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Blood safety and availability: Blood donor screening assays regulated by the U.S. Food and Drug Administration

Abdur Razzaque

Division of Emerging and Transfusion Transmitted Diseases, Center for Biologics Evaluation and Research, FDA, USA

Blood safety is a global public health priority but infection risk varies greatly around the world. The availability of resources to support blood safety measures and the epidemiology of blood-borne diseases have a major impact on blood safety. In the United States, there are over 3000 blood establishments that collect and test approximately 15 million units of blood for transfusion per year. The Food and Drug Administration (FDA) is responsible for regulating blood safety in the United States and regulates blood donor screening assays and establishments through defined regulatory processes and policies. Blood establishments use a number of processes to establish and maintain blood safety. These measures include a) selection of low risk populations, b) careful screening and questioning of donors, c) laboratory testing of donations, d) maintenance of records and e) quarantine of untested and reactive donations.

Blood donor screening assays include tests for infection with hepatitis B and C viruses (HBV and HCV), HIV-1 and HIV-2, HTLV-1 and HTLV-2, West Nile Virus (WNV), T. cruzi and syphilis. Different types of assays are used in the screening of these agents, such as serology tests and nucleic acid (NAT) based assays. FDA regulates blood donor screening assays through Investigational New Drug Applications (IND) and Biologics License Applications (BLA). Several licensed serological and NAT tests are available for blood donor screening. Some critical factors that are considered for licensing of these assays will be discussed in this presentation.

Biography

Abdur Razzaque completed his Ph.D at the age of 31 years from Kyushu University, Japan and postdoctoral studies from the National Cancer Institute, National Institutes of Health, Bethesda, Maryland. He is a Senior Regulatory Scientist in the Division of Emerging and Transfusion Transmitted Diseases at the Center for Biologics Evaluation and Research, FDA. Dr. Razzaque conducted a broad research program to understand the role of herpesviruses in human cancer. He has been nationally and internationally recognized for his pioneering work in identifying the transforming functions of HHV 6. He has published more than 32 papers in peer-reviewed journals. He chaired many scientific sessions in national and international meetings and also helped in organizing scientific meetings. Dr. Razzaque is currently a subject matter expert for hepatitis test kits for blood donor screening at FDA/CBER.