

# Resource Utilization of Pediatric Patients Exposed to Venom

## abstract

**BACKGROUND AND OBJECTIVE:** Treating envenomation with antivenom is costly. Many patients being treated with antivenom are in observation status, a billing designation for patients considered to need care that is less resource-intensive, and less expensive, than inpatient care. Observation status is also associated with lower hospital reimbursements and higher patient cost-sharing. The goal of this study was to examine resource utilization for treatment of envenomation under observation and inpatient status, and to compare patients in observation status receiving antivenom with all other patients in observation status.

**METHODS:** This was a retrospective study of patients with a primary diagnosis of toxic effect of venom seen during 2009 at 33 freestanding children's hospitals in the Pediatric Health Information System. Data on age, length of stay, adjusted costs (ratio cost to charges), ICU flags, and antivenom utilization were collected. Comparisons were conducted according to admission status (emergency department only, observation status, and inpatient status), and between patients in observation status receiving antivenom and patients in observation status with other diagnoses.

**RESULTS:** A total of 2755 patients had a primary diagnosis of toxic effect of venom. Of the 335 hospitalized, either under observation ( $n = 124$ ) or inpatient ( $n = 211$ ) status, 107 (31.9%) received antivenom. Of those hospitalized patients receiving antivenom, 24 (22.4%) were designated as observation status. Costs were substantially higher for patients who received antivenom and were driven by pharmacy costs (mean cost: \$17 665 for observation status, \$20 503 for inpatient status). Mean costs for the 47 162 patients in observation status with other diagnoses were \$3001 compared with \$17 665 for observation-status patients who received antivenom.

**CONCLUSIONS:** Treatment of envenomation with antivenom represents a high-cost outlier within observation-status hospitalizations. Observation status can have financial consequences for hospitals and patients.

## INTRODUCTION

Venomous snakes are indigenous throughout the United States, with the exceptions of Maine, Alaska, and Hawaii.<sup>1</sup> The American Association of Poison Control Centers' National Poison Data System reported >6600 snake bite/envenomation exposures in 2011, more than one-third of which involved children and adolescents aged <20 years.<sup>2</sup> Of those exposed, ~79% sought treatment at a health care facility. Children often present with more severe symptoms of envenomation than adults because snakes deliver the same amount of venom regardless of the victim's size.<sup>1,3</sup>

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## KEY WORDS

billing, envenomation, observation status, pediatrics, reimbursements, resource utilization

## ABBREVIATIONS

CI: confidence interval

CMS: Centers for Medicare & Medicaid Services

ED: emergency department

LOS: length of stay

PHIS: Pediatric Health Information System

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Treatment of envenomation can range from local wound care in mild cases to hospitalization and administration of multiple doses of antivenom in more severe cases.<sup>4,5</sup> When indicated, treatment with antivenom requires close patient monitoring to respond to potential anaphylaxis.<sup>1</sup> Many forms of antivenom, including that for snake bites, are very expensive. Although some of the treatment costs may be absorbed by the hospital, patients have encountered very large hospital bills as a result of receiving various types of antivenom therapy.<sup>6-8</sup> However, few studies have addressed the treatment burden associated with envenomation cases or the impact of the designated medical service type on resource utilization and costs.

The Centers for Medicare & Medicaid Services (CMS) coined the term “observation status” to describe patients not meeting inpatient Diagnosis Related Group criteria and deemed by payers to be in a state of clinical decision-making between discharge-to-home and admission-to-inpatient status.<sup>9</sup> They defined the care a patient receives while in observation status as a set of services delivered “before a decision can be made regarding

whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital.”<sup>10</sup> Because patients in observation status have not officially been admitted to the hospital, the care they receive in emergency departments (EDs) or in the hospital is considered outpatient care and is commonly reimbursed at lower rates than care provided to patients with an inpatient status, as observation-status care is presumed to be less resource-intensive.<sup>11</sup> Antivenom treatments followed by ongoing care (including being observed for complications)<sup>12</sup> in inpatient units could be designated as “observation status” or as “inpatient status,” with different implications for patients and hospitals in terms of billing and reimbursements (Table 1).

Given the potential financial implications associated with antivenom administration for both hospitals and patients, the present study sought to examine the resource utilization associated with treatments of pediatric envenomation under observation status compared with inpatient status in freestanding children’s hospitals in the United States. The objectives were to analyze the characteristics

of patients treated for envenomation under observation status and inpatient status, and to compare patients in observation status for envenomation versus all other patients cared for under observation status. We hypothesized that patients who received antivenom would have higher costs than patients who did not receive antivenom, and that costs would be lower for patients who received antivenom under observation status compared with patients who received antivenom under inpatient status.

