A POLICY ANALYSIS OF CHAGAS DISEASE

IN THE U.S. AND TEXAS

by

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Presented to the Faculty of The University of Texas

School of Public Health &

LBJ School of Public Affairs

in Partial Fulfillment

of the Requirements

for the Degrees of

MASTER OF PUBLIC HEALTH &

MASTER OF GLOBAL POLICY STUDIES

THE UNIVERSITY OF TEXAS
SCHOOL OF PUBLIC HEALTH
Houston, Texas

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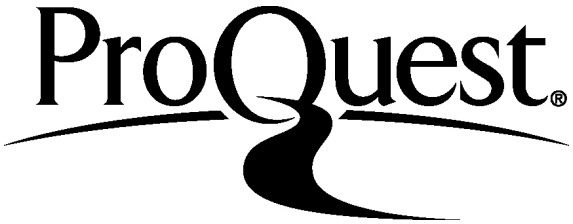
Austin, Texas

December, 2014



ACKNOWLEDGEMENTS

I would like to thank my three committee members, Dr. Shelton Brown, Dr. Bill Kohl and Dr. David Warner, for offering their time and insights as I worked on this project. I also want to thank the 13 individuals who acted as key informants for this project and openly spoke with me about Chagas disease and related policies. Finally, I thank the Peace Corps Bolivia staff, friends in Bolivia who suffer from Chagas disease, and infectious disease professors at UTSPH, all of whom played a part in sparking my interest in Chagas disease and how it is being addressed in the United States.

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Chagas disease is an emerging public health issue that affects as many as 300,000 to 1 million people across the nation.[1] The objective of this project was to examine and prioritize possible policy actions to address Chagas disease in the U.S. so that health authorities, and Texas officials in particular, can better address this emerging health threat.

The methods included a literature review, interviews with key informants, and policy analysis. Research revealed several existing federal and state policies that currently address Chagas disease in the U.S. and the organizations involved in addressing the public health threat. The literature and key informants also identified eight federal and five state policy proposals that could further address Chagas disease. The 13 proposed policies were evaluated and ranked using three criteria: level to which they fill gaps identified by the scientific community, level of practicality in the policymaking sphere, and level to which they align with current CDC objectives for addressing neglected parasitic infections.

Three policy recommendations for federal and state policymakers emerged from this work. Federal policymakers should pursue (1) FDA drug approval, (2) legislation on neglected tropical diseases, and (3) organ donor screening. Texas state policymakers should consider (1) state-recommended targeted screening, (2) Local health department policies, and (3) state legislation on neglected tropical diseases. In addition, I also describe non-government objectives and strategies that advocates should consider to immediately increase the response to Chagas disease in the U.S.

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Disease Overview

Chagas disease, also known as American trypanosomiasis, is a parasitic disease caused by the protozoan parasite, *Trypanosoma cruzi* (*T. cruzi*).[2] The parasite is widespread among animals and is enzootic in 22 American nations, including the United States.[3] *T. cruzi* also infects humans and is endemic in parts of 21 Latin American countries.[4] The triatomine bug, or "kissing bug", acts as the disease vector and typically transmits the parasite to humans and animals when taking a blood meal. Carlos Chagas first discovered the parasite in 1909 when he recognized infections in both animals and humans and identified Triatomids as the vector. Scientists have further identified six major lineages of the parasite (*T. cruzi I - VI*), which differ in geographic distribution, clinical manifestations, and drug resistance.[5] Though the discovery of Chagas disease is relatively recent, there is evidence that Chagas disease has persisted in nature and infected humans for thousands of years in the Americas.[6] This ancient disease triggers few initial symptoms in humans but causes lifelong infection, often leading to long-term disability and/or death.[7]

Chagas disease is a global health problem. The WHO recognizes Chagas disease as one of the 13 most neglected tropical diseases (NTDs), a set of diseases that disproportionately affect the world's poorest people.[8] Chagas disease is a particular threat in the Americas where it is the leading parasitic cause of death in humans.[9] However, due to human migration and non-vectoral transmission, Chagas disease is prevalent in both endemic and non-endemic nations.[10] As a result, Chagas disease causes substantial disease burden in infected individuals and financially impacts nations around the globe.[11]

Transmission

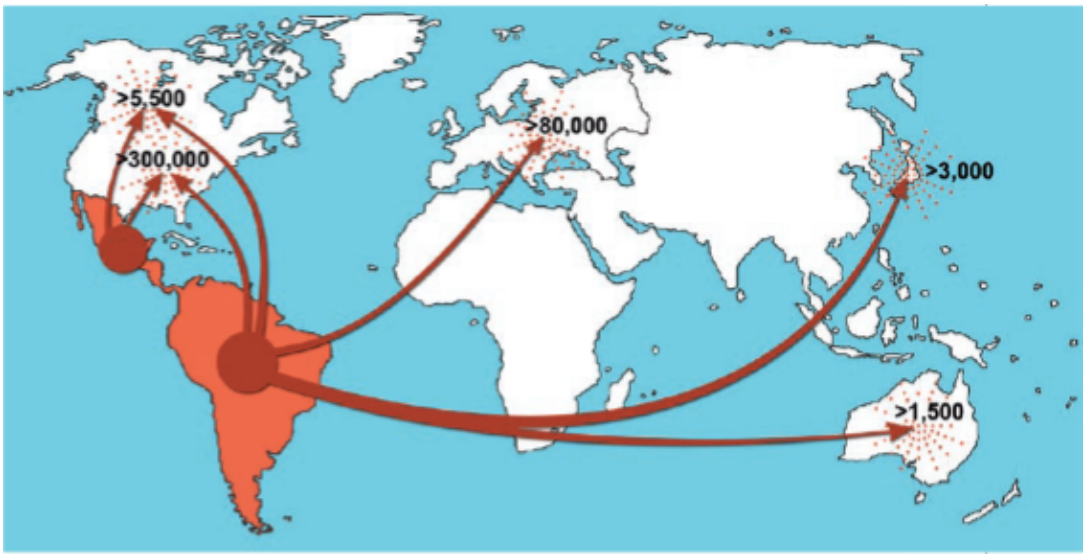
The primary transmission mechanism for human Chagas disease is vectoral transmission through a triatomine bite.[12] Triatomine bugs are nocturnal, blood-sucking reduviids that commonly burrow in rodent or animal nests and sometimes live in the walls and ceilings of substandard human dwellings.[13] Homes with thatched roofs or adobe walls are particularly susceptible to infestation. In infested homes, triatomine bugs typically infect sleeping inhabitants by biting them to take a blood-meal and then defecating at the wound site, passing the parasite from the triatomine feces to the human.[14] Individuals may also be at risk for triatomine bites during outdoor activities, such as camping, hunting, or gardening.[15] There are at least 130 species of triatomine bugs throughout the Americas, but only a few species are efficient parasite vectors and approximately ten species commonly infest human homes.[16] The most competent vectors are those that tend to defecate while taking a blood-meal and include *Triatoma infestans*, *Rhodnius prolixus*, and *Triatoma dimidiate*.[17] These species are most common in South America, Central America, and Mexico.[18]

Non-vectoral transmission also occurs in several forms and is significant in both endemic and non-endemic areas.[19] The two most common non-vectoral mechanisms are mother-to-child transmission and transfusion of contaminated blood.[20] Pregnant women infected with the parasite transmit the disease transplacentally to their children between <1 percent and 10 percent of the time.[21] This transmission mechanism now accounts for an estimated 26 percent of human infections.[22] Congenital transmission cannot be prevented; however, treatment of infants is almost 100 percent effective.[23] Transmission through contaminated blood occurs at a 10 to 25 percent transmission rate.[24] This transmission mechanism accounts for approximately 10 percent of Chagas disease cases and is considered the most common mechanism in non-endemic regions.[25] Less commonly, transmission occurs through organ transplants, ingestion of triatomine-contaminated food, and exposure to contaminated blood through laboratory accidents or animal field dressing.[26]

Epidemiology

In 2012 there were estimated to be 10 million people living with Chagas disease in the world.[27] Roughly 8-9 million people are infected in Latin America, where vectoral transmission accounts for most infections.[28] Over the past couple decades, thousands of cases have also been identified in non-endemic nations, where the actual number of infected individuals is estimated in the hundreds of thousands, if not millions (see Figure 1).[29] These cases generally occur through migration from endemic regions and non-vectoral transmission, such as blood transfusion or mother-to-child.[30] The geographic distribution of cases is depicted in Figure 1. In addition to migration patterns, disease distribution is impacted by disease control policies and programs, urbanization, and socio-economic shifts.[31]

Figure 1: Migration routes from Latin America and estimation of the total number of infected individuals in non-endemic countries[32]



Source: Coura & Viñas (2010)

Latin America

Historically, Chagas disease primarily affected rural areas of Latin America.[33] This case concentration is due to poor housing conditions, which favors triatomine infestation.[34] Other factors include high prevalence of efficient vectors and hosts and poor access to basic services.[35] In 1985 approximately 17.4 million people in Latin America were infected with T. cruzi.[36] Since then, several national and regional control efforts, such as the Southern Cone Initiative to Control Chagas Disease, have decreased disease incidence through primary prevention measures.[37] These programs focus on vector control through continuous application of insecticide and minimization of non-vectoral transmission through blood donation screening.[38] Although coverage is incomplete, these initiatives have successfully eliminated vector transmission in Uruguay (1997), Chile (1999), and Brazil (2006) and have drastically reduced the number of new cases.[39] Urbanization and increases in standard of living also play a role in reducing vectoral transmission.[40] By 2005, the number of Latin Americans infected with Chagas disease dropped to roughly 8 million and approximately 20 percent (60 million people) were at risk for infection.[41] Disease incidence is expected to continue to decrease in Latin America.[42] Still, approximately 50,000 new cases still occur each year in Latin America[43], surveillance and control efforts are not comprehensive[44], and pockets of high prevalence persist, particularly in rural and peri-urban areas of poverty.[45]

United States

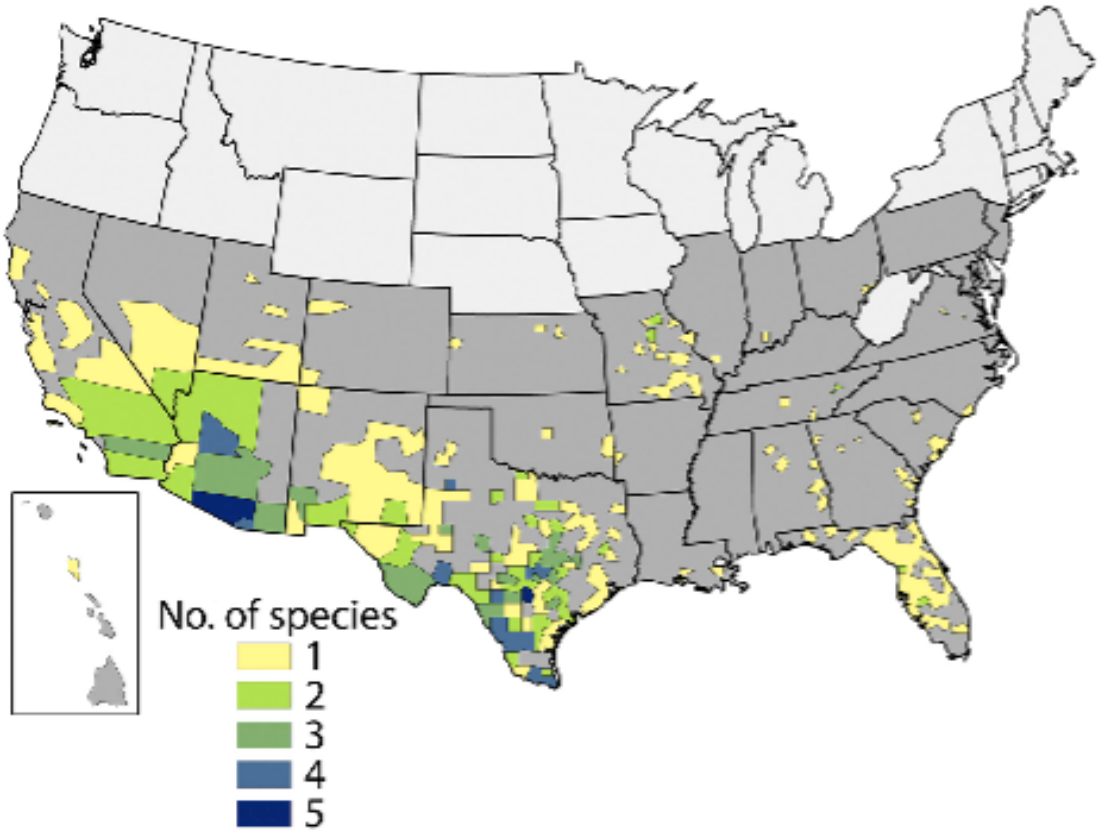
Most estimates suggest that more than 300,000 individuals are infected with Chagas disease in the United States, though some estimates are as high as 1 million.[46] Based on these numbers, the United States has the highest number of infected persons among non-endemic nations[47] and the seventh highest number of Chagas disease cases in the world.[48] The U.S. public health system does not conduct widespread surveillance for Chagas disease, so prevalence estimates are based on the number of immigrants from each endemic country and the prevalence estimates in those nations.[49] This method has limitations[50] and may underestimate the size of the problem by excluding undocumented immigrants[51], Americans who have traveled to endemic regions[52], unreported non-vectoral transmissions, and unidentified indigenous vector-borne cases.[53]

