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VARIATION IN POST EXPOSURE PROPHYLAXIS OF RABIES IN PATIENTS PRESENTING WITH AN ANIMAL EXPOSURE TO THE PENN STATE HERSHEY EMERGENCY DEPARTMENT

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ABSTRACT

Rabies infection is caused by the RNA virus, *Lyssavirus Rhabdoviridae*. Rabies leads among infectious diseases in mortality by victimizing an estimated 40,000 – 60,000 people globally every year. There is no standard protocol for patients presenting with an animal exposure and suspected rabies infection to the emergency department. Routine treatment for animal bites includes cleaning and irrigation of the wound, debriding the wound, imaging for residual matter, and suturing followed by a tetanus booster and antibiotics. Rabies PEP is administered on a case-by-case basis. The Penn State Hershey Medical Center Emergency Department currently issues rabies post exposure prophylaxis at a rate of eleven times that of the national average of actual cases of rabies per year. Few studies have been conducted regarding the variation among emergency medicine providers as compared to the Advisory Committee of Immunization Practices. This study aims to detect variation between providers and their adherence to Advisory Committee Immunization Practice guidelines in patients presenting to the Penn State Hershey Medical Center Emergency Department for a complaint of an animal exposure between January 1, 2011 and January 1, 2016. Participant charts were reviewed and data was abstracted according to four collection instruments specific to patient demographics, the involved animal, wound care, and rabies post exposure prophylaxis compliance. The data was analyzed (n = 400) as a binary outcome variable and the probability of a "yes" event (provider adherence to the ACIP protocol) was estimated along with its 95% confidence interval. Of the 400 patients examined, providers disagreed with the ACIP directives at a rate of 13%, in which an important discrepancy was error in immunoglobulin dosage.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

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Chapter 1. INTRODUCTION

Rabies infection is a fatal, zoonotic infectious disease caused by the RNA virus *Lyssavirus Rhabdoviridae*.[1-3] Rabies leads among infectious diseases in mortality by victimizing an estimated 40,000 – 60,000 people globally every year.[4] In the US, rabies is aggressively controlled by veterinary vaccination programs, laboratory diagnostics and prevention programs at a national cost of $300,000,000.00 annually, leaving the majority of exposures to encounters with wildlife.[4] Humans are at risk of contracting rabies from animal bites, scratches, aerosols and handling of infected tissues.[2] Incubation of the virus can occur in a few days or lay dormant for several years.[1-3] Upon infection, the virus disseminates from the inoculation site to the peripheral nervous system, where it uses the sensory and motor neurons to access the spinal cord and brain for further spread to the organ systems.[2] Persons that become infected with rabies are in need of immediate prophylaxis.

In the United States, an average of 23,000 potential cases of rabies are seen across the nation in which 80% of the caseload fall on the shoulders of private practice.[3,4,6] In the last 35 years, the US mortality rate for rabies infections has maintained at 2-4 deaths per year.[3]

There is no standard protocol for patients that present with an animal exposure and suspected rabies infection to the emergency department (ED). Routine treatment for animal bites includes cleaning and irrigation of the wound, imaging for residual matter, debridement and sutures, tetanus booster and possibly antibiotics.[1,2,4,5] Wound cleaning varies between water, saline, betadine, chlorhexidine, or a dilution of water or saline with soap or hydrogen peroxide.[4,5] Antibiotic therapy is at the discretion of the provider however patients that demonstrate the high-risk conditions of immunosuppression, diabetes or signs of infection, are

routinely prescribed antibiotics.[4] The Advisory Committee on Immunization Practices (ACIP), a working group under the Centers for Disease Control (CDC), provides guidelines for providers to decide if a patient is in need of rabies post exposure prophylaxis (RPEP).

