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Implementation of Screening to Benefit Mother and Infant

Morven S. Edwards, MD[a,*], **Susan P. Montgomery, DVM, MPH**[b]

[a]Texas Children's Hospital, Feigin Center, 1102 Bates Avenue, Suite 1120, Houston, TX 77030, USA

[b]Parasitic Diseases Branch, Division of Parasitic Diseases and Malaria, Center Global Health, Centers for Disease Control and Prevention, 1600 Clifton Road, Northeast, Atlanta, GA 30333, USA

Keywords

Cardiomyopathy; Chagas disease; Congenital infection; Serologic screening; *Trypanosoma cruzi*

INTRODUCTION

Chagas disease is a vector-borne infection caused by the protozoan parasite, *Trypanosoma cruzi*. Carlos Chagas, working in Brazil in 1909, identified the parasite and its vector, the triatomine bug. He also identified the manifestations of the disease bearing his name.[1] Chagas disease is underappreciated as a health care concern in the United States, in part because the infection usually has occurred years before those affected become residents in the United States. In addition, the acute infection is often asymptomatic. It can cause a mild illness with low-grade fever that does not come to medical attention and does not raise concern for Chagas disease. Without treatment, infection becomes chronic and persists for life.[2] People in the chronic phase can remain asymptomatic and may remain unaware that they contracted the infection. However, 20% to 30% will develop cardiac and/or gastrointestinal manifestations after years or decades of being asymptomatic.[2,3] Heart failure can result in debilitation and death, and cardiac outcomes from Chagas disease carry a worse prognosis than does heart failure from other causes.[4]

Epidemiology and Transmission

Chagas disease is endemic in Mexico, Central America, and South America. Approximately 300,000 persons in the United States have Chagas disease (Fig. 1). Most US residents with Chagas disease acquired infection in Mexico, El Salvador, Guatemala, or Honduras.[5,6] *T cruzi* is transmitted by infected triatomine bugs, which carry the parasite in their intestinal tracts. Triatomine bugs defecate after taking a blood meal, and transmission occurs when fecal material, containing trypomastigotes of the parasite (Fig. 2), is rubbed into a bite

*Corresponding author. morvene@bcm.edu.

DISCLOSURE

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wound or the conjunctivae. Transmission also can occur by blood transfusion, organ transplantation, or congenitally.

Chagas disease awareness increased in the United States through implementation of widespread blood donor screening. The first assay for screening blood donations for *T cruzi* antibody gained Food and Drug Administration (FDA) approval in 2006. Between 2007 and 2019, there were 2462 blood donations confirmed as positive. The highest numbers were from California (890), Florida (325), Texas (199), New York (166), and Virginia (119). All US states, except Hawaii, Wyoming, and South Dakota, had at least 1 confirmed positive blood donation.[7] Blood donor screening and pretransplant screening of donors and recipients of organ transplants have rendered these modes of transmission rare in the United States.

T cruzi is established in southern US states where triatomines transmit the parasite to mammals, typically woodrats, raccoons, and opossums. Although human transmission within the United States has been documented, it is uncommon with fewer than 100 cases to date.[8-10] Chagas disease is reportable in Arizona, Arkansas, Louisiana, Mississippi, Tennessee, Texas, Utah, and Los Angeles County, California.[11]

Chagas disease contributes substantively to the total US burden of heart disease. The estimated number of people in the United States who have Chagas disease cardiomyopathy is 30,000 to 45,000.[1] Chagas disease–associated cardiomyopathy is clinically similar to non–Chagas disease cardiomyopathy. In a cross-sectional study, 13% of Latin American immigrants in New York City with dilated cardiomyopathy had *T cruzi*–related heart disease.[12] Chagas disease was diagnosed in more than 5% of 327 patients in Los Angeles with conduction abnormalities on electrocardiogram.[13] Right bundle branch block, in particular, is a common early manifestation of Chagas cardiomyopathy. Progression of heart disease can lead to complete heart block, arrhythmias, or embolic phenomena. Death can result from apical aneurysm, heart failure with dilated cardiomyopathy, or ventricular arrhythmias.[14]

An estimated 40,000 women of childbearing age in the United States have Chagas disease.[1] Most of these women acquired infection in an endemic region and are unaware they have an infection that is transmissible congenitally and can cause progressive heart disease, affecting them personally as well as their children. Screening of 4755 Latin American–born adults in Los Angeles County, of whom at least one-half were women of childbearing-age, found a prevalence of Chagas disease of 1.24%, suggesting that there are more than 30,000 people with Chagas disease in Los Angeles County alone and highlighting the magnitude of Chagas disease as a public health concern.[15]

