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Ibrahim Zaganjor Date

The Cost-Effectiveness of CDC Form 75.37 "Notice to Owners and Importers of Dogs"

By

Ibrahim Zaganjor
Master of Public Health

Emory University
Rollins School of Public Health
Hubert Department of Global Health

_____

[Rob Stephenson, PhD, MSc]
Committee Chair

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By

Ibrahim Zaganjor

Bachelor of Science
University of California, Los Angeles
2012

Thesis Committee Chair: [Rob Stephenson, PhD, MSc]

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Abstract

The Cost-Effectiveness of CDC Form 75.37 "Notice to Owners and Importers of Dogs"

By: Ibrahim Zaganjor

To prevent the risk of rabies infection, the United States federal government regulates that all importers of dogs from rabies-enzootic countries provide a rabies vaccination certificate upon entry into the country. Owners and importers of dogs that have not been adequately immunized are issued a signed confinement agreement, which mandates that the animal be confined and vaccinated according to federal regulations (42 CFR 71.51). These regulations were developed in the 1950s: the goal of this evaluation is to determine if the form is a cost-effective method of preventing the importation of rabid or unvaccinated dogs given the high rates of travel and trade in today's society. The operational costs of the program were compared to the number of canine rabies cases potentially prevented by the 2,130 forms issued during the 2012 calendar year. It was estimated that federal government spent approximately $1,050,000 to prevent less than one case of rabies that year (0.039 - 0.622 cases). Information gathered from state and local partners highlighted that there are also many issues associated with the form affecting its function, such as a lack of clear duties for state and local offices and ill-defined consequences for noncompliant importers. Findings from this study suggest that the federal government should eliminate the dog confinement agreement process and develop a more stringent dog importation policy that will be a better use of resources and directly prevent the importation of rabid and unvaccinated dogs.

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Chapter 1 - Introduction

1.1 U.S. Quarantine History & CDC/DGMQ/QBHSB Background

Quarantine has played a crucial public health role in protecting Americans from infectious disease transmission for generations. Prior to the development of a strong federal government in the United States (U.S.), state and local municipalities had been responsible for protecting citizens from imported infectious agents [11]. However, throughout the late nineteenth century and early twentieth century, quarantine responsibilities slowly transitioned from local and state jurisdictions to the federal government. This shift was officially recognized under the Public Health Service Act of 1944, which granted the U.S. Public Health Service (PHS) quarantine authority [11]. In 1967, this authority was transferred to the agency now known as the Centers for Disease Control and Prevention (CDC), which still upholds this responsibility under its Division of Global Migration and Quarantine (DGMQ) [11]. Within DGMQ, the Quarantine and Border Health Services Branch (QBHSB) is the sector of the agency responsible for "*protecting the public's health through detection of and response to communicable diseases related to travel and imported pathogens and improves the health of globally mobile populations transitioning into U.S. communities*" [CDC, 2013].

According to the CDC, quarantine is *"used to separate and restrict the movement of well persons who may have been exposed to a communicable disease to see if they will become ill*" [CDC, 2014]. The CDC currently has 20 quarantine stations across the country located at ports of entry and land-border crossings. As seen in Figure 1, the 20 quarantine stations are presently located in: San Juan, Washington DC, Atlanta, Philadelphia, Newark, New York, Boston, Miami, Detroit, Chicago, Minneapolis, Dallas,

Houston, El Paso, San Diego, Los Angeles, Seattle, San Francisco, Anchorage, and Honolulu [Figure 1].

Quarantine station personnel work very closely with many other federal government agencies such as Customs and Border Protection (CBP) and U.S. Fish and Wildlife Services (USFWS) on a variety of tasks. One such task is the regulation and inspection of animal imports and animal products. This is a key public health task that helps protect the United States from zoonotic diseases, which are contagious diseases capable of spreading from animals to humans. There are numerous zoonotic diseases that have been scientifically documented, but one that CDC and other federal agencies are highly concerned with is the rabies virus. This is because without immediate intervention, rabies has a close to 100% fatality rate [5].

Figure 1: Map of CDC's 20 quarantine stations. Available from:
Quarantine and Isolation – Quarantine Station Contact List, Map and Fact Sheets. Centers for Disease Control and Prevention. http://www.cdc.gov/quarantine/QuarantineStationContactListFull.html

1.2 Rabies Virus

Rabies is a preventable viral zoonotic disease that affects the central nervous system and is nearly always fatal [3]. The virus is part of the Mononegavirales order, the Rhabdoviridae family, and the Lyssavirus genus [6]. Like other members of the Rhabdoviridae family, the virus is approximately 180 nm long, 75 nm wide, and bullet like in shape [6]. The virus is most commonly transmitted through a bite from a rabid animal and worldwide over 90% of human cases are due to exposure to a rabid dog [4]. It is estimated that more than 55,000 human deaths annually are due to rabies with 99% of all cases occurring in the developing world [34]. Rabies related deaths are estimated to be attributable to 1.74 million DALYs lost annually [34].

Once the virus is transmitted to an animal or human, it travels from the site of the bite to the brain through the nerves. Initially, an infected individual or animal shows no symptoms. This time prior to symptom onset is known as the incubation period and typically lasts approximately two to twelve weeks [7]. This is a crucial period because it is usually the only time in which an infected animal or human can be treated successfully [7]. However, since 2004 there have been three separate documented instances in the United States in which a patient with clinical rabies has recovered [37].

In humans, the initial symptoms of the virus include fever, fatigue, headaches, and other symptoms, which can be confused with other less serious illnesses [7]. This period in which less serious symptoms are visible lasts approximately two to ten days [7]. The human patient then proceeds into a phase in which the symptoms are more severe and detrimental to his or her physical health. This phase of the illness can take one of two forms: furious or paralytic rabies [7]. Furious rabies accounts for about 80% of all cases

and is characterized by aggressive behavior, hallucinations, fever, and delusions [7]. Individuals experiencing paralytic rabies can have loss of sensation, muscle weakness, paralysis, or any combination of these symptoms. Regardless of symptoms, patients of both furious and paralytic rabies typically die of heart or lung failure [7].

1.3 Rabies Treatment – Post-Exposure Prophylaxis (PEP)

As stated previously, rabies is preventable. Upon exposure to a potentially rabid animal, a person should seek medical attention promptly. However, it is important to note there is a different treatment method for those who have been previously vaccinated against rabies and those who have not. In both cases, a potentially exposed human should properly cleanse the wound. For an individual who has not been previously vaccinated, he or she should receive Human Rabies Immune Globulin (HRIG) and either the Human Diploid Cell Vaccine (HDCV) or the Purified Chick Embryo Cell Vaccine (PCEC) [8]. No more than the recommended dose of HRIG should be administered to a patient, 20 IU/kg body weight, because it can negatively affect the production of antibodies [8]. Also, a previously unvaccinated patient should receive 1.0 mL of either vaccine on days 0, 3, 7, and 14 [8].

In the United States, the pre-exposure vaccination regimen requires three intramuscular injections of HDCV or PCEC on days 0, 7, 21 or 28 [15]. If an individual has been previously immunized, they should only receive two doses of either vaccine on days 0 and 3. In this case, no Human Rabies Immune Globulin (HRIG) should be administered.

These are the current recommendations for post-exposure prophylaxis (PEP). Previously, unvaccinated persons received five doses of the vaccine; however, in 2009 the Advisory Committee on Immunization Practices (ACIP) updated these recommendations from a five to a four-dose regimen [9]. This will save the U.S. health care system an estimated $16.6 in costs [9].

