Proposed Changes to ICD-10-CM Diagnosis Coding for Babesiosis

March 6, 2019

ICD-10-CM Coordination and Maintenance Committee Meeting

Mikhail Menis, PharmD, MS Epi, MS PHSR
Epidemiologist
Office of Biostatistics and Epidemiology
CBER/FDA

Introduction

- The FDA's Center for Biologics Evaluation and Research (CBER's) mission is to ensure safety and efficacy of biological products, including blood and blood products, and thus to protect and improve public health;

- Under the Food and Drug Administration Amendments Act (FDAAA) of 2007, CBER is responsible for conducting U.S. population-based active surveillance of blood and blood product safety;

- CBER is using large public (e.g., CMS) and private medical databases to:
  - Conduct active surveillance of blood component and product safety and utilization;
  - Evaluate spread of transfusion-transmissible infections.

Background

- Human babesiosis is a protozoal zoonotic disease caused by intraerythrocytic protozoan parasites of *Babesia spp.*;
- In elderly, splenectomized, and/or immunocompromised persons, babesiosis infection is more likely to be symptomatic (e.g., malaise, fever, chills, fatigue) with increased risk for complications (e.g., hemolytic anemia, acute respiratory failure), including mortality;
- In younger persons, babesiosis may be asymptomatic and can result in further transmission through blood donations;
- Human *Babesia* infections are considered endemic in Northeastern states (Connecticut, Rhode Island, Massachusetts, New York, and New Jersey) and in Midwestern states (Minnesota and Wisconsin);
- Geographic range of the disease is expanding to other states (e.g., ME, NH, VT, PA, MD, VA);

Background

- Over the past decade, there have been a growing number of reported tick-borne and transfusion-transmitted babesiosis cases in the United States;

- Although the majority of U.S. babesiosis cases are caused by *B. microti*, other *Babesia spp.* (e.g., *B. duncani, B. divergens/B. divergens-like strains)* have been implicated in transmission in multiple U.S. states;

- In response, risk mitigation strategies are being developed, including donor screening tests and testing strategies:

  - FDA has recently approved a Nucleic Acid testing to identify specific *Babesia species*: *B. microti, B. duncani, B. divergens, and B. venatorum*. https://www.fda.gov/BiologicsBloodVaccines/ucm629998.htm

Figure 1. Babesiosis Occurrence Among Elderly Medicare Beneficiaries, 2006 (Babesiosis Heat Map)