## METHODS

### Data Source

This retrospective, cross-sectional study used resource utilization data from 33 freestanding tertiary care children’s hospitals that contribute data to the Pediatric Health Information System (PHIS). Participating hospitals are located in noncompeting markets in 27 states and Washington, DC, and are affiliated with the Children’s Hospital Association (Overland Park, KS). The PHIS database includes inpatient, ED, ambulatory surgery, and observation data from participating hospitals. The data warehouse function for PHIS is managed by Truven Health Analytics (Ann Arbor, MI). For external

**TABLE 1** Definitions

Observation status	A billing designation applied prospectively or retrospectively to patients who do not meet predetermined criteria for inpatient-status reimbursement. Originally intended for stays no longer than 24 to 48 h, during which time a decision to admit or discharge was made.
Observation unit	An area designated for patients expected to require <24 h of evaluation and management to determine their need to be admitted as inpatients or their readiness for discharge from the hospital.
Carve-out reimbursement	Specific services (eg, high-cost drugs) that may be separated from per diem or case-based reimbursements due to the special circumstances of these services.
Per diem reimbursement	Payer reimburses the hospital a fixed amount for each day a member patient is hospitalized.
Case-based reimbursement	Payer reimburses the hospital for each discharged inpatient at rates prospectively established for groups of cases with similar clinical profile and resource requirements.
DRGs	Classification scheme that provides a means of relating the type of patients a hospital treats; although all patients are unique, groups of patients have common clinical characteristics that determine their resource needs. DRG-based payments use DRGs as the basis for case-based reimbursement.
Percentage of charges (or discount off charges) reimbursement	Payer reimburses the hospital a negotiated percentage of the total charges incurred in caring for the patient.

DRGs, diagnosis-related groups.

benchmarking, participating hospitals provide discharge/encounter data, including demographic characteristics, diagnoses, and procedures, as well as resource utilization data such as pharmaceutical, imaging, and laboratory costs. Charges for antivenom treatments are recorded in the database as specific supply charges associated with the number of whole antivenom vials used. All charges were converted to estimated costs by using hospital and departmental specific ratios of cost to charges. The database also indicates whether a patient spent time in an ICU. Data are de-identified before inclusion in the database, but encrypted medical record numbers allow for longitudinal tracking of individual patients across admissions. Data are also subjected to reliability and validity checks before inclusion in the database.<sup>13</sup>

In accordance with the Common Rule (45 CFR 46.102(f)) and the policies of The Children’s Hospital of Philadelphia institutional review board, this research, which used a de-identified data set, was not considered human subjects research.

**Study Participants and Treatments**

Patients seen in and/or admitted from an ED in the 33 pediatric hospitals in calendar year 2009 with a primary diagnosis of toxic effect of venom (*International Classification of Diseases, Ninth Revision, code 989.5*)<sup>1</sup> were included in the study. This code includes bites of venomous snakes, lizards, spiders, scorpions, marine animals, and tick paralysis. Our analyses focused on patients who received Crotalidae Polyvalent Immune Fab (CroFab) for crotaline snake bites.

**Data Analysis**

We described patient characteristics, including age, gender, race, and payer,

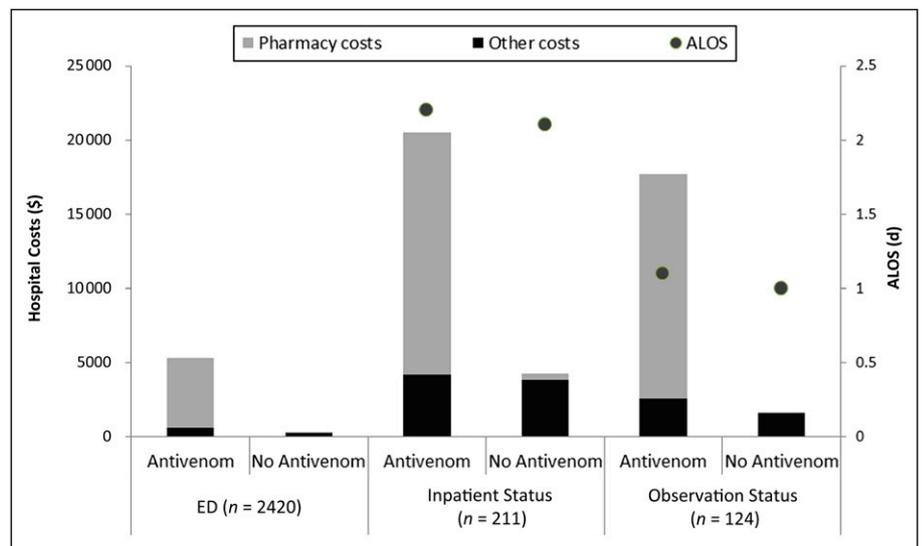
as well as hospital resource utilization characteristics, including length of stay (LOS), antivenom utilization, total costs, and costs grouped by category (eg, pharmaceutical, imaging, laboratory). To obtain costs, all charges were converted to costs according to hospital-specific ratios of costs to charges and adjusted for geographic region by using the CMS wage index.<sup>14</sup> Comparisons were conducted: (1) by patient admission status (ED only, observation status, or inpatient status); and (2) between patients in observation status who received antivenom and patients in observation status for any other type of diagnosis or treatment. Statistical analysis was performed by using SAS version 9.2 (SAS Institute, Inc, Cary, NC), and *P* values <.05 were considered statistically significant.