Prophylaxis for rabies is an intramuscular vaccine of human diploid cell vaccine (HDCV) or purified chick embryo cell vaccine (PCECV) at a dose of 1 mL, administered in the deltoid on days 0, 3, 7 and 28.[1-4] Small children may also receive this medication in the thigh muscle, however it should never be issued in the gluteal muscles.[1,2,4]

Passive immunization of human rabies immunoglobulin (HRIgG) is administered into the wound site at the formulated dosage of 20 IU/kg of body weight.[1,2,4] This dose is to be exact in amount for the patient to receive enough HRIgG to neutralize the rabies antigen without impeding immune response. HRIgG and vaccine should never be administered near the same site or using the same syringe to avoid neutralization of the vaccine.[1,2,4]

The Penn State Hershey Medical Center Emergency Department (PSHMC-ED) was queried using Informatics for Integrating Biology at the Bedside, I2B2 (Partners Healthcare) to determine the current prescription rate of RPEP. Two queries were designed to assess the amount of available data for this study between January 2011 and January 2016. An estimated 1429 patients presented to the emergency department for an animal exposure as identified by ICD9 and ICD 10 billing codes. During a second query, billing codes specific to RPEP were integrated, which narrowed the patient count to 155. The data indicated that 11% of patients that presented to the PSHMC-ED with a complaint of an animal exposure, received RPEP. The national average of rabies cases in humans is 0.00007%.[1,2,4,6] Over-prescription of rabies PEP burdens patients with undue pain, cost, and the inconvenience of multiple clinic visits. Each

completed course of RPEP has the potential to deplete the national supply of rabies vaccine by four doses.

Few studies have been conducted regarding the variation among emergency medicine providers as compared to the ACIP guidelines in treatment for animal exposures and RPEP. Jerrard investigated the administration of rabies immune globulin after the new guidelines of 1992 were adapted, in which a large number of patients were found to be receiving inappropriately administered treatment of human rabies immunoglobulin.[7] Moran investigated the overuse of rabies PEP with findings that providers and patients would benefit from restructured guidelines.[8] Dubnov examined the compliance of guidelines for rabies PEP in Israel, where they found that using a committee of trained faculty to determine whether or not a patient should have RPEP based on their department of health (DOH) guidelines proved an adherence rate of nearly 100% after examining almost 2500 patients.[9]

This study aimed to detect variation of treatment between providers and the ACIP directives regarding prescription of RPEP. Demographic predictors of RPEP and qualitative analysis of treatment served as a secondary analysis.

Chapter 2. METHODS

2.1 Patient Sample

Inclusion Criteria

Participants for this study were of any demographic, that presented to the PSHMC-ED for a complaint of an animal exposure between January 1, 2011 and January 1, 2016. All patient

records with a documented ICD9 diagnostic code of E906.5, E906.3, E906.9, E906.8, E906.0, V04.5, 071, 99.44, V01.5 or an ICD 10 diagnostic code of: W54.0XXA, W54.0XXS, W54.0XXD, W54.8XXA were included in the study. Persons that received any one of the four administered vaccination doses, booster, or RHIgG were included. Patients that were requested to return to the PSHMC-ED by the Department of Health (DOH) or recalled by the provider due to a quarantined or euthanized animal with a positive rabies examination, were included.

Exclusion Criteria

Patients were omitted upon any of the following exclusion criteria: lack of an ICD 9 diagnostic code of: E906.5, E906.3, E906.9, E906.8, E906.0, V04.5, 071, 99.44, V01.5 or ICD 10 diagnostic code of: W54.0XXA, W54.0XXS, W54.0XXD, W54.8XXA, T14.8; complaints involving arthropods, arachnids or other insects; patients transferred from an outside institution, due to incomplete documentation in the Penn State Health system; animal encounters that did not involve a bite, scratch, salivary or aerosol exposure; complaint of being trampled, thrown, or stampeded by livestock that did not also involve a bite, scratch or salivary exposure; and patients that returned due to cellulitis or a non-rabid infection secondary to initial treatment.

Consent

Patient consent for this study was waived and approved for data abstraction by the Penn State Institutional Review Board. No patient care was affected over the course of this study and no additional patient care regarding this study is expected from the participants.

