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Screening for Babesia microti in the U.S. blood supply

Babesia microti is a tickborne intraerythrocytic parasite that may be transmitted through blood transfusions. Babesia infection may range from an asymptomatic infection in a healthy person to a fatal infection in an immunocompromised person. Concern about bloodborne transmission of B. microti from infected donors is increasing. From 1979 to 2009, 162 cases of transfusion-transmitted babesiosis were reported, of which 159 were caused by B. microti. There is no FDA licensed test for screening for B. microti in donated blood. Donor screening consists of asking donors if they have ever had babesiosis; those that answer "yes" are deferred indefinitely. This screening method is considered to be very ineffective. The authors conducted a study to assess data from a largescale investigational product-release testing protocol and donor follow-up program. From June 2012 through September 2014, they performed arrayed fluorescence immunoassays for B. microti antibodies and real-time polymerase chain-reaction (PCR) assays for B. microti DNA on blood samples obtained in Connecticut, Massachusetts, Minnesota, and Wisconsin. Of 89,153 blood donation samples tested, 335 were confirmed to be positive, of which 67 were PCR positive. Only nine samples were antibody negative, which represented 13 percent of all PCR-positive samples. PCR-positive samples were identified throughout the year, while antibody-negative infections occurred from June through September. Donor follow-up showed DNA clearance in 86 percent of the donors but antibody seroreversion in only eight percent after one year. Overall, 29 cases of transfusion-transmitted babesiosis were linked to blood from infected donors, including blood from 10 donors whose samples were PCR positive two to seven months after the implicated donation. The authors concluded that blood donation screening for antibodies to B. microti and DNA from the parasite was associated with a decreased risk of transfusiontransmitted babesiosis. Data from this study may help provide a potential blood donor testing strategy for preventing transfusion-transmitted babesiosis.

Moritz ED, Winton CS, Tonnetti L, et al. Screening for *Babesia microti* in the U.S. blood supply. *N Engl J Med.* 2016;375:2236-2245.

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Perspectives on whether WES is ethically disruptive in pediatrics

Whole exome sequencing is beginning to transform pediatric oncology by refining cancer diagnoses and providing unexpected information about new noncancer diagnoses, risk assessment for cancer and noncancer diagnoses, reproductive risk assessment, pharmacogenomics, and variants of unknown clinical significance. The concern is that whole exome sequencing (WES) may be an ethically disruptive technology that leaves clinicians and parents of pediatric cancer patients ill-prepared or unprepared to make clinical decisions based on the results. As part of the Baylor Advancing Sequencing in Childhood Cancer Care study, the authors conducted semi-structured interviews with 16 pediatric oncologists and 40 parents of pediatric cancer patients prior to the return of WES results. The interviews were intended to assess whether the physicians or parents expected to be ill-prepared or unprepared to incorporate WES into decision-making about pediatric cancer care. The authors showed that neither pediatric oncologists nor parents anticipated sequencing to be an ethically disruptive technology. This is because they expected to be prepared to integrate sequencing results into their existing approaches to learning and using new clinical information for the patient's care. The pediatric oncologists planned to incorporate the results into

evidence-based approaches to clinical practice, although they were concerned about the impact on parents. The parents' perspective was that genomic information would better prepare them to participate in decisions about their child's care. The authors concluded that the data from this study do not support the concern that introducing genome sequencing into pediatric cancer care will be ethically disruptive, leaving physicians and parents ill-prepared or unprepared to make responsible decisions using the new genetic information.

McCullough LB, Slashinski MJ, McGuire AL, et al. Is whole-exome sequencing an ethically disruptive technology? Perspectives of pediatric oncologists and parents of pediatric patients with solid tumors. *Pediatr Blood Cancer.* 2016;63:511–515.

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