**RESULTS**

In 2009, a total of 2755 patients in the 33 hospitals had a primary diagnosis of toxic effect of venom. Of these, 2420 (88%) were treated and released

from the ED, including 4 (0.17%) who received antivenom. The remaining 335 were hospitalized under observation (*n* = 124) or inpatient (*n* = 211) status. Of the hospitalized patients, 107 (31.9%) received antivenom. In total, 64 patients received care in an ICU (2 observation status, 62 inpatient status). Of the 64 patients treated in an ICU, 42 (65.6%) received antivenom. All 42 patients who received antivenom in an ICU were in the inpatient-status group.

Of the 107 patients who received antivenom in the hospital, 24 (22.4%) were assigned an observation status. Antivenom was administered on day of arrival (day 0) for 97 patients, and on day 1 for 10 patients. Average LOS for observation-status patients was shorter than inpatient-status patients (~1 vs 2 days), but differences were not observed within each hospitalization category based on administration of antivenom (Fig 1). Patients who received antivenom were seen



**FIGURE 1** Average hospital costs for non-ICU patients with toxic effect of venom treated in ED only, as inpatient status, or as observation status. The bars indicate average costs according to patient grouping, split for pharmacy costs versus all other costs. Box dots refer to average LOS (ALOS) for each patient type among those hospitalized in inpatient or observation status.

at 22 different hospitals representing all regions of the country except the Pacific Northwest and New England: 88 (79.3%) in the south, 5 (4.5%) in north-central regions, and 18 (16.2%) in the west.

**Comparison of Antivenom Recipients Across Admission Status**

Costs were substantially higher for patients who received antivenom, regardless of hospitalization status (ED only, observation, or inpatient) (Fig 1), and the preponderance of costs was for pharmacy. Mean pharmacy costs for those who received antivenom in observation status was \$15118 (95% confidence interval [CI]: 10304–19931), whereas those in inpatient-status had mean costs of \$16300 (95% CI: 13666–18933).

Among patients who received antivenom, the number of vials received ranged from 1 to 42, with an average of 7.2 and a median of 16.5. Table 2 presents patient hospitalization status and resources used. For observation-status patients who received antivenom, mean costs were \$17665 (95% CI: 12292–23037), whereas observation-status patients with envenomation diagnoses who did not receive antivenom had mean costs of \$1683 (95% CI: 1444–1921) ( $P < .001$ ).

**Comparison of Antivenom Recipients With All Other Observation-Status Patients**

A total of 47286 patients across all diagnoses were assigned to observation status in 2009; 47162 had diagnoses other than toxic effect of venom. The total costs for patients in observation status with diagnoses other than envenomation averaged \$3001. Mean total costs for patients in observation status who received antivenom was