2.2 Data Collection

Participant charts were reviewed and data was abstracted into a secure dataset in Research Electronic Data Capture (REDCap). REDCap is a secure, web-based application designed to support data capture for research studies, providing an intuitive interface for validated data entry; audit trails for tracking data manipulation and export procedures; automated export procedures for seamless data downloads to common statistical packages; and procedures for importing data from external sources.[10] Four instruments were designed to collect the data. Demographics of the patients included an assigned subject number, date of visit, medical record number (MRN), age, sex, race, ethnic background, and county. Data collected on the animal included animal type, provocation, rabies vaccination status, socialization status, and ownership of the animal. Data collected on wound care included type of provider, where the incident occurred, type of animal exposure, body region affected, wound cleaning, status of tetanus shot, antibiotics administered and documentation of a DOH animal bite form in the chart. Data concerning rabies PEP directives used the ACIP guidelines (Figure 1) to classify what the ACIP recommended for that particular patient versus what the provider chose for treatment. Data was also collected on the custody of the animal post the exposure, previous vaccination of the patient for rabies, whether or not the provider suggested the patient postpone treatment for a ten-day quarantine of the animal, whether or not the patient received any type of RPEP, administration of RPEP, and patient follow up to finish the series of shots. All data in this chart review are strictly retrospective and were finalized in the medical record prior to data abstraction.

Rabies postexposure guidelines

Type of animal	Observation or testing of animal	Postexposure prophylaxis recommendations
Dogs, cats, and ferrets	Rabid or suspicion of rabies	Immediately begin prophylaxis
	Healthy and available for 10 days observation	Do not begin prophylaxis unless: Bite or non-bite exposure is to the head and neck OR Animal develops signs of rabies
	Unavailable for observation or testing	Consult public health officials; consider immediate vaccination
Raccoons, foxes, skunks, coyotes and other carnivores; bats	Consider rabid unless available for testing and proven not to be infected	Consider immediate vaccination
Large rodents, small rodents, livestock, lagomorphs and other mammals	Consider on an individual basis	Consult public health officials
Non-mammals	Do not harbor rabies	Prophylaxis **never** required

UpToDate®

Figure 1. ACIP guidelines for determining rabies post exposure prophylaxis [13]

2.3 Statistical Analysis

The dependent variable was binary (yes or no) and is the comparison of the APIC guidelines with the treatment that the patient received and whether the APIC recommendations were followed. A control group was not used.

The data were analyzed (n = 400) as a binary outcome variable and the probability of a "yes" event (provider adherence to the ACIP protocol) was estimated along with its 95%

confidence interval. The minimum sample size of 400 provided a 95% confidence interval with a precision of ± 0.1. Secondary analysis was performed in SAS 9.4 using logistic regression to detect if any of the independent variables were predictors of whether or not the APIC guidelines were followed.

Chapter 3. RESULTS

3.1 Demographics

Women (54%) accounted for more animal exposures than men (46%). Patient ages ranged from under a year to 90 years with a mean age of 29 and a median of 27 years. Age reflected that of the patient at the time of the ED visit as documented by the provider in the summary notes, and not the age listed at present day in the medical record.

Age groups were stratified into eighteen-year increments in order to isolate minors under eighteen years old. Age grouping of 18-37 was used as the reference for logistic regression.

Racial breakdown presented as Caucasian (90%), African American (4.5%), Asian (0.75%), Native American (0.25%) and Other (4.5%). Hispanic ethnicity represented (4%), and non-Hispanic (96%). Race was combined to variables of white (90%) or nonwhite (10%) for logistic regression analysis.

Animal exposures by county were Cumberland (3.5%), Dauphin (51.5%), Lancaster (10%), Lebanon (26%), Perry (1.5%), York (2.3%), and Other (5%). Counties were separated into four variables for logistic regression as Dauphin (52%), Lebanon (26%), Lancaster (10%) and Surrounding (12%). Dauphin County was used as the reference. County of exposure was determined from the Dauphin County Department of Health animal exposure form submitted

by the patient. Medical records that were missing this form were categorized using the home location provided by the patient during registration.

