



Chagas Disease Screening and Treatment: A Military Clinician's Perspective in South Texas

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Chagas Disease Project ECHO

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COI/Disclaimers

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- COI: None



Objectives

- Review the Blood Bank Screening Process for *T cruzi* infection
- Describe military-unique challenges to diagnosing and treating Chagas disease



Joint Base San Antonio

- Large joint (Army, Air Force, Marines, Navy, Space Force) base in San Antonio, TX
- Only point of entry for USAF and USSF enlisted force (~38k a year from around the world)

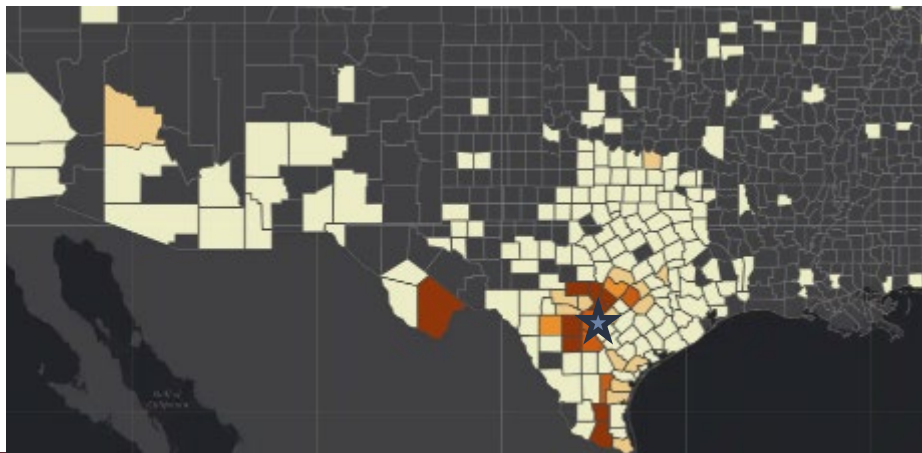


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Vectors

- Significant Triatominae population around San Antonio
- Concern for acquisition both before and after military entry



<https://kissingbug.tamu.edu/Map/>



A military case of Chagas cardiomyopathy

- In October 2016, a basic trainee screened positive for *T. cruzi* antibodies. Confirmed positive at CDC
- Screening EKG showed first degree AV block, L anterior hemiblock, and right bundle branch block.
- Normal echocardiogram and stress test.
- Cardiac MRI demonstrated early cardiac disease.
- Patient medical declined therapy.

A Case of Chagas Cardiomyopathy Following Infection in South Central Texas

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Does the US Military Routinely Screen for Chagas Disease?

- No
- However, screening studies performed in the past.



Screening of Military Populations

- Screening 1033 service members in Summer/Fall 2015+2016 with 8,130 weeks of outdoor exposure
 - Mainly trainees with significant outdoor exposure
 - 5 (0.5%) reported a triatomine bite
 - All PCR, ELISA, and IFA were negative, except for one service member with an indeterminate ELISA

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Prevalence and Seroprevalence of *Trypanosoma cruzi* Infection in a Military Population in Texas

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Most Chagas Screening is through the Blood Bank

- Military blood banks check *T. cruzi* antibodies with EVERY donation
 - FDA only requires screening with first donation
- Deferrals for Blood Donation are common
 - Anemia, Acute Illness, Taking Antibiotics
 - Travel to malaria-endemic area (3 months), Residing in malaria-endemic area (3 years)



Blood Donation-Screening Tests

	ABBOTT PRISM	ABBOTT Alinity s
Test	Chemiluminescent immunoassay	Chemiluminescent microparticle immunoassay
Targets	<i>T. cruzi</i> recombinant antigens (FP3, FP6, FP10, TcF)	<i>T. cruzi</i> recombinant antigens (FP3, FP6, FP10, TcF)
Sensitivity	100%	100%
Specificity	99.86%	99.98%



Current Targets for Diagnostic Tests

- Hemagen ELISA: purified antigens from parasites
- InBios Chagas Detect Plus: Recombinant antigen: ITC8.2
- ORTHO *T. cruzi* ELISA: purified antigens from parasites
- Weiner Chagatest recombinant antigens: 1, 2, 13, 30, 36, and SAPA