Most researchers think that the vast majority of infected individuals in the U.S. acquired the disease in Latin America and later migrated to the United States.[54] Thus, the distribution of cases throughout the U.S. largely depends upon migration patterns from endemic regions into the states. Most infected individuals in the U.S. are from Mexico, which reflects the large number of Mexican immigrants in the US.[55] States in the U.S. with high numbers of Latin American immigrants, such as those along the U.S.-Mexico border, are likely to have more cases of Chagas disease. Dr. Hotez, a leading Chagas disease researcher and advocate, asserts that NTDs such as Chagas disease are widespread in Texas.[56]

U.S. Vector-borne Transmission

The U.S., however, is not an entirely non-endemic nation, particularly in the southern states. Within the U.S., eleven species of triatomine bugs carry *T. cruzi* (See Figure 2) and transmit the parasite (*T. cruzi I* and *IV*) to wild and domestic animals through triatomine bites and animal ingestion of bugs. Eight of the eleven species have been implicated in human bites in the states.[57] However, vectoral transmission to humans is thought to be rare in the U.S. given that U.S.-based vectors are less efficient disease transmitters than those in Latin America and U.S. homes are generally well sealed.[58] The CDC currently recognizes 23 autochthonous cases in the United States.[59] But many other infections may go undetected.[60] Based on their 2012 study, Cantey et al. extrapolate that as many as one in every 354,000 U.S. blood-donors may have contracted Chagas disease domestically through a triatomine bite.[61]

Figure 2: Triatomine species diversity in the U.S.[62]



Note: States shaded gray have reported at least one species of triatomine bug.
Source: Bern et al. 2011

U.S. Vertical Transmission

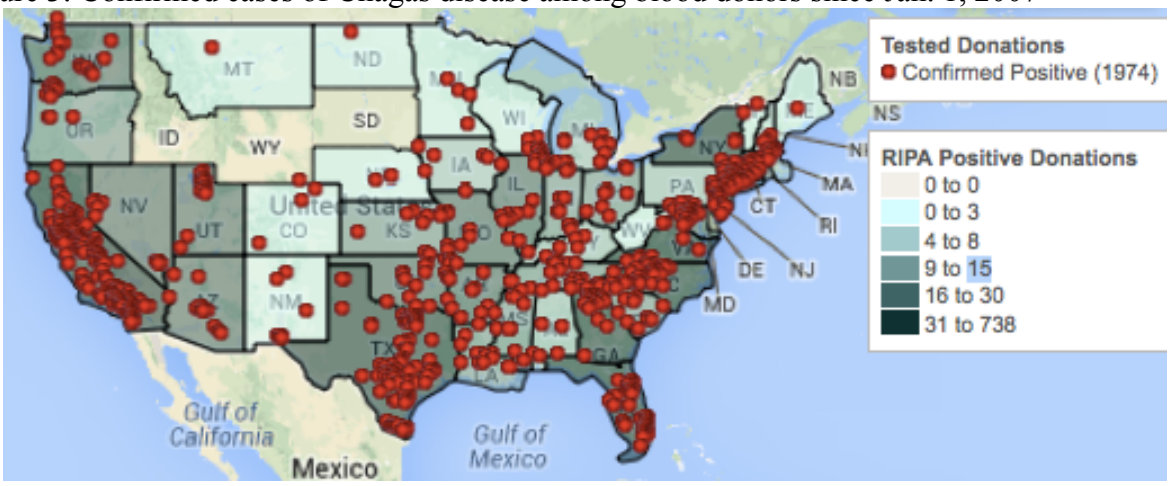
Non-vectoral transmission also occurs in the United States, mostly through mother-to-child transmission and receipt of contaminated blood/organ donations.[63] Few data are available regarding the frequency of these vertical transmissions and many may go unrecognized due to lack of screening and distinctive symptoms.[64]

Neither pregnant women nor infants are regularly screened for Chagas disease and both are often asymptomatic.[65] In 2009 researchers estimated that between 63 and 315 congenital infections occur annually in the U.S., disproportionately among the poor.[66] The first confirmed case of congenital transmission in the U.S. occurred in Virginia in 2010.[67] In a 2014 press release, the CDC claimed that more than 300 U.S. babies are born infected with Chagas disease each year, which could indicate a recent increase in awareness and diagnoses.[68]

Five cases of transfusion-associated transmission[69] and nine cases of infection via organ transplant have been reported in the U.S.[70] These cases were generally detected because the individuals that received the donations were immunocompromised and experienced acute reactions to the contaminated blood or tissues, which is considered uncommon. This suggests that cases among immunocompetent patients may go unrecognized.[71]

In 2007 some U.S. blood banks began to voluntarily test new donor blood for Chagas disease before adding the donor blood to the blood supply.[72] Currently, about 65% of the blood supply is screened for Chagas using FDA approved tests.[73] The U.S. Chagas Biovigilance Network, collects and publishes the data on confirmed cases among blood donors from blood banks.[74] As of June 7, 2014 there were 1,974 confirmed cases of Chagas disease among blood donors (See Figure 3).[75] Identification of these cases among blood donors before the use of their blood presumably prevented numerous new transfusion-associated transmissions. Although blood donor case data are useful for developing a preliminary understanding of case distribution, the data cannot be used to extrapolate prevalence estimates since blood donors are a biased, unrepresentative sample of Americans.[76]

Figure 3: Confirmed cases of Chagas disease among blood donors since Jan. 1, 2007[77]



Source: Chagas Biovigilance Network, American Association of Blood Banks
Note: These data are dated June 7, 2014.

Other Non-endemic Nations

Chagas disease exists in several other non-endemic nations, where it is an emerging public health issue.[78] Unlike in the U.S., Chagas disease is purely non-endemic in these nations and there is no risk of vectoral transmission.[79] All cases are due to migration and vertical transmissions.[80] Chagas disease is a particular threat in non-endemic nations that have experienced recent influxes of Latin American immigrants, such as Spain.[81] Following the U.S., Spain has the highest estimated number of Chagas infected individuals (48,000-67,000 people). Other countries with significant numbers of cases include other European countries, Canada (>5,500), Japan (>3,000), and Australia (>1,500).[82] Like the U.S., these nations lack formal Chagas disease surveillance systems so the validity of estimates is limited. Affected non-endemic nations vary in their public health and policy response to Chagas disease.[83] Currently, only six European countries, including Spain, Italy, France, Switzerland, the United Kingdom, and Sweden, have legislation to control blood supply transmission of Chagas disease. Even fewer European nations and sub-national regions have policies to control congenital transmission and organ-based transmission.[84]

Pathology

Chagas disease affects people in stages and manifests in various forms, which are not yet fully understood or defined.[85] Once infected, individuals typically experience an incubation period of 1-2 weeks and then enter the acute phase of the disease.[86] The acute phase lasts 4-12 weeks, depending on the transmission type.[87] During the acute phase, infected individuals may present febrile illness, inflammation at the entry point (if vectoral transmission), or no symptoms.[88] In less than 1% of cases – more for small children – individuals experience

severe acute disease, which is often fatal.[89] Most frequently, though, the acute phase is asymptomatic and goes unnoticed and undiagnosed.[90]

Following the acute phase, infected individuals enter the chronic phase of Chagas disease, which persists throughout their lifetime.[91] The chronic phase begins in an indeterminate form. The indeterminate form is a latent disease stage characterized by low parasite levels, no visible symptoms, and the potential weakening of cardiac and/or gastrointestinal systems.[92] Despite a lack of symptoms, infected persons can still transmit the disease to others through vertical routes. Sixty to 70 percent of Chagas patients remain in the indeterminate form throughout their lifetime.[93] However, 30-40 percent of cases enter the determinate form, which can be triggered by a compromised immune system.[94] The determinate form usually manifests as progressive cardiac and/or gastrointestinal destruction through parasite persistence in tissues.[95] Resulting cardiac complications often lead to heart failure, ventricular arrhythmias, or v-fib-induced sudden death.[96] Gastrointestinal complications, which are les common than cardiac, often lead to megacolon or megaesophogus.[97] Regardless of the specific symptoms, the determinate form of Chagas disease causes severe disability and death within 10-30 years after infection.[98]

Diagnosis & Treatment

Diagnosis of Chagas disease faces several challenges. First, the pathology of the disease is somewhat elusive. Both the acute phase and indeterminate chronic phase present either no symptoms or indistinctive symptoms, which makes the disease difficult to recognize. Moreover, the symptoms of the determinate form are varied and frequently mimic other cardiac and gastrointestinal conditions, which often leads to misdiagnosis.[99] Second, Chagas disease diagnostic tools have low specificity and sensitivity, particularly during the chronic phase when parasite levels are low.[100] During the acute phase, diagnosis can sometimes be made through microscopic detection of trypomastigotes in blood smears, but the parasite can be confused with *trypanosome rangeli*.[101] Real-time polymerase chain reaction is a more sensitive tool for diagnosis during the acute phase.[102] During the chronic phases, when parasite levels are low, diagnosis often requires at least two immunoassays to confirm the presence of IgG antibodies against T cruzi antigens.[103] Standardized testing and diagnosis of Chagas disease have not been agreed upon and several immunoassay methods are used. Recommended methods include conventional or recombinant enzyme-linked immunosorbent assays (ELISAs), indirect hemagglutination assay, and indirect immunofluorescence assay.[104] The multitude of methodologies reflects the complexity of the disease and the lack of appropriate diagnostic tools.

In the absence of a Chagas disease vaccine or cure, medical professionals rely on two treatment forms: parasite eradication and treatment of disease symptoms.[105] To target the parasite, the World Health Organization (WHO) recommends two anitrypanosomal drugs (Benzinidazole and nifurtimox).[106] Drug treatment is very effective during the acute phase and has a near-100% cure in congenitally infected infants.[107] However, drug effectiveness

significantly decreases with the onset of the chronic phase.[108] Moreover, the drugs have toxic side effects, require lengthy drug regimens, and are not widely available.[109] Symptom treatment varies based on the disease manifestation.[110] Due to a lack of pathology knowledge and treatment guidelines, doctors usually address Chagasic patients with generic heart and GI treatments, including pacemakers, defibrillators or even heart transplant.[111]

There are numerous barriers to Chagas disease treatment in the United States. First, physician surveys suggest that U.S. doctors, particularly obstetricians, are largely unaware of Chagas disease. As a result, doctors infrequently recognize signs and symptoms in high-risk individuals and fail to test for the disease.[112] Without a diagnosis, patients do not receive treatment, including during the acute phase when parasite eradication is most effective. Second, disease confirmation and baseline evaluations currently require a costly series of office visits and tests, which may be difficult for high-risk populations, such as immigrants, to complete.[113] Hispanic immigrants historically have low rates of health insurance coverage and regular health care.[114] Third, the FDA has not approved anitrypanosomal drug treatment, so Chagas patients or their physicians must go through the CDC to obtain drugs.[115]

Public Health Significance

Chagas disease is a little-known public health threat with significant disease burden in the United States. The disease affects as many as 300,000 to 1 million people across the nation, many of whom are poor and disenfranchised members of American society.[116] Latin American immigrants comprise the largest affected group. However, at-risk populations also include children of Latina immigrants, blood and organ donation recipients, and – in endemic regions of the country – people living in sub-standard housing and individuals who spend time outside at night, such as hunters, campers, and homeless persons. More than 300 babies are born infected with Chagas disease in the U.S. every year.[117] Approximately 30,000-45,000 individuals in the U.S. suffer from Chagas-induced cardiomyopathy, which is preventable with early diagnosis.[118] Lee et al. recently estimated that the annual health care costs for Chagas disease in the U.S. and Canada are $62.7 million and that the annual disease burden including Disability-Adjusted Life Years (DALYs) rivals the cost of Lyme disease.[119] The persistence of Chagas disease in the U.S. causes unnecessary morbidity and mortality and financially burdens both families and health systems.[120]

To date, the U.S. public health system has done little to address Chagas disease within its borders. There are no comprehensive Chagas disease surveillance and control programs in the United States. There is a scarcity of disease awareness and pathological knowledge among health professionals, policymakers, and the general public. There are few effective screening tools to detect infections and interrupt new transmissions. Treatments are both widely unavailable and largely ineffective. As a result, infected individuals continue to silently suffer the disease, health systems are unnecessarily burdened, and new transmissions presumably occur.

Current budget constraints and competing public health needs may limit the ability of policymakers and public health officials to manage Chagas disease comprehensively across the U.S. In order to facilitate policy action, Chagas disease policy options should be identified and prioritized. This report aims to describe and analyze existing and proposed Chagas disease policies in the U.S. and in Texas, in particular. In addition, the report will prioritize future policy actions, which may aid state and federal policymakers in effectively responding to Chagas disease in the United States.

Specific Aims & Objectives

Chagas disease researchers and advocates claim that the U.S. public health system has not appropriately addressed the problem of Chagas disease in the nation. Authors of many journal articles identify specific gaps in Chagas disease surveillance, prevention and control in the United States. The CDC also recognizes the insufficiency of the health system efforts to confront emerging infectious diseases like Chagas disease.[121] The objective of this project is to examine and prioritize possible policy actions that would fill existing gaps so that U.S. health authorities, and Texas officials in particular, can better address the emerging health threat of Chagas disease.

