] TDM assigns therapy oversight to the clinical pharmacist, who monitors administration and compliance with timely trough collection, and adjusts the dose accordingly, thus preventing the need to place doses on hold and risk delayed or omitted doses.[16] This method of monitoring commonly involves communication between the lead provider, the pharmacist, and nurses who are involved

with direct patient interactions.[2,3] Technological tools assist with the implementation of TDM, offering new and efficient ways of developing safe medication administration practices.[14] Conditions for acceptance of electronic TDM programs are unique at each clinical site and thus mandate local modifications.[14] While TDM is very helpful, it does not replace clinical judgement.

IV administration. Administration issues are related to IV access, rate, timing, and concomitant administration. Infiltration of caustic medications such as vancomycin can lead to extravasations and necrosis of surrounding tissues when they escape the vascular pathway.[15] Peripheral IV access is an acceptable practice for short-term vancomycin administration, while midline and peripherally inserted central catheter (PICC) access methods are preferred for severely ill patients and long-term infusions.[15–18] Hyaluronidase, such as vitrase, has been used to reduce the effect of vancomycin infiltration and extravasations.

The most common adverse effects related to vancomycin administration, excluding IV infiltration, are hypotension, chills, fever, and red man syndrome (RMS). These reactions are often associated with a rate of administration in excess of 1 gram over 60 minutes. For many patients, administering the dose over a longer period and premedication with diphenhydramine reduces this response. Vancomycin administration tables and "smart" IV pumps with embedded clinical decision support have been implemented to reduce the frequency of rapid administration errors.[2,3,19–21,22]

As with other drugs, in order to maintain therapeutic levels of vancomycin and have effective treatment, it is essential that the drug be given at consistent intervals. Case studies describing organizational barriers to schedule adherence include the missed delivery of a dose from pharmacy, delay in collecting and reporting of predose trough levels, and patients being off their unit for testing or treatment.[23,24]

Patients are frequently treated with vancomycin in combination with other antibiotics.[25,26] Evidence suggests that the antibiotics piperacillin/tazobactam, when co-administered with vancomycin, can induce greater kidney injury.[27–29] Also, other potentially nephrotoxic medications, such as nonsteroidal anti-inflammatory drugs (NSAIDs), can increase the risk of acute kidney injury. Kidney injury may be mild, but some severe cases may require temporary or permanent hemodialysis. Some antibiotics from the β-lactam class cannot be administered concurrently in the same IV line as vancomycin.[23] Consultation with a clinical pharmacist and accessibility of intranet-based compatibility software have reduced errors related to medication co-administration.[30]

Workflow and communication issues. Transitions in care between facilities, hospital departments, and shifts have been extensively studied as factors that increase risk for adverse events.[31,32] Additionally, dialysis-dependent patients, as well as patients with significant decline in renal function, require different dosing, administration, and monitoring protocols. Some patients need to go off a unit to receive dialysis, leading to an opportunity for missed or incorrect doses of vancomycin. Orders for vancomycin dosing during or after dialysis are often not visible to dialysis nurses using some electronic health records (EHRs). This lack of situation awareness has contributed to both under and overdosing.[33] In a similar fashion, prophylactic vancomycin dosing before surgery may be ordered to be given "on call" to the operating room (OR); however, breakdowns in communication between surgical floors and OR scheduling are frequent and have contributed to both missed and extra doses.[33] Patients treated with vancomycin in the emergency department (ED) are often seriously ill and may receive a loading dose in order to quickly initiate therapy. One study noted that nearly 12% of patients admitted to the hospital from the ED have a medication discrepancy and that 36% of these discrepancies result in omitted drug doses.[33] Differences in EHR views between inpatient units and EDs, as well as multiple handoffs by both nursing and provider teams, have resulted in medication errors.[31,32] Health information technology (IT) solutions have been explored to improve situation awareness.

Study Focus

Despite the literature recognizing safety issues associated with IV vancomycin use and the existence of some proposed solutions to address these recognized issues, IV vancomycin–related safety issues persist. In this study, we analyzed recent IV vancomycin–related PSE reports to identify current safety issues associated with IV vancomycin use, with a focus on healthcare system factors that may be contributing to these types of events. Our analysis of PSE reports focused on identifying where in the medication-use process issues were arising, the types of medication errors associated with the reports, and identification of themes that characterize the contributing factors from each report. Comparing the results of our analysis of recent safety event reports with the recognized safety hazards and proposed solutions from the literature, we identified important next steps to improve IV vancomycin patient safety in clinical practice and developed an infographic and self-assessment tool to begin to address safety hazards.

Figure 1. Event Data Review Process



Methods

A nurse and pharmacist identified and analyzed IV vancomycin–related PSE reports with input from human factors experts throughout the process. They performed a rigorous thematic analysis to identify common safety issues across the event reports. The analysis was focused on reports that resulted in patient harm.

Data Source and Selection

Data were comprised of 68,277 acute care PSE reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS)* between April 1, 2019, and June 30, 2019. To identify IV vancomycin–related reports, we searched the free-text event details and other relevant fields of each report for

- Reports containing the characters "vanc" or "vanco". A space character was included after the term "vanc" to eliminate false positives such as matching on a report that describes an "advancement."
- Reports that ended with the string "vanc".