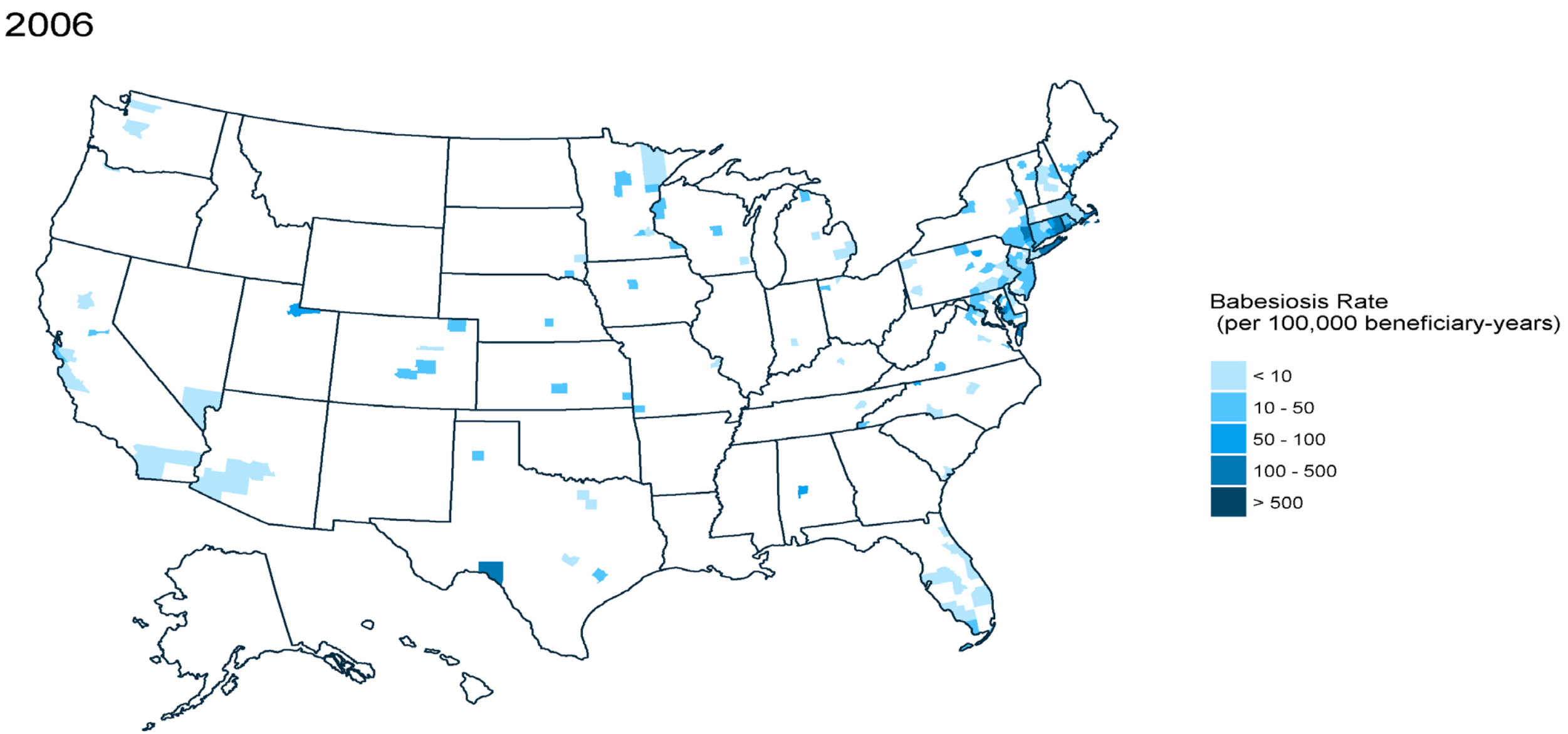


Figure 2. Babesiosis Occurrence Among Elderly Medicare Beneficiaries, 2017 (Babesiosis Heat Map)

