

June 2016**Blood Supply – How safe Is It?**

Before laboratory testing of donated blood was available, behavioral deferrals (blood donor deferrals for high-risk behavior) were commonly used as surrogates, which resulted in reduction of infectious disease transmission including hepatitis B (HBV), hepatitis C (HCV), and human immunodeficiency virus (HIV) by approximately 80%. FDA approved serological donor tests, introduced in 1993, further reduced the transmission of HBV, HCV, and HIV to one in 63,000, one in 103,000, and one in 493,000, respectively. Meanwhile, behavioral deferral was retained as a layer of protection against false-negative test results, test errors, and erroneous component distribution. In 1996, FDA mandated direct viral testing including HIV p24 antigen in an effort to avert risk of disease transmission during the HIV seronegative window. Concurrently, nucleic acid amplification tests (NATs) were being developed, since several studies showed that these test were more sensitive during acute infection compared to either antibody or antigen detection. Introduction of NAT for blood and blood products, therefore was a major step in significantly reducing the residual risk of viral infectious diseases (Louis M. Katz JID 2008:198).

Recent episodes of arboviral diseases in the western hemisphere including West Nile virus, dengue viruses, chikungunya virus, and most recently Zika virus have brought the safety of blood products into the forefront. In relatively rapidly expanding infectious outbreaks, such as those seen with Zika virus, the need to develop clinical diagnostic tests for accurate detection of acute and recent infection becomes urgent. These diagnostic tests should not only have high sensitivity but also be very specific to avoid false-positive results and unnecessary donor deferrals. Further, optimization of diagnostic tests for high-throughput systems, such as those used to test donated blood in a timely manner, offers additional challenges.

While diagnostic tests for Zika virus are being developed, FDA has recommended that donors at risk for Zika virus infection be deferred for 4 weeks.

Individuals at risk include those with exposure to and symptoms suggestive of Zika virus infection (fever, arthralgia, maculopapular rash, and conjunctivitis), those who have had sexual contact with a man who has traveled to or resided in an area with active Zika virus transmission in prior 3 months, and those who have traveled to or resided in areas with active Zika virus transmission in the past 4 weeks. Additionally, in areas of active Zika transmission, as defined by Center for Disease Control and Prevention (CDC) (currently including Puerto Rico, the US Virgin Islands, and American Samoa), FDA recommends obtaining whole blood and blood products from areas in the United States without active transmission. If Zika virus infection expands to the southern part of the United States as predicted, a highly accurate donor screening test with high-throughput capability would greatly facilitate blood management (Peter W. Marks *et. al.* JID 2016:213).

Meanwhile, alternative technologies that focus on pathogen-reduction in whole blood and blood products are also being developed. Most of these act on nucleic acids, with the goal of protecting the blood supply against the majority of existing and emerging pathogens. In March 2016, the FDA approved use of INTERCEPT blood system in single donor platelets. Briefly, psoralen derivative, a chemical that binds to nucleic acid, is added to platelets. Upon exposure of platelets to UVA illumination, cross-linking of any nucleic acid bound to psoralen derivative occurs, which prevents pathogen replication. Platelets are then passed through a filter present in the system, to remove residual psoralen derivative. A similar FDA approved system is available for plasma. Although the initial cost of implementation of these techniques may be higher, over time, the reduction in need for donor screening tests could potentially balance this added cost. The final FDA recommendations regarding use of these technologies will be out by 2017.

Zika Virus Testing Update

As of June 22, 2016 there have been 819 travel-associated cases of laboratory-confirmed Zika virus infection within the continental U.S. and Hawaii, with no infections yet reported as locally acquired. Fewer than 10 total cases have been reported in Missouri & Kansas. However, the number of cases is nearing 2000 in Puerto Rico, where local transmission is occurring.

Zika PCR testing for acute infection is now available either through the Centers for Disease Control (CDC) or as a send-out test through a reference laboratory. Notably, Zika PCR testing is clinically appropriate only in symptomatic patients. Because the virus clears the bloodstream rapidly, Zika PCR is reliable for detection of virus in serum for approximately only 4-7 days following symptom onset. Data published by the CDC (MMWR, 5/10/16) indicates that urine PCR testing may detect virus for an additional few days. Current recommendations for Zika PCR testing are serum samples collected <7 days and urine samples collected <14 days after symptom onset. Both serum and urine specimens should be submitted when Zika PCR testing is indicated.

Negative Zika PCR results do not exclude the possibility of Zika virus infection, especially if testing is performed after 7-14 days of symptom onset. Serological testing for evidence of IgM antibody to Zika virus should be considered in patients with negative Zika PCR results who are within 12 weeks of symptom onset. Serologic testing is currently available only through consultation with public health departments or the CDC, as commercial laboratories at present only offer Zika PCR.

Suspected cases of Zika virus infection are required to be reported to local & state health departments, who can facilitate the appropriate testing through the CDC when indicated. Submission of specimens through the Missouri State Public Health Laboratory requires the

requesting physician to contact the state epidemiologist through the Bureau of Communicable Disease Control and Prevention at 573/751-6113 (Monday-Friday, 8 am-5 pm) or 800/392-0272 (after hours and weekends), for consultation and to assure that appropriate specimens are collected. The Kansas Department of Health and Environment is available at 877-427-7317 for questions regarding testing. Additionally, the Missouri Department of Health and Senior Services recently launched a new website with specific testing information for physicians, <http://health.mo.gov/emergencies/ert/med/zika.php>. This website also has links to other clinical, epidemiological and guidance documents for Zika virus.

To protect against mosquito bites, the CDC recommends using an Environmental Protection Agency (EPA)-registered mosquito repellent. A list of repellents along with their efficacy and recommendations for use are available at the CDC website (cdc.gov), along with other mechanisms for avoidance of bites. The recommended repellents include those containing DEET, picaridin, IR3535, or lemon eucalyptus oil. A variety of natural mosquito repellents that underwent consumer testing are not recommended for reliable protection when applied topically. These products include several oils such as citronella, cedar, geranium, and lemongrass. Likewise, there is no evidence that garlic, wristbands, or ultrasonic devices are useful in prevention of mosquito bites.

Antibiograms on EPIC

Antibiograms for all Saint Luke's Health System hospitals are located under the Clinical Reference tab in Epic. Separate data is reported for isolates from urine versus those of systemic origin. This information is reviewed by the Antimicrobial Stewardship Committee, and updated every 6 months.