1.4 Federal Regulations (42 CFR 71.51) and Confinement Agreements

CDC regulates the importation of both dogs and cats under current federal regulations, 42 CFR No. 71.51. The dog import regulations require that dogs be healthy upon arrival, and if not healthy, the CDC may require examination, testing, and treatment as needed. Currently, the U.S. government policy only requires that imported dogs from rabies endemic countries provide proof of rabies vaccination. If an imported dog from a rabies endemic country does not have a valid vaccination certificate that clearly states the dog is at least four months of age and has been vaccinated thirty days prior to entry into the U.S., the owner or importer of the dog will be issued a confinement agreement (CDC Form 75.37) [10, Appendix B]. The owner or importer must then confine and vaccinate the dog according to federal regulations. Imported dogs that are at least three months of age must be vaccinated within 4 days of arrival at their final U.S. destination and within ten days of entry into the United States and then confined for a minimum of thirty days after the date of vaccination [10]. Owners or importers of a dog that had been too young to vaccinate prior to entry into the United States (i.e. less than three months of age) must confine the dog until it is old enough to vaccinate and then for at least thirty days after the date of the first dose of vaccine [10]. Lastly, an imported adult dog (i.e., ≥15 months old)

requiring a booster rabies vaccination will only be confined until vaccination, given that the dog's initial vaccination occurred when the dog was at least three months of age.

CDC Form 75.37 "Notice to Owners and Importers of Dogs" (aka confinement agreements) are issued by CDC Quarantine Station staff and Customs and Border Protection officers. Signed confinement agreements are entered into the Quarantine Activity reporting System (QARS) and provided to state authorities who then have the choice as to whether to follow up with the importer to ensure that the terms of the agreement are adhered to. It is important to note that each state and local health office may manage and conduct follow-up differently. Moreover, many state and local governments individually require that importers of dogs provide proof of rabies vaccination prior to entry.

1.5 Quarantine Activity Reporting System (QARS)

All signed confinement agreements are scanned and entered into the Quarantine Activity Reporting System (QARS) by CDC personnel. The system has ten different report modules (e.g., human death, human illness, etc), but confinement agreements are entered specifically into the importation module and are further classified into the animal importation category. Each dog confinement agreement report in QARS receives a unique ID number and provides information regarding the dog's country of origin, arrival date, transport entry method, reason for confinement, age range, breed, most recent rabies vaccination date, and a scanned copy of the confinement agreement. If it is a problematic shipment requiring additional follow-up, air conveyance details and importer and broker

information are also included. QARS only records the number of dogs that received a confinement agreement and does not log the number of dogs entering the U.S. annually.

1.6 "Rabies-Free" List

As stated in the CDC's standard operating procedure (SOP) [Appendix A], dogs that have located in a "rabies-free" country for a minimum of six months or since birth are allowed to enter the U.S. without proper rabies vaccination documentation. The countries cited on the "rabies-free" list [Appendix C] receive this title because they had no documented indigenous cases of rabies for a given time frame [15]. However, such designation does not imply that rabies cannot occur in these countries. For example, Taiwan, a country considered to be "rabies-free" in 2012, experienced an outbreak of rabies among local ferret-badgers in 2013 [14]. Regardless, the list serves as a guide for the CDC and other public health agencies. The "rabies-free" country list was most recently updated in 2012.

1.7 Rabid Dog Importation Cases in the United States (2003-2014)

Between 2003 and 2014, four rabid dog importation cases have occurred in the United States. These importations include dogs in transit from foreign countries and U.S. territories such as Puerto Rico. Each case had a lengthy follow-up period and required an in-depth public health investigation.

In 2004, two different unvaccinated, imported puppies tested positive for rabies [16]. One of the puppies had been imported from Thailand and the other had been flown in from Puerto Rico as a part of an animal rescue program [16]. In March of 2007, an

adopted puppy from India was determined to be rabies positive by the Alaska Department of Health and Social Services [16]. Most recently, an imported dog from Iraq tested positive on June 26, 2008 for a variant of rabies associated with dogs of the Middle East [16]. These cases and their subsequent investigations will be discussed in greater depth in the following chapter.

1.8 Project Purpose, Aims, and Significance

The current federal dog regulations (42 CFR 71.51) were developed in the 1950s [38]. The CDC has decided to investigate whether CDC Form 75.37 [Appendix B] is still the best use of resources to prevent dogs infected with rabies or unvaccinated dogs from entering the United States. Therefore, the purpose of this study is to determine the cost-effectiveness of CDC Form 75.37 [Appendix B] as represented by the resources used to implement this program.

CDC Form 75.37 was designed to confine and prevent imported dogs infected with rabies from transmitting rabies to the U.S. population of humans and animals. However, since the development of the form, the number of imported dogs has risen, as have the costs of administering the program. Recent data estimates indicate that approximately 287,000 dogs enter the U.S. annually [17]. Thus, it is vital to evaluate whether or not the form is cost-effective for the U.S. government given the high number of dog importations each year. Furthermore, because individual state and local health departments are responsible for conducting follow-up with importers, CDC needs to consider whether or not the public health state partners consider this an effective federal

policy, and also whether or not state partners have enough resources to administer the program.

This is a critical evaluation because unvaccinated imported dogs present a huge public health risk. Rabies has a nearly 100% case-fatality rate and the United States is enzootic to various rabies variants [5]. An unvaccinated dog therefore has the potential to already be infected upon arrival or to become infected later if exposed to a rabid animal during its time in the United States. Moreover, this analysis is important because as of 2007 the U.S. has been declared free of canine rabies virus variant [18]. Since the potential reintroduction of canine variant rabies is of great concern to public health officials, it is important that the CDC and the federal government verify that current dog importation regulations are a useful means of avoiding the risk of reintroducing this public health threat.

CDC does not want to simply eliminate the form or alter the rabies vaccination certificate program without analysis. CDC must weigh the expenditures on the program against the goal of protecting public health against the risk of imported rabies. Even if the program is expensive, rabies cases are also very expensive and there is the potential that the costs associated with avoided rabies cases might out outweigh the costs of the program.

This study is significant in that the evaluation of operational costs and public health concerns will help shape dog import policies and regulations. The study results will indicate whether the number of cases of disease prevented by the regulation are worth the resources spent to administer the policy. It will also gather information from state and local health departments to understand role of the form at these levels and any

difficulties associated with it. The analysis will help in assess whether CDC Form 75.37 should be maintained, altered, or eliminated.

Chapter 2 – Literature Review

2.1 Current United States Dog Importation Trends and Issues

In recent times, the global population has become intensely interconnected through various ways and multiple media, including frequent international travel and trade. Although some consider this a success, the rate and volume of current international travel and trade presents increased means for infectious disease transmission. This is not simply a risk for travellers, but also entire populations [19]. However, this increase in international travel is true for both humans and animals. Recent extrapolated data from 2006 estimates that over 287,000 dogs had been imported into the U.S. that year alone [17]. Of those 287,000 dogs, it is approximated that 70,600 (25%) crossed U.S. borders without being appropriately vaccinated for rabies or proper evidence of vaccination [17]. The extremely high number of annual dog importations poses numerous public health threats and potential for transmission of countless zoonotic diseases. Specifically, the estimated number of imported unvaccinated dogs establishes the potential for the reintroduction of canine-variant rabies within the U.S. This is because although the U.S. has been declared free of canine variant rabies, this variant of the virus is enzootic in most regions of the world [17].

Currently, there is also a concern about imported puppies that are being smuggled across the United States and Mexican border. During a two-week long project to gather statistics conducted during the mid 2000s at two points of entry by the Border Puppy Task Force, 362 puppies less than three months of age were imported into the United States. [20]. This would equate to approximately 10,000 puppies entering the U.S. annually at these two points of entry [20]. Some of the puppies were found hidden in

spaces such as glove compartments and trunk beds [20]. This is a huge public health threat because these puppies are not old enough to be fully vaccinated against rabies. Therefore, if sold in the United States, these smuggled puppies can potentially spread rabies to humans and other animals.

2.2. Current Status of Rabies among Domestic Dogs

According to the World Health Organization (WHO), more than 55,000 humans die due to rabies annually [5]. Most cases occur in Asia and Africa with approximately 40% of infections occurring in individuals under the age of 15 [5]. Throughout the world, dogs account for over 90% of human exposures to the virus and are the cause of 99% of all human rabies fatalities globally [4]. In order to assess the risk of infection imported dogs place on United States citizens, this evaluation will examine the current status of rabies among domestic dogs in the U.S. and the five countries that accounted for the greatest number of confinement agreements in 2012: Canada, Germany, Mexico, Dominican Republic, and Colombia [22].