Supplemental-ESA Chagas

- Test: Enzyme Strip Assay
- Targets: *T cruzi* recombinant antigens (FP10, FP6, FP3, TcF)

Table IV
Supplemental Testing of Specimens Repeatedly Reactive by a Licensed Screening Test for Antibodies to *T cruzi*

ABBOTT ESA Chagas	<i>T cruzi</i> RIPA				Total <i>T cruzi</i> Antibody Status
	Total	POS	IND	NEG	
			4 TP ^c	19 TP ^d	174 TP
POS	180	151 TP	1 INC ^c	4 INC ^a 1 TN ^f	5 INC 1 TN
IND	14	1 INC ^a	0	3 INC ^g 10 TN ^h	4 INC 10 TN
NEG	135	1 TN ^b	0	134 TN	135 TN
Total	329	153	5	171	329

Table VI
Supplemental Testing of ABBOTT PRISM Chagas Repeatedly Reactive Specimens

Category	Number of Specimens Tested	ABBOTT PRISM		ABBOTT ESA	
		Chagas Repeatedly Reactive/Number of Specimens Tested	Chagas Positive/ Number of Specimens Tested	Chagas Positive/ Number of Specimens Tested	Chagas Positive/ Number of Specimens Tested
US Blood Donors	41,760	58/41,760 (0.14%)	9/58 (15.52%)		



Blood Donor Screening Data (2014-2016)

- 23 of 43,402 persons who donated blood screened positive for Chagas disease at JBSA
- 2/23 (8%) with confirmed disease by CDC testing (1 with cardiomyopathy)
- Patient without symptoms remained in military with annual EKG screening.

Diagnostic Evaluation of Military Blood Donors Screening Positive for *Trypanosoma cruzi* Infection

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Blood Donor Screening Data (2017-2022)

TABLE 1 Number of blood donors deferred at Joint Base San Antonio for positive screen and confirmation of transfusion-transmissible pathogen by year.

Year	Total donors	HBV	HCV	HIV	HTLV-I/II	<i>T. cruzi</i>	WNV	<i>T. pallidum</i>	Zika virus	<i>B. microti</i>
2017	19,760	6	3	0	2	0	2	9	-	-
2018	17,832	3	3	0	1	2	0	7	0	-
2019	15,841	4	9	1	2	1	0	7	1	-
2020	12,016	1	6	0	0	0	0	5	3	0
2021	11,915	5	7	0	0	2	0	7	0	0
2022	12,095	0	6	0	0	0	1	10	-	0
Total	89,459	19	34	1	5	5	3	45	4	0

Abbreviations: *B. microti*, *Babesia microti*; HBV, Hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; HTLV, human T-lymphotropic virus; *T. cruzi*, *Trypanosoma cruzi*; *T. pallidum*, *Treponema pallidum*; WNV, West Nile virus.



A note of caution...last 49 blood donors who screened positive

	Count (%) or Median [IQR]
Male	39 (79.6%)
Age	21 [19 - 24]
Active Duty (Y/N)	48 (98%)
Service	
Air Force	40 (83.3%)
Army	4 (8.33%)
Navy	4 (8.33%)
Rank/Status	
Officer	5 (10.2%)
Enlisted	44 (87.8%)
Confirmatory Testing Result	
Positive	4 (8.2%)
Indeterminate	15 (30.6%)
Negative	30 (61.2%)
Work-up	
Document Risk Factors Asked (Y/N)	16 (43.2%)
Risk Factors Present (Y/N)	2 (12.5%)



Work-up

	Total (n=49)	Pos/Indeterminate (n=19)	Negative (n=30)	P-Value
Follow-up Appointment	38	17 (89.5%)	21 (70%)	
Obtained Repeat Testing	21 (42.9%)	16 (84.2%)	5 (16.7%)	0.00001
T cruzi IgG-ARUP	16	12 (63.2%)	4 (13.3%)	0.0001
State/CDC Testing	3	2 (10.5%)	1 (3.3%)	0.6
Saw a Specialist	7 (14.3%)	6 (31.6%)	1 (3.3%)	0.01
Total Number of Primary Care Visits	68	39	29	
Total number of Specialist Visits	13	10	3	
Number of days of Work-up per patient, median [IQR]	20.5 [12 - 41.5]	32 [21 - 42]	14 [12 - 26.5]	.07
Number of days in Med Hold, median [IQR]	11.5 [7 - 18.5]	17.5 [12 - 22.25]	8 [4.5 - 12]	0.004