No demographic characteristics were found to be significant predictors of whether or not providers deviated from the ACIP guidelines in prescribing RPEP.

3.2 Animals

Animals in the study were dogs (65%), cats (23%), bats (7%), livestock (1%), other (10%), lagomorphs (1%), wild animals (1%) and ferrets (0.3%). Forty-two different breeds of dogs were recorded. The majority of breeds were of single representation. Pit bull terriers, German Shepherd Dogs, and Labrador Retrievers were the most common breeds. Animals were analyzed by logistic regression as dog (65%) or non-dog (35%).

Animal provocation occurred as provoked (59%), unprovoked (24%), and unknown provocation (17%). Variable provoked was used as the reference group for logistic regression analysis.

Rabies vaccination status of the animals was up to date (62%), previously vaccinated but not currently up to date (3%), not up to date (9%) and unknown (26%). Animal vaccination status was analyzed in logistic regression as up to date (62%) or not up to date (32%).

Social status of the animals was domestic (75%), stray or feral (11%), livestock (1%), owned by a facility or in foster care (3%), and wild (10%). Social status of the animals was analyzed in logistic regression as domestic (75%) or non-domestic (25%).

Ownership of the animal involved in the exposure was categorized as the victim's own animal (48%), owned by an extended family member (5%), facility (3%), friend (9%), neighbor

(7%), stranger (6%), unknown owner (12%), or wild (10%). Animal ownership was analyzed in logistic regression as the owner's animal, or not the owner's animal.

Unknown provocation, unknown vaccination status, non domesticated socialization of the animal and animals not of the victim's ownership were the only predictors found to be statistically significant of whether or not providers deviated from the ACIP guidelines in prescribing RPEP. (Table 1)

Table 1. Predictors of animals influencing deviation from ACIP guidelines for RPEP.

	Total	Percentage	P value	Estimate	95% CI
Unknown provocation	67	17%	.0122	2.557	[1.23, 5.3]
Vaccination not up to date	151	38%	<.0001	0.036	[.013, .103]
Non domestic socialization	80	25%	.0024	2.6	[1.410, 4.960]
Unknown owner	209	62%	<.0051	2.364	[1.295, 4.314]

3.3 Wound Care

Providers were distributed as MD (33%), DO (11%), CRNPs (2%) and PA-Cs (54%). Providers were analyzed in logistic regression as a doctor or mid-level provider.

Location of the animal exposures, were shown as victim's home (60%), animal's home (17%), street (12%), facility (3%), and unknown (8%). Location was analyzed in logistic regression as occurring at the owner's home, or not at the owner's home.

The average number of exposures was two, median of one with a maximum number of exposures at sixteen. Exposure type included bites (84%), scratches (10%), salivary (1%), and aerosol (5%). Animal bites were further classified as punctures (45%), or lacerations (51%). Body regions were divided as head and neck (36%), right upper extremity (33%), left upper extremity (28%), anterior trunk (1%), posterior trunk (1%), right lower extremity (4%) and left lower extremity (6%). Victims with multiple bites were counted in multiple categories of affected body regions. Exposure number, exposure type, bite type, and body region were analyzed in logistic regression.

Wound care was divided into cleaning of the wound, antibiotic therapy and administration of a tetanus shot. Wound cleaning was distributed as not documented cleaned (25%), cleaned with water or saline (44%), soap (11%), hydrogen peroxide dilution (2%), bactericidal or virudical (14%), or cleaned pre-arrival by the patient (11%). Patients that experienced multiple cleaning methods were counted in multiple categories. Antibiotic administration was given in 82% of cases. Tetanus shot was shown as up to date (54%), boosted (36%), not documented (10%) and refused by the patient (.5%) Only 41% of cases included a PA-DOH animal bite form.