This resulted in 974 event reports. Reports with harm scores of A (unsafe condition) and B (event, no harm) were excluded given that these events did not reach the patient. Ten percent of the reports with a harm score of C (event, no harm, reached the patient) were screened to determine whether they were qualitatively different from the remaining reports. They were not different and were also excluded since they were less severe and did not add any insight. This resulted in 411 reports. Clinicians manually reviewed these reports to ensure they were IV vancomycin–related as opposed to a report describing an unrelated occurrence that contained the word vancomycin. This further excluded 32 events, resulting in 379 reports. Since our analysis focused on identifying healthcare system factors contributing to IV vancomycin safety hazards, we removed events where system factors could not be identified. One hundred forty-nine IV infiltration events were removed since they did not include enough detail to identify system contributing factors. Seventy-nine adverse drug events were also removed since they were newly diagnosed drug allergies with no contributing system factors described. Finally, eight reports did not have enough information to identify the contributing system factors and were removed from analysis. This resulted in a total of 143 reports for descriptive and thematic analysis. The data review filtering process is shown in **Figure 1**.

Analysis Methods

The 143 IV vancomycin reports were first analyzed with a focus on descriptive statistics and were then qualitatively analyzed.

Descriptive Analysis. Descriptive analysis of the 143 events included the event type, harm score, and patient age as reported by healthcare facilities to PA-PSRS.

Qualitative Analysis. Using a grounded theory approach, two clinicians, pharmacist AK and nurse EF, manually coded all the reports for medication-use process, medication error type, and contributing factor emerging themes. To establish inter-rater reliability, 51 reports (35.7%) were dually coded by AK and EF. Differences were reconciled through joint discussion. After establishing inter-rater reliability, the remaining reports were split between the two coders and individually reviewed. Inter-rater reliability was calculated using Cohen's kappa, which resulted in 0.74 for medication-use process, 0.77 for medication error type, and 0.81 for contributing factor emerging themes.

Coding of Vancomycin Reports. The 143 reports were coded to understand medication-use process stage, medication error type, and contributing factor emerging themes, as described in the codebook in **Appendix C**. The medication-use process stages were modeled after the American Society of Hospital Pharmacists (ASHP) medication use categories.[35] The medication error type was adopted from the National Coordinating Council for Medication Error Reporting

*PA-PSRS is a secure, web-based system through which Pennsylvania hospitals, ambulatory surgical facilities, abortion facilities, and birthing centers submit reports of patient safety-related incidents and serious events in accordance with mandatory reporting laws outlined in the Medical Care Availability and Reduction of Error (MCARE) Act (Act 13 of 2002). All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

and Prevention taxonomy.[36] Contributing factor emerging themes (e.g., care coordination and information exchange) and subthemes (e.g., incomplete information flow, handoff) were identified through an iterative process of reviewing vancomycin-related reports.[34] The free-text narrative served as the foundation for coding. Each report was assigned a single medication-use process stage, if one could be identified from the report, and a single medication error type if identifiable from the report. However, a single report could be assigned more than one contributing factor theme.

Results

We first report on the descriptive analysis of the vancomycin reports to provide general context followed by the results from the expert review.

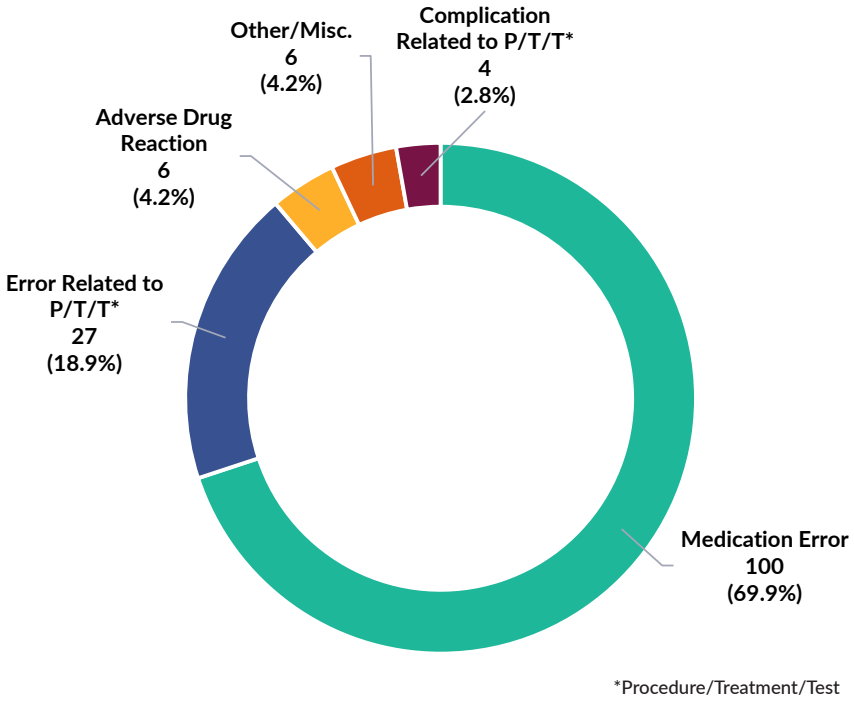
Descriptive Analyses

Event Type. We first analyzed the general event type categories assigned by the event reporter to each report in PA-PSRS. The reported event type category of *Medication Error* (n=100 of 143, 69.9%) had the highest frequency of vancomycin events, as expected. The event type *Error Related to Procedure, Treatment, or Test* (n=27 of 143, 18.9%) was the second-most frequent category for vancomycin cases (**Figure 2**).