This written culminating experience has four specific aims:

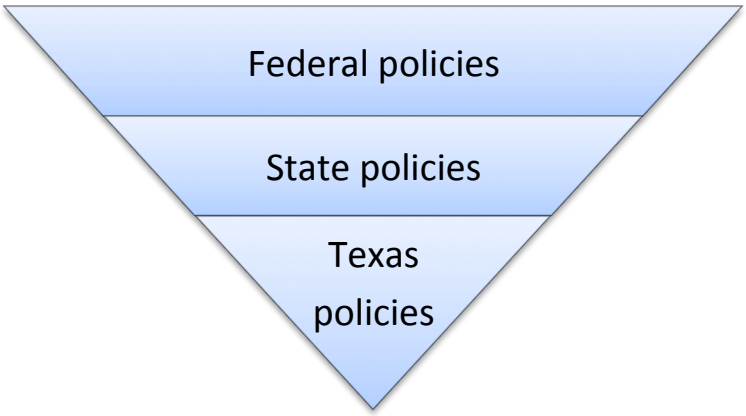
Aim 1: Outline the threat of Chagas disease in the U.S. (provided in literature review)

Aim 2: Review existing Chagas disease policies in the U.S., with a specific focus on Texas. Attempt to identify when, why and how each policy was established.

In this report, "policies" is defined as any law, regulation, guideline, action, or resource allocation documented by federal or state governments to address the problem of Chagas disease within its borders.

I conduct the analysis on three geographic levels (see Figure 4). I begin at the national level, examining federal policies. Second, I assess state policies in the few states that have taken action on Chagas disease. Finally, I do a deep dive into Texas state policies. Since I am located in Austin, near the Texas Department of State Health Services headquarters, I have greater access to information on Texas state policies than other state policies. Though proximity and convenience drives this concentration on Texas, the focus is relevant and important, as Texas is presumed to have one of the highest prevalence rates of Chagas disease in the U.S.

Figure 4: Geographic levels of policy analysis



Aim 3: Identify and examine proposed federal and Texas state policies, including policy objectives and progress made towards implementation.

Aim 4: Prioritize proposed policies based on the following criteria:

(1) To what degree it fills the gaps identified by the scientific community
(2) To what degree it is politically tractable, including financial and logistical feasibility, strength of actors involved, and potential for widespread support
(3) To what degree it adheres to the CDC strategy for addressing Neglected Parasitic Infections (NPIs)

METHODS

Data Collection

I collected data using two methods, outlined below.

(1) Literature review

I gathered data on existing policies and proposed policies by reviewing the following types of documents:

Journal articles
Cost-benefit analyses
Newspaper articles, press releases and other media
Webpages of relevant agencies and organizations
Government documents

(2) Interviews with key informants

I interviewed key informants to gather information about existing and proposed policies. Interviewees include public health officials and staff from the following organizations and groups:

Texas Department of State Health Services
AABB Chagas Biovigilance Network
Scientific/Research Community
Sabin Institute
CDC
FDA

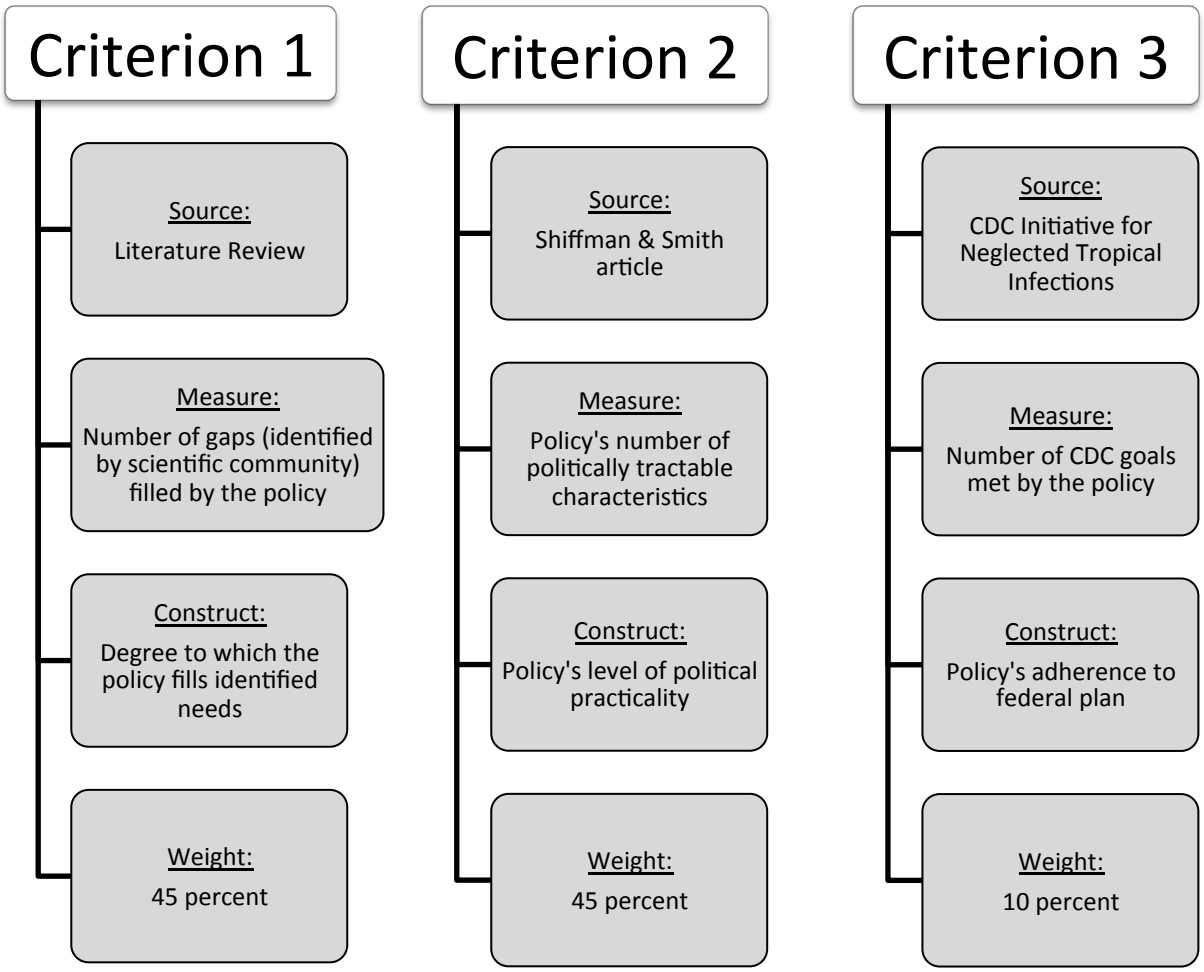
Data Analysis

After gathering the information and data described above, I evaluated the proposed Chagas disease policies (Aim 4). I used three criteria, described below, to assess the relevance and strength of the proposed policies. I evaluate and rank the proposed policies by assigning a score to the policy in each of the three criteria and then calculating a cumulative score based on the scores in each section.

Evaluation Criteria

The purpose of the three criteria is to identify the policy recommendations that are most appropriate for addressing the problem of Chagas disease in the U.S. Each set of criteria measures a different aspect of the policy's suitability (see *Figure 5*).

Figure 5: Overview of three criteria for evaluating Chagas policy options



Criterion 1: Fills gaps identified by scientific community

Over the past decade, a handful of researchers, scientists, and medical professionals in the United States have published articles in peer-reviewed journals regarding the state of Chagas disease in the U.S. In these works, several authors point out the research and public health gaps in addressing Chagas disease and the areas that require greater funding and attention. During the literature review stage of this project, I created a list of the most salient gaps that the scientific community identified in their works (see *Table 1*). The most commonly cited challenges include lack of data on Chagas disease epidemiology in the U.S., lack of technical

innovation including effective diagnostics, lack of disease awareness among physicians, public officials, and the public, lack of available effective drugs, and lack of systematic Chagas disease screening and control.

The list of gaps in *Table 1* comprises the first set of criteria for evaluating policy proposals for Chagas disease. The authors of these articles are arguably the nation's most informed experts regarding Chagas disease and its risks in the U.S. Thus, it is important to weigh their expertise in the evaluation process. The use of this criterion to evaluate the proposed policies on Chagas disease is an attempt to measure the validity or potential effectiveness of the policy to fill an established need. The potential weakness of *Criterion 1* is that the scientific community may overvalue research or lack an understanding of the policy process.

The gaps identified by U.S. scientists can be generally separated into four categories: (1) awareness, (2) research and innovation, (3) treatment, and (4) regulations (See *Figure 5*). Some gaps fall into more than one category; however, each gap is classified into what was deemed the most appropriate section.

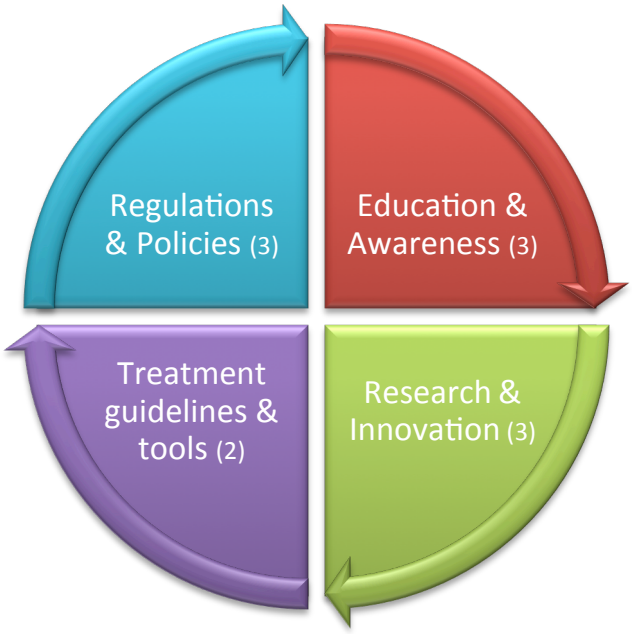
Table 1: Gaps in Addressing Chagas Disease, according to the Scientific Community

Gap	Source(s)
Education & Awareness	
Disease awareness and education among physicians (particularly obstetricians, cardiologists, and neurologists)	Hanford et al., 2007; Carod-Artal, 2013; Hotez, 2012; Hotez et al., 2013; Gascon et al., 2010; Parise et al. 2014,
Disease awareness among the public	Hanford et al., 2007;
Political will to address Chagas disease	Dias et al., 2008; Parise et al. 2014
Research & Innovation	
Greater understanding of Chagas disease epidemiology in the U.S., including distribution and transmission routes	Hanford et al., 2007; Hotez, 2012; Hotez, 2008; Parise et al. 2014
Technical expertise and innovation for diagnostics, treatment, and control	Dias et al., 2008; Hotez et al. 2013; Hotez, 2008; Parise et al. 2014; Dumonteil et al. 2012; Rassi Jr et al., 2010

Table 1 Continued

Multilateral collaboration among endemic and non-endemic nations to advance diagnostic, treatment, and prevention strategies	Gascon, et al., 2010; Hanford et al., 2007; Hotez et al., 2013; Dumonteil et al. 2012
Treatment	
Improved evaluation and treatment strategies and guidelines to facilitate physician management of patients	Gascon et al., 2010; Rassi Jr et al., 2010; Parise et al. 2014
More effective drugs with fewer side effects	Gascon et al. 2010; Rassi Jr et al., 2010; Hotez et al., 2008; Parise et al. 2014; Dumonteil et al. 2012
Policies	
Widespread availability of low-cost drugs and identification of access barriers	Rassi Jr et al., 2010; Hotez et al., 2008; Hotez et al., 2013; Carod-Artal, 2013; ; Dumonteil et al. 2012
Expanded surveillance and disease mapping to determine prevalence and burden of disease	Hotez et al., 2007; Hotez, 2012; Hotez et al., 2013
Sustainable screening and control programs, particularly among patients from endemic nations (focused on blood banks, organ procurement agencies, pregnant women, stroke and neurology patients)	Dias et al., 2008; Gascon et al., 2010; Carod-Artal, 2013; Milie et al., 2009

Figure 5: Four Categories of Gaps in Addressing Chagas Disease in the U.S.



Note: (#) indicates the number of scientific community gaps in each category

A policy's potential to fill these gaps determines the policy's score in *Criterion 1*. A policy's total *Criterion 1* score, which is referred to as the "scientific" score, is the percentage of gaps that it would reasonably fill if enacted. The scientific score comprises 45 percent of the policy's final score because filling these gaps is a significant determinant of appropriateness.

Criterion 2: Provides a politically tractable solution

The second set of criteria measures the political tractability of a proposed policy. Political tractability is a policy's aptitude for success or its feasibility based on certain characteristics. Many policies look great on paper but will never be endorsed for lack of tractability. A well-prioritized, feasible policy has many distinct qualities, such as cost-effectiveness, widespread support, and practicality. *Criterion 2* is used to ensure that the policy recommendations are realistic solutions to the Chagas disease threat.

The components of *Criteria 2* are loosely based on Shiffman and Smith's framework for the generation of political priority, outlined in their 2007 *Lancet* article "Generation of political priority for global health initiatives: a framework and case study of maternal mortality." This article provides useful guidance for assessing an issue or policy's potential for gaining

political priority. Shiffman and Smith's framework is adapated to fit the context of Chagas disease policies, focusing on seven characteristics of tractability:

Table 2: Characteristics of a Politically Tractable Chagas Disease Policy

Characteristic	Description
Leadership	The presence of individuals or strong champions for the cause capable of uniting the policy community around the proposal
Institutional support	The support and presence of effective organizations with a mandate to lead the proposed initiative
Civil society support	The presence of grassroots and external pressure to enact the policy
Simplicity	The policy has clearly explained objectives and is simple to implement once approved
Cost effectiveness	The policy's benefits are estimated to outweigh its costs
Inexpensiveness	In addition to being cost effective, the upfront costs of the approved policy are low
Scientific Evidence	The policy and its tie to the problem are backed by scientific evidence

Source: Adapted from Shiffman & Smith (2007)

A policy's level of feasibility determines its score in *Criterion 2*. For each policy, the number of *Criterion 2* characteristics is assessed. A policy's total *Criterion 2* score, which is referred to as the "tractability" score, is the percentage of characteristics that it possesses. The tractability score comprises 45 percent of the policy's final score. Like *Criterion 1*, tractability is a significant determinant of a proposed policy's relevance and is weighted appropriately.