Bites that caused a laceration, bites that caused a puncture wound and administration of antibiotic therapy were the only significant predictors of whether or not a provider deviated from the ACIP guidelines. (Table 2).

Table 2. Predictors of Wound Care Influencing Provider Deviation from ACIP Guidelines

	Number of patients	%	P Value	Estimate	CI
Laceration bite	**170**	**51**	**.0264**	**.483**	**[.254, .298]**
Puncture bite	**149**	**45**	**.0016**	**.302**	**[.143, .636]**

Antibiotics	**328**	**82**	**.0287**	**.475**	**[.244, .925]**

3.4 Rabies PEP

Patients that received RPEP treatment were 20%. All 400 patients were subjected to the ACIP guidelines (Figure 1), and their case recorded as a numeric value. A second variable was recorded using the same guideline tool based on the RPEP decision of the provider and also recorded as a numeric value. Difference in RPEP was obtained by subtracting the provider's numeric value from the ACIP numeric value. Any value greater or less than zero upon this subtraction step, indicated deviation from the ACIP guidelines. The proportion of providers that matched the ACIP guidelines when determining rabies treatment was 87% [84, 91]. The proportion of providers that did not follow the ACIP guidelines when determining rabies treatment is 13%. Figure 2 demonstrates the individual values of each category of the ACIP guidelines.

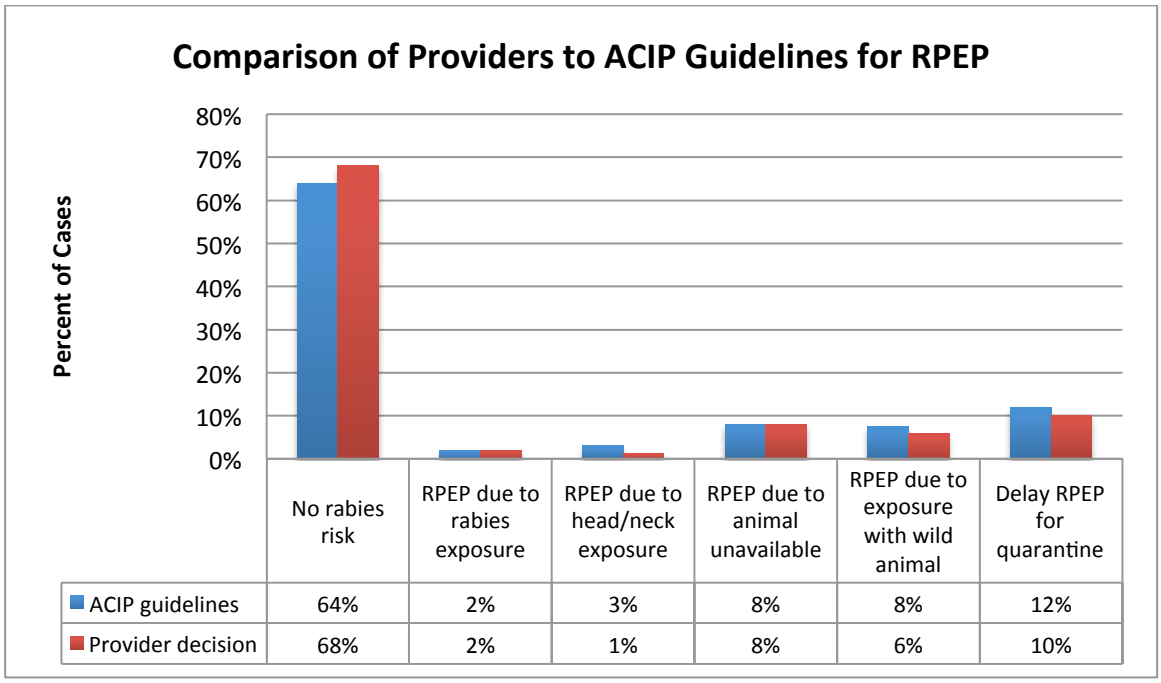

Figure 2. Comparison between providers and ACIP guidelines in prescribing RPEP

Animals that remained with their owner after the exposure was (70%), recommended for quarantine (8%), euthanized and not tested (3%), euthanized and tested positive for rabies (2%), euthanized and tested negative for rabies (1%), and unknown status (15%). Providers suggested animals for quarantine in 14% of cases.