Harm Score. Of the 143 reports analyzed, nearly all events were reported as harm score *D* (n=141 of 143, 98.6%). One event was reported as harm score *E* (0.7%) and one event was reported as harm score *F* (0.7%).

Patient Age. Over half of all vancomycin reports reviewed were related to the adult population (ages 18–69) (n=92 of 143, 64.3%). Older adults (ages 70+) contributed to nearly one-third of all reports (n=45 of 143, 31.5%) and the pediatric population accounted for 6 reports (4.2%).

Figure 2. Event Type Category and Frequency



*Procedure/Treatment/Test

Qualitative Analyses

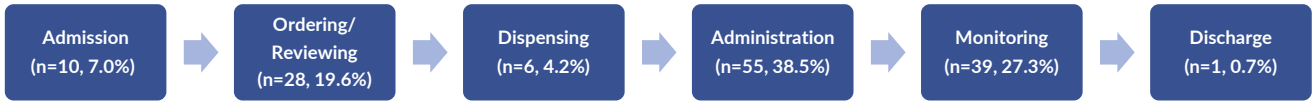
Medication-Use Process. Of the 143 reports analyzed, the medication-use process stage was associated with reported safety issues in 139 of the 143 reports, with 4 reports not containing enough information to identify this stage. Events were most commonly associated with Administration (n=55 of 143, 38.5%), followed by Monitoring (n=39 of 143, 27.3%), and then Ordering/Reviewing (n=28 of 143, 19.6%), as shown in **Figure 3**.

Medication Error Type. Of the 143 reports analyzed, the medication error type was identified in 135 of the 143 reports, with 8 reports not containing enough information to identify the medication error type. The most frequent errors identified were Dose Omission/Delay or Receipt of Partial Dose (n=59 of 135, 41.3%), Improper Dose (n=42 of 135, 29.4%), and Monitoring Errors (n=26 of 135, 18.2%), as shown in **Figure 4**.

Contributing Factor Emerging Theme. The contributing factor thematic analysis revealed that Appropriate Therapy Management was associated with most event reports (n=104 of 143, 72.7%), followed by issues with Care Coordination and Information Exchange (n=61 of 143, 42.7%), Documentation (n=21 of 143, 14.7%) and Workflow (n=19 of 143, 13.3%), as shown in **Table 1**. The contributing factor emerging themes were also evaluated in the context of the medication process stage (**Table 2**) and the type of medication error (**Table 3**).

Within the theme of Appropriate Therapy Management (n = 104), issues with Timing were the most prevalent (n = 70 of 104, 67.3%), followed by Monitoring (n = 53 of 104, 51.0%). Looking at where these issues occurred within the medica-

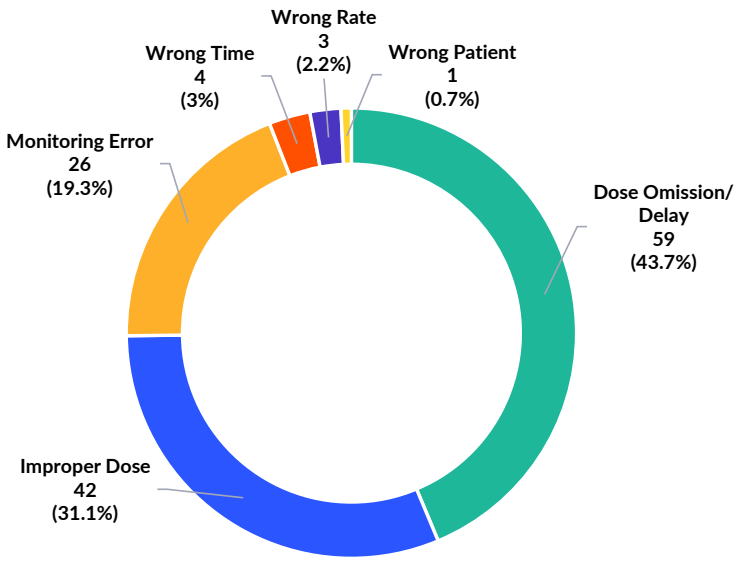
Figure 3. Medication process stage associated with vancomycin reports[34]



tion-use process stage, they often occurred during Administration (n = 41 of 104, 39.4%) and Monitoring (n = 39 of 104, 37.5%), followed by the Ordering/Reviewing (n = 16 of 104, 15.4%), **Table 2.** These issues often resulted in Dose Omission/Delay or Receipt of a Partial Dose errors (n = 43 of 104, 41.3%), followed by Improper Dose (n = 26 of 104, 25%) and Monitoring errors (n = 26 of 104, 25%), **Table 3.**

Looking specifically at the Appropriate Therapy Management theme and the administration medication-use process stage together, common challenges occurred when (1) there were delays in receiving the first dose or in continuation after the first dose, (2) vancomycin was combined with the administration of Zosyn, and (3) a patient was transferred while there was an active order for vancomycin. There were instances where the dose of vancomycin was available (explicitly stated in the report) and not administered. Of the 41 Administration medication-use process stage issues related to Appropriate Therapy Management, more than half (n=24 of 41, 58.5%) resulted in Dose Omission/Delay or Receipt of a Partial Dose errors. Next, looking at the Appropriate Therapy Management theme and the Monitoring medication-use process stage together nearly all challenges were centered around timing of troughs. Difficulties were noted when doses and/or timing needed to be adjusted, including starting, restarting, and stopping IV vancomycin. Of the 39 events occurring during the Monitoring medication-use process stage related to Appropriate Therapy Management, nearly two-thirds (n=25 of 39, 64.1%) resulted in Monitoring medication errors.