Criterion 3: Adheres to CDC initiative on Neglected Parasitic Infections (NPIs) in the U.S.

The third criterion for policy evaluation is based upon the CDC's strategy for targeting neglected parasitic infections (NPIs) in the U.S. In May 2014, the CDC issued a press release, entitled "Parasitic infections also occur in the United States," that describes the burden of Chagas disease and other NPIs in the U.S. and outlines the CDC strategy to address these health threats (See *Table 2*). During that same month, Dr. Susan Montgomery, Epidemiology Team Lead of the CDC Parasitic Diseases Branch, authored a journal article that outlines the CDC-identified gaps in addressing Chagas disease in the U.S. (*See Table 2*). In combination, these two documents clarify the CDC's strategy for mitigating the threat of Chagas disease in our nation.

The inclusion of *Criterion 3* is important for gauging the level to which the proposed policies align with national goals and priorities for addressing Chagas disease. This criterion allows the measurement of the potential validity of a proposed policy and its political strength. The more a proposed policy aligns with the CDC strategy, the more it meets the established federal objectives for addressing legitimate health threats. In addition, the greater a proposed policy's alignment with documented agency goals, the greater its existing political support and, thus, tractability. It should be noted that the CDC-identified gaps and subsequent goals largely overlap with the gaps identified by the scientific community.

Table 3: The CDC's Strategy for Controlling Chagas Disease in the U.S.

CDC Goals for Addressing NPIs[122]	CDC-Identified Gaps in Chagas Disease Control[123]
Goal 1: Increase awareness among physicians and the public	• Lack of Chagas disease awareness and knowledge among health care providers, public health professionals, and the public • Lack of effort to reduce disease stigma
Goal 2: Synthesize the existing data to help better understand these infections	• Lack of high-quality data on epidemiology of existing cases and distribution of risk
Goal 3: Improve diagnostic testing	• Lack of effective and available diagnostic and screening tests

Table 3 continued

Goal 4: Advise on treatment, including distribution of otherwise unavailable drugs	• Lack of safe, effective, readily available drugs

Sources: "Parasitic infections also occur in the United States," CDC Newsroom. May 8, 2014. "Neglected parasitic infections in the United States: Chagas disease," Montgomery et al, CDC Division of Parasitic Diseases and Malaria. May, 2014.

The scoring in *Criterion 3* is based on a policy's potential to meet the goals established by the CDC. A policy's total *Criterion 3* score, which is referred to as the "CDC" score, is the percentage of CDC goals that it fulfills. The CDC score comprises only 10 percent of the policy's final score, which is less than the weight assigned to *Criterion 1* and *2*. Although alignment with CDC goals can be important, it does not significantly determine the strength of a proposed policy.

Ranking & Prioritization

A final score is calculated for each proposed policy by applying a weight to the three categories. Criteria 1 and 2 (scientific and tractability) are each given a weight of 45 percent because these criteria significantly determine the appropriateness and practicality of the proposed policies. The third criteria (CDC) is given a weight of 10 percent and signifies a policy's alignment with CDC agency goals for NPIs, which is of secondary importance. Based on the final scores, the proposed policies are ranked at the federal and state levels. If the criteria accurately measure the strength and relevance of the proposed policies, the top-ranked policies should be recommended to policymakers to address Chagas disease in the U.S.

Human Subjects Considerations

The human subjects consideration in this WCE is the protection of the privacy of key informants. I have protected their privacy by (1) providing written and/or oral explanation of my project before the interviews, (2) only asking questions that fall within their professional purview, and (3) only using interviewees' names in the report with prior written permission to do so. This UTSPH Review Board approved this project and these methods of privacy protection before I initiated the study.

RESULTS

Relevant Actors

In order to understand existing policies, it is important to recognize the organizational actors involved in addressing Chagas disease in the U.S. and Texas. These stakeholders have played and will presumably continue to play key roles in developing, shaping and supporting policy actions related to Chagas disease (see *Tables 1 and 2*).

U.S.-based Organizations

Table 4: Organizations in the U.S. addressing Chagas Disease

Organization (Location)	Type	Chagas-related Goal
Center for Disease Control and Prevention (Atlanta, GA)	Federal government	To diagnose Chagas disease cases, provide free benznidazole to infected individuals, conduct research, and increase awareness
U.S. Agency for International Development (D.C.)[124]	Federal government	To provide support for Chagas disease control in Latin America and facilitate int'l cooperation in addressing the disease
U.S. Food and Drug Administration (D.C.)	Federal Government	To regulate diagnostics and drugs for Chagas disease, and to regulate testing of the blood supply
Chagas Biovigilance Network (Bethesda, MD)	Public-private partnership	To record new diagnoses of Chagas disease in the U.S. identified by blood banks
United Network for Organ Sharing (Richmond, VA)	Non-profit with federal contract	To regulate transplant procedures in the U.S., including disease screening
Sabin Vaccine Institute (Houstin, TX)	Non-profit	To develop and manufacture a Chagas disease vaccine and to advocate for increased access to preventative medicine
The Chagas Disease Foundation (Bogart, GA)[125]	Non-profit	To promote Chagas disease diagnosis, control, prevention and treatment and to monitor and support research efforts worldwide

Table 4 continued

Institute for OneWorld Health (San Francisco, CA)[126]	Non-profit	To develop K-777, a new parasite drug being tested to treat Chagas disease
Latin American Society of Chagas (D.C.)[127]	Civil society	To advocate for Chagas disease screening
Bolivian Consulate (northern Virginia)[128]	Foreign government	To screen Bolivian immigrants for Chagas disease
Bayer Healthcare (Montville, NJ)[129]	Corporation	To donate Nifurtimox for Chagas disease treatment in Latin America
University of Georgia, Center for Tropical and Emerging Diseases (Athens, GA)[130]	University Center	To research Chagas disease, including vaccine techniques to protect animals
A&M University, Veterinary Medicine & Biomedical Sciences (College Station, TX)	University & Animal Hospital	To research, diagnose, and treat Chagas disease in animals and study the vectors in Texas
National School of Tropical Medicine at Baylor College of Medicine (Houston, TX)[131]	University & Hospital	To treat patients, conduct research, and train specialists in Chagas disease
Olive View-UCLA Medical Center (L.A. County)[132]	Hospital	To operate the nation's only Chagas disease Center of Excellence: to conduct research, outreach, screenings and treatment of Chagas disease
The American Society of Tropical Medicine and Hygiene (Deerfield, IL)[133]	Advocacy group	To support legislative action on Chagas (supported the Act), etc.
Global Chagas Disease Coalition (unspecified)[134]	Advocacy group	To advocate for increased access to health tools, innovation, transmission control, and greater public and policy awareness

Table 4 continued		
Albert Einstein College of Medicine (New York, NY)[135]	University	To research the T-cruzi parasite and study Chagas disease pathogenesis
Chagas in Transplant Working Group (unspecified)	Advocacy	To make evidence-based recommendations to U.S. organ transplant organizations to minimize risk of Chagas disease transmission
Drugs for Neglected Diseases initiative (DNDi)	Non-profit	To develop new treatment drugs for Chagas disease and other NTDs

Note: List accumulated through literature review and interviews with key informants

Texas-based Organizations

Table 5: Organizations in Texas addressing Chagas Disease

Organization (Location)	Type	Chagas-related Goal
Department of State Health Services (Austin)	State Government	To monitor and control Chagas disease in accordance with guidelines for reportable diseases in Texas
Texas Medical Association – The Public Health Coalition (Austin)	Advocacy	To educate Texas physicians and policymakers about public health topics, including emerging diseases, and to lobby for policy changes, such as centralization and increased funding for disease surveillance
National School of Tropical Medicine at Baylor College of Medicine (Houston)[136]	University & Hospital	To treat patients, conduct research, and train specialists in Chagas disease
Sabin Vaccine Institute (Houston)	Non-profit	To develop and manufacture a Chagas disease vaccine and to advocate for increased access to preventative medicine

Table 4 continued

A&M University, Veterinary Medicine & Biomedical Sciences (College Station)	University and Animal Hospital	To research, diagnose, and treat Chagas disease in animals and study the vectors in Texas

Note: List accumulated through literature review and interviews with key informants

Existing Policies

This section identifies existing policies related to Chagas disease in the U.S. and explores the process by which the policy was enacted. Although the response to Chagas disease in the U.S. is limited, a few federal policies exist, possibly initiating a greater response to the emerging risk of Chagas disease. Each of the policies described below was enacted by agencies or partnerships within the U.S. Department of Health and Human Services (HHS).

Federal Policies

Centers for Disease Control and Prevention

The CDC's Division of Parasitic Diseases and Malaria addresses Chagas disease through several efforts, which could be considered internal policies. According to agency personnel, this work has been done for several years. In 2009 CDC collaborated with external partners to conduct a briefing about NPIs in Washington D.C. More recently, CDC issued a press release about its Initiative on Neglected Parasitic Diseases in the U.S. The statement explains CDC's existing work on NPIs and is meant to increase awareness and engage new partners.[137] Table 2 on page 16 outlines the goals of the NPI Initiative. The agency's efforts on Chagas disease are particularly important in that they fill gaps in the healthcare system, such as the unavailability of treatment drugs. However, the CDC applies a multi-pronged approach to addressing Chagas disease that extends beyond treatment. The agency implements the following internal policies to address Chagas disease in the U.S.:

1) Diagnose cases using the international standard for diagnosing chronic phase Chagas disease, which includes testing with two different assays with different formats and based on different antigen preparations. Specifically, the CDC lab tests patient serum samples with an immunoblot using trypomastigote excreted secreted antigens and an ELISA that uses recombinant antigens. Commerical labs in the U.S. only use one assay, so CDC's diagnostics provide more definitive results.[138]
2) Provide Chagas disease patients with free doses of benznidazole using investigational protocols. The drug is not approved by the Food and Drug Administration and is currently unavailable to patients outside the CDC program.[139]

3) Offer a free continuing education online course and online diagnostic information to health care providers, intended to educate providers about the disease.[140]
4) Collaborate with clinics, researchers and scientists, patient advocacy groups, and other government organizations to support their efforts and increase attention to the disease.[141]

Each of these internal policies comprises critical efforts to monitor Chagas disease in the U.S., increase awareness of the disease, and address the risks and challenges it poses to the public and the U.S. health system.

U.S. Biovigilance Network

The U.S. Biovigilance Network is a public-private partnership created in 2006 by the U.S. Department of Health and Human Services (HHS) and private organizations, such as the American Association of Blood Banks (AABB), blood and tissue centers, and hospitals.[142] The Chagas Biovigilance Network is one branch of the U.S. Biovigilance Network. It records and confirms data on new cases of Chagas disease reported by blood banks across the country and displays the case locations by zip code on a publicly-accessed website.[143] The AABB Transfusion Transmitted Diseases Committee, a group of representatives from blood banks laboratories and other infectious disease experts, prompted the initiation of the case data collection and the development of the website.[144] The CDC funded the development of the data collection system and map enhancements[145], though funding is also sought from private partners and private donors.[146] The HHS decisions to collaborate on and partially fund this project are important federal policy actions for addressing Chagas disease. Although case data derived solely from blood banks has limitations, this data collection effort may be a first step towards more widespread screening, surveillance, and awareness of Chagas disease.

U.S. Food & Drug Administration (FDA)

The U.S Food & Drug Administration (FDA) has approved three tests for Chagas disease screening. In the early 2000s, FDA and the Blood Products Advisory Committee (BPAC) recognized that Chagas disease was transmissible through blood transfusions and posed a risk to the blood supply.[147] To facilitate screening, FDA rolled out the testing platform.[148] In December 13, 2006, FDA approved a new commercial Ortho *T Cruzi* ELISA test system for blood donation screening.[149] The Ortho ELISA test is currently the most widely used testing method for Chagas disease in the U.S.[150] In April 30, 2010 FDA approved the Abbott Prism test, a second blood donor screening test, used to screen blood, tissue, and organ donors for T. cruzi parasite.[151] Most recently, in November 2011, FDA approved the Abbott ESA Chagas test, a supplemental confirmatory assay to verify the results of the first donor screening tests.[152]

In December 2010, FDA issued a recommendation to U.S. blood centers to test all blood donors once for Chagas disease. The recommendation came four years after the approval of the first screening test and followed BPAC's evaluation of scientific data supporting the recommendation and suitability of the guidance.[153] Some U.S. blood banks had already begun testing donors as early as 2007, after the approval of the Ortho ELISA test.[154] The recommendation is outlined in FDA document, "Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruiz* infection in Whole Blood and Blood Componenets Intended for Transfusion" and specifies that blood centers should test all new and past donors one time.[155] There is no FDA guidance or recommendation for any specific state.[156] FDA recommends that centers first use a screening test and then retest reactive samples with the same test (the international standard requires two different tests and is more accurate).[157] In 2014, four years since the recommendation was issued, approximately 65% of the U.S. blood supply is tested for Chagas disease.[158] It is unclear which blood centers adhere to the recommendation, though interviewees speculate that decision factors include cost, competing priorities, estimated prevalence in region or donor pool, standard of care, and pressure from nearby centers and/or hospitals.[159] When a blood center identifies a case of Chagas disease, the center advises the donor to consult with his physician, defers the donor from future blood donation, and, in states where the disease is reportable, notifies the local health department.[160]

State Policies

A few states have initiated a response to the threat of Chagas disease. The clearest state policy action is the addition of Chagas disease to the statewide list of reportable diseases. Four states have taken this action, including Arizona, Massachusetts, Tennessee, and Texas. In many other states, Chagas disease is an implicitly reportable disease in that Chagas disease falls under a "catch-all" umbrella of uncommon communicable diseases of public health concern. In these states physicians are encouraged to report new cases of rare diseases like Chagas disease.[161] Although the addition of Chagas disease to the state list of notifiable diseases does not trigger new funding or programming for the disease, it may indirectly facilitate testing, case investigations, and treatment of existing cases.[162] Additional state policy actions include funding for Chagas disease related programs, such as triatomine testing and at-risk patient diagnosis and treatment at public hospitals and clinics. In addition, some states are home to universities, hospitals, consulates, and non-profit organizations with internal policies and programs to address Chagas disease. Those programs that appear to receive funding from state or local health departments are included on this list.