Infants born to women with Chagas disease are at risk for congenital infection, including in the United States. Using the total US birth cohort, *T cruzi* prevalence in home countries of Latin American–born women, and an estimated 1% to 5% transmission, 63 to 315 infected infants are born each year in the United States.[5] The number of *T cruzi*–infected children in the United States with undiagnosed congenital infection was estimated to exceed 2000 over a decade ago.[16]

Congenital transmission occurs during the second or third trimester of pregnancy. Women with Chagas disease can transmit *T cruzi* during sequential pregnancies. Thus, without treatment, each pregnancy carries a risk to the fetus of congenital infection. High maternal parasitic load and human immunodeficiency virus coinfection enhance transmission.[17] Transmission risk continues for women with chronic infection even when they are living in nonendemic regions.[18]

Clinical Relevance to Mother and Infant

Pregnant women with undiagnosed Chagas disease usually have chronic infection contracted before migration to the United States and are unaware that they have *T cruzi* infection. Serologic screening of women from endemic regions benefits both mother and infant.[19,20] Women in the childbearing years diagnosed as having Chagas disease can receive antitrypanosomal treatment after delivery of their infant and completion of breastfeeding.[21] Although treatment of longstanding infection in adults does not reverse existing cardiac damage, treatment may decrease likelihood of Chagas cardiomyopathy.[2] Treatment also prevents transmission of infection to infants during subsequent pregnancies by reducing parasitemia.[22,23]

At birth, 10% to 40% of infants with congenital Chagas disease have signs of infection, such as prematurity, hepatosplenomegaly, and anemia.[24,25] Congenital infection is not associated with malformations because transmission occurs after organ formation is completed. Some of the common and less common clinical features of congenital Chagas disease are shown in Table 1.[24,26-28] Common features occur in one-fourth to greater than one-half of affected infants who have signs of infection. Less common features occur in 10% to 25% of affected infants with signs of infection. Presentation with fetal hydrops, ascites, and pericardial effusion in a preterm infant confirmed to have US-acquired congenital infection highlights the potential severity of congenital *T cruzi* infection.[29] Life-threatening manifestations, such as meningoencephalitis or pneumonitis, are not unique to Chagas disease. Disease usually is unrecognized because defining clinical features are lacking and health care clinicians may not suspect the diagnosis. Healthy-appearing congenitally infected infants usually are discharged without evaluation. However, 20% to 30% develop cardiomyopathy or debilitating gastrointestinal manifestations after years or decades of silent infection.[30,31]

Evaluation of Women During Pregnancy

Pregnant women from a Chagas-endemic region should undergo serologic screening for *T cruzi* antibodies through a commercial laboratory. Pregnancy offers the optimal access point for identifying Chagas at-risk family units because delivery is the most likely time for interaction with the health care system.[19] Pregnancy-based screening for antibody to *T cruzi* has the advantage that results will be available at delivery. Unfortunately, no single serologic test has high enough sensitivity and specificity to establish the diagnosis. For this reason, diagnosis is based on positive results from 2 or more tests that use different techniques and that detect antibodies to different antigens. Commonly used techniques include enzyme-linked immunosorbent assays and immunofluorescent antibody tests. Confirmatory testing is available through a reference laboratory, such as the Parasitic Diseases Reference Laboratory at the Centers for Disease Control and Prevention (CDC). Requests for confirmatory testing

should be coordinated with the respective state health department. A study of 4000 deliveries at 1 Houston hospital, where 85% of mothers cited a Chagas endemic country of origin, found that among 28 women with a positive initial screening test at delivery, 10 had proven chronic Chagas disease by confirmatory testing.[32]

Screening at admission for delivery or screening of neonates offers alternative approaches to identification of women and their infants with Chagas disease. The finding of immunoglobulin G (IgG) antibody to *T cruzi* in cord blood or infant serum is a reflection of the maternal antibody status and indicates that an infant is at risk for congenital infection. A disadvantage to delivery-based screening is that most infants and their mothers, including asymptomatic infants with congenital infection, will have been discharged when results of screening at delivery become available.