Figure 4. Medication error type associated with vancomycin reports



The theme of Care Coordination and Information Exchange (n = 61) was the second-most common theme associated with the vancomycin events. Incomplete Information Flow was the most common contributing factor within this theme (n = 35 of 61, 57.4%). The Administration medication-use process stage was associated with most of these issues (n = 28 of 61, 45.9%), followed by the Ordering/Reviewing stage (n = 13 of 61, 21.3%) and Monitoring stage (n = 12 of 61, 19.7%), **Table 4.** Dose Omission/Delay or Receipt of a Partial Dose errors (n = 27 of 61, 44.3%) and Improper Dose errors (n = 20 of 61, 32.8%) were the most frequent type of medication errors associated with the Care Coordination and Information Exchange theme, **Table 3.**

Looking specifically at the Care Coordination and Information Exchange theme and the Administration medication-use process stage together, common challenges included workflow issues of handoffs and transfers. More specifically, we noted issues within the ED and OR. In these settings, vulnerabilities were associated with one-time preoperative prophylaxis or with ED loading doses of vancomycin. Incomplete Information Flow between the OR or ED and the receiving patient units precipitated errors in the medication-use process stages of Administration and Monitoring.

Table 1. Contributing factor emerging themes associated with vancomycin reports

Contributing Factor Emerging Theme	Frequency	%
Appropriate Therapy Management	**104**	**72.7% (of 143 total reports)**
Timing	70	67.3% (of 104 reports)
Monitoring	53	51.0% (of 104 reports)
IV Access	8	7.7% (of 104 reports)
Care Coordination and Information Exchange	**61**	**42.7% (of 143 total reports)**
Incomplete Information Flow	35	57.4% (of 61 reports)
Handoff	17	27.9% (of 61 reports)
Renal Function	14	23.0% (of 61 reports)
Documentation	**21**	**14.7% (of 143 total reports)**
Workflow	**19**	**13.3% (of 143 total reports)**
OR System	11	57.9% (of 19 reports)
ED System	9	47.4% (of 19 reports)

Table 2. Vancomycin reports by medication process stage and contributing factor themes

Medication Process Stage	Appropriate Therapy Management	Care Coordination & Information Exchange	Documentation	Workflow
Admission	2 (1.9%)	3 (4.9%)	9 (42.9%)	2 (10.5%)
Ordering/Reviewing	16 (15.4%)	13 (21.3%)	4 (19.0%)	6 (31.6%)
Dispensing	4 (3.8%)	2 (3.3%)	2 (9.5%)	0 (0.0%)
Administration	41 (39.4%)	28 (45.9%)	4 (19.0%)	11 (57.9%)
Monitoring	39 (37.5%)	12 (19.7%)	1 (4.8%)	0 (0.0%)
Discharge	1 (1.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)
Not Enough Info to Determine	1 (1.0%)	2 (3.3%)	1 (4.8%)	0 (0.0%)
TOTAL REPORTS	104	61	21	19

Table 3. Vancomycin reports by medication error type and contributing factor themes

Medication Error Type	Appropriate Therapy Management	Care Coordination & Information Exchange	Documentation	Workflow
Dose Omission/Delay or Receipt of a Partial Dose	43 (41.3%)	27 (44.3%)	7 (33.3%)	11 (57.9%)
Improper Dose	26 (25.0%)	20 (32.8%)	9 (42.9%)	2 (10.5)
Monitoring Error	26 (25.0%)	6 (9.8%)	1 (4.8%)	6 (31.6%)
Not Enough Info to Determine	4 (3.8%)	5 (8.2%)	2 (9.5%)	0 (0.0%)
Wrong Time	3 (2.9%)	1 (1.6%)	1 (4.8%)	0 (0.0%)
Wrong Rate	2 (1.9%)	1 (1.6%)	1 (4.8%)	0 (0.0%)
Wrong Patient	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)
TOTAL REPORTS	104	61	21	19

Order sets within the EHR were noted to be confusing and further complicated by the use of paper, fax, and verbal communication to order and review vancomycin effectively. Nearly all the challenges in the Care Coordination and Information Exchange theme that were also in the Monitoring medication-use process stage were centered around troughs. More specifically, there was a lack of awareness of (1) the trough being ordered but not drawn, (2) trough results not transmitted/received, and (3) trough results not being acted upon appropriately in a timely manner. Of the 12 medication-use process stage Monitoring issues related to Care Coordination and Information Exchange, half of the events resulted in monitoring medication errors.

The theme of Documentation was associated with 21 events. These events were mostly associated with the Admission (n = 9 of 21, 42.9%) medication-use process stage, followed by Ordering/Reviewing (n = 4 of 21, 19.0%) and Administration (n = 4 of 21, 19.0%). The most common medication error types were Improper Dose (n = 9 of 21, 42.9%) and Dose Omission/Delay or Receipt of a Partial Dose (n = 7 of 21, 33.3%).

The theme of Workflow was associated with 19 events. Within this theme two more events were associated with OR workflows (n = 11) than ED workflows (n = 9). These issues were most frequently associated with the Administration (n = 11 of 19, 57.9%) and Ordering/Reviewing (n = 6 of 19, 31.6%) medication-use process stages. The most frequent medication error types were Dose Omission/Delay or Receipt of a Partial Dose (n = 11 of 19, 57.9%) and Monitoring Errors (n = 6 of 19, 31.6%).