2.2.1 United States

Data from 2011 shows that 6,031 rabid animals and 6 human rabies cases had been reported to the CDC by 49 states and Puerto Rico [21]. Figure 2, from "*Rabies Surveillance in the United States during 2011*", shows the geographical distribution of rabies cases involving both cats and dogs during that year [21, Figure 2]. Seventy (1.2%) of these reported rabies cases had been domestic dogs [21]. This value demonstrates a 1.4% increase from the value reported in the previous year [21]. Georgia (12), Oklahoma

(10), and Texas (9) were the states that reported the greatest number of cases among domestic dogs in 2011 [21]. All other states reported less than four cases that year [21]. Of the 70 cases, 19 dogs had their vaccination status reported to CDC [21]. Three of these 19 dogs had been previously vaccinated against rabies; however, all 3 of these vaccinations were not considered current [21].

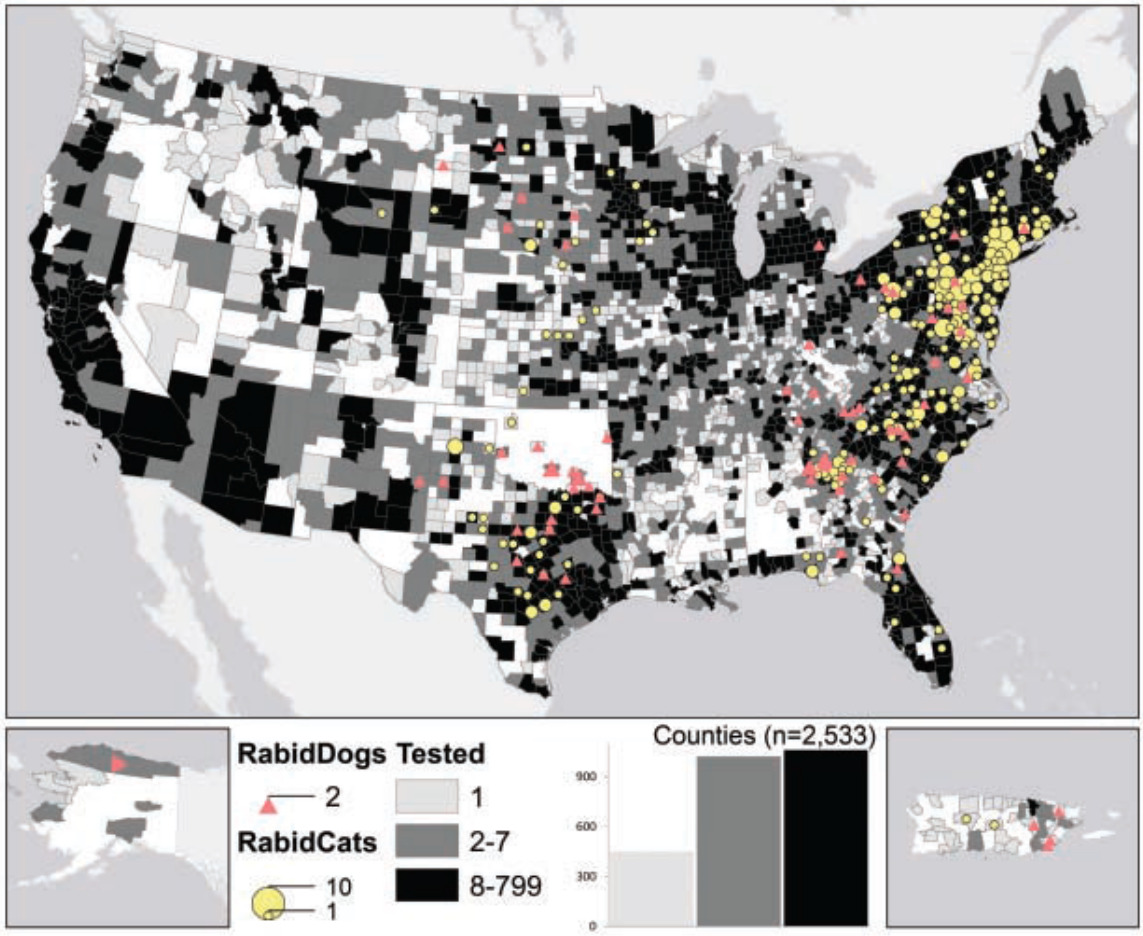

Figure 2: Reported cases of rabies involving dogs and cats in the United States, 2011. From: Blanton, Jesse, Jessie Dyer, Jesse McBrayer, and Charles E. Rupprecht. "Rabies Surveillance in the United States during 2011." *Journal of the American Veterinary Medical Association* 241.6 (2012): 712-22. http://avmajournals.avma.org/doi/pdf/10.2460/javma.241.6.712.

2.2.2 Canada

The Canadian Food Inspection Agency (CFIA) documented 141 rabid animal cases in 2012 [23]. Table 1 shows that during that year, domestic dogs accounted for

11.4% (16) of all rabies cases [23, Table 1]. OIE's World Animal Health Information Database (WAHID) Interface recorded 16 rabid dog cases in 2012 as well [24]. This was a substantial increase from 2011 in which there was only two incident cases of rabies among domestic dogs [23]. Other reports illustrate a relatively similar number of incident cases in Canada over the last 15 years. A survey conducted by WHO in 1999 reported ten cases and another source reported eight cases of rabies among domestic dogs in 2002 [25, 26].

Table 1: Number of Positive Animal Rabies Cases in Canada, 2012. Adapted From: "Positive Rabies in Canada." *Government of Canada,Canadian Food Inspection Agency,Animal Health Directorate*. 18 Nov. 2013. http://www.inspection.gc.ca/animals/terrestrialanimals/diseases/reportable/rabies/positive-rabies/eng/1356156989919/1356157139999.

Species	Total # of Positive Rabies Cases	% Total
Dogs	16	11.4
Cats	2	1.4
Bovine	2	1.4
Equine	2	1.4
Skunks	32	22.85
Bats	45	31.9
Foxes	41	29.08
Wolves	1	0.71
Total	**141**	**100%**

2.2.3 Germany

Data from OIE's WAHID Interface and WHO's European Rabies-Bulletin surveillance indicates that there were no rabies cases among domestic dogs throughout the country in 2012 [24, 39]. Other survey data from 1999 collected by WHO shows that out of 71 non-human rabies cases, there was only one report about rabies in a domestic dog [25]. A majority of the reported cases that year had been among wild animals, primarily foxes [25]. However, Germany recently experienced a rabid dog importation. In 2010, a rabid puppy was transported from Bosnia-Herzegovina to Germany by motor

vehicle [40]. Seventeen individuals were required to receive PEP due to exposure to the puppy [40].

In 2012, Germany had been placed on the rabies-free list [15, Appendix A]. This designates that there had been no reported indigenous cases of rabies during the last surveillance period [15]. Therefore, individuals currently importing dogs into the United States from Germany will not be required to provide the appropriate rabies vaccination documentation.

2.2.4 Mexico

Since 1999, there has been a huge decrease in the number of reported cases of animal rabies in Mexico. In 1999, WHO's world rabies survey reported 551 confirmed cases of rabies among domestic and wild animals [25]. This same report shows that domestic dogs accounted for approximately 57.5% (317) of total confirmed cases that year in Mexico [25]. By 2002, there had only been 105 cases of rabies in dogs, illustrating a huge decline from 1999 [26]. Recent literature cites that there were only 20 incident cases of rabies among domestic dogs in Mexico during both 2010 and 2011 [21].

2.2.5 The Dominican Republic

Data from WHO's world rabies survey showed that 41 rabid dog cases occurred in the Dominican Republic during 1999 [25]. This value increased to 71 in 2002 according to data reported to the Pan American Health Organization (PAHO) [26]. 2012 information on the OIE WAHID Interface illustrates another increase in the number of reports and documents 93 incident canine rabies cases in the Dominican Republic during

that calendar year [24]. Thus, the number of rabid dog cases in the Dominican Republic in 2012 is more than double the value reported in 1999.