Evaluation for Congenital Chagas Disease

Evaluation for suspected congenital Chagas disease should occur as soon as possible after birth. Infants of mothers with a positive *T cruzi* screening serologic test or with confirmed Chagas disease and those with clinical features of Chagas disease require evaluation (Fig. 3).[25,33] Serologic testing of maternal blood, if not performed during pregnancy, or of cord blood, is the initial step to determining infant risk. Within the first months of life, the diagnosis relies on detection of motile trypomastigotes through microscopic examination of fresh anticoagulated whole blood or buffy coat, by microscopic examination of Giemsa-stained blood for trypomastigotes, or by polymerase chain reaction (PCR) testing for *T cruzi* DNA in whole blood. This testing is available through the Parasitic Diseases Reference Laboratory at CDC. Infants with an initially positive PCR should undergo repeat testing to exclude contaminating maternal DNA or specimen contamination, each of which is rare. Infants with an initially negative PCR should undergo repeat testing at 4 to 6 weeks of age to confirm absence of infection, as parasitic load increases in the first 1 to 2 months of life. After age 3 months, the parasite is no longer detectable by PCR, and congenital Chagas disease in the first year of life is confirmed by serologic testing (Fig. 4). Placentally transferred *T cruzi* antibodies should generally not be detectable after 9 to 12 months of age.[34]

Implications for Family Members of an Index Patient

Diagnosis of Chagas disease in a pregnant woman or newborn infant signals the need to test the woman's other children as well as her parents and siblings. A US-based convenience sample of 189 relatives of 86 Chagas disease patients found a *T cruzi* prevalence of 7.4%.[35] In Catalonia, active surveillance identified 178 siblings of index infants. Testing revealed that 14 (7.8%) siblings also had *T cruzi* infection.[36] Perinatal health care clinicians should consider coordinating follow-up with pediatric caregivers who can provide a pivotal role in providing families with information and testing.

Treatment Options for Mothers Infants and Children

The 2 therapeutics for *T cruzi* are benznidazole and nifurtimox.[2,37] Benznidazole received approval by the FDA for use in children 2 to 12 years of age and is available from www.benznidazoletablets.com/. The total daily dose is 5 to 8 mg/kg/d administered orally

in 2 divided doses for a duration of 60 days (Table 2 provides full prescribing information). Prescribing benznidazole to treat a patient outside of the FDA-approved age range is based on clinical diagnosis and decision by a treating physician.

In August 2020, the FDA approved nifurtimox for the treatment of Chagas disease in pediatric patients from birth to less than 18 years of age and weighing at least 2.5 kg. This indication gained accelerated approval based on the number of treated patients who became IgG antibody negative or who demonstrated a 20% or greater decrease in optical density on *T cruzi* IgG antibody tests. Continued approval for this indication may be contingent on verification and description of clinical benefit in a confirmatory trial or trials. The total daily dose of nifurtimox in pediatric patients is 10 to 20 mg/kg/d administered orally in 3 doses for 60 days for children less than 40 kg and 8 to 10 mg/kg/d administered orally in 3 doses for children greater than 40 kg (Table 2 provides full prescribing information).

Antiparasitic treatment is recommended for all *T cruzi*–infected infants and children younger than 18 years of age.[37] Treatment is also recommended for all women with chronic disease in the childbearing years who do not have advanced Chagas cardiomyopathy. Adverse effects are common with both drugs but are less frequent and less severe during infancy and childhood than during adulthood.[38] Consultation with an infectious diseases physician is advisable when initiating treatment. Additional information is available at the CDC web site (https://www.cdc.gov/parasites/chagas/health_professionals/tx.html). Questions regarding treatment can be directed to CDC's Parasitic Diseases Inquiries (404-718-4745; chagas@cdc.gov).

DISCUSSION

Maternal screening with infant testing and maternal and infant treatment for confirmed Chagas disease would be cost-saving.[19,20] At current costs, targeted screening, including the pricing of benznidazole, would result in savings of $1314 per birth and $670 million in lifetime savings per birth-year cohort.[19,20] Universal screening of all newborns would be similarly cost-saving. An alternate approach to identification of infants with congenital Chagas disease is by newborn screening. The current national US Recommended Uniform Screening Panel (RUSP) for newborn screening detects 35 disorders by point-of-care screening and dried blood spot (DBS) specimens.[39] The RUSP recommends point-of-care screening to identify critical congenital heart defects and hearing loss. Among the 33 disorders on the RUSP identified by DBS screening, those most prevalent are cystic fibrosis, primary congenital hypothyroidism, and sickle cell disease. Based on the expected number of cases per year, congenital Chagas disease is more common than greater than one-half of these 33 disorders, even using the most conservative estimates of the expected number of congenital cases of Chagas disease per year.