Discussion

The descriptive analysis shows that most events involving vancomycin are reported under the event type *Medication Error*, followed by *Error Related to Procedure, Treatment or Test*. Most of the reports are associated with adults between the ages of 18 and 69. The coding of event reports into the medication-use process stage showed that most reports are associated with Administration (38.5%), Monitoring (27.3%) and Ordering/Reviewing (19.6%). The coding of event reports into the medication error types revealed that most reports were related to Dose Omission/Delay or Receipt of Partial dose (41.3%), followed by Improper Dose (29.4%), and Monitoring Errors (18.2%). The thematic analysis of event reports revealed that issues with Appropriate Therapy Management and Care Coordination and Information Exchange were the most prevalent, indicating an opportunity for focused efforts to improve these issues.

In many ways, the overall results from this analysis of IV vancomycin–related PSE reports are not surprising, since other researchers have identified many of these issues. However, the fact that these issues persist given this existing literature highlights the gap between patient safety research and improvements to actual clinical practice. To close this gap with a specific focus on IV vancomycin safety, we believe several actions should be taken.

First, it is important to raise clinician awareness of the complexities and risks associated with vancomycin. Although it is recognized that clinician awareness and training initiatives are generally ineffective as long-term solutions to identified patient safety hazards, they can temporarily begin to address recognized risks. For example, nursing may reinforce the practice of reviewing vancomycin trough levels prior to dosing as they do for lab values associated with safe insulin and anticoagulant administration. To increase awareness, we have created a single page infographic that can be displayed in healthcare facilities either electronically (e.g., as a screensaver) or in paper format posted in high visibility areas (e.g., nurse's station or break room); see **Appendix B**.

Second, given the nuances in clinical workflows, policies, health IT, and processes across different healthcare facilities, we have developed a self-assessment tool that provides a framework for healthcare facilities to identify specific IV vancomycin–related hazards within their institution; see **Appendix C.** This self-assessment tool brings knowledge from the literature to frontline practice in a format that allows application to specific clinical environments.

Finally, with pervasive use of health IT for medication ordering, administration, and monitoring, these technology systems should be a central focus of safety improvement efforts. Recent research has highlighted some effective health IT solutions to address IV vancomycin–related safety issues, specifically to support ordering and monitoring, which were prevalent in our event report analysis. Using a weight-based vancomycin EHR order set, specifically in ED settings, resulted in a 20% increase in appropriate dosing.[37] Evidence-based guidelines informing the structure and design of order sets should be more effectively disseminated to healthcare facilities for inclusion in their implemented EHR products. One study created an EHR process to address monitoring such that when a new vancomycin order was placed, a trough was automatically ordered 30 minutes before the fourth dose.[38] Further, an alert was included in the nurse's barcode administration system to prevent administration of vancomycin if no trough level had been drawn. This resulted in nearly a 20% increase in trough levels being drawn between the third and fourth dose. This research demonstrates that health IT solutions can be implemented to

address vancomycin-related safety issues. The clinical guidelines from these previous studies should be shared with healthcare facilities and health IT vendors to expand dissemination of these best practices into implemented products.

Conclusion

The complexities associated with IV vancomycin introduce the potential for patient safety hazards. While the literature has identified many of these hazards and there are some proposed solutions, a recent analysis of PSE reports demonstrates that these safety hazards persist. By increasing awareness of the risks associated with vancomycin, identifying local hazards, and utilizing clinical decision support, healthcare facility leaders and frontline providers can improve medication safety.

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Appendix A—IV Vancomycin Safety Assessment Tool

IV Vancomycin Safety Assessment Tool

Purpose: This self-assessment tool is designed to increase awareness of *known* IV vancomycin patient safety risk factors, determine how your facility may or may not be addressing these risks, and identify areas of opportunity to improve patient safety. It is intended to support intrafacility risk identification and organizational learning. The assessment tool is based on current literature and a recent analysis of patient safety event reports.[1-4]

Assessment Organization: The tool is organized around three factors that have been identified as important to IV vancomycin safety: practitioner and organizational knowledge, workflow processes and tasks, and health information technology. Under each factor, items that promote the safe use of IV vancomycin are described. These items are organized under phases of the medication process: medication ordering, medication administration, and medication monitoring and maintenance.

How to use this Assessment Tool:

1. Form a multidisciplinary team that may include nurses, pharmacists, physicians, patient safety analysts, laboratory services, and informatics or information services.
2. Review all assessment items prior to beginning the assessment.
3. Complete the assessment by indicating "yes," "no," or "not applicable (N/A)" for whether a safety strategy is used in your organization. For certain items, indicate frequency of use by marking "never," "sometimes," "always," or "not applicable (N/A)." Where frequency of use is not relevant, the row is grayed out indicating it need not be completed.
4. Review the items with a focus on those marked "no" as well as those marked as "yes" that are "never" or "sometimes" used. Create an action plan to address the gaps and identify which stakeholders need to be engaged to make the improvements.

This assessment tool provides one method to identify IV vancomycin–related safety hazards in your organization. By using this tool, certain safety hazards can be mitigated, resulting in improved patient safety.