2.2.6 Colombia

In Colombia there was 110 laboratory or clinically confirmed cases of canine rabies in 1999 [25]. In 2002 this value dropped significantly and there was only 13 Colombian canine rabies cases reported [26]. Moreover, recent literature cites that for 2001 through 2006 the unadjusted incidence rate of canine rabies in Colombia is 0.4 cases per 100,000 dogs/year [27].

The reduction of canine rabies cases in both Colombia and Mexico can be highly attributed to the Latin American countries' goal to eliminate human rabies transmitted by dogs by 2005 [46]. This was an effort supported by the Pan American Health Organization (PAHO) and made successful through the mass vaccination of the Latin American dog population. [45, 46] It is estimated that 42 million dogs in the region are vaccinated each year, which helped decrease the number of human rabies cases transmitted by dogs in Latin America from 251 in 1990 to 35 in 2003 [46].

2.3 Imported Canine Rabies Cases – United States

Between 2004 and 2014, there have been approximately eighteen rabid dog importation cases documented globally [28]. Of these eighteen cases, four occurred in the United States [28]. These four dogs were either from either a foreign country or U.S. territory. Specifically, they had been imported from Thailand (2004), Puerto Rico (2004), India (2007), and Iraq (2008) [28].

The most recent case that occurred in June of 2008 had been due to an Iraqi dog that arrived at the Newark Liberty International Airport [16]. This case resulted in an investigation by the CDC, New Jersey Department of Health and Senior Services, and Bergen County Department of Health [16]. This entailed an evaluation of 24 exposed animals in 16 states, and 28 exposed individuals of whom 13 (46%) required post-exposure prophylaxis [16]. Moreover, all 24 animals had to be quarantined and monitored for a 6 month period [16].

On March 14, 2007, a rabid puppy from New Delhi, India that was approximately 11-weeks of age arrived in Seattle, Washington [29]. Within a week, the puppy had been adopted and flown as cargo to Juneau, Alaska. To complete this interstate transport, a Washington State Department of Agriculture health certificate had been completed by a veterinarian certifying that the "*animal was not known to be exposed to rabies, did not originate in a rabies quarantined area, and was free of symptoms of communicable disease*" [Castrodale et al., 2008, 428]. The puppy died two days after arriving in Alaska and the Alaska Department of Health and Social Services had been immediately notified. The same day fluorescent antibody testing confirmed the dog had been rabies positive [29]. A public health investigation started immediately in which more than 20 individuals and one other dog was evaluated for potential rabies exposure [29]. This one dog was later euthanized and eight individuals from Alaska and Washington received PEP [29].

Two rabid canines were imported into the U.S. in 2004. One dog that was 12-weeks of age arrived in Massachusetts from Puerto Rico in May of that year [29]. At least six potentially exposed individuals had been recommended for PEP due to exposure to this unvaccinated puppy [29]. In June of 2004, another unvaccinated 12-week old puppy

arrived in Los Angeles, California from Bangkok, Thailand [29]. After a public health investigation, it was determined that 12 potentially exposed individuals required PEP [29].

All four of these cases demonstrate that the public health efforts conducted after the importation of a rabid canine are labor intensive, time consuming, and expensive. They also show that the current policy has not always been effective and has allowed for rabid dogs to cross U.S. borders unnoticed.

2.4. Costs of Rabies Exposure

The CDC cites that in the U.S. alone, the costs related to rabies are greater than $300 million dollars annually [30]. For human exposures, there is a multitude of medical, public health, and veterinary costs [31]. There have been scant economics studies that have attempted to quantify these costs. However, some of the literature has been criticized for poorly defining cost methodology [31].

One study in San Luis Obispo and Santa Barbara County assessed these costs using local clinic, hospital, and public health records between 1998 and 2002 [31]. Patients were also contacted and interviewed to determine indirect costs related to their exposure and treatment [31]. This study defined direct costs as "*those costs associated with the provision and administration of PEP and associated PEP charges*" [Schwiff et al, 2007; 253]. The researchers also calculated indirect costs, which included wages lost by the patient, expenses incurred by government agencies, and various other expenses [31]. The study determined the mean of the direct costs to be $2,564 (range: $303 - $6,455) and mean indirect costs to be $1,124 (range: $418-$2,742) [31]. The mean of the

total costs related to a potential human exposure to rabies equaled $3,688 (range: $721-$9,197) [31].

Another study which assessed PEP reports documented by the Massachusetts Department of Public Health (MDPH) between August 1994 and December 1995 estimated the total costs for PEP in Massachusetts during 1995 was between $2.4 million and $6.4 million [32]. The same study also found that the median costs for biologics alone per PEP patient in Massachusetts during this time period were $1,646 (range: $632 - $3,435) [33]. When hospital and doctor's fees were included, this figure rose to $2,376 (range: $1,038 - $4,447) per patient [32]. Although these studies do not provide current cost estimates, they illustrate that administering PEP in the United States is an expensive undertaking.

2.5 Trends in Rabies Post-Exposure Prophylaxis

Although administering PEP has shown to be a very expensive process, it is considered to be overprescribed in some western countries [48, 49]. In the United States, a recent study showed that approximately 23,000 courses of rabies PEP are administered annually [50]. Another study assessing rabies PEP treatment in southern France determined that the annual incidence of injured individuals pursuing rabies PEP treatment in the region was 16/100,000 [49].

One concern regarding these trends is the reoccurring shortages of PEP globally [47]. To alleviate the high costs associated with rabies PEP and issues related to vaccine shortages, recent studies have found that the intradermal (ID) regimen is a more cost-effective means of administering the treatment than the intramuscular (IM) routine [51,

52]. Since the ID regimen uses a smaller volume of vaccine, this method of treatment can be extremely valuable in low-income countries that are endemic to canine rabies and suffer from frequent vaccine shortages [51].

Chapter 3 - Methods

3.1 Number of Cases of Canine Rabies Potentially Prevented

3.1.1. Data Sources

Data regarding the number of imported dogs issued a confinement agreement in 2012 was retrieved from CDC's Quarantine Activity Reporting System (QARS) [22]. Since this study assessed the cost-effectiveness of the process during a one-year scope, only confinement agreement reports issued between 1/1/12 and 12/31/12 were included. This data was exported into Microsoft Excel© and sorted by the dogs' country of origin. Microsoft Excel© pivot tables were used to quantify the number of confinement agreements issued during that calendar year.

Estimates for the number of cases of rabies among dogs in each country was gathered from peer reviewed literature, government publications, and Internet databases [15, 24, 25, 26, 39]. Due to issues with rabies surveillance and reporting in many countries around the world, a variety of sources had been included. A limitation of these sources is that they represent a wide range of time, 1999-2012, which may not best represent the current status of rabies globally. Dog population reports were also highly limited in number and lack credibility. For consistency purposes, the World Society for the Protection of Animals' "*Global Companion Animal Ownership and Trade: Project Summary, June 2008*" was used to provide pet population data for individual countries [33]. These estimates were based on human demographics (i.e. population and economic status) and sources such as Euromonitor and OIE's WAHID Interface [33]. Although this is not a peer reviewed source or government publication, it is the most comprehensive report including global dog populations currently available. Moreover, this source also

presented values similar to other country level reports. One limitation of this source is it did not include a value for the number of dogs in the Dominican Republic [33]. To address this issue, Puerto Rico's value was substituted in all calculations regarding the Dominican Republic. This value was considered an appropriate substitute because of Puerto Rico's relative proximity to the Dominican Republic and similar size and population statistics.

3.1.2 Calculations

The data sources were used to calculate the number of imported canine rabies cases potentially prevented through CDC form 75.37 in 2012. Due to the limitations and the variety of sources, four different values were calculated using the same mathematical model.

QARS data illustrated that dog importations from Canada (n=641), Germany (n=410), Mexico, (n=317) the Dominican Republic (n=237), and Colombia (n=145) represented a majority of the dogs issued confinement agreements in 2012 (65.4%, 1750/2677) [22]. Thus, in the first three calculations, the rabies threat these canines presented had been assessed individually. The remaining 927 dogs issued confinement agreements in 2012 had been imported from 78 other countries, but were considered as one group in the calculations. Therefore, there were six different groups to consider in these 3 calculations: imported dogs from Canada, Germany, Mexico, the Dominican Republic, Colombia, and all other countries.