Treatment of congenital Chagas disease within the first year of life is always recommended,[37] is well tolerated, has cure rates exceeding 90%, and is highly effective in preventing long-term complications of Chagas disease.[21] In addition, children and adolescents diagnosed with Chagas disease should always receive treatment. Women diagnosed with Chagas disease should receive treatment after delivery and completion of

breastfeeding for their own benefit and for protection against *T cruzi* transmission during subsequent pregnancies.

Improving health care clinicians' knowledge of Chagas disease diagnosis, treatment, and prevention is essential to improving Chagas disease outcomes. A survey, tailored for 5 medical specialties, found a general lack of awareness of Chagas disease and knowledge deficits of clinical aspects of the disease.[40] Most US obstetrician-gynecologists had very limited knowledge of Chagas disease.[41] Most Pediatric Infectious Diseases Society members never or rarely considered the diagnosis when caring for infants born to parents from Latin America.[42]

Information that is accurate, practical, and targeted will increase awareness and knowledge of Chagas disease among clinicians.[3] Addressing knowledge gaps will positively affect patient health and will promote congenital transmission screening. Clinicians should be educated as to the outcomes of untreated Chagas disease to understand the importance of screening for and treating of *T cruzi* infection. Improved knowledge should equip clinicians to embrace the feasibility of congenital transmission screening and to engage in efforts to conduct targeted screening and to improve detection and early intervention that will improve outcomes for women, infants, and children infected with *T cruzi*.

SUMMARY

At least 40,000 women in their childbearing years who are living in the United States have chronic Chagas disease acquired years earlier when they were living in Mexico, Central America, or South America. Most are unaware of their infections and do not know that the infection can cause cardiac damage with a usual onset 10 to 30 years after acquisition and that it can be transmitted congenitally. The risk of congenital transmission is 1% to 5% and, although most infants are asymptomatic at birth, 10% to 40% have signs suggestive of congenital infection and all are at risk for later Chagas cardiomyopathy. Implementation of targeted maternal pregnancy-based screening for *T cruzi* IgG or, alternatively, as a component of newborn screening for congenital infections could benefit both women and their infants. Treatment of acute infant infection affects cure, and treatment of chronically infected women prevents transmission in subsequent pregnancies and reduces the likelihood of development of Chagas cardiomyopathy. Evidence demonstrating feasibility of maternal screening and codifying its benefit to both women and their infants should be a priority so that guidelines endorsing screening are included in policy statements related to maternal and infant care.

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KEY POINTS

- Chagas disease is underappreciated as a health concern in women in their childbearing years, resulting in potentially fatal cardiac morbidity owing to *Trypanosoma cruzi* infection in women at risk and their children.
- Pregnancy-based serologic screening for *T cruzi* provides the optimal mechanism to identify Chagas disease in at-risk family units because the results will be available at delivery when both mother and infant are in contact with the health care system.
- Treatment of Chagas disease within the first year of life is well tolerated, has a cure rate exceeding 90%, and is highly effective in preventing long-term *T cruzi*–associated cardiac complications.
- Targeted screening, including the cost of treatment with benznidazole, would be cost-effective and would result in $1314 savings per birth and $670 million in lifetime savings per birth-year cohort.

CLINICS CARE POINTS

- Pregnant women from a Chagas disease endemic region should undergo serologic screening for *Trypanosoma cruzi* IgG through a commercial laboratory.
- Evaluation for suspected congenital Chagas disease should occur as soon as possible after birth.
- Treatment of congenital Chagas disease in the first year of life has cure rates exceeding 90%.

Best practices

What Is the Current Practice for Chagas Disease Serologic Screening?

- Chronic Chagas disease is rarely considered a diagnostic possibility in US pregnant women who formerly resided in Chagas endemic regions.[41]
- Congenital Chagas disease is not consistently included in the differential diagnosis for infants with signs suggesting a congenital infection.[25]
- Serologic screening for Chagas disease is not integrated into recommended maternal prenatal screening platforms for at-risk women.

What Changes in Current Practice Are Likely to Improve Outcomes?