Previous vaccination of patients was noted in nine cases, of which only 2 were given booster shots of PCECV. One patient received HDCV in conjunction with Rig. The remaining 96% of patients that received RPEP were administered Rig and PCECV. Of the 78 patients that received RPEP, Rig was administered in error in 46% of cases. Four patients had the RIgG injected into the wrong site and thirty-one patients received the wrong dose. Vaccine application had two errors in administration where one patient was injected in the gluteal muscles and an immunosuppressed patient was not administered the fifth shot. Two patients

chose against medical advice to have RPEP, and three patients demanded RPEP although the provider felt it unnecessary. Only 69% of patients completed the rabies vaccination series.

Chapter 4. DISCUSSION

4.1 Primary Outcome

This study sought to investigate variation between the ACIP guidelines and the clinical decisions of providers when treating patients that present with an animal exposure. Of the 400 patients examined, providers disagreed with the ACIP directives by 13%. Providers had exact agreement with the guidelines when patients presented with an exposure of a known or suspected rabid animal. Additionally, providers paralleled closely with the ACIP in instances where no animal was available for quarantine, or in cases where the DOH should be consulted.

The largest difference between the ACIP and providers occurred in determining whether or not a rabies risk existed. According to the ACIP guideline comparison (Figure 2), providers have a 4% difference when compared to the ACIP in determining if there is a rabies risk. One explanation may be due to incomplete information in patient charts. As this study was a retrospective chart review, the only information included in the study is the documented information by the staff. Personal conversations between patient and providers, or patients and nursing staff may not always be documented. Providers may have had additional knowledge from the patient that may not have been recorded, which could influence their decision. Without that pertinent knowledge, the picture used to determine what the ACIP directive should be, may not be the correct choice. The error therein lies with the subjectivity of

following the guidelines without sufficient information. The remaining categories had a negligent difference of 2% or less, between the ACIP and Providers. [12]

Improvements in the discretion of whether a patient should receive rabies PEP, may be better served from revision of the ACIP guidelines as suggested by Moran[8] or the use of a trained faculty advising committee as studied by Dubnov[9].

4.2 Secondary Outcomes - Predictors

Race appears strongly biased in this study to the Caucasian population. However, the collected demographics aligned with the current population distribution of the year 2010, as demonstrated in Table 3.

Table 3.

Pennsylvania Percent Race Alone and Hispanic Origin Decennial Population, 2010*

Prepared by The Pennsylvania State Data Center

Source: U.S. Census Bureau,Census 2000 & 2010 Redistricting Data (Public Law 94-171) Summary File.

March 9, 2011

**Detail may not sum to 100% due to rounding.*

		Race Alone							Ethnicity	
State & County FIPS Code	Geographic Area	White Alone	Black or African American Alone	American Indian & Alaska Native Alone	Asian Alone	Native Hawaiian & Other Pacific Islander Alone	Some Other Race Alone	Two or More Races	Not Hispanic or Latino	Hispanic or Latino
42000	Pennsylvania	81.9	10.8	0.2	2.7	0.0	2.4	1.9	94.3	5.7

Statistics concerning the animals involved in the animal bites, remained consistent with previous studies. Dog bites accounted for almost 50% of the animal exposures, followed by cats. These statistics mirror those of the Mendoza study in Marseille France, and the Kentucky surveillance study of 1994.[11-12]