Factor 1: Practitioner and Organizational Knowledge									
Rationale: With up-to-date knowledge and information, an organization and its clinical staff can identify risks associated with vancomycin and deploy strategies and tactics to minimize this risk.									
		Safety Strategy Used?			**Frequency of Use**				
		Y	N	N/A	Never	Sometimes	Always	N/A	
Medication Ordering									
1	An antibiotic stewardship program is in place and provides facility-specific guidelines on when IV vancomycin is indicated, what diagnostic approaches should be used, and how the use of vancomycin will be audited.								
2	There is education for frontline clinical staff around the need for accurate weight measurement in metric units (g/kg) and how to document it correctly upon admission.								
3	Providers are aware of available vancomycin order sets and how to access them.								
4	Your organization is monitoring usage of the vancomycin order sets.								
5	There is a process for reporting and reviewing vancomycin ordering errors.								
6	There is a process for giving feedback to staff about vancomycin ordering errors.								
Medication Administration									
7	Nurses are evaluated for competency in obtaining and maintaining appropriate IV access for vancomycin.								
8	Nurses can describe the process for obtaining a stat, initial, or missing dose of vancomycin.								
9	Nurses have knowledge or access to knowledge about drugs that are incompatible with vancomycin.								
10	There is a process for reporting, reviewing, and reducing delays in initiation of vancomycin therapy.								
11	There is education and/or training for treating infiltration/extravasation of vancomycin.								
12	Clinicians have access to current information regarding vancomycin extravasation antidotes.								
13	There is a process for reporting and reviewing vancomycin administration errors.								
14	There is a process for giving feedback to staff about vancomycin administration errors.								
Medication Monitoring and Maintenance									
15	Clinicians (including nursing, pharmacy, and ordering providers) can describe the purpose for obtaining a vancomycin trough 30 minutes prior to a specified dose.								
16	Clinicians (including nursing, pharmacy, and ordering providers) can describe the purpose for obtaining a random vancomycin level for specific patient populations (e.g., patients with renal disease).								
17	Phlebotomy and lab employees, as well as nurses, can describe the need to prioritize the timely collection and processing of vancomycin troughs.								
18	Clinicians (including nursing, pharmacy, and ordering providers) can describe the purpose for regularly monitoring creatinine levels for patients receiving vancomycin.								

19	Clinicians (including nursing, pharmacy, and ordering providers) can describe the actions they need to perform after vancomycin trough results become available.							
20	Clinicians (including nursing, pharmacy, and ordering providers) can describe their specific role in monitoring and responding to evidence of diminishing renal function for patients receiving vancomycin.							
21	There is a process for reporting and reviewing vancomycin monitoring errors.							
22	There is a process for providing feedback to clinical staff about vancomycin monitoring errors.							

Factor 2: Workflow Processes and Tasks								
Rationale: Having a complete understanding of the detailed workflow and tasks associated with IV vancomycin therapy will enable care teams to mitigate risk.								
		Safety Strategy Used?			**Frequency of Use**			
		Y	N	N/A	Never	Sometimes	Always	N/A
Medication Ordering								
1	Equipment to obtain weights for patients of all sizes and mobility levels is consistently available within the organization.							
2	Scales are routinely calibrated as specified by manufacturer's operational instructions.							
3	On each admission, a patient's weight is measured in metric units (g/kg) and the value is readily accessible by all clinicians.							
4	When a provider orders an initial or stat dose of vancomycin, there is a mechanism for pharmacy to be notified of the urgency of the order.							
5	When a provider orders an initial or stat dose of vancomycin, there is a mechanism for nursing to be notified of the urgency of the order.							
Medication Administration								
6	Timing of scheduled vancomycin doses is specifically communicated during handoffs, especially high-risk handoffs from the ED to inpatient and transfers from unit to unit.							
7	There is a standard process for communicating perioperative antibiotic dosing during handoffs from floor to OR and OR to PACU/floor.							
8	Dialysis nurses have access to electronic medication administration records (eMAR) and have a process for ensuring their patients on vancomycin do not miss or do not have delayed administration of vancomycin doses.							
9	Dialysis nurses have a standard process for obtaining peridialysis vancomycin doses from inpatient units or from the pharmacy.							
10	Your organization has a policy addressing venous access site selection for the administration of caustic medications.							
11	Nurses have resources for obtaining adequate IV access prior to vancomycin administration at all hours.							
12	Pharmacy maintains a stock of extravasation antidote medications (e.g., hyaluronidase).							

Medication Monitoring and Maintenance								
13	There is a standard process for ensuring the timely collection of vancomycin troughs or random levels.							
14	There is a standard process for ensuring the timely collection of serum creatinine samples.							