**TABLE 2** Costs, Vials Used, and LOS According to Patient Hospitalization Type

Billing Status	ED Only		Inpatient		Observation		All
	Antivenom Received	No Antivenom	Antivenom Received	No Antivenom	Antivenom Received	No Antivenom	
No. of cases	4	2416	83	128	24	100	2755
Mean ± SD costs, \$	5339 ± 3799	224 ± 194	20503 ± 13208	4224 ± 3883	17665 ± 13856	1683 ± 1244	1218 ± 4721
Median costs (IQR), \$	4793 (2905–7773)	168 (113–285)	16168 (10922–26491)	2779 (1674–5209)	13512 (8572–23066)	1426 (1003–2013)	187 (116–348)
Mean ± SD pharmacy costs, \$	4748 ± 3977	10 ± 28	16300 ± 12210	402 ± 579	15118 ± 12413	108 ± 110	656 ± 3912
Median pharmacy costs (IQR), \$	4364 (2157–7340)	1 (0–8)	13418 (8830–21131)	191 (103–460)	12011 (7125–21170)	76 (22–153)	2 (0–16)
Mean pharmacy costs as % total mean costs	88.9%	4.4%	79.5%	9.5%	85.6%	6.4%	53.8%
Mean (median) vials of antivenom received	2.8 (2); range 1–4	–	All: 7.3 (17); range 1–28 Non-ICU: 6.3 (18.5); range: 1–22 ICU: 8.4 (12); range: 1–28	–	7.4 (22); range: 1–42	–	7.2 (16.5); range: 1–42
Mean ± SD LOS, d	1.0 ± 0.0	1.0 ± 0.0	2.2 ± 1.4	2.1 ± 1.7	1.1 ± 0.3	1.0 ± 0.2	1.1 ± 0.5
LOS, median (IQR), d	1.0 (1.0–1.0)	1.0 (1.0–1.0)	2.0 (1.0–3.0)	1.0 (1.0–3.0)	1.0 (1.0–1.0)	1.0 (1.0–1.0)	1.0 (1.0–1.0)

–, not applicable; IQR, interquartile range. All costs based on ratio of costs to charges and adjusted for region with the CMS wage index.<sup>14</sup>

\$17 665, and median total costs were \$13 512. These costs were substantially higher than the mean  $\pm$  SD (\$3572  $\pm$  \$4363), median (\$2445 [interquartile range: \$1517–\$4004]), and 99th percentile (\$9831) costs for all other observation-status patients not receiving antivenom. Pharmacy costs for the antivenom observation-status patients averaged \$15 118 (Table 2), which was substantially higher than the 99th percentile of pharmacy costs for all other observation-status patients (\$952). Among observation status patients with diagnoses other than toxic exposure to venom, 99% had LOS  $\leq$  2 days.

## DISCUSSION

We present a resource utilization study of the receipt of antivenom among children evaluated in the ED and treated at freestanding children's hospitals for envenomation. Regardless of designation as observation or inpatient status, children treated for envenomation with antivenom consume high-cost therapies. In 2007, ~44% of envenomation cases reported to US poison centers were treated with antivenom, compared with 30% in 2000.<sup>5,15</sup> This trend is noteworthy given our finding that care for envenomation when antivenom is administered represents an unusually high-cost service among observation-status hospitalizations. The bulk of costs from envenomation treatment results directly from the administration of antivenom. Pharmacy and other costs associated with antivenom treatment and observation-status stays were significantly higher compared with observation-status stays for all other diagnoses combined.

The high costs associated with treatment of envenomation result largely from the antivenom supply chain. Crotalidae Polyvalent Immune Fab

(CroFab), which is widely used in the United States to treat crotaline envenomation, is a purified preparation of sheep Fab immunoglobulin fragments that have been hyperimmunized with venom from 4 species of pit vipers.<sup>16</sup> It is made by a complex 3-continent supply chain, and the retail price in 2013 was approximately \$4700 for a 2-vial pack.<sup>17</sup>

The range of treatment settings, from ED discharge to ICU hospitalization, and the range in costs may reflect that the effects of envenomation can vary from mild local reactions to life-threatening systemic disease. The severity of a reaction to envenomation depends on the snake species, the quantity of venom injected, and patient characteristics (including age, size, and health status).<sup>1,18</sup>

CMS' original intent when introducing "observation status" was to differentiate between patients needing inpatient care and patients who needed low-resource care while clinicians decided whether admission to inpatient status was required.<sup>19</sup> Treatment of envenomation with antivenom, which requires resource-intensive care with close monitoring for a brief period of time, does not fit these criteria: it is treatment for a known injury, not treatment provided while clinicians determine whether admission is warranted.<sup>12</sup> Despite the fact that envenomation, when treated with antivenom, requires high-resource utilization and monitoring, 22% of patients who received antivenom were coded as observation status.