Of those with Pos Screen+ESA

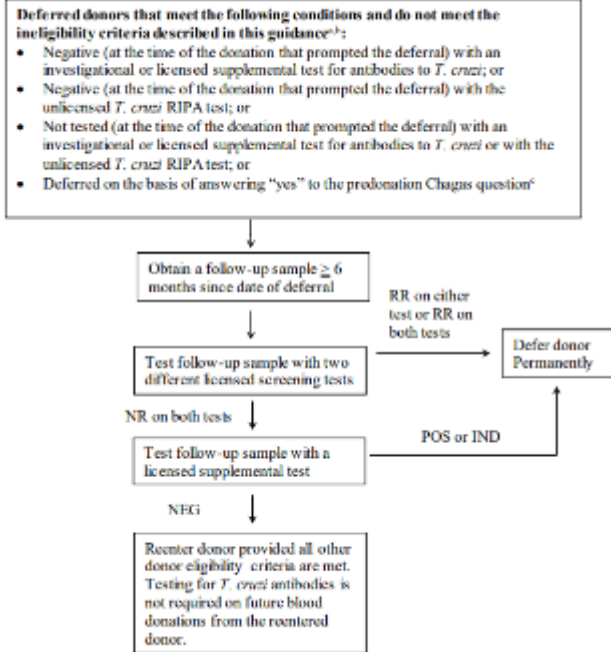
Patient Number	Risk Factors Asked (Y/N)	Risk Factors Present (Y/N)	T cruzi IgG result	ABBOTT PRISM result	CDC Results
1	No	N/A	Negative	Negative	N/A
2	No	N/A	Negative	Negative	N/A
3	Yes	No	Negative	Negative	N/A
4	Yes	No	Negative	Reactive x2	Negative



T. Cruzi Reentry Algorithm

- Donors with pos/indeterminate ESA receive lifelong deferral
- Those with neg ESA can be tested in 6 months with two different screening tests (not currently possible in DOD)

APPENDIX: Reentry Algorithm for Donors Deferred on the Basis of Screening Test Results for Antibodies to *T. cruzi* or Pre-donation Screening Question



RR = repeatedly reactive; NR = non-reactive; POS = positive; NEG = negative; IND = indeterminate



What happens after a patient screens positive

- Our practice:
 - Send to state health department/CDC for confirmation
 - Challenges:
 - ✓ Out of state positives
 - ✓ Contact at state health department for communications



For those with confirmed disease

- Determine if heart disease is present
 - Cardiology evaluation -> Service limitations if cardiomyopathy
- For indeterminate form of Chagas disease
 - Annual EKG
 - World-wide assignments, no limitations on deployability

Forsyth et al. 2021



Both Benznidazole and Nifurtimox are on DOD formulary

Results for Benznidazole 100 Mg, Tablet

Pharmacy	Coverage	Active duty	Non-active duty
Military (MTF)	Uniformed Services University of the Health Sciences	\$0.00	\$0.00
Home Delivery - Up to a 90 days supply - Secure delivery to your door	Covered	\$0.00	\$39.00
Retail - Up to a 30 days supply	Covered	\$0.00	\$43.00

Results for Lampit 120 Mg, Tablet

Pharmacy	Coverage	Active duty	Non-active duty
Military (MTF)	Uniformed Services University of the Health Sciences	\$0.00	\$0.00
Home Delivery - Up to a 90 days supply - Secure delivery to your door	Covered	\$0.00	\$38.00
Retail - Up to a 30 days supply	Covered	\$0.00	\$45.00



Challenges and Next Steps

- How to address false positives screens
 - How can we have them re-enter the donor pool?
- Policy questions remain
 - Are we screening the right people?
- Multi-disciplinary One Health engagement
 - Combining efforts of veterinarians, public health officers, entomologists and physicians across military services



Conclusion

- Significant Chagas screening in the military current through volunteer blood donors
 - Many false positives
- Access to confirmatory diagnostic through state health departments and CDC
- Chagas therapeutics are on DOD formulary and do NOT require prior authorization.



Questions



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