

QUALITY CONTROL DIVISION

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During the year under report, the Quality Control Division was involved in quality control testing of plasma derived hepatitis B vaccine, Hepatitis B virus research, vaccine preventable arboviral research on Japanese encephalitis and chikungunya viruses, and research on development of rabies vaccine. Quality control testing was done starting from raw materials to final product to get safe and effective vaccine. The research projects were mostly involved in disease surveillance of viral infections for timely prevention of disease outbreaks. Some of the studies aimed to monitor the emergence of new viral strains or subtypes to provide base-line data for the formulation of effective candidate vaccines and for elucidating the contribution of viral genetics to the changing patterns of disease.

RESEARCH PROJECTS

1. COMMUNICABLE DISEASES

1.1 VIRAL HEPATITIS

1.1.1. Quality control testing of plasma derived hepatitis B vaccine (2015)

During 2015, a total of 550 units of blood samples were determined for HBs antigen by counter-current-immunoelectrophoresis (CIEP) and 87 units of blood samples with high HBs antigen titre were again tested for anti-HCV and anti-HIV 1 & 2 by using ELISA and for syphilis by using antibody test. A total of 2 blood samples were infected i.e. HCV 2.29 % (2/87). Eighty five out of 87 units of blood were free from the above infections and were entitled to be used for Hepatitis B vaccine production. CIEP test was done not only for HBs antigen determination in raw blood units, but also used for in-process control of intermediate products for HBsAg in vaccine production (91 tests). Other important tests for vaccine preparations such as pyrogen test (1 test), Lowry's protein test (41 tests), abnormal toxicity test (6 tests), mouse potency test (1 test), general safety (abnormal toxicity test) (10 tests), sterility tests (6 tests), mouse immunogenicity test (2 tests) and one test for extraneous viruses were also performed. Room sterility test (1 test) and Polymerase chain reaction (12 tests) were also done for in-process control of intermediate products for HBsAg in vaccine production.

1.1.2. Whole Genome Sequencing of Hepatitis B virus (HBV) strains from Myanmar (2015) (Please refer to Annual Report of Bioinformatics Division)

1.2. JAPANESE ENCEPHALITIS

1.2.1. Detection of Japanese encephalitis virus infections among hospitalized encephalitis patients in selected hospitals in Yangon (2015)

Japanese encephalitis (JE) is one of the vaccine preventable diseases, but is also one

of the most important causes of epidemic encephalitis worldwide. Disease surveillance is important to get timely intervention before outbreaks. From January to December 2015, a total of 79 serum samples 73 from Yangon General Hospital and 6 from Yangon Children Hospital were collected from the patients who were admitted with sign and symptoms of encephalitis. The presenting clinical signs