Arizona

Arizona was the first state to add Chagas disease to its list of reportable diseases. On February 14, 2007, the Arizona Director of Health Services executed an Order that required

healthcare providers to report cases to the health department and to provide treatment.[163] The order cites several reasons for the new law, including increasing immigration rates from endemic nations, the need to assess the impact of the disease on Arizona's population, the recent (January 2007) initiation of blood bank testing for Chagas disease, the need to connect newly diagnosed individuals with treatment and avoid transmission to fetuses, and the fact that CDC was considering making Chagas disease nationally reportable.[164] According to one federal health official, Arizona anticipated that the risk of vector transmission to humans would be higher in Arizona and that the state would need to track cases to better understand the risk, but despite strong evidence of high prevalence of infection among animals few human cases have been detected in Arizona. [165] In November 2013, the Chagas Biovigilance Network had only confirmed 29 cases among blood donors in Arizona, though many more cases likely exist among non-blood-donors.[166]

California

Chagas disease is not a notifiable disease in California, though human prevalence reports are as high as 1.0-1.5% in parts of the state.[167] However, the state has indirectly taken policy action on Chagas disease through county level support of the Olive View Clinic in Los Angeles county. The Olive View clinic is the only Center of Excellence for Chagas disease in the U.S., recognized as such by the CDC in 2007. A Center of Excellence is a facility that provides leadership, research, and best practices for a disease or health focus. As such, the Olive View clinic regularly diagnoses and treats patients at the hospital and through screenings at community health fairs. County administrators are very supportive of the program, noting its cost-effectiveness and success. In turn, the county financially supports a portion of the program by providing phlebotomy equipment and the space for physicians to see patients.[168] Through the county's provision of funds, the state indirectly supports the work at the Chagas disease Center of Excellence.

Georgia

Although Chagas disease is not a notifiable disease in Georgia, state or local health department may support Chagas disease screening efforts at a local clinic. A public health antenatal clinic in Georgia screens at-risk pregnant women. This unidentified clinic may be a state-funded facility, but confirmation was not available.[169]

Massachusetts

In 2007, Massachusetts was the second state to pass a law requiring healthcare providers and donor banks to report Chagas disease cases to the health department.[170] According to a federal health official, Massachusetts added Chagas disease to the list because some blood centers in the state were beginning to screen donors with the newly approved Ortho ELISA

test and the state health department wanted to monitor the cases that emerged from screening. Given the context of the Massachusetts healthcare system, the state had an interest in tracking cases and ensuring treatment.[171] However, according to the December 2013 "Summary of Amendments: 105 CMR 300.00," the state health department removed Chagas disease from its list of reportable diseases.[172]

New York

Chagas disease is not a notifiable disease in New York. However, a few physicians in New York City, including Dr. Tanowitz at Albert Einstein Medical School, regularly test at-risk patients to identify unrecognized infections and conduct research on Chagas disease. This screening effort is important, given the high number of Hispanic immigrants in New York City.[173] Some of the work done by NYC physicians may be partially or indirectly funded by the state.[174]

Tennessee:

The Tennessee state health department passed a law requiring healthcare providers to report Chagas disease to authorities within one week of knowing or suspecting the disease.[175] The Tennessee health department also urges healthcare providers to direct cases to treatment and test other at-risk family members.[176] According to a health official, Tennessee added Chagas disease to the list of notifiable diseases because the authorities wanted to better understand the possible risk of local transmission to humans and domestic dogs throughout the state, given the prevalence of infected triatomines and wild animals.[177]

Virginia

Virginia is home to the highest number Bolivian immigrants in the U.S., a group that faces high risk of prior Chagas disease infection.[178] Despite this fact, Virginia has not added Chagas disease to the list of notifiable diseases or enacted any Chagas disease related policies. It should be noted, though, that a foreign government agency – the Bolivian consulate – has implemented its own internal policies in Virginia. In 2013, the Bolivian consulate began conducting Chagas disease screenings throughout northern Virginia through the Bolivian consulate's mobile clinics.[179]

Overall, states added Chagas disease to the list of notifiable diseases due to a perceived threat of vector-borne transmission. Massachusetts is the anomaly, having added the disease to fulfill treatment objectives and later removed Chagas disease from the list. All other policy actions at the state level are minor, indirect, and often the result of an initiative led by academics or physicians who are concerned about a specific patient population and/or have an interest in the disease.

Texas State Policies

This report focuses on Texas state policies both because Texas is one of the areas in the U.S. most threatened by Chagas disease.

Texas is one of the few states that has developed policy directives for Chagas disease. Although the state does not have a specific policy on Chagas disease, two Texas codes impact Chagas disease control in the state. These policies, described below, require the state health department to control communicable diseases, particularly those included on the list of reportable conditions.

Texas Health and Safety Code Chapter 81: "Communicable Diseases Prevention and Control Act", effective September 1, 1989.

Points specifically pertaining to Chagas disease control:

- The state of Texas has a responsibility to prevent and control communicable diseases.
- The Texas Department of State Health Services may spend funds to identify, report, prevent, or control communicable diseases. This includes spending on health education presentations (including "mass media productions, outdoor display advertising, newspaper advertising, literature, bulletins, pamphlets, posters, and audiovisual displays") and public school health curriculum recommendations to the State Board of Education.
- The department is responsible for maintaining a list of reportable diseases and that clinics, hospitals, blood banks, mobile units and other laboratory facilities and personnel should report those diseases in accordance with procedures adopted by the board.
- Health authorities should submit case information including "(1) an infected person's city and county of residence, age, gender, race, ethnicity, and national origin; and (2) the method by which the disease was transmitted."
- Furthermore, physicians should apply control measures and prevent transmission by treating and educating patients.[180]

Texas Administrative Code Title 25, Part 1, Chapter 97, Subchapter A "Control of Communicable Diseases," originally effective March 16, 1994, most recent amendment effective April 20, 2014

Points specifically pertaining to Chagas disease control:

- The Subchapter lists the diseases deemed reportable and provides instructions for reporting and controlling the diseases. The list includes Chagas disease.
- Physicians and administrators at hospitals, laboratories and blood banks should report human cases of Chagas disease to the local health authority within one week of being suspected or identified.

- Animal cases should be reported to the DSHS regional zoonosis control office within one working day of diagnosis.
- "As the circumstances may require," health authorities should investigate cases to verify diagnosis and causative agent.
- Where appropriate, control measures should be taken, including environmental sanitation, education, and prevention.[181]

In 2013, state health authorities added Chagas disease to the list of reportable conditions during the annual review of the reportable disease list. Rule 97.3 of Texas Administrative Code Chapter 97 states that Chagas disease is a reportable condition in humans and animals in the state of Texas.[182] Though there are no specific criteria for adding a disease to the list, health authorities often add diseases when they want to know more about a disease's prevalence and risk in the state. Other considerations include the morbidity/mortality rate of the disease, transmissibility, and availability of treatment.[183]

According to one health official, several factors lead Texas authorities to add Chagas disease to the list. First, health authorities were concerned about the risk of vector-borne transmissions in Texas. The health department recognized evidence of risk in Texas, including A&M research revealing an infection prevalence up to 80% among triatomine insects in the state, increased diagnoses of Chagas disease in domestic dogs, and documentation of vector-borne human transmissions.[184] Second, health authorities recognized that Texas has a large population of immigrants from countries that are highly endemic, which poses a risk of vertical transmission, including congenital transmission and through blood donations. Finally, the health department reasoned that since Texas blood banks were uncovering cases through screening it made sense for the state to monitor the cases.[185]

In being added to the list of reportable diseases, Chagas disease became a more actionable disease under Texas Administrative Codes Chapter 81 and Chapter 97. Texas does not allot additional funding for diseases added to the list; however, the state is required to take certain actions based on the mandates outlined in Texas Codes. First, the state must maintain a registry of cases.[186] This is an important surveillance measure, though it is limited by the fact that few, if any, physicians in Texas test and diagnose Chagas disease. Second, the state has the responsibility to investigate each case and attempt to determine the source of transmission.[187] This increases the quality of the data on identified cases and can encourage identification of additional cases.[188] Third, the state has the responsibility to facilitate physician and public education as well as treatment of cases. The state has done this by creating new webpages about Chagas disease on the DSHS website that direct physicians and patients to CDC treatment programs and responding to questions about Chagas disease.[189] In addition, the state increases awareness by hosting an annual Diseases in Nature Conference

that includes talks on Chagas disease. There is no dedicated education staff, though, and the health department is limited by staff and budget.[190]

When Texas laboratories, physicians or veterinarians detect a Chagas disease case they report the case to the local or regional health department. The report flows up through the National Electronic Disease Reporting System (NEDS) and health authorities determine whether the case qualifies as an official case of Chagas disease using the Chagas case definition. If it qualifies, the local or regional health department investigates the case by collecting demographic and clinical data as well as information on risk factors, such as travel to endemic areas, presence of triatomines in or around the home, pet infection of Chagas disease, and/or history of bug bite. These details help identify the transmission route and potential existing risks to others. In addition, the state facilitates triatomine identification and testing services. Moreover, when case investigators, private citizens, or researchers collect triatomine samples, they can submit the bugs to the DSHS laboratory, which identifies the bug. In cases where a human bite is suspected, DSHS will send the bug to the CDC for testing to determine if it carries the *T. cruzi* parasite.[191]

The policy decision to add Chagas disease to the list of reportable diseases has generated new evidence of vector-borne transmission in Texas. In 2013, the first year of data collection in Texas, the state recorded 19 human cases and 207 canine cases of Chagas disease. Case investigators determined eight of the human cases (42%) acquired the disease locally. This new evidence of vector-borne transmission risk could encourage additional programming and policy action.

Proposed Policies

This section explores possible federal and state policies that could be enacted to address Chagas disease in the United States. Each policy action was proposed by a public health official, a public health leader, and/or a Chagas disease researcher. I accumulated the list of potential policies through interviews with key informants, reviews of journal and news articles, and examination of government documents.

Proposed Federal Policies

(1) Mandatory blood donor screening
Proposed/Suggested by: World Health Organization (WHO)
Total Score: 33%
Scientific: 36%
Traction: 14%
CDC: 100%

The WHO recommends that endemic nations screen the blood supply for Chagas disease to prevent transmission through the route of transfusion.[192] Since Chagas disease is endemic in parts of the U.S., it may be appropriate for the FDA to require blood bank screening, especially in endemic U.S. states. Although many blood banks currently adhere to the FDA recommendation to screen blood donors for Chagas disease, only approximately 65% of the blood supply is screened. This introduces unnecessary transfusion transmission risk, particularly if blood is not properly screened in endemic areas of the country. The FDA has made no indication of internal discussions of this proposed policy.

(2) Blood donor reentry guideline
Proposed/Suggested by: Food and Drug Administration (FDA)
Total Score: 58%
Scientific: 18%
Traction: 100%
CDC: 50%

Although the FDA is not considering mandatory blood donor screening, the agency is discussing new donor testing and reentry guidelines. Currently the FDA recommends that blood banks test donors for Chagas disease and confirm cases through multiple testing with the same test. Repeat-reactive donors are indefinitely deferred. On July 31, 2014, the agency's Blood Product Advisory Committee (BPAC) discussed a reentry algorithm that would allow donors that initially screen positive for Chagas disease to undergo supplemental testing with the FDA-approved ESA Chagas test. If the supplemental testing is negative, the donor would be eligible for reentry into the donor pool in six months.[193] This change would further align FDA testing guidelines with the international standard. However, given that there is no "gold standard" test for Chagas disease, it may actually decrease the stringency of blood bank screening.

(3) FDA approval of new treatment drugs
Proposed/Suggested by: Drugs for Neglected Diseases *initiative* (DNDi)
Total Score: 62%
Scientific: 55%
Traction: 71%
CDC: 50%

FDA approval of treatment drugs would decrease barriers to patient treatment. Currently, the only way for U.S. patients to access drugs is by going through the CDC, which requires cumbersome paperwork and procedures and poses mail delivery challenges. This creates extra barriers for both physicians and patients. If the FDA approved a treatment drug, physicians could prescribe medication and patients could easily obtain it at a pharmacy.[194] An available treatment drug would also likely increase physician and public awareness

through manufacturer advertisements and would encourage physicians to test and diagnose patients appropriately.

