Ambulatory infusion adverse drug reaction (ADR) prevalence and workflow standardization

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OVERVIEW

- **Adverse Drug Reactions (ADRs):** Unintended, harmful responses distinct from expected side effects, following WHO definitions:[1]
  - **Mild:** Transient and requires no special treatment or intervention; infusion able to be continued
  - **Moderate:** Alleviated with simple therapeutic treatments; infusion able to be continued
  - **Severe:** Requires therapeutic intervention (will become classified as serious if hospitalization is required for treatment)
  - **Serious:** Results in any of the following outcomes: death, life-threatening condition, inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/ incapacity, or a congenital anomaly/birth defect
- **Current Challenge:** Implemented ADR SmartForm in 2019 to capture discrete data elements across home and alternate site infusion.[2] Variability in ADR reporting protocols across sites leads to inconsistent documentation, underreporting, and missed opportunities for quality improvement.
- **Workflow Gaps:** Differences in staff training, recognition, and management of ADRs hinder uniform patient safety practices.
- **Need for Standardization:** Unified ADR management and reporting protocols will improve data accuracy, facilitate trend analysis, and enhance patient safety outcomes.

OBJECTIVES

1. Identify trends in ADR reporting based on the current SmartForm

2. Develop standardized ADR documentation and management processes for our organization

METHODS

- **Design:** Post-implementation quality improvement project reviewing ADR SmartForm data (July 2019 – June 2025)
- **Inclusion Criteria:** ADR reports from home infusion and eight ambulatory infusion suites (AIS) actively using the SmartForm
- **Exclusion Criteria:** Two AIS sites pending SmartForm implementation; ADRs with ineligible missing documentation
- **Data Collected:** ADR severity, associated symptoms, interventions made, medication involved, method of communication with ordering prescriber, outcomes
- **Data Analysis:** Descriptive statistics to characterize ADR elements

RESULTS

Total of 106,169 encounters reviewed → 1,137 ADRs reported (1.1%) → 812 ADRs included in final analysis*

*325 ADRs excluded due to ineligible missing documentation (i.e., missing medication name and/or associated symptoms)

Table 1. ADR Severity

Severity	n (%)
Mild	464 (57.1)
Moderate	307 (37.8)
Severe	29 (3.6)
Serious	12 (1.5)

Table 2. Associated Symptoms

Symptom	n (%)**
Other/Unknown	661 (81.4)
Rash/Hives	115 (14.2)
Nausea	54 (6.7)
Shortness of breath/Dyspnea	51 (6.3)
Headache	25 (3.1)
Vomiting	22 (2.7)
Tinnitus/Ringing in ears	17 (2.1)
Chills	16 (2)
Pain	11 (1.4)
Fever	8 (1)
Red Man Syndrome	6 (0.7)
Diarrhea	4 (0.5)
Blurred Vision	3 (0.4)
Syncope/Unconsciousness	2 (0.2)

Table 3. Interventions Made

Intervention	n (%)**
Adjunctive treatment administered	391 (48.2)
Provided additional teaching/education	313 (38.5)
Other	117 (14.4)
Dose held	80 (9.9)
Therapy discontinued	65 (8)
Referred to Emergency Department for evaluation	30 (3.7)
Therapy changed	25 (3.1)
Unplanned hospitalization	4 (0.5)
Unscheduled nursing visit performed	2 (0.2)
Unscheduled labs drawn	1 (0.1)

Table 4. Most Reported Medications with ADR

Medication	n (%)
Ocrelizumab	384 (47.3)
Rituximab and biosimilars	201 (24.8)
Infliximab and biosimilars	48 (5.9)
Iron products	46 (5.7)
IVIg products	31 (3.9)
Other (e.g., mAbs, antibiotics, chemotherapy)	102 (12.6)

Table 5. Method of Communication with Ordering Prescriber

Method of Communication	n (%)**
Via electronic health record	353 (43.5)
Secure chat message	226 (27.8)
Routing patient chart	91 (11.2)
Unable to be determined	36 (4.4)
Email	253 (31.2)
Phone	124 (15.3)
Face to face	71 (8.7)
Verbal	58 (7.1)
Unable to be determined	7 (0.9)
Fax	1 (0.1)

Table 6. Outcomes

Outcome	n (%)**
Continuation of therapy with no interruption	536 (66)
Interruption of clinical services	114 (14)
Other	85 (10.5)
No documentation	59 (7.3)
Infusion services discontinued	13 (1.6)
Infusion services continued at site other than home (infusion only)	5 (0.6)

Time Spent on ADR
- Mean: 44 min (SD 76 min)
- Median: 30 min (IQR 25-46 min)

**Note: Total is greater than 100% due to selection of multiple symptoms.

DISCUSSION & APPLICATION OF RESULTS

- **Inconsistent Documentation and Workflows:** ADR documentation and workflows varied across AIS sites and home infusion settings.
- **Clinical Relevance:** Most ADRs were mild/moderate, but severe/serious events highlighted need for consistent protocols.
- **Documentation Gaps:** Overuse of "Other/Unknown" and missing fields limited data quality.
- **Original SmartForm Limitations:** Original design lacked specificity for high-frequency symptoms and interventions.
- **SmartForm Updates Made:**
  - Automatically classifying the ADR severity
  - Reordering symptom fields by prevalence and grouping related symptoms (e.g., fever with chills/rigors)
  - Adding high-frequency symptoms: itching, flushing, swelling
  - Removing low-prevalence symptoms: diarrhea, blurred vision
  - Reordering interventions and removing unused fields
  - Refining communication methods to allow for discrete selection
- **Implications:** Standardized documentation will improve accuracy, enhance care coordination, and reduce variability in ADR reporting.
  - Development of new standard operating procedure (SOP) to support consistent implementation across AIS and home locations currently underway

NEXT STEPS

1. Educate staff (pharmacy, nursing, providers) on SmartForm updates, standardized workflows, and new SOP.

2. Track ADR prevalence, documentation accuracy, and workflow adherence post-implementation of new SmartForm.

REFERENCES

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DISCLOSURES

The authors have nothing to disclose.