- Promoting education for perinatal health care clinicians on the risk and impact of Chagas disease to infant and maternal health
- Incorporating *T cruzi* IgG serologic screening into pregnancy testing platforms for at-risk pregnant women or, alternatively, into the US RUSP for newborn screening[19,20,39]
- Providing treatment for women identified as having chronic Chagas disease and for infants with congenital Chagas disease to prevent later development of Chagas cardiomyopathy[37]

Major Recommendations

- Modify electronic medical record formats to prompt order entry for *T cruzi* IgG serologic screening into pregnancy test platforms.
- Conduct studies to demonstrate feasibility of Chagas disease maternal and congenital transmission screening.
- Generate sufficient data to inform organizations that develop guidelines for care of women and infants at risk for Chagas disease to endorse Chagas disease screening in policy statements for maternal and infant care.

Rating for strength of the evidence: Quality of evidence strong; strength of recommendation moderate.

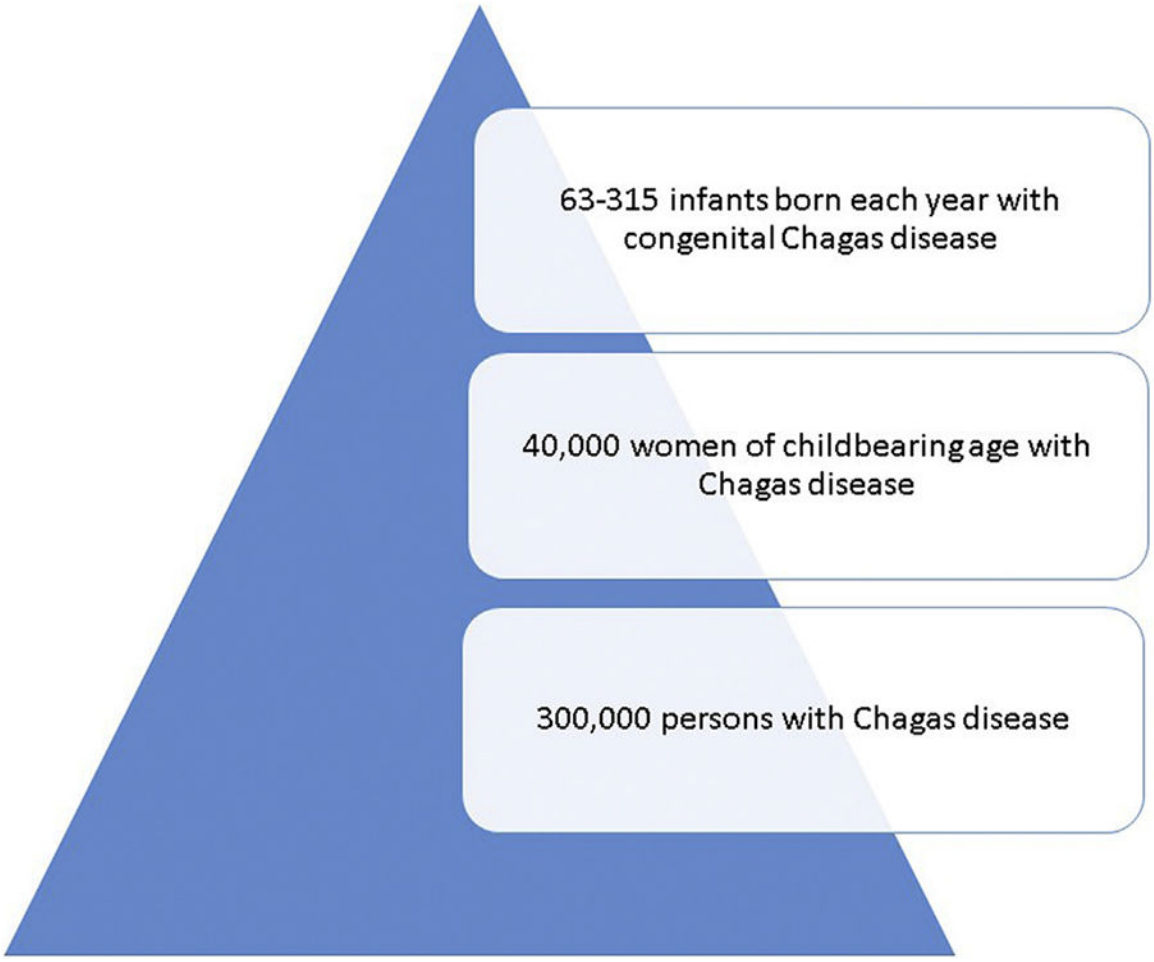

Fig. 1.
Chagas disease burden in the United States.[5,6]