The FDA drug approval process is arduous, and drug producers have little incentive to invest in Chagas disease drugs. In order to get a drug approved, the manufacturer has to go through many steps, including scientific innovation, data collection, clinical trials, and presentation of information at various FDA meetings. This process requires significant investment. Given the relatively small number of identified cases in the U.S. and the typical purchasing power of those afflicted, manufacturers do not foresee a payoff and have little incentive to invest in the process. Currently, a Brazilian company manufactures benzidomel – one of the two existing treatment drugs – but the company has not made the business decision to seek FDA approval in the U.S.[195]

Despite the challenges, several organizations are making progress towards FDA approval of a Chagas treatment drug. A key player in this effort is the Drugs for Neglected Diseases *initiative* (DND*i*), a non-profit research and development organization that develops new treatments for NTDs. DND*i* has short, medium, and long term goals for addressing unmet Chagas disease treatment needs. By the end of 2014, the organization hopes to deliver one new pediatric dosage formula for Chagas disease, one new drug registered for treatment, and a robust pipeline for future treatments.[196] The Sabin Vaccine Institute is also working on a Chagas disease treatment drug. Sabin's Chagas disease drug is still in early stages of development but staff clarified that they will absolutely pursue FDA approval of the drug since the FDA is internationally considered the "gold standard" among regulators.[197]

(4) Mandatory organ donor screening
Proposed/Suggested by: Chagas in Transplant Working Group
Total Score: 43%
Scientific: 27%
Traction: 57%
CDC: 50%

Organ transplant organizations (OPOs) are not currently required to screen donors for Chagas disease, despite the fact that there is evidence of donor-derived *T. cruzi* infection in U.S. organ transplant recipients.[198] The United Network for Organ Sharing (UNOS), a non-profit contracted by the federal government under HHS, is the agency that develops organ transplant policies.[199] Currently, UNOS does not require or recommend that OPOs screen potential organ donors for Chagas disease in the U.S., though UNOS does require screening for other infectious disease.[200] Prior to 2011, a survey of OPOs indicated that only 19% of OPOs voluntarily conducted any donor screening for Chagas disease.[201] In 2013, only four OPOs voluntarily screened all donors for Chagas disease.[202]

In 2011, the Chagas in Transplant Working Group, comprised of transplant infectious disease specialists and organ transplant organization (OPO) representatives, recommended targeted Chagas disease screening of organ donors.[203] At a minimum, the group recommends that OPOs conduct serological testing for all donors born in Mexico, Central America, or South America. The group recommends that OPOs in areas with higher potential prevalence consider universal testing of donors.

In addition to reducing transplant transmission risk, screening organs for Chagas disease is not prohibitively expensive. The cost of the test is approximately $130, well within the range of other infectious disease tests for organs (See Table 6).[204] That said, OPOs are not likely to be interested in taking on additional expenses unless there is strong evidence of risk.

Table 6: Market price of serology associated with organ and tissue donation

Serology	Cost, $
Ortho *T. cruzi* ELISA (Chagas disease)	130
HIV 1 and 2 antibody	120
Hepatatis B core antibody	250
Hepatatis B surface antigen	110
Hepatitis C antibody	200
Cytomegalovirus antibody	131

Source: Wallace, et al. "Chagas disease: a proposal for testing policy for solid-organ transplant in the United States" *Progression in Transplantation*, vol. 23:3 pages 272-277, September 2013.
Original Source: Laboratories at Bonfils Inc

(5) Pregnancy screening guidelines
Proposed/Suggested by: World Health Organization (WHO)
Total Score: 43%
Scientific: 45%
Traction: 29%
CDC: 100%

The WHO recommends that physicians conduct Chagas disease screening for pregnant women who live in disease-endemic areas, have lived in endemic areas, or whose mothers were born in endemic areas.[205] Given that Chagas disease is endemic in areas of the U.S. and that many Latino immigrants live in the U.S., public health authorities should consider recommendations for routine screening of at-risk pregnant women.[206] Three regions of Spain (Catalonia, Valencia, and Galicia), which is a non-endemic nation with high rates of immigration from Latin America, have already implemented pregnancy screening for at-risk women.[207]

There are currently no policies or recommendations to screen pregnant women for Chagas disease in the U.S., despite the risk of congenital transmission. Pregnant women infected with the parasite transmit the disease transplacentally to their children at a rate between <1 and 10 percent.[208] The absence of pregnancy screening is a missed opportunity for prevention, particularly given that newborns are often asymptomatic and treatment in newborns is highly effective.[209]

The U.S. Preventive Services Task Force (USPSTF) provides federal guidelines for perinatal screening, including for several infectious diseases.[210] Currently, USPSTF recommends physicians screen all pregnant women for syphilis, HIV, hepatitus B, and asymptomatic bacteriuria and screen at-risk pregnant women for gonorrhea and chlamydia.[211] In order for USPSTF to recommend screening, the disease must be relevant to clinical practice, involve services that can be implemented in a primary care setting or referable, and have a significant public health burden. Furthermore, there must be substantial evidence that the benefits of screening outweigh the costs.[212] Given the stringency of these requirements, the lack of epidemiological data on Chagas disease, the paucity of studies conducted on congenital transmission of Chagas disease, and the cost of screening, USPSTF is not likely to recommend universal or targeted screening of pregnant women across the U.S.

National recommendations from non-governmental agencies, such as the American Academy of Family Physicians Family Doctor and the American Pregnancy Association, may be more realistic pursuits for advocates. In addition, state and local governments may be more willing than federal agencies to make screening recommendations. Both options are discussed later in this report.

(6) Newborn screening guidelines
Proposed/Suggested by: World Health Organization (WHO)
Total Score: 37%
Scientific: 45%
Traction: 14%
CDC: 100%

The World Health Organization recommends screening newborns of infected mothers to ensure early diagnosis and treatment of infants.[213] In the absence of pregnancy screening, newborn screening could be a starting point for detection of congenital transmissions. As noted earlier, the failure to recognize infections in newborns is a missed treatment opportunity given the high cure rate among infants.

The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) creates the Recommended Uniform Screening Panel (RUSP), a list of 31 core conditions and 26 secondary conditions. This list comprises the national recommendations

on newborn screening, though each state determines its own panel of screening.[214] The RUSP screening panel does not include any infectious diseases: all but one are genetic disorders and the other is for hypothyroid.[215] Moreover, the process to add a disease to the list is cumbersome. Chagas disease is not a likely candidate for the RUSP since it is an infectious disease and there is little evidence of congenital transmission in the U.S.

There may be alternative methods to increase newborn screening. Non-governmental bodies, such as the American Academy of Pediatrics and American Congress of Obstetricians and Gynecologists, might recommend screening. Also, state or local governments could make screening recommendations. These alternatives are discussed later in this report.

(7) Nationally reportable disease
Proposed/Suggested by: Council of State and Territorial Epidemiologists (CSTE)
Total Score: 41%
Scientific: 36%
Traction: 43%
CDC: 50%

According to the 2007 Arizona order to make Chagas disease reportable, at that time the CDC was considering making Chagas disease a nationally reportable disease and the Council of State and Territorial Epidemiologists (CSTE) planned to discuss national surveillance at its June 2007 meeting.[216] The CSTE did not, in fact, add Chagas disease to the list of nationally notifiable infectious diseases. In order to add a disease, a proportion of states at the CSTE must want it to become reportable, which has not happened.[217] States do not have an incentive to make Chagas disease reportable because the disease is not highly transmissible and does not pose a severe public health threat, particularly in non-endemic states. States are overburdened, so they are not eager to add diseases to the state or national list of reportable diseases.[218]

Although the CSTE is unlikely to add Chagas disease to the national list of reportable diseases, national case investigation and data collection would vastly improve the existing surveillance efforts. As an alternative, The Chagas Foundation, a non-profit organization in Georgia, has considered creating an independent disease registry for Chagas disease.

(8) Legislation to increase domestic attention & funding
Proposed/Suggested by: Congressman Christopher Smith
Total Score: 51%
Scientific: 64%
Traction: 29%
CDC: 100%

Proposed legislation on NTDs has the potential to elevate the status of Chagas disease as a national health topic and to ensure funding for research. If Congress passes a bill on NTDs it demonstrates that legislators recognize the importance of the bill's content. In turn, during the formal appropriations process, when Congress decides agency priorities and appropriates money, Congress would likely stipulate funding and resources towards NTDs.[219]

In the past there has been only periodic attention and funding for Chagas disease and other NTDs.[220] The lack of sustained attention creates barriers to research and the subsequent accumulation of scientific evidence. Without a solid evidence base, federal agencies are unwilling to make policies.[221] The lack of attention also creates barriers to widespread physician and public awareness about the disease. This is important given that several advocates and scientists believe that widespread awareness is the first step in addressing Chagas disease in the U.S.[222]

In the past decade, NTD advocates have helped draft several Acts for presentation to Congress. These include the "Elimination of Neglected Diseases Act of 2006" and the "Neglected Infections of Impoverished Americans Acts" of 2010 and 2011. The objective of these bills was to raise awareness of NTDs like Chagas disease in Congress and in HHS. No money was appended to the bills, yet none of the bills passed.[223]

In June 2014, Congressman Smith of New Jersey introduced the "End Neglected Tropical Diseases Act of 2014," which has garnered promising support on both sides of the aisle.[224] This bill is more comprehensive than its predecessors and has the potential to have money appended to it. The bill proposes both international and domestic policy actions. The domestic agenda includes an HHS report to Congress on the risk of NTDs in the U.S., HHS promotion of NTD programs and activities, and federal funding for NTD Centers of Excellence.[225] These actions have the potential to increase attention to Chagas disease and possibly lead to greater funding for Chagas disease research and education.

Currently there is only one Center of Excellence for Chagas disease in the U.S., Olive View Clinic in Los Angeles County. This Center has been one of the most important sources of Chagas disease research, diagnostics and treatment in the country.[226] Moreover, Centers of Excellence tend to reach quality standards that qualify them for special federal reimbursements, which indirectly create more funding opportunities.[227] Financial support for the existing Center and/or the creation of new Centers could facilitate much needed Chagas disease research, such as large, multi-center community-based screening surveys. These types of studies build a solid evidence base for disease control, which appears to be a prerequisite for institutional support of new disease-related federal policies in the U.S.[228]

Proposed State Policies

(1) More states initiate formal reporting
Proposed/Suggested by: Authors of "Neglected parasitic infections in the United States: Chagas disease" (2014)
Total Score: 41%
Scientific: 36%
Traction: 43%
CDC: 50%

Though the data would be limited, more formal state reporting would help gather information about the prevalence and risk of Chagas disease in the U.S.[229] Adding Chagas disease to the list of notifiable diseases would empower states to gather new and higher quality data on existing cases of Chagas disease, particularly if state health departments investigate each case. Formal reporting also tends to increase disease awareness among physicians and facilitate treatment through guidance from the state and CDC.[230]

As noted earlier, however, states have little incentive to add diseases to the list of reportable diseases unless the disease poses an immediate public health threat.[231] With the exception of Massachusetts, the states that have initiated formal reporting for Chagas disease have done so because they are concerned and want to know more about the risk of vector-borne transmissions.[232] Therefore, additional states that face the same risk – through presence of triatomines, infection among bugs and wild animals, and/or numerous human cases identified by blood banks – may consider initiating formal reporting. These states could include California, Louisiana, Florida and others.

(2) State legislation to increase NTD programs
Proposed/Suggested by: Texas scientists and physicians
Total Score: 43%
Scientific: 45%
Traction: 29%
CDC: 100%

Like at the federal level, the state legislature may be an appropriate avenue for increasing awareness and funding for Chagas disease and other NTDs. If state legislators become concerned about the risk of Chagas disease and other NTDs, they can empower the state health department to take action through legislation and appropriations. These state-level actions might include active surveillance, physician awareness, increased access to diagnostics, and public health control.[233]

Unlike at the federal level, there is currently little traction for NTD legislation at the state level, at least in Texas. According to one Texas advocate, "there's nothing going on in the state legislature… this is not on their radar at all."[234] Advocates in the state are now working to build support. In December, Texas Medical Association will host an informational session for legislators in which presenters will explain the prevalence and threat of NTDs like Chagas disease in Texas. If champions for the cause emerge in the state legislature and associated costs were kept low, there may be future opportunities to increase attention and funding through state legislation.

(3) Addition to state newborn screening panel
Proposed/Suggested by: Authors of "Prevalence of antibody to Trypanosoma cruzi in pregnanct Hispanic women in Houston" (1999)
Total Score: 37%
Scientific: 45%
Traction: 14%
CDC: 100%

Each state determines its own screening panel, though federal law requires states to perform at a minimum the primary screening panel under RUSP.[235] States consider adding new conditions to the panel when there is evidence of public health benefits. Several states have policies for routine screening of diseases similar to Chagas disease. For example, some states regularly screen newborns for toxoplasmosis, another parasitic disease with low estimated incidence rates (400-4,000 per year).[236] Also like toxoplasmosis, there is effective treatment for congenital Chagas disease, which otherwise remains undiagnosed and untreated.[237]

However, it is difficult to add a disease to the Texas state screening panel. In order to add a disease, states conduct a pilot study. These pilot studies, however, are often arduous and expensive. In most states, including Texas, state law requires researchers to secure parental permission for each child before pilot testing. When Texas has attempted pilot studies in the past, the parental permission requirement lead to cumbersome paperwork and low participation rates. At least in Texas, the parental permission requirement and the cost of pilot studies discourages state health departments from adding diseases to the screening, making the addition of Chagas disease an unlikely policy action.