The data sources provided the incidence of rabies among domestic dogs in these five countries, the global incidence of rabies in all other countries, and dog population values. The incidence values had been divided by the dog populations of each group to

determine the canine rabies prevalence rate. This value was then multiplied by the number of dogs issued confinement agreements in each group to calculate the number of rabies cases potentially prevented. The sum of these six groups represents the estimated total number of rabies cases potentially prevented through CDC Form 75.37 that year. This value will be utilized as a proxy for effectiveness.

$$\sum [(\text{Incidence}/\text{Population}) \text{ X } (\#\text{ Dogs Issued Confinement Agreements in Each Group})]$$

Since underreporting is an issue with canine rabies around the world, a fourth value was calculated to function as an appropriate upper bound [34]. In this calculation, all 2,677 dogs issued confinement agreements in 2012 were considered in one group. The highest prevalence rate in the previous calculations (0.00011625) was multiplied by 2 and then multiplied by the total number of dogs issued the form in 2012 (2,677). This value thus attempts to account for all canine rabies cases not reported globally.

$$[(\text{Highest Prevalence Rate X } 2) \text{ X } (\text{Total \# of Dogs Issued Confinement Agreements})]$$

3.2 Costs of CDC Form 75.37

Since no cost data regarding CDC Form 75.37 is available, all labor costs were estimated based on the expected time per event associated with each part of the confinement agreement process. This evaluation only assesses the federal government's expenditures related to CDC Form 75.37. However, it is important to note the costs

related to the form do not simply stop at the federal level and that state and local health departments have their own expenses related with the form.

The process and each event's estimated time was quantified from information gathered from the Standard Operating Procedure (SOP), qualitative interviews with Customs and Border Control (CBP) officers and quarantine station staff, and a key informant interview with a quarantine veterinary medical officer.

Labor costs were categorized into six different groups: importation related tasks, follow-up with importers, QARS tasks, dog importation training related tasks (CBP and CDC field staff), inspection related tasks, and form development tasks. The total annual time commitment for individual tasks in each group was calculated by multiplying the number of events each year by the estimated time per event. Since the form is updated every three years, some tasks were discounted appropriately.

The annual labor costs for an individual task was the calculated by taking this value and multiplying it by the number of full time federal employees responsible for these tasks and the average hourly rate of these positions. The average hourly rates for the 2012 calendar year were gathered from the Office of Personnel Management's General Schedule (GS) pay tables [35]. Benefits were calculated at 38% of pay, the median value of the range (26%-50% of pay) published in the Congressional Budget Office's (CBO) "*Characteristics and Pay of Federal Civilian Employees*" [36].

A. Total Annual Time Commitment Per Task (hours)=

[(Time per individual event (minutes) X # of events) / 60 minutes]

B. Annual Labor Costs Per Task ($) =

[(Total Annual Time Commitment (hours)) X (# of FTEs) X (Average Hourly Rate ($))]

C. Value of Benefits ($) =

[(Annual Labor Costs Per Task) X (38%)]

D. Total Costs Per Task ($) =

[(Annual Labor Cost Per Task) + (Value of Benefits)]

E. Additional Tasks/Resource Costs/Overhead ($) =

(Total Costs of Direct Labor X 35%)

The economic model did not capture some components and duties related to the process. Such tasks include CDC-INFO labor and unquantifiable efforts from other government agencies. To account for these tasks, resources (i.e. printing/scanning), and indirect costs, an additional 35% was added to the costs calculated in the model [42 & Personal Communication, Coleman, 2014] Indirect costs refer to those costs "*that have been incurred for common or joint objectives and cannot be readily identified with a particular final cost objective*" [Department of Labor, 2012 & OMB Circular A-122 (2 CFR Part 230), 2005]. These costs and the direct labor costs associated with process were summed to estimate the total cost of the program in 2012. A ten percent sensitivity range was applied to account for any uncertainty in this final estimate.

3.3 State and Local Health Department Evaluation Survey

Although this evaluation is strictly focused on the cost-effectiveness of CDC Form 75.37 at the federal level, it was important to get an understanding of how the form is functioning at the state and local health departments. A survey [Appendix D] was composed to analyze whether or not these health departments had enough resources to adequately enforce the form and conduct follow-up with importers. The survey also attempted to understand these departments' general attitudes towards the form. To best capture this information, a mixed methods survey was developed that gathered both quantitative and qualitative information.

Only nine state and local health partners were administered the survey, in order to maintain the regulations outlined in the Paperwork Reduction Act. In accordance with these regulations a nationally representative convenience sample was selected that included departments from each major region of the country. The surveys were administered over the phone and took approximately 20 minutes each.

Chapter 4- Results

4.1 Number of Cases of Imported Canine Rabies Potentially Prevented

The purpose of this evaluation was to examine whether or not current federal dog importation regulations are a cost-effective means of preventing the entry of rabid or unvaccinated dogs into the United States. It was a one-year assessment of the current regulations and estimated the costs and effectiveness of the process for the 2012 calendar year (1/1/12-12/31/12).

CDC requires that all importers transporting dogs from rabies-endemic countries provide documentation certifying that their dog had been properly vaccinated against rabies at least 30 days prior to arrival [10, Appendix B]. Those that fail to do so must complete a dog Confinement Agreement and *"confine the animal until it is considered adequately vaccinated against rabies*" (CDC, 2013). Between 1/1/12 and 12/31/12, 2130 confinement agreements were issued to a total of 2,677 dogs from 83 different countries [22].

To determine if the form is an effective method of preventing the entry of rabid and unvaccinated dogs into the United States, the number of canine rabies cases potentially prevented by the 2,130 forms was estimated. Due to the limitations and the variety of sources, 4 different values were calculated using the same mathematical model [Table 2, 3, 4, 5]. To best represent the potential effectiveness of the form, a range was developed.

These calculations illustrate that the number of cases potentially prevented in 2012 was less than 1, with an estimate between 0.039418527 and 0.6224025 cases [Table 2, 5]. Although tables 2, 3, and 4 used differing sources to estimate these values, they did

not differ by more than 0.01 of a case [Tables 2, 3, 4]. These 3 estimates show that based on the calculated prevalence rates, the confinement agreement process is potentially preventing roughly 0 cases annually (0.039418527-0.04668755 cases) [Tables 2,3,4].

The value estimated in Table 5 (0.6224025) was calculated by multiplying the highest prevalence rate by 2 [Table 5]. While this value is very different than the other estimates, it was calculated under the assumption that canine rabies cases are extremely underreported globally. It thus serves as the upper bound for this range of potential effectiveness.

Table 2: Number of Canine Rabies Cases Potentially Prevented via CDC Form 75.37 (2012), Lower Bound Estimate Calculated by [∑ (Prevalence Rate) X (# Dogs Issued Confinement Agreements in Each Group)]

Country of Origin	**Number of Dogs Listed on Confinement Agreements in 2012**	**Number of Incident Cases of Canine Rabies**	**Dog Population**	**Prevalence Rate**	**Number of Canine Rabies Cases Potentially Prevented**
Canada	641[22]	10[25]	5,002,000[33]	1.9992E-06	0.001281487
Germany	410[22]	1[25]	5,245,000[33]	1.90658E-07	7.81697E-05
Mexico	317[22]	317[25]	17,500,000[33]	1.81143E-05	0.005742229
Dominican Republic	237[22]	41[25]	800,000[33]*	0.00005125	0.01214625
Colombia	145[22]	110[25]	4,331,600[33]	2.53948E-05	0.003682242
Other Countries	927[22]	7099[25]	399,121,400[33]	1.77866E-05	0.016488149
Total	**2677[22]**				**0.039418527**

*Dog populations for Dominican Republic had not been reported, so Puerto Rico's dog population count was utilized.