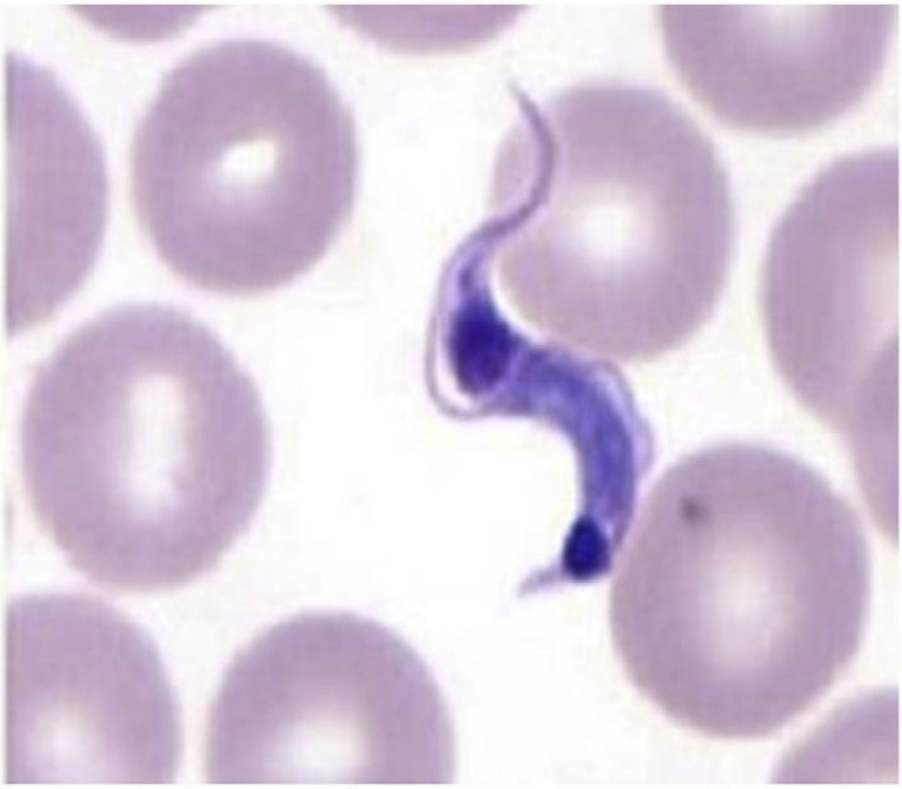

Fig. 2.

T cruzi trypomastigote in a thin blood smear stained with Giemsa. (*From* Parasites - American Trypanosomiasis (also known as Chagas Disease). Centers for Disease Control and Prevention. Accessed January 6, 2021 at: https://www.cdc.gov/parasites/chagas/.)

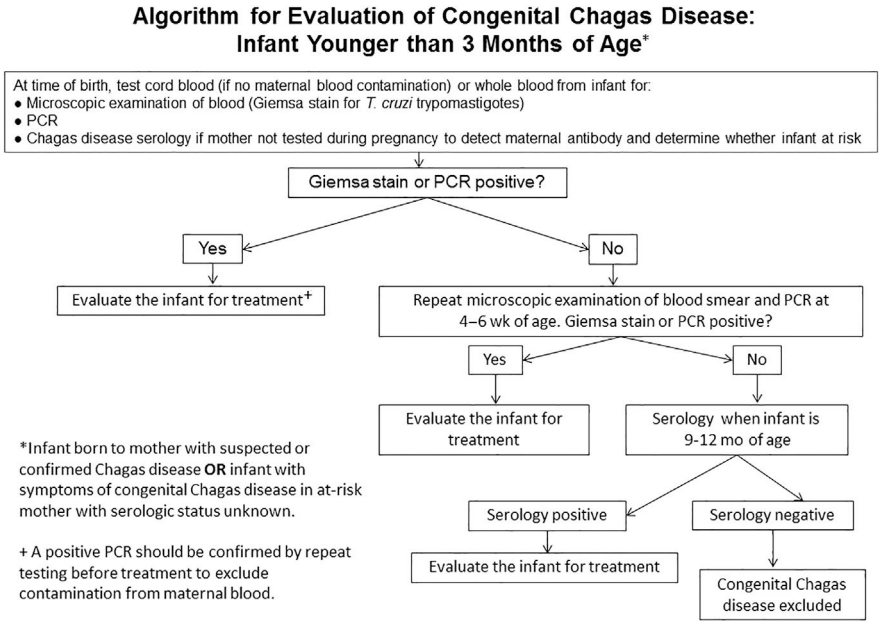

Fig. 3.