(4) State recommendation for targeted screening
Proposed/Suggested by: A Texas researcher and a Texas advocate, during interviews
Total Score: 56%
Scientific: 45%
Traction: 57%
CDC: 100%

A state recommendation for physicians to conduct targeted Chagas disease testing has the potential to uncover new cases and facilitate treatment. Very few, if any, primary care physicians test at-risk patients for Chagas disease in Texas, despite the fact that there are likely thousands of unidentified cases throughout the state.[238] It may be appropriate for the state to issue guidance for testing for Chagas disease, particularly in certain geographic regions of the state, for certain at-risk populations, and among certain types of physicians (ie. primary care physicians, cardiologists, and obstetricians). A targeted approach is less expensive than a universal testing recommendation.[239] In addition, with physicians being so busy and overwhelmed, a targeted approach may more successfully communicate the information and change physician behaviors.[240]

The state health department could also issue guidance to specific health organizations or networks of physicians, such as the Migrant Clinicians Network or the Texas Association of Community Health Centers. These organizations and their associated clinics predominantly serve populations that face high risk of Chagas disease infection, such as Latina American immigrants and sub-standard housing dwellers. A recommendation from the state could encourage appropriate testing, diagnosis, and treatment. However, these organizations would need to overcome barriers to action, including the cost of diagnosis and the comparatively low priority of Chagas disease for these patient populations with severe health problems. New grant opportunities could help address the economic challenges of Chagas disease diagnostics. Even without state guidance, however, these organizations could potentially act independently to address Chagas disease in Texas, perhaps by looking to the model provided by Olive View Center of Excellence.

This proposed policy is in line with the state health department's current objectives for addressing Chagas disease. According to a Texas state health official, the state priorities are to keep *T. cruzi* parasites out of the blood supply, collect good data on existing cases to evaluate the public health risk, and assist infected individuals and their physicians with accessing treatment.

There are several avenues by which the state health department might expand Chagas disease programs. It could come through an internal decision-making process at DSHS, if agency personnel deemed program expansion valuable and feasible with existing resources and if it did not displace activities related to a legislative mandate or higher priority.[241] It could come through a legislative mandate on NTDs or other Chagas-related legislation. Advocacy efforts could also lead to program expansion: DSHS staff listen to community concerns and take action when and if it is valuable and feasible. Finally, a federal grant program could be an impetus for action if it made funds available to support state, regional, and local-level testing, surveillance, and education activities.

It is uncommon for states to issue targeted screening recommendations, although one state health official speculated that the HIV office may do it. However, the Texas state health department has the technical capacity and network to administer such a recommendation.

Each regional office maintains a distribution list of local hospitals, physicians, veterinarians, and medical associations, so DSHS can send messages – and potentially screening recommendations – out to regional offices, which they can send out to their contacts.[242] Barriers to this policy action include lack of precedence, the non-emergency nature of the disease risk, and absence of a dedicated education staff at DSHS. [243]

(5) Local health department policies
Proposed/Suggested by: Scientist/Physician, during interview
Total Score: 43%
Scientific: 45%
Traction: 29%
CDC: 100%

States with decentralized health systems may harbor potential for local-level Chagas disease policies. Local health department support could come in the form of funding, in-kind donations, community education initiatives, or screening recommendations. For example, the Los Angeles county health department supports Chagas disease programs at its local Olive View Clinic, a Chagas disease Center of Excellence. After recognizing the public health importance of the clinic's work and the effectiveness of its programs, the county provided space for physicians to see patients, phlebotomy equipment, and shipping to send samples to CDC. Through county support, clinic leaders are expanding the Chagas disease program to seven other primary care centers in the county and developing local protocols for screening and diagnosis. With evidence of 1.0-1.5% prevalence in the community, clinic leaders hope to make Chagas disease a primary care issue so that every Latin American immigrant is screened for Chagas disease. According to a clinic leader, screening Latino immigrants is cost-effective: testing is inexpensive and effective treatment mitigates huge costs associated with heart failure. Ultimately, the clinic would like their work in L.A. county to become a national model for diagnosing and treating Chagas disease.[244]

Local health departments (LHDs) in Texas may have the capacity to develop local policies and educational programs on Chagas disease. According to the DSHS website, LHDs have the funds to strengthen local public health infrastructure, which they largely do through community education and outreach for disease prevention. LHDs also have the authority to develop "local policies to safeguard and protect the community's health and safety."[245] When a Chagas disease case is reported, the local health department (or regional health department in areas where LHDs do not exist) investigates the case. Areas of the state that investigate numerous cases may be inclined to initiate community and physician awareness and screening programs or policies. The local and regional health departments that cover the Texas/Mexico border counties might also have an interest in developing Chagas disease programming since their respective populations likely have higher prevalence and exposure rates. Public officials in more affected regions could consider implementing targeted educational and screening programs and policies.

Analysis of Proposed Policies

I evaluate the proposed policies using three criteria: capacity to fill recognized gaps (scientific), level of political practicality (tractability), and adherence to existing federal agency plan (CDC). I apply 45 percent weights to the scientific and tractability categories and a 10 percent weight to CDC to determine a "total" score. Each policy's total score numerically summarizes its potential to appropriately and practically address Chagas disease in the U.S. and provides a platform for comparison with other proposed policies.

Federal Policy Analysis

Table 7: Scores of Federal Proposed Policies

Proposed Policy	Total Score	Scientific Score	Tractability Score	CDC Score
FDA Approval of Treatment Drugs	62%	55%	71%	50%
Blood Donor Reentry Guideline	58%	18%	100%	50%
Legislation to Increase NTD Attention & Funding	51%	64%	29%	100%
Mandatory Organ Donor Screening	43%	27%	57%	50%
Pregnancy Screening Guidelines	43%	45%	29%	100%
Nationally Reportable Disease	41%	36%	43%	50%
Newborn Screening Panel	37%	45%	14%	100%
Mandatory Blood Donor Screening	33%	36%	14%	100%

The federal policy total scores range from 33 to 62 percent, indicating that, overall, the proposed polices have medium-low to medium-high capacities to address Chagas disease in the U.S. The highest-ranking federal policy is the FDA approval of drugs (62%), which scored well in each of the three categories. Following treatment drugs, two policies accrued total scores in the fifties: blood donor re-entry (58%) and NTD legislation (51%). These two policies scored well in two out of three of the categories. With 43 percent scores, the pregnancy screening policy and organ screening policy comprise the median and mode scores. And the lowest-ranking policies are newborn screening (37%) and mandatory blood donor screening (33%). The screening policies comprise the majority of the lower-ranking policies due to low tractability scores.

The scientific scores of federal proposed policies range from 18 to 64 percent. The highest scores were attained by the NTD legislation (64%) and approval of treatment drugs (55%). These two policies have the highest capacity to fill established gaps in addressing Chagas disease in the U.S. Among other things, these policies would increase public awareness, advance innovation and expertise, and improve treatment guidelines. With 45 percent scores, the pregnancy screening and newborn screening proposals have the potential to improve surveillance and disease control. Both mandatory blood donor screening and national disease reporting earned 36 percent scientific scores. The two policies with the lowest potential to fill gaps are organ donor screening (27%) and blood donor re-entry (18%). Although organ donor screening (27%) is a strong policy for gathering data and controlling disease transmission, it did not score well in the scientific category because it would not increase awareness or improve treatment. The blood donor re-entry policy (18%) fills few gaps since it is simply an amendment of the FDA recommendation for blood donor screening.

The tractability scores for federal proposed policies range widely, from 14 to 100 percent. The blood donor re-entry policy earned 100 percent in this category, largely because it is well supported within the FDA, is inexpensive, and has external support. Of the federal proposed policies, it has the most potential for enactment. The drug approval policy (71%) and organ donor screening policy (57%) also earned high tractability scores. Both of these policies enjoy leadership and external support and would be relatively simple to implement once approved. National disease reporting accrued 43 percent, reflecting that it is a low-cost, simple policy but lacks leadership and scientific evidence. Both pregnancy screening, and the NTD bill only earned 29 percent in this category. Despite its relative simplicity, pregnancy screening scored low due to the lack of scientific evidence and support, particularly given the stringency of USPSTF. However, the low NTD legislation score (29%) may be not reflect its true tractability. The bill may actually be one of the more tractable policy options due to the fact that it links Chagas disease to the larger NTD problem and because policies made in Congress may not be subject to the same rigidities as those made in agencies with strict policy-making requirements. Two policies earned only 14 percent "tractability," including mandatory blood donor screening and newborn screening.

In the CDC category, which is comprised of four agency goals, half of the policies earned 50 percent and half earned 100 percent. Those that fully aligned with the CDC objectives for addressing NPIs include mandatory blood donor screening, pregnancy screening, newborn screening, and the NTD legislation. These policies may enjoy a little more leadership and support because they support the CDC agency goals. The four policies that partially aligned with the goals are blood donor re-entry, approval of drugs, organ donor screening, and national disease reporting.

State Policy Analysis

Table 8: Scores of State Proposed Policies

Proposed Policy	Total Score	Scientific Score	Tractability Score	CDC Score
State Recommendation for Targeted Screening	56%	45%	57%	100%
Local Health Department Policies	43%	45%	29%	100%
State Legislation on NTDs	43%	45%	29%	100%
More States Initiate Formal Reporting	41%	36%	43%	50%
State Newborn Screening Panel	37%	45%	14%	100%

The total scores of state-level proposed policies range from 37 to 56 percent, which is similar to the range of federal proposed policies. The highest-ranking state policy (56%) is the state recommendation for targeted screening, which had relatively high scores in each category. Two policies earned 43 percent total scores: local health department policies and the proposal for state legislation on NTDs. Both of these policies scored well in scientific and CDC categories and not very well in tractability. The initiation of formal reporting in more states accrued a 41 percent total score. And the lowest-ranking policy is the proposal for state

newborn screening (38%), which scored very poorly in tractability. Overall, the state proposed policies scored similarly to the federal proposed policies. The mean total score for state policies is 44 percent while it is 46 percent for federal policies.

The scientific scores of state proposed policies are clustered. Four policies earned 45% in this category, including state recommended targeted screening, state newborn screening, local health department policies, and state legislation on NTDs. The two screening policies and LHD proposal fill the same scientific gaps, such as increased awareness, epidemiological research, surveillance and control. The NTD legislation overlaps somewhat but largely fills different gaps, including increased political will and advancement of innovation and expertise. The fifth policy, the proposal for more state-level reporting of Chagas disease, scored 36% in the scientific category. This policy has the potential to increase awareness, research and control, but to a lesser degree than the screening proposals. The proposed policies at the state level share a medium level of potential to fill established scientific gaps in Chagas disease.

Similar to the federal policies, the tractability scores for state proposed policies range widely. The highest-ranking policy is the state recommendation for targeted screening (57%). This proposed policy scored well largely because there is evidence of prevalence in targeted populations and because it is a relatively inexpensive policy action. The second-highest tractability score was earned by the proposal for more state reporting. This policy is also a relatively inexpensive option, though it does increase the burden of state health departments. Both LHD policy action and state legislation on NTDs earned tractability rates of 29 percent, reflecting the lack of existing leadership for these relatively inexpensive initiatives. Finally, state newborn screening earned only 14% tractability due to high costs and the lack of evidence and leadership.

In the CDC category, all but one of the state policies fully fills the CDC goals for addressing NPIs. These four policies include state recommended targeted screening, state newborn screening, local health department policies, and state legislation on NTDs. Like in the scientific category, the outlier and lowest-ranking policy is the proposal for more state-level reporting of Chagas disease, which earned a 50% in this category.

DISCUSSION

Policy Recommendations

The results suggest that federal and state policymakers should consider and prioritize certain policy actions over others to appropriately address Chagas disease in the U.S. The top-scoring federal and state policies are listed in Table 9. These lists are a good starting point

for policy recommendations. However, though critical examination, it is possible to pare down the lists and identify the *most* appropriate Chagas disease policy actions.

Table 9: Top-scoring policy proposals at federal and state levels

Rank	Federal Proposals	Rank	State Proposals
1	FDA drug approval	1	State rec. for targeted screening
2	Blood donor re-entry	2	LHD policies
3	NTD legislation	2	NTD legislation
4	Pregnancy screening	3	Formal reporting in more states
4	Organ donor screening		

The federal recommendations can be reduced from five to three policy proposals. First, we can remove the blood donor re-entry policy from the list. This policy scored well overall because it is has a high tractability score. It is supported by the FDA, has external supporters, and is inexpensive. As a result, the policy is moving through the agency approval process. However, the blood donor re-entry proposal fills few scientific gaps and does not align well with CDC goals for Chagas disease. Since the policy would do little to advance the diagnosis and treatment of Chagas disease and would not increase awareness or research, I do not include it in my final list of recommendations. Second, in the near future, the proposal for government-recommended pregnancy screening is not a viable policy option. As noted earlier, USPSTF will not consider a screening guideline unless there is substantial evidence of public health burden and net benefit of screening to the community. At this time this evidence has not been accumulated, as there is a paucity of research on Chagas disease in the U.S. Until this is remedied, it is not worth pursuing the policy. After eliminating these two policies from the federal proposal list, there are three federal policy recommendations: (1) FDA drug approval, (2) NTD legislation, and (3) organ donor screening.

If we focus on Texas, it is also possible to reduce the list of recommended state policies. Although the policy to add Chagas disease to the list of reportable diseases is a strong policy proposal in several other states, in Texas it is not necessary to pursue this policy. Texas is one of the few states that already mandate formal state reporting of Chagas disease. In eliminating this policy from the list, there are three remaining Texas-appropriate state policy recommendations: (1) state-recommended targeted screening, (2) LHD policies, and (3) NTD legislation.