Factor 3: Health Information Technology								
Rationale: When designed, developed, implemented, and used appropriately, health information technology can increase medication safety by providing guidance and reminders throughout the medication process.								
		Safety Strategy Used?			**Frequency of Use**			
		Y	N	N/A	Never	Sometimes	Always	N/A
Medication Ordering								
1	Standardized order sets are used when ordering IV vancomycin.							
2	Standardized IV vancomycin order sets support stat, loading, and maintenance dosing.							
3	The electronic health record (EHR) supports the ordering of IV vancomycin outside of standard order sets under limited conditions, such as when therapy is being directly managed by infectious disease physicians.							
4	Vancomycin order sets include clinical decision support (CDS) for adjusting therapy for patients with severe renal dysfunction, including those dependent on dialysis.							
5	The EHR indicates the most recent patient weight in metric units (g/kg) and this is available at the time of ordering.							
6	The EHR notifies the ordering provider if a patient's weight was not verified during the current encounter.							
7	Standardized order sets require providers to document that they have reviewed the patient's current renal function.							
8	Unless vancomycin monitoring and dose adjustment are managed by your pharmacy, standardized order sets require providers to order a vancomycin trough and to designate timing of trough sample for patients with normal renal function.							
9	Unless vancomycin monitoring and dose adjustment is managed by your pharmacy, standardized order sets require providers to order and designate timing of a (random) vancomycin level for patients with severe renal dysfunction, up to and including dialysis dependence.							
10	Standardized order sets require providers to order and define the frequency for serum creatinine sampling.							
11	The EHR notifies pharmacy and nursing of the ordering of stat and/or loading doses of vancomycin.							
12	The eMAR is accessible to all clinicians across departments to support awareness of vancomycin dosing (e.g., ED, OR and dialysis medication administration record is interoperable with inpatient EHR software).							
13	The EHR alerts the admitting provider when a vancomycin dose is administered in the ED and no order is placed to continue therapy.							
14	There are EHR downtime contingencies that support the safe use of IV vancomycin.							

Medication Administration							
15	Nurses receive an automated reminder through barcode medication administration software, where available, to hold a specified dose until a vancomycin trough is obtained and results are reviewed.						
16	Smart IV pumps are programmed for safe vancomycin administration.						
17	There is a reliable process for updating and maintaining current drug libraries within smart pumps.						
Medication Monitoring and Maintenance							
18	The EHR notifies clinicians (including nursing, pharmacy, and ordering providers) if an ordered trough level is outside of therapeutic parameters.						
19	The EHR notifies clinicians (including nursing, pharmacy, and ordering providers) if an ordered serum creatinine is outside of therapeutic parameters.						
20	The EHR notifies clinicians (including nursing, pharmacy, and ordering providers) of a scheduled vancomycin dose delayed more than two hours.						

Assessment Tool References

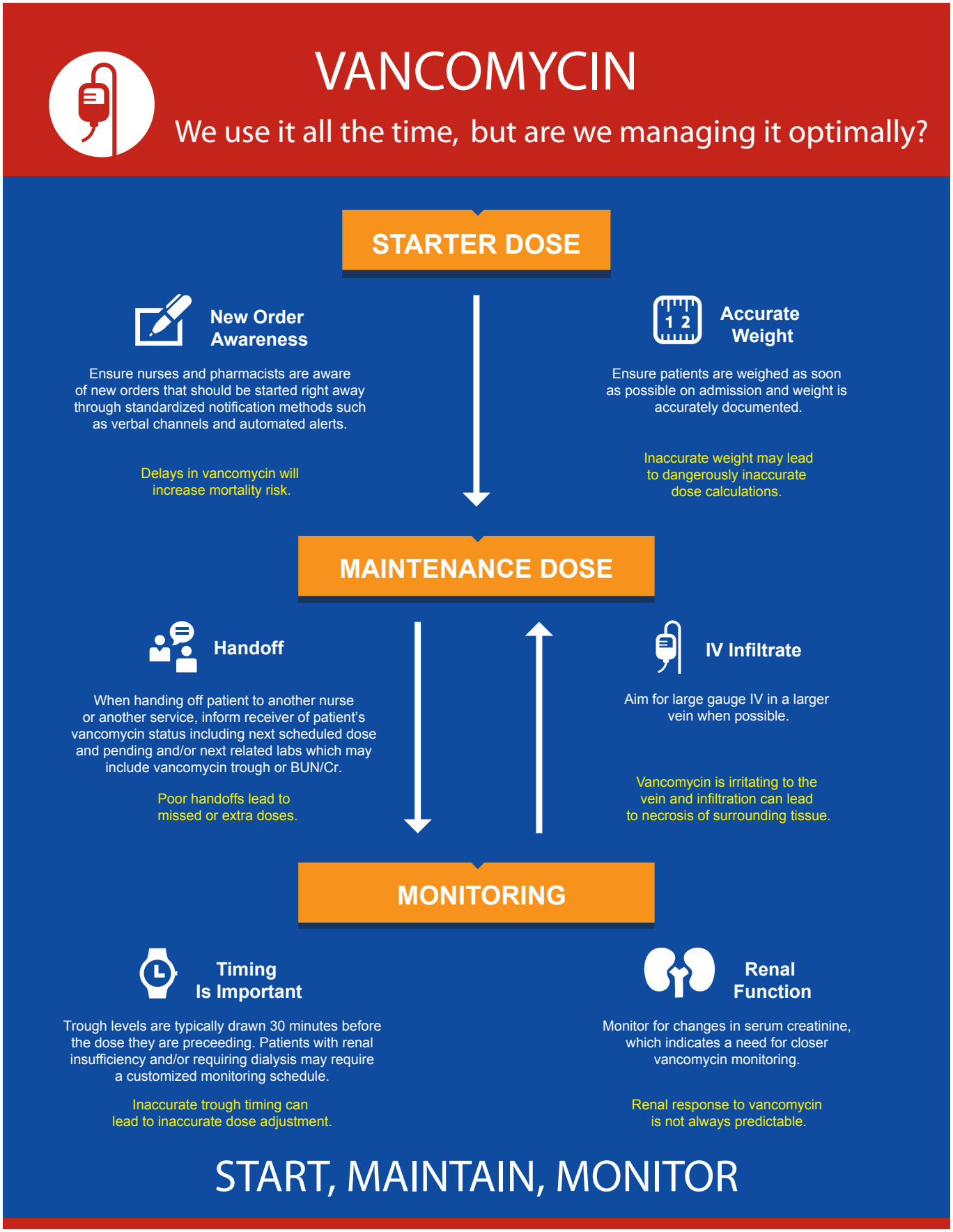
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Appendix B. IV Vancomycin Safety Infographic