Animal provocation was defined as anything initiating the animal including grooming, startling, playing, fighting, handling, or entering an animal's domain. This study found patients experiencing an animal exposure of unknown provocation are at a 2.5 [1.2 , 5.3] increased risk of their provider to deviate from the ACIP guidelines during their course of treatment.(p=.0122). Patients exposed to animals of no vaccination status, or unknown vaccination status were found to be at a 4% increased risk of their provider to deviate from the ACIP guidelines during treatment (p= <.0001). Exposure to a non-domesticated animal had a 2.6 increased risk of their provider deviating from ACIP guidelines (p=.0024). Patients that presented with a puncture bite had a 30% [.14, .64] increased risk of their provider to deviate from ACIP directives (p=.0016). Patients that presented with a laceration bite had a 48% [.25, .98] increased risk of their provider to deviate from ACIP directives (p=.0264). Patients that received antibiotic therapy had a 48% [.24, .92] increased risk of their provider to deviate from ACIP directives (p=.0287).

The most significant conclusion of this study came to be an administration error of RIgG. Thirty one patients, (88.6%) of those that received RPEP, were administered the wrong dose of RIgG. Errors in dosage of RIgG occurred from 5 IUs and even up to 500 IUs. Dosage of RIgG for each patient that received RPEP, was recalculated based on their individual body weight in kg at the time of the animal exposure. Sources of error may be simple miscalculation. However another reason may be in the aliquots that the supplier uses to package the RIgG. Staff may be posed with a choice of discarding valuable excess RIgG to achieve a proper dose, and therefore decide to short or increase the patient's dosage to avoid wasting the medication. Excess RIgG can hinder a patient's immune response from producing enough of their own rabies antibodies

due to the presence of the excess RIgG. Additionally, patients that are shorted RIgG are at risk of the rabies virus spreading before the person's immune system is able to produce enough antibodies to fight the virus. Further investigation is required to uncover the reasons behind this variation in dosage of RIgG.

4.3 Limitations

Providers collect histories from their patients to form a clinical picture and decide on the best medical treatment. Unfortunately, this information may not always be reliable. Patients may mislead providers to avoid RPEP due to cost, fear of needles, or inconvenience of having to return for additional shots. Providers are also left to rely on patient information regarding whether or not an animal is vaccinated. Persons may not want to admit an animal is not vaccinated, due to further repercussions from the victim or an unwarranted fear that the provider may report their animal to the DOH.

Region where the animal incident occurred was obtained from documentation in the chart. The most accurate regional data was obtained using the Dauphin county animal bite documentation form, however this form was not always uploaded into the medical record. In cases where this form was missing, the county and zip code listed in the patient information of the medical record were substituted as location unless otherwise stated by the patient or staff in the record narratives. Unfortunately a retrospective chart review cannot account for patients that change residences, therefore regional data may not truly reflect the location where the animal exposure occurred.

Chapter 5. CONCLUSION

Providers at the PSHMC-ED deviated from the ACIP directives 13% of the time when treating patients that presented with an animal exposure. The largest difference occurred during the decision of whether or not a rabies risk existed. Notable agreements of providers with the ACIP guidelines occurred when patients presented with an exposure of a known or suspected rabid animal, exposures where no animal was available for quarantine, and or cases where providers were prompted to consult with DOH. Secondary outcomes supported attacks from animals where provocation was unknown, animals that are not up to date with vaccinations, animals that are not domesticated, and animals of unknown ownership to be important predictors influencing providers to deviate from the ACIP guidelines. Puncture wounds, laceration wounds and administration of antibiotic therapy were also significant predictors. Of most interest was the discovery that 87% of patients that were administered RPEP, were given the wrong dose of immunoglobulin. This discrepancy may be due to simple calculation errors, or preventative measures of the staff to conserve excess drug. Further investigation is warranted to investigate a solution to this dosing error. Additionally, this data provides a roadmap for a prospective study on animal bite exposures. Collection of data by interviewing the patient directly and recording the varied practices of providers for wounds and administration of antibiotic therapy related to animal exposures may prove valuable for future patients that require treatment for an animal exposure.

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