This finding is particularly noteworthy because observation status is also a billing designation associated with lower hospital reimbursements relative to inpatient status.<sup>20,21</sup> Consequently, medical services associated with

envenomation may receive lower reimbursement due to an observation-status designation even if there is no significant difference in the treatment and resources used relative to inpatient status. Without an appropriate reimbursement mechanism (or a high-cost medication carve-out), hospitals may not be fully reimbursed for the costs of treating patients for envenomation. The assumption is that treating patients in observation status is less resource-intensive,<sup>11</sup> but in practice, this notion is not always true. Providers caring for observation-status patients often are not even aware of their patients' designation and do not differentiate them from their inpatient-status patients.<sup>22,23</sup>

Observation status is determined by payers, typically using criteria provided by InterQual<sup>24</sup> and Milliman,<sup>25</sup> which differ from each other and add to the inconsistency. Although the present study cannot determine how or why certain patients were assigned to observation status, the fact that patients receiving antivenom are consuming high-resource, high-cost treatments raises questions about the appropriateness of this billing designation for these patients. Inconsistent application of billing status may lead to patients of the same complexity and resource utilization being coded as observation status in one hospital and inpatient in another. This inconsistency may even exist between patients treated with antivenom in the same hospital.

The inconsistent use of the observation-status designation is also concerning because observation-status billing can expose patients to greater responsibility for payment.<sup>26</sup> Although patients without insurance or without adequate insurance will undoubtedly be exposed to extremely large bills due

to the high cost of treatment,<sup>6,7</sup> observation status may put even insured patients at risk for higher cost-sharing. Observation-status care is considered outpatient care for billing purposes, and patients receiving this designation may therefore be responsible for the higher cost-sharing as opposed to the lower cost-sharing for inpatient care.<sup>11,27</sup> Thus, a higher proportion of treatment costs may be passed on to families of patients in observation status.<sup>21,28</sup> This scenario is especially true for families with insurance plans that require patients to pay a fixed percentage of total costs for outpatient services compared with a flat rate for inpatient care. These cost-sharing differences may not be commensurate with the difference, if any, in treatments received.

Observation-status care for billing is not the same as the important clinical practice of observing patients for disease progression or response to therapy; it is also not the same as care provided in an observation unit. Patients in an observation unit may not be designated as observation status for billing purposes.<sup>23</sup> Although observation unit care may be an effective setting to care for some pediatric patients exposed to poisons of a nonvenomous nature,<sup>29</sup> observation status does not seem to be an appropriate billing designation for patients being treated with antivenom. Although these patients may spend only a short time in the hospital, the receipt of antivenom includes high levels of resource utilization, particularly in terms of the purchase price of the treatment and the need for subsequent monitoring of response to therapy; it is not a state of decision-making. Thus, this classification for these patients seems counter to the original intention of observation status.<sup>28,30</sup> In addition to the unintended

consequences related to higher financial burdens for hospitals, clinicians, and patients, there are also increased inefficiencies as clinicians and administrators must spend time communicating with payers to justify coding status and obtain commensurate reimbursements.

Toxicologists and hospitalists providing observation care for envenomation may benefit from investigating their local reimbursement patterns (Table 1). The divergence between clinical resource and monitoring intensity and billing designation requires attention, especially because treatment can be lifesaving despite it being a brief intervention. Although observation-status patients are supposed to have lower-resource utilization, antivenom treatment demonstrates that this assumption is not always the case. Our finding is consistent with other work demonstrating that observation status does not necessarily reflect lower resource utilization than inpatients with similar conditions and severity of illness.<sup>21</sup>

This analysis has several limitations. First, because the hospitals included are freestanding children's hospitals, the findings may not be generalizable to other settings. Although these hospitals represent 33 of the 50 freestanding children's hospitals in the country, many snake bites are likely treated in community and rural hospitals where practices, status designations, and billing structures may differ. Second, coding errors related to diagnosis, admission type, and dates of admission or discharge would affect the results. It is hard to estimate the direction of bias, as miscoding could lead to the appearance of higher or lower LOS and/or charges, although there is no obvious reason why this outcome would be more likely in patients designated as

observation status versus inpatient status. Third, we have limited information about the use of coding practices at each hospital. If hospitals do not have payers that recognize observation status, fewer admissions may be categorized that way. Similarly, although there is evidence that outpatient cost-sharing is higher than inpatient cost-sharing, the degree to which this is the case will differ according to insurance company and insurance plan. Because we do not have access to individual patients' bills, we must rely on general trends. Finally, we used ratio of costs to charges to obtain costs to serve as a proxy for patients' clinical needs, but these ratios do not represent true costs to hospitals, payers, and families.

## CONCLUSIONS

Treatment of envenomation with antivenom represents an unusually high-cost encounter among observation-status hospitalizations. Whether designated as observation status or inpatient status, these patients receive high-cost therapy, albeit for a brief time. Despite the therapy being the same, patients in observation status are likely exposed to a higher degree of cost-sharing, and hospitals receive lower reimbursements for care provided. Thus, the observation-status designation for patients being treated for envenomation may be unwarranted.

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