Table 3: Number of Canine Rabies Cases Potentially Prevented via CDC Form 75.37 (2012), Low-Middle Estimate Calculated by [∑ (Prevalence Rate) X (# Dogs Issued Confinement Agreements in Each Group)]

Country of Origin	Number of Dogs Listed on Confinement Agreements in 2012	Number of Incident Cases of Canine Rabies	Dog Population	Prevalence Rate	Number of Canine Rabies Cases Potentially Prevented
Canada	641[22]	8[26]	5,002,000[33]	1.59936E-06	0.00102519
Germany	410[22]	0[15, 39]	5,245,000[33]	0	0
Mexico	317[22]	105[26]	17,500,000[33]	0.000006	0.001902
Dominican Republic	237[22]	71[26]	800,000[33]*	0.00008875	0.02103375
Colombia	145[22]	13[26]	4,331,600[33]	3.0012E-06	0.000435174
Other Countries	927[22]	7099[25]	399,121,400[33]	1.77866E-05	0.016488149
Total	**2677[22]**				**0.040884263**

*Dog populations for Dominican Republic had not been reported, so Puerto Rico's dog population count was utilized.

Table 4: Number of Canine Rabies Cases Potentially Prevented via CDC Form 75.37 (2012), Middle-High Estimate Calculated by [∑ (Prevalence Rate) X (# Dogs Issued Confinement Agreements in Each Group)]

Country of Origin	Number of Dogs Listed on Confinement Agreements in 2012	Number of Incident Cases of Canine Rabies	Dog Population	Prevalence Rate	Number of Canine Rabies Cases Potentially Prevented
Canada	641[22]	16[24]	5,002,000[33]	3.19872E-06	0.00205038
Germany	410[22]	0[24]	5,245,000[33]	0	0
Mexico	317[22]	33[24]	17,500,000[33]	1.88571E-06	0.000597771
Dominican Republic	237[22]	93[24]	800,000[33]*	0.00011625	0.02755125
Colombia	145[22]	0[24]	4,331,600[33]	0	0
Other Countries	927[22]	7099[25]	399,121,400[33]	1.77866E-05	0.016488149
Total	**2677[22]**				**0.04668755**

*Dog populations for Dominican Republic had not been reported, so Puerto Rico's dog population count was utilized.

Table 5: Number of Canine Rabies Cases Potentially Prevented via CDC Form 75.37 (2012), Upper Bound Estimate Calculated by [(Highest Prevalence Rate X 2) X (Total # of Dogs Issued Confinement Agreements)]

Number of Dogs Listed on Confinement Agreements in 2012	Prevalence Rate	Number of Canine Rabies Cases Potentially Prevented
2677[22]	**0.00023250***	**0.6224025**

*Highest Prevalence Rate (0.00011625) X 2 = 0.00023250

4.2 Costs Associated with CDC From 75.37

The evaluation determined that if 2,130 confinement agreements were issued in 2012 and 287,000 dogs entered the United States that year, then the majority of the direct labor associated with program was estimated to cost the federal government $776,265.84 (10% sensitivity: $737,452.55 - $815,079.13) [Table 6]. Additional tasks not captured by the economic model and indirect costs were assumed to be 35% of this value and calculated to be $271,693.04 (10% sensitivity: $258,108.39 - $285,277.70) [Table 6]. Thus, in 2012 the entire process associated with CDC Form 75.37 was approximated to cost the federal government $1,047,958.88 (10% Sensitivity: $995,560.94-$1,100,356.83) [Table 6].

These estimates are only representative of the costs associated to administer the form at the federal level. They do not consider state and local government expenses and efforts that are often very expensive and long lasting. Additionally, these values do not reflect labor necessary to conduct a contact investigation if a rabid dog is actually imported into the United States.

Table 6: Estimated Cost of CDC's Dog Confinement Agreement Process in 2012 (95% - 105%)

	95% of Costs*	100% of Costs	105% of Costs*
Cost of Direct Labor	$737,452.55	$776,265.84	$815,079.13
Additional Tasks/Resource/Overhead Costs (+35%)	$258,108.39	$271,693.04	$285,277.70
Total Program Costs	**$995,560.94**	**$1,047,958.88**	**$1,100,356.83**

*10% Sensitivity Range of Total Costs

4.3 Cost-Effectiveness of CDC Form 75.37

Based upon the findings, it is estimated to cost the federal government approximately $1,050,000 annually to potentially prevent less than one case of rabies annually (0.039418527 - 0.6224025 cases). However, most of the data illustrates that the United States government is spending an estimated $1,050,000 to enforce dog confinement agreements and potentially preventing about 0 cases each year through this process (0.039418527-0.04668755 cases).

4.4 State and Local Health Department Evaluation Survey

Although this evaluation is focused on the cost-effectiveness of CDC Form 75.37 at the federal level, nine state and local partners were surveyed to identify how dog confinement agreements functioned within these departments. Of the nine partners surveyed, seven were employees of their respective state health department and two were employees of county health departments.

One third of the partners surveyed (3/9) responded that they were not "content" with the federal procedures currently associated with the dog confinement agreement

[Table 7]. Those that cited that they were not content with the form commented that there is a lack of well-defined consequences for noncompliant importers and the process does not capture many fraudulent documents. Also, one partner noted that their office has no way of determining that a dog is actually being confined.

Moreover, four (44.44%) of the departments surveyed stated that they believe that their office does not have sufficient labor or personnel to respond adequately to each dog confinement agreement received [Table 7]. Lastly, three out of nine (33.33%) partners believed that the federal government should develop a simpler process to replace the current dog confinement agreement procedures [Table 7]. Some of the partners suggested that greater effort should be placed on animal inspection upon entry, animal importations should be limited to specific points of entry, and the process should be redefined so expectations for state and local partners are clearer.

Table 7: State and Local Health Department Evaluation Survey Results

Survey Question	Response Frequency (N)	Percent (%)
Is your office content with current federal procedures associated with the dog confinement agreement?	No……..3	33.33%
Do you believe your office has sufficient labor or personnel resources to respond adequately to each dog confinement form received, including follow-up with importers?	Yes……..…….....4	44.44%
	No…….....4	44.44%
	No Response…….....1	11.11%
Do you believe your office has sufficient resources other than labor or personnel, for example availability of an official vehicle or wireless internet access, to respond adequately to each dog confinement form received including follow-up with importers?	Yes……..……..5	55.56%
	No……..3	33.33%
	No Response……..1	11.11%
Do you believe the federal government should develop a simpler process to replace current dog confinement procedures? By simpler, we mean one that would take less labor or personnel time and use fewer resources. If you have specific ideas for improvement, please list in the comments.	No……..6	66.67%
How difficult is it for your office to make follow-up contact with dog importers (1-6)?	1 = Very Easy…..……...0	00.00%
	2 = Easy…….……....0	00.00%
	3 = Moderate…..…….3	33.33%
	4 = Somewhat difficult.....1	11.11%
	5 = Difficult……..….1	11.11%
	6 = Very Difficult…....…1	11.11%
	No Response……..…3	33.33%

Chapter 5 - Discussion and Public Health Recommendations

5.1 Discussion

Recently, the world has become incredibly interconnected through multiple media of international travel and trade. As globalization efforts expand, it is important for the United States to either update or create new public health policies that can effectively protect its citizens from the increased infectious disease transmission that these changes in global travel and trade present. This is very important in the case of extremely fatal diseases and as emerging infectious diseases become more of a concern.

Due to the changes in international travel and trade, the federal government determined it was important to evaluate the current federal dog importation regulations. This is a critical evaluation because these regulations were developed in the 1950s and may not be an effective means of preventing the importation of rabid or unvaccinated dogs in today's intensely globalized world [38]. Moreover, this is a serious issue since rabies has a nearly 100% case-fatality rate and dogs serve as the primary reservoir for rabies transmission to humans [4,5].

A recent study found that approximately 287,000 dogs enter the United States annually [17]. It also estimated that 25% (~70,000) of these animals lacked proper proof of vaccination or were not vaccinated appropriately upon arrival [17]. However, CDC's QARS data confirmed that the federal process only identified 2677 dogs that posed a public health risk and required a confinement agreement in 2012 [22]. Therefore, the process may be missing thousands of unvaccinated dogs annually.

Since only 2677 dogs were issued confinement agreements in 2012, the cost-effectiveness evaluation demonstrates that the program is currently underperforming. At

best, the process potentially prevented 0.62 cases of rabies for approximately $1,050,000 in 2012. Moreover, the federal government is spending over a million dollars to simply know that 2130 confinement agreements were issued that year. This is because issuance of a confinement agreement does not guarantee importer compliance and does not directly prevent rabies cases.