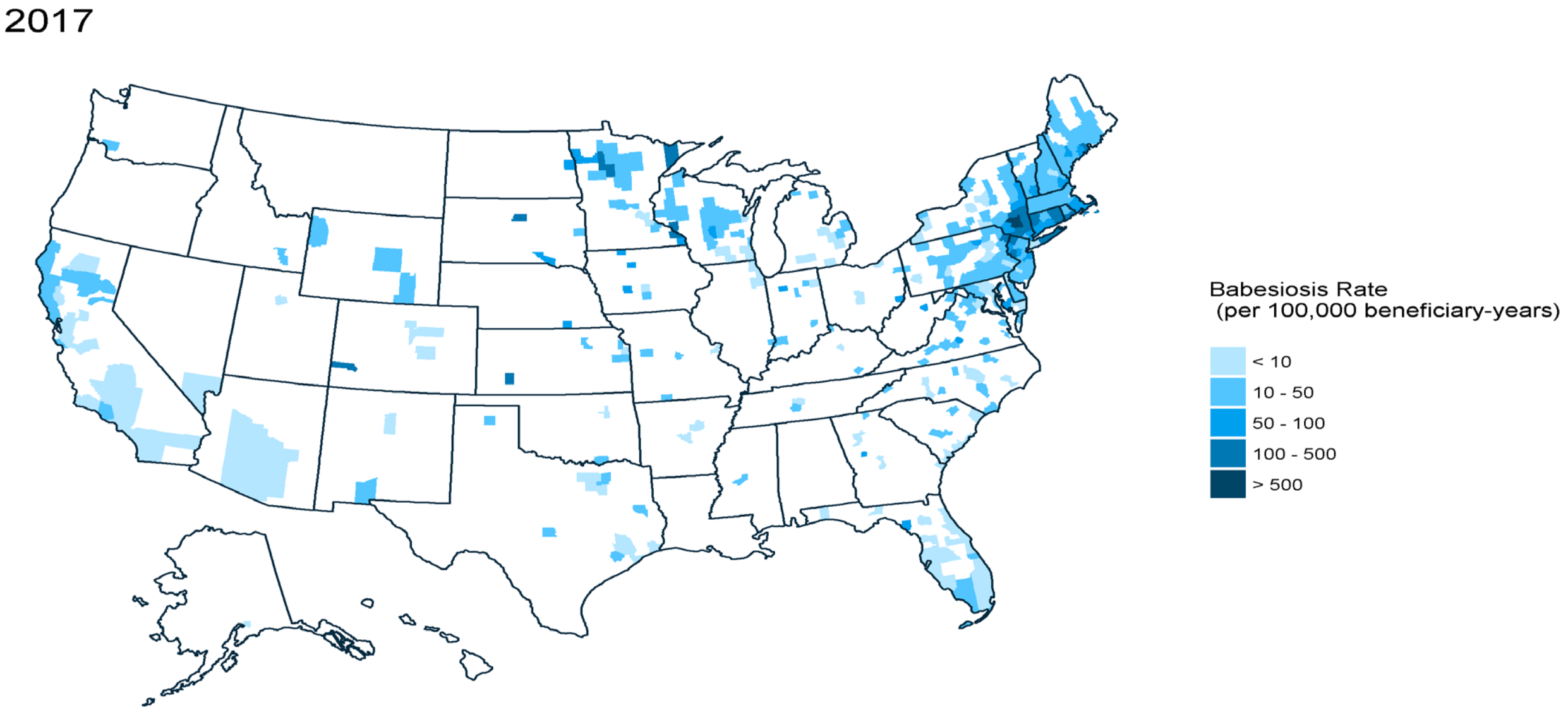
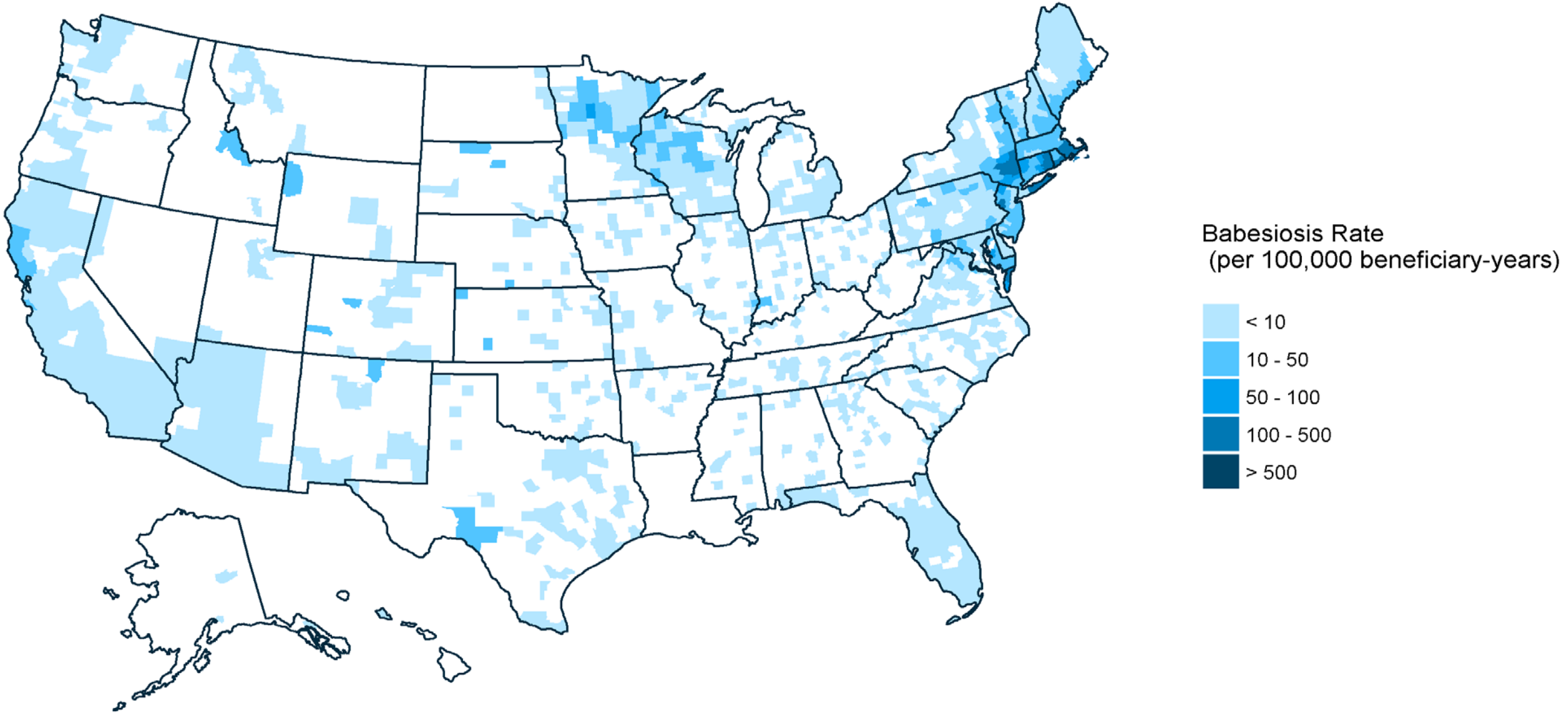