Table 10: Policy Recommendations

Recommended Federal Policies	Recommended Texas State Policies
FDA drug approval	State recommendation for targeted screening
NTD legislation	LHD policies
Organ donor screening	NTD legislation

Based on my analysis of all proposed policy actions, these recommended federal and state policies possess the most potential to effectively and practically address Chagas disease in the near future. Moreover, these policies complement each other and could be pursued simultaneously. At the federal level, drug approval could provide new treatment options and guidelines and increase physician awareness; NTD legislation could increase public awareness, research, innovation and expertise; and organ donor screening could improve surveillance and control. At the state level, a state recommendation for targeted screening could increase physician awareness and improve disease surveillance and control throughout the state; LHD policies could improve public awareness and diagnosis in specific geographic regions; and state NTD legislation could facilitate more research and surveillance through the state health department. Each of these policies could play a unique role in improving the response to Chagas disease in the United States.

Strategies of Recommended Policies

The strength of these policy recommendations is the policies' potential to sidestep barriers to Chagas disease policy action. As a neglected disease, Chagas disease in the U.S. does not possess the disease qualities that typically motivate government action, such as evidence of high prevalence, high transmissibility rate, high mortality/morbidity rate, impact on an empowered population, scientific evidence, and the potential to create new markets. Without these qualities policymakers are unlikely to support policy action. And yet, several scientists and researchers fiercely maintain that Chagas disease is an unrecognized, widespread public health threat in the U.S. that requires further research and policy action. Addressing this threat, thus, requires certain strategies.

One important strategy is issue-linkage. By linking Chagas disease to related issues, such as other NTDs or NPIs, it is possible to compound issue resources and attention. Two of the recommended policies employ this strategy, including the proposal for federal NTD

legislation and state NTD legislation. By aligning Chagas disease with other relevant neglected diseases, advocates can ride the coattails of other disease research and momentum, help create new joint appropriation and regulatory opportunities, and increase national and state attention.

Another critical strategy among the recommended policies is the use of a targeted approach. Both the state recommendation for targeted screening and LHD policies focus on specific communities, physicians, and patients. This strategy recognizes that governments and individuals are overwhelmed with information and overburdened with competing demands. In this climate, it is difficult to gain support for blanket policies that affect a minority unless the issue enjoys strong advocacy or market opportunity. A targeted approach enables policymakers and health officials to concentrate on the most relevant actors and create a dialogue with specific groups. Ultimately, this facilitates a greater impact on affected individuals with the added bonus of growing the evidence base. Starting small also creates leadership and a model for others to emulate. The Olive View Clinic in L.A. county, for example, has developed protocols for Chagas disease and is now training other clinics. A concentrated effort can build norms and patterns that public health workers and policymakers can expand and scale-up in the future.

The third important strategy is the creation of new partnerships and collaborations. When different actors come together to discuss and develop policies, they increase coordination and influence. Two policy recommendations illustrate this strategy: FDA approval of treatment drugs and organ donor screening. Recent collaborations instigated the proposal of both policies. The DND*i*, which initiated Chagas disease drug development, is a collaborative research and development organization that partners with private industry, public institutions, academia and NGOs. The Chagas in Transplant Working Group, which recommends policies for organ donor screening, is an independently formed coalition of transplant infectious disease specialists, laboratory medicine specialists, organ procurement organization representatives and epidemiologists with expertise in Chagas disease. In bringing together a variety of actors, these two groups have been able to increase evidence, build traction for budding policy proposals, and create new, non-governmental authority.

Alternative Recommendations & Strategies

Although the focus of this paper is policy action, it is important to recognize alternatives to government policies. As one researcher said, "in many ways, we are several steps away from real policy action in the U.S."[246] Using alternative strategies now could lead to policy action in the future. Moreover, governmental policies are not the only way to increase the response to Chagas disease in the U.S. Non-governmental actors and alternative goals and strategies have the potential to fill some established gaps and may be more practical avenues for doing so. Some advocates and researchers already use these strategic approaches to improve the response to Chagas disease in the U.S.

Building relationships and forming new coalitions is one important strategy. When new coalitions form and coordinate their efforts, they gain new influence and agenda-setting power. As discussed earlier, the DND*i* and Chagas in Transplant Working Group, exemplify this approach. The recently established Global Chagas Coalition is another example of this strategy. When the coalition first formed it was not very active, but as it has become more inclusive it has gained momentum. One advocate hopes to see the coalition generate new policies, procedures, and initiatives in the coming years.[247] Collaborations can take many forms, including public-private partnerships, regional cooperatives, and transnational coalitions. Each non-governmental group has a unique opportunity to build momentum for Chagas disease response and encourage accountability among physicians and public health officials. Chagas disease advocates seem to recognize the power of coordination, but there is room for growth. Existing collaborations could become more influential. And new regional groups, such as a "Chagas in the South" cooperative, could help set agendas in particular regions.

Conversely, unilateral action is an important strategy for increasing public health response. When one organization recognizes an issue and takes action to address the problem, the organization can single-handedly "move the needle" on the issue. Unilateral action has the potential to provide leadership and create new models for action. The Olive View Clinic is an excellent example of this type of unilateral action. Largely through its own creative approaches, the clinic is developing new methods for Chagas disease diagnosis, treatment, and community outreach. Other organizations, such as the Migrant Clinicians Network Texas Association of Community Health Centers, could pursue unilateral action, as well.

Informal meetings and iterations are another important strategy. In fact, informal gatherings are very useful in cultivating relationships and coordination. Another benefit of meetings is the presentation of new evidence or information, which drives progress and moves a group towards solutions. Iterations to address an issue like Chagas disease also enable advocates and researchers to recognize their movement towards larger goals, which lengthens the time horizon for an appropriate Chagas disease response. Chagas disease groups have already begun utilizing this strategy. For example, on November 3, 2014, Chagas disease advocates and experts held a panel discussion titled "Changing the Face of Chagas Disease: Scaling up Diagnosis, Treatment and R&D for People Living with Chagas Disease in the Americas," which coincided with the annual meeting of the American Society of Tropical Medicine and Hygiene in New Orleans. Also, over the past few years the Texas state health department has hosted an annual Diseases in Nature Conference that includes talks on Chagas disease. These forums facilitate continual conversation and drive progress. They lead to new ideas and increase momentum to address the issue of Chagas disease. It is important that Chagas disease advocates continue and increase these informal meetings.

Lastly, advocates and researchers can pursue soft law as an alternative to government policies. Soft laws are non-binding "rules" that can strongly influence behavior by setting

norms and applying pressure to conform. In terms of Chagas disease, soft laws could be recommendations or standards of care issued by well-respected non-governmental organizations (NGOs). For example, since federal and state governments are unlikely to issue recommendations for Chagas disease pregnancy screening, NGOs that care about the cause could take on the task. The American Academy of Family Physicians (AAFP) or American Pregnancy Association could issue a recommendation to screen at-risk women. In fact, the American Pregnancy Association screening recommendations already include diseases that are not on the USPSTF list. Similarly, the AAFP or American Heart Association might issue screening recommendations for at-risk cardiology patients. These organizations and newly formed Chagas disease organizations can influence physician awareness and behavior through soft law, without the complications of the policymaking process. The Chagas Foundation may soon illustrate this strategy. Since CSTE has not enacted a national surveillance policy for Chagas disease, The Chagas Foundation is creating a national registry for Chagas disease patients. This is a great example of how non-governmental organizations can assume typically governmental tasks and generate new norms to address an issue. Chagas disease advocates should continue to use this strategy, particularly when policymaking is not a viable option.

Strengths and Limitations of the Project

There are several strengths of this study. The first strength is the combination of guidance from two disciplines. The combined curriculum from The School of Public Health and The LBJ School of Public Affairs offers a unique lens for understanding the problem of Chagas disease in the U.S. and possible solutions. The second strength is the interviews with key informants. Although they were limited, the interviews provided a wealth of knowledge regarding health systems and the federal and state policy processes, particularly as they relate to neglected tropical diseases. Third, by providing analysis at both the federal and Texas state level, this project provides important insights into two distinct sets of challenges and opportunities for addressing Chagas disease.

Several limitations affected this study. First, due to restrictions of time, geography, and human subjects considerations only 13 key informants were interviewed, none of who suffer from Chagas disease. Additional interviews with physicians, federal and state policymakers, and advocates may have provided new insights into the problem and possible solutions. Second, comprehension of the policymaking process at the federal and state levels is limited by the author's education, experiences, and the information provided by key informants. Third, the method of analysis used is only one way to score and rank the policy proposals. A different method – such as using different criteria, applying different weights, or using a non-metric approach – might have delivered different results. This particular ranking methodology favors broad policy solutions that fill many gaps and have wide practicality, whereas policies with specific, focused impacts could be equally or more appropriate. In addition, the system attempts to quantify policy characteristics that are difficult to quantify.

It may have been more appropriate to independently evaluate each policy proposal and make policy-by-policy recommendations, noting each policy's strengths and weaknesses.

CONCLUSION

The U.S. federal and state governments currently take minimal steps to diagnose and treat residents who suffer from Chagas disease and to protect residents from contracting this avoidable disease. This paper assesses various proposed policies to increase the response to Chagas disease in the U.S. Through careful analysis, I determine the top three policy proposals at the federal and state levels. The three top-ranking federal policy proposals are (1) FDA drug approval, (2) NTD legislation, and (3) organ donor screening. The top state policy recommendations are (1) state-recommended targeted screening, (2) LHD policies, and (3) NTD legislation. Policymakers and advocates should consider these policy recommendations as a means to improving current measures. The strengths of these policies is their use of issue linkage, targeted approaches, and coalition-building. If and when policymakers deem it valuable and feasible to address Chagas disease in the U.S., these are the policies that they should pursue.

In addition, advocates should consider alternative strategies for immediately increasing the response to Chagas disease in the U.S. Given the lack of evidence of a Chagas disease threat, limited resources, and competing priorities, the government is unlikely to independently take action to address the disease. Alternative strategies for advocates and non-governmental actojrs include formation of new partnerships, unilateral action, meetings and iterations, and soft law.

APPENDICES

Appendix A: Scores for Federal Policy Proposals

	Mandatory Blood Donor Screening	Blood Donor Reentry Guideline	FDA Approval of Treatment Drugs	Mandatory Organ Donor Screening	Pregnancy Screening Guidelines	Newborn Screening Panel	Nationally Reportable Disease	Legislation to Increase NTD Attention & Funding
Physician Awareness	0	0	1	0	1	1	1	1
Public Awareness	1	0	0	0	1	1	0	1
Political Will	0	0	0	0	0	0	0	1
Epi Research	1	1	0	1	1	1	1	1
Expertise & Innovation	0	0	1	0	0	0	0	1
Multilateral Collab.	0	0	0	0	0	0	0	1
Treatment Guidelines	0	0	1	0	0	0	0	1
Better Drugs	0	0	1	0	0	0	0	0
Drug Availability	0	0	1	0	0	0	0	0
Surveillance	1	0	0	1	1	1	1	0
Control Measures	1	1	1	1	1	1	1	0
TOTAL	4	2	6	3	5	5	4	7
%	36%	18%	55%	27%	45%	45%	36%	64%
Phys/Public Awareness	1	0	1	0	1	1	1	1
Epi Data Analysis	1	1	0	1	1	1	1	1
Better Diagnost. Testing	1	1	0	1	1	1	0	1
Provide Treatment	1	0	1	0	1	1	0	1
TOTAL	4	2	2	2	4	4	2	4
%	100%	50%	50%	50%	100%	100%	50%	100%
Leadership	0	1	1	1	0	0	0	1
Institutional Support	0	1	0	0	0	0	0	1
Civil Society/External Support	0	1	1	1	0	0	0	0
Simplicity	1	1	1	1	1	1	1	0
Cost effectiveness	0	1	1	0	1	0	1	0
Inexpensiveness	0	1	1	0	0	0	1	0
Scientific Evidence	0	1	0	1	0	0	0	0
TOTAL	1	7	5	4	2	1	3	2
%	14%	100%	71%	57%	29%	14%	43%	29%
TOTAL	13	13	19	12	16	15	13	20
%	33%	58%	62%	43%	43%	37%	41%	51%

Appendix B: Scores for State Policy Proposals

	More Formal State Reporting	State Legislation to Increase NTD Programs	State Newborn Screening Panel	State Rec. for Targeted Screening	Local Health Dept. Policies
Physician Awareness	1	1	1	1	1
Public Awareness	0	1	1	1	1
Political Will	0	1	0	0	0
Epi Research	1	1	1	1	1
Expertise & Innovation	0	1	0	0	0
Multilateral Collab.	0	0	0	0	0
Treatment Guidelines	0	0	0	0	0
Better Drugs	0	0	0	0	0
Drug Availability	0	0	0	0	0
Surveillance	1	0	1	1	1
Control Measures	1	0	1	1	1
TOTAL	4	5	5	5	5
%	36%	45%	45%	45%	45%
Phys/Public Awareness	1	1	1	1	1
Epi Data Analysis	1	1	1	1	1
Better Diagnost. Testing	0	1	1	1	1
Provide Treatment	0	1	1	1	1
TOTAL	2	4	4	4	4
%	50%	100%	100%	100%	100%
Leadership	0	0	0	0	0
Institutional Support	0	0	0	0	0
Civil Society/External Support	0	0	0	0	0
Simplicity	1	0	1	1	0
Cost effectiveness	1	1	0	1	1
Inexpensiveness	1	1	0	1	1
Scientific Evidence	0	0	0	1	0
TOTAL	3	2	1	4	2
%	43%	29%	14%	57%	29%
TOTAL	5	4	3	6	4
%	41%	43%	37%	56%	43%

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