Steps to establish the diagnosis of congenital Chagas disease in infants younger than 3 months of age. (*From* Congenital Chagas disease. Available at: https://www.cdc.gov/parasites/chagas/health_professionals/congenital_chagas.html. Accessed December 30, 2020.)

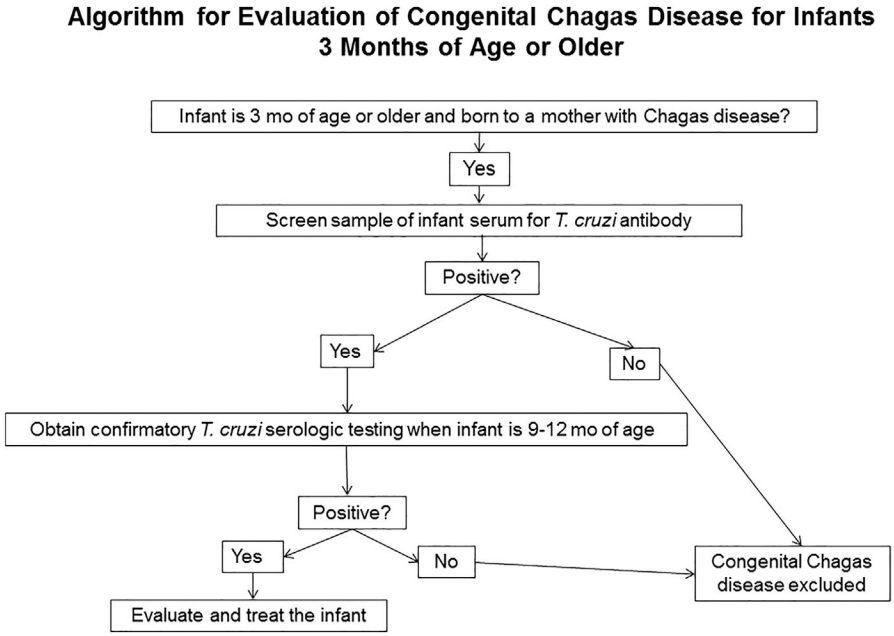

Fig. 4.

Steps to establish the diagnosis of congenital Chagas disease in infants 3 months of age or older. (*From* Congenital Chagas disease. Available at: https://www.cdc.gov/parasites/chagas/health_professionals/congenital_chagas.html. Accessed December 30, 2020.)

Table 1

Clinical features of congenital Chagas disease

Common Features[a]	Less Common Features[b]
Low birth weight	Prematurity
Respiratory distress	Cardiac findings[c]
Hepatomegaly	Meningoencephalitis
Splenomegaly	Neurologic signs
	Edema/anasarca
	Hematologic findings[d]

[a] Observed in 25% or more of infants with signs of infection.

[b] Observed in 10% to 25% of infants with signs of infection.

[c] Includes cardiomegaly, heart failure, arrhythmias.

[d] Includes thrombocytopenia, anemia.

Table 2

Chagas disease resources

Resource	Content for Health Care Providers
https://www.cdc.gov/parasites/chagas/health_professionals/congenital_chagas.html	**Centers for Disease Control & Prevention:** Information about congenital Chagas disease; algorithms for evaluation of Chagas disease in pregnant women and infants
https://www.chagasus.org	**Chagas Disease Center of Excellence:** General information on Chagas disease
https://LASOCHA.org/en/	**Latin American Society of Chagas:** (LASOCHA) General information on Chagas disease
https://www.uschagasprovidersnetwork.org/	**US Chagas Providers' Network:** Listing of US Chagas disease providers by state; general Chagas disease information
https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209570lbl.pdf	**Benznidazole prescribing information:** Highlights and full prescribing information for benznidazole
https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213464s000lbl.pdf	**Nifurtimox prescribing information:** Highlights and full prescribing information for nifurtimox