Figure 3. Babesiosis Occurrence Among Elderly Medicare Beneficiaries, 2006-2017 (Babesiosis Heat Map)



Babesiosis Coding Proposal

- **The objective of the FDA/CBER's proposal is to improve *Babesia* infection coding granularity and thus help distinguish *Babesia spp.* infecting humans;**
- **If introduced, *Babesia spp.*-specific coding will allow:**
  - Providers to record specific *Babesia spp.* infecting humans in the U.S., and thus will improve diagnosis precision;
  - Public Health Organizations and researchers to ascertain and characterize occurrence of different *Babesia spp.* in the U.S.;
  - To monitor geographic spread of *Babesia species* in the U.S. over time;
  - To develop *Babesia spp.*-specific national (e.g., donor testing, public health messaging) and local (e.g., deer population control) prevention strategies to reduce spread of human *Babesia spp.* infections, both tick-borne and transfusion-transmitted;
- **Overall, the new codes will improve provider awareness of *Babesia spp.* infections and lead to better treatment and prevention strategies.**

References

- Herwaldt BL, Linden JV, Bosserman E, et al. Transfusion-associated babesiosis in the United States: a description of cases. Ann Intern Med, 2011; 155(8):509-519.
- Vannier E and Krause PJ. Human babesiosis. N Engl J Med 2012; 366(25): 2397-2407.
- Persing DH, Herwaldt BL, Glaser C, et al. *Infection with a babesia-like organism in northern California.* N Engl J Med 1995; 332(5):298-303.
- Conrad PA, Kjemtrup AM, Carreno RA, et al. *Description of Babesia duncani n.sp. (Apicomplexa: Babesiidae) from humans and its differentiation from other piroplasms.* Int J Parasitol 2006; 36(7):779-789.
- Krause PJ, McKay K, Gadbaw J, et al. *Increasing health burden of human babesiosis in endemic sites.* Am J Trop Med Hyg 2003; 68(4):431-436.
- Gubernot DM, Lucey CT, Lee KC, et al. Babesia infection through blood transfusions: reports received by the U.S. Food and Drug Administration, 1997–2007. CID 2009 48:25–30.
- Recommendation for reducing the risk of transfusion-transmitted babesiosis: draft guidance for industry [Internet]. Silver Spring (MD): US Food and Drug Administration;2018 [cited 2018 Aug 24]. Available from: https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM614734.pdf.
- Menis M, Forshee RA, Anderson SA, et al., *Babesiosis Occurrence among the Elderly in the United States, as Recorded in Large Medicare Databases during 2006-2013.* PLoS One 2015; 10(10):e0140332.
- Menis M, Anderson SA, Izurieta HS, et al. Babesiosis among elderly Medicare beneficiaries, United States, 2006–2008. Emerg Infect Dis 2012; 18(1):128–131. doi: 10.3201/eid1801.110305 PMID: 22257500.

Acknowledgments

- Richard A. Forshee, PhD
- Barbee I. Whitaker, PhD
- David A. Leiby, PhD
- Steven A. Anderson, PhD, MPP
- Jeffrey A. Kelman, MD
- CMS
- Acumen LLC