Appendix C. Codebook with Categorization Label, Definition, and Example

Categorization Label	Definition	Example
Medication-Use Process		
Admission	The primary error occurred in the admission phase, including documentation of patient weight or documentation of current vancomycin therapy in home or a subacute care setting.	"During admission process, nurse incorrectly documented patient's weight in electronic health record as 131 kilograms instead of 131 pounds."
Ordering/Reviewing	The primary error occurred in the provider ordering or pharmacy reviewing phase.	"a second dose of Vancomycin was inadvertently ordered and administered to the patient 6 hours after the first dose."
Dispensing	The primary error or delay occurred in the pharmacy dispensing stage.	"IV vancomycin was ordered for sepsis prevention at 11:10 but was not available for administration until 13:30."
Administration	The primary error occurred in the administration phase.	"Nurse noted that the 10:00 dose of vancomycin was not signed off as being given by the nurse from the previous shift. Nurse confirmed that the medication was inadvertently omitted"
Monitoring	The primary error occurred in the monitoring of drug levels or of renal function.	"Vanc trough level ordered for 15:00 was not drawn until 17:30"
Discharge	The primary error occurred in the discharge phase.	"Patient was discharged with an order for 8 weeks of IV vancomycin via PICC. But, later learned that patient was not able to fill prescription and home health was not established."
Medication Error Types		
Improper Dose	Ordering, dispensing, or administering an improper dose, which may result in an overdose, underdose, or extra dose.	"Patient was on 1g of vancomycin Q24h which resulted in a trough of 11.4. As a result, dose was increased to 1500 mg Q24h. After receiving one dose of 1500 mg, order was erroneously changed to 2000 mg Q8h."
Dose Omission/Delay or Receipt of Partial Dose	An intended dose was not ordered, dispensed, or administered, or it was delayed or only partially infused.	"Additional 1g dose of vancomycin was ordered for 1030, for a total 2g dose. Additional dose was not administered."
Monitoring Error	Inadequate monitoring of therapy response, which may include monitoring delays or failing to monitor.	"Vancomycin level scheduled for 1600 was never drawn"
Wrong Rate	The wrong rate was ordered, dispensed, or administered (e.g., too fast or too slow).	"Vancomycin infusion was administered over 30 minutes instead of one hour. The bag was labeled as 500 mL but actually contained 250 mL."
Wrong Time	Medication administered outside of the clinically appropriate time window.	"Vancomycin was ordered to be given in EP lab but was administered while patient was still on the nursing unit."
Wrong Patient	Medication was ordered, dispensed, or administered to a different patient than was intended.	"Day shift nurse noticed that the vancomycin bag was labeled with another patient's name, birth date, and room number."

Categorization Label	Definition	Example
Contributing Factor Emerging Themes		
Care Coordination and Information Exchange		
Incomplete information flow	Report suggests necessary information was not effectively communicated to appropriate caregivers verbally or by other means, contributing to a breakdown in vancomycin therapy.	"Night shift nurse advised that no information regarding the vancomycin order was passed on from day shift"
Handoff	Report suggests challenge related to patient care handoff between different individuals or teams (e.g., OR, ED, shift change, transfer of unit, transfer from other hospital, etc.).	"Patient was received as a transfer from an outside hospital. Receiving hospital was not informed that vancomycin loading dose was ordered and administered prior to transfer."
Renal Function	Report suggests challenges related to adjusting vancomycin therapy for patients with renal impairment. This includes patients on dialysis and with acute or chronic kidney injury.	"After receiving dialysis treatment, it was discovered that patient was on vancomycin therapy."
Workflow		
Operating Room (OR) System	Report suggests challenge related to OR processes such as unanticipated adjustment in OR schedule affecting timing of prophylactic (preop) vancomycin.	"Nurse called the OR and confirmed that dose of Vancomycin, sent with patient, would be hung immediately following surgery."
Emergency Department (ED) System	Report suggests challenges related to ED processes such as standalone health information technology systems that don't integrate with inpatient computer physician order entry.	"Vancomycin dose ordered and administered in ED. Following admission, hospitalist service was unaware of prior dose and ordered an additional dose, which was administered, resulting in an extra dose to the patient"
Documentation		
Documentation	Report suggests challenges relating to documentation, such as patient weight error, progress note not matching medication orders, etc.	"Nurse inadvertently documented vancomycin administration in wrong patient's chart."
Appropriate Therapy Management		
Timing	Report suggests error relating to a time-sensitive process of vancomycin therapy.	"Vancomycin trough was ordered for 1730, prior to the 1800 dose. However, the lab was not drawn prior to administration."
Monitoring	Report suggests challenge related to monitoring of vancomycin blood levels.	"Vancomycin trough was drawn one hour before the next dose was due. Trough came back elevated, but vancomycin was already hung."
Intravenous (IV) Access	Report suggests challenge related to IV access that affects vancomycin therapy.	"IV access lost in the middle of vancomycin infusion. IV access was not able to be re-established until 4 hours later."