Considering that this is a process that requires time to review and verify documents, to be considered a cost-effective policy a substantially larger number of dogs lacking proper documentation or vaccination need to be identified upon arrival. Although detecting a greater number of dogs that require confinement agreements would increase costs associated with issuing the form, follow-up, and QARS maintenance, it would at least ensure that costs related to trainings, form and policy development, and other mandatory tasks are being well spent. Moreover, it would demonstrate that the program is meeting the demands of today's high rates of international travel and trade.

Information gathered from state and local partners illustrated that there are multiple issues also limiting the effectiveness of the form. Most importantly, a third of local partners surveyed reported that they do not have the manpower to adequately follow-up with importers; therefore, many noncompliant importers have the potential to remain unidentified. Also, some of the partners cited other key problems related to the overall process. Such problems include a lack of clear duties for state and local offices, ill-defined consequences for noncompliant importers, and an inability to successfully capture all fraudulent paperwork. Together, the cost-effectiveness analysis and survey information from state and local partners demonstrated that the confinement agreement process is underperforming at various levels and should either be reconsidered to match

the current trends in international travel and trade and economic capabilities of all partners included or eliminated entirely.

5.2 Study Limitations

This evaluation had several limitations. Since CDC only had the number of confinement agreements and dogs issued confinement agreements available, a multitude of the information had to be gathered from different peer-reviewed literature, government publications, and reporting databases to determine the number of cases of rabies among dogs globally and dog population estimates. These sources represent a multitude of surveillance and estimation methodologies and a wide range of time, 1999-2012, which may not best characterize the current status of rabies. To address this limitation, these values were used to develop a range. This provides the federal government a relative scale of the form's relative effectiveness.

One limitation of the dog population counts from the World Society for the Protection of Animals' "*Global Companion Animal Ownership and Trade: Project Summary, June 2008*" is that these values only estimated the global population of pet dogs [33]. The global stray dog population was not considered in these counts and treated as a separate estimate.

Since no cost data was available an economic labor model had to be developed based on the expected time per event associated with each part of the confinement agreement process. This was a limitation of the project because calculations from this model could only serve as estimates and it was not able to capture the cost of additional tasks, resources and indirect costs that could not be quantified.

Lastly, the project only had the ability to survey nine state and local health partners because of regulations outlined in the Paperwork Reduction Act. Although, this was a small convenience sample, it did gather a multitude of information that provided the federal government great insight on how the form is functioning at these levels. It also yielded critical qualitative data that was extremely beneficial to the study.

5.3 Public Health Recommendations

Since the federal government spent over a million dollars to simply know they issued 2,130 forms in 2012, it is important that the United States government reconsider the entire confinement agreement process. It is a timely and administratively heavy procedure that is not a cost-effective means of directly preventing rabies transmission and entails numerous issues that inhibits its overall success. Findings from this study suggest that the form and process should be completely removed and replaced with more a stringent dog importation standard operating procedure.

CDC should fully use its statutory authority and develop a process that does not permit the entry of unvaccinated dogs. Although this may increase some operational costs, it would have a multitude of benefits. Primarily it would directly prevent potential rabies cases and remove many of the administrative costs currently tied with the dog confinement agreements process at the federal, state, and local levels. Moreover, it may reduce the number of annual dog importations, making it easier to identify and capture dogs that do not meet federal regulations.

This policy change should also be accompanied with greater coordination from other federal agencies responsible for regulating live animal imports. As noted by the

Government Accountability Office's (GAO) publication *"Live Animal Imports: Agencies Need Better Collaboration to Reduce the Risk of Animal-Related Diseases",* a detrimental gap in current federal animal importation regulations is coordination among agencies such as CDC, CBP, and FWS [44].

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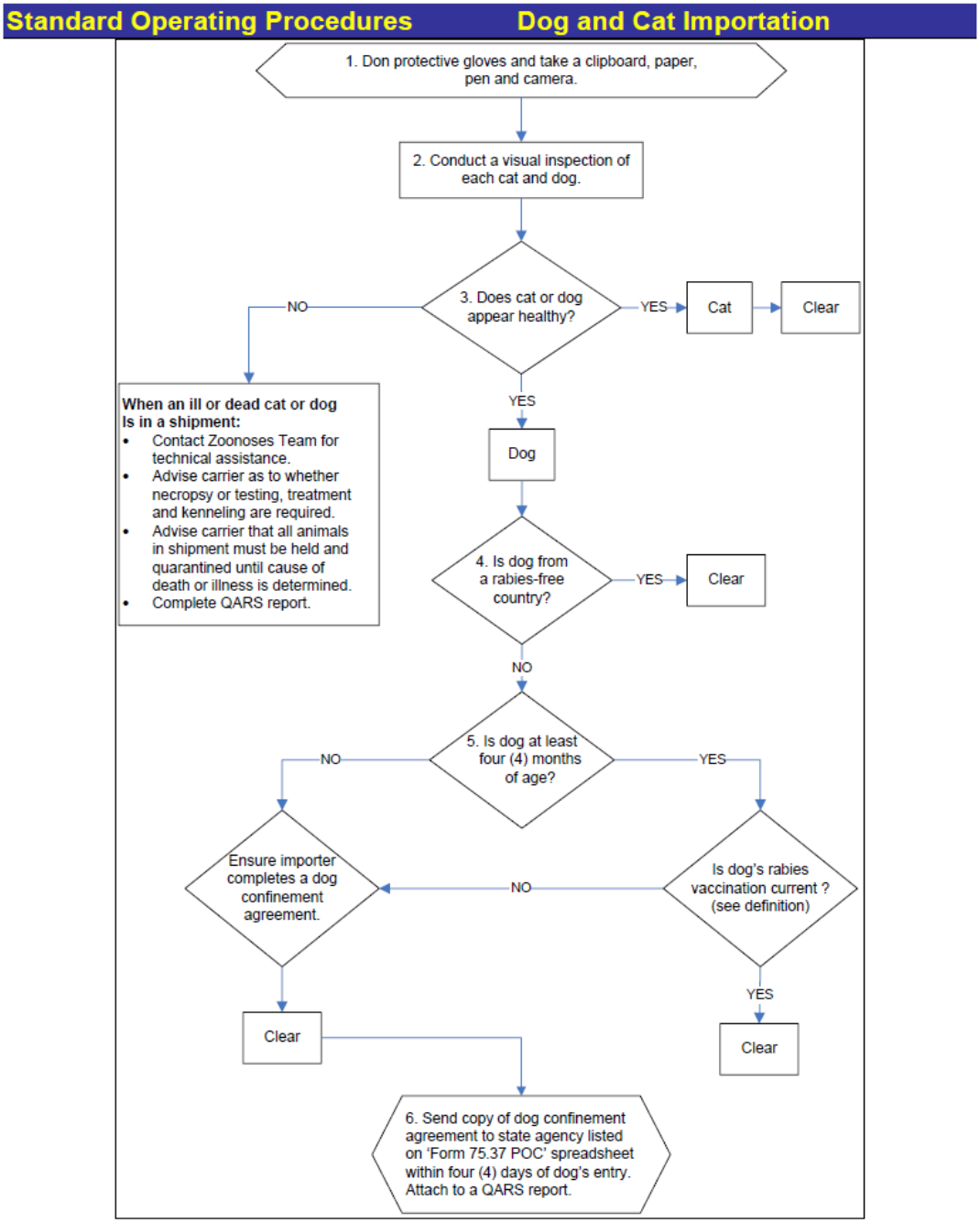
Appendix A: Standard Operating Procedure, Dog and Cat Importation



Appendix B: Confinement Agreement Form

Department of Health and Human Services
Centers for Disease Control and Prevention (CDC)

CDC 75.37 (E) (f. 4.421), Revised July, 2012
OMB # 0920-0134
Expiration date: 07/31/2015

NOTICE TO OWNERS AND IMPORTERS OF DOGS
Requirement for Dog Confinement

*Asterisk indicates a required field.

	***POINT OF ENTRY** (City, State/Territory)	***FORM MUST BE COMPLETED FULLY*** ***THIS IS A BINDING AGREEMENT ENTERED INTO WITH CDC***	***ENTRY DATE** (mm/dd/yyyy)
OWNER	***Name:**	Office or Mobile Phone #:	***Home Phone #:**
	***Driver's License or Passport #:** (State/Territory or Country)	***Street Address:** ***City, State** (Territory), **Zip Code:**	Email Address:
AGENT	***~Name:***	*Office or Mobile Phone #:*	***~Home Phone #:***
	~Driver's License or Passport #: *(State/Territory or Country)*	***~Street Address:*** ***~City, State** (Territory), **Zip Code:***	*Email Address:*
DOG(S)	***Confinement Location:** Check if same as Owner's Address ☐	***Street Address:** ***City, State** (Territory), **Zip Code:**	***Phone #:**
	***Number from Same Litter (i.e., same mother) in this Shipment: _____**	***Age/Birth Date:**	Microchip or Tattoo #:
	***Sex** **#Male_____ #Female_____**	***Breed/Color/Description:**	
	^*Country of Origin:	***Airline and Flight Number/Ship Name/Vehicle Tag #:**	Waybill #:

~Agent's information is only required if owner's agent signs this form instead of the owner.
^Country where dog(s) has lived the past six (6) months or since birth.

Above dog(s) is/are admitted to the United States, subject to restrictions of section 71.51 of the Public Health Service Foreign Quarantine Regulations checked below:

☐ 1. Confinement for _____ days, which will complete a 30-day period from the date of initial antirabies vaccination.
☐ 2. Confinement until 3 months of age, then initial antirabies vaccination to be followed by confinement for 30 days.
☐ 3. Confinement until initial antirabies vaccination at destination (within 10 days of entry into the United States) to be followed by "confinement" for 30 days.
☐ 4. Confinement until booster antirabies vaccination at destination (within 10 days of entry into the United States) provided that initial rabies vaccination was given at ≥ 3 months of age.

The above restrictions are imposed under section 71.51 Title 42, Code of Federal Regulations, and compliance is necessary before the animal(s) is released from confinement.

"Confinement" as used above means "restriction of an animal by the owner or his agent to a building or other enclosure in isolation from other animals and from persons except for contact necessary for its care, or, if it is allowed out of such enclosure, muzzling the animal and keeping it on a leash."

NOTICE TO OWNER or AGENT: Criminal penalties may be imposed for violating regulations enacted under 42 U.S.C. § 264. Under 42 U.S.C. § 271, as enhanced by 18 U.S.C. §§3559 & 3571, individuals violating a quarantine regulation may be sentenced to one year in jail and/or a maximum fine of $100,000, if the violation does not result in a death or $250,000, if the violation results in a death. Violations by an organization are punishable by a maximum fine of up to $200,000 per violation, if the violation does not result in a death, or $500,000 per violation, if the violation results in a death.

Statement to U.S. Government Officer (PLEASE READ):

I certify that I am the owner, or authorized agent of the owner, of the above listed dog(s). I further certify that I acknowledge and will comply with the confinement restrictions checked above. Also, I will be responsible for complying with any additional public health measures that may be required by health departments or other authority in the State of destination. I acknowledge and understand that the dog(s) listed on this form are <u>not</u> transferable to another person or confinement location other than those listed on this form.

Signature of Owner or Agent _____, ***Date*** _____

OFFICIAL USE ONLY: **I have verified that this document is legible and complete.**

Signature of Government Officer _____, *Title* _____, *Date* _____

Appendix C: Rabies-Free List

Table 3-14. Countries and political units that reported no indigenous cases of rabies during 2012[1]

REGION	COUNTRIES/LOCALITIES
Africa	Cape Verde, Mauritius, Réunion, São Tomé and Príncipe, and Seychelles
Americas	North: Bermuda, Saint Pierre and Miquelon Caribbean: Antigua and Barbuda, Aruba, The Bahamas, Barbados, Cayman Islands, Dominica, Guadeloupe, Jamaica, Martinique, Montserrat, Netherlands Antilles, Saint Kitts (Saint Christopher) and Nevis, Saint Lucia, Saint Martin, Saint Vincent and Grenadines, Turks and Caicos, and Virgin Islands (UK and US)
Asia and the Middle East	Hong Kong, Japan, Kuwait, Malaysia (Sabah), Qatar, Singapore, Taiwan, United Arab Emirates
Europe[2]	Albania, Austria, Belgium, Corsica, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Gibraltar, Greece, Hungary, Iceland, Ireland, Isle of Man, Liechtenstein, Luxembourg, Monaco, Netherlands, Norway (except Svalbard), Portugal, Slovakia, Slovenia, Spain(except Ceuta and Melilla), Sweden, Switzerland, and United Kingdom
Oceania[3]	Australia,[3] Cook Islands, Fiji, French Polynesia, Guam, Hawaii, Kiribati, Micronesia, New Caledonia, New Zealand, Northern Mariana Islands, Palau, Papua New Guinea, Samoa, and Vanuatu

[1] Global surveillance efforts and reporting standards differ dramatically, conditions may change rapidly because of animal translocation, and bat rabies may exist in some areas that are reportedly "free" of rabies in other mammals.
[2] Bat lyssaviruses have been reported throughout Europe, including areas that are reportedly free of rabies in other wild mammals.
[3] Most of Pacific Oceania is reportedly "rabies-free," with the exception of Australia, where lyssaviruses in bats have been reported, as well as fatal human rabies cases.

Appendix D: State and Local Partner Survey Instrument

Dog Confinement Agreements- Notice to Owners and Importers of Dogs (CDC Form 75.37) Evaluation Survey: State and Local Level

Survey Introduction and Consent Script-
Hello, my name is …

The CDC Division of Global Migration and Quarantine is conducting an evaluation of CDC Form 75.37 "Notice to Owners and Importers of Dogs" and current dog confinement agreement procedures for international imports of unvaccinated dogs from rabies-endemic countries. The purpose is to evaluate costs to both states and the US Government as well as public health benefits associated with the issuance of confinement agreements and subsequent follow-up by states and CDC. Your input would be greatly appreciated. Any additional comments you provide will help to further define positive or negative aspects of form 75.37 and current procedures related to confinement of unvaccinated dogs.

Participation in this survey is voluntary; there will be no consequences to a decision not to participate.

The interview should take approximately 20 minutes.

Do you agree to participate? Y/N

If no, thank and end.

1. Is your office content with current federal procedures associated with the dog confinement agreement?

   Yes_____ No_____

   Comments:

2. Do you believe your office has sufficient labor or personnel resources to respond adequately to each dog confinement form received, including follow-up with importers?

   Yes_____ No _____

   Comments:

3. Do you believe your office has sufficient resources other than labor or personnel, for example availability of an official vehicle or wireless internet access, to respond adequately to each dog confinement form received including follow-up with importers?

   Yes_____ No _____

   Comments:

4. How difficult is it for your office to make follow-up contact with dog importers? **(1 = Very Easy, 2 = Easy 3 = Moderate, 4 = Somewhat difficult, 5 = Difficult, 6 = Very Difficult)**

   _____

   Comments:

5. Do you believe the federal government should develop a simpler process to replace current dog confinement procedures? By simpler, we mean one that would take less labor or personnel time and use fewer resources. If you have specific ideas for improvement, please list in the comments.

   Yes_____ No_____

   Comments:

6. Does your office encounter any difficulties enforcing federal dog confinement agreements due to conflict with state or local requirements for rabies vaccination of dogs (e.g., state law does not require rabies vaccination or requires vaccination after 4 months of age)?

   Yes_____ No_____

   Comments:

7. Do you believe your office would have enough resources to adequately respond to an imported rabid dog in your state? (e.g., Contact investigation and possible 6 month follow-up of animals exposed to the rabid animal.)

Yes_____ No_____

Comments:

8. May we contact you with any further questions if clarification is needed?

Yes_____ No_____

Comments:

Person(s) interviewed (list titles and contact information):

Thank you for your time. If you have any questions about this evaluation you may contact me at xxxx or call the CDC quarantine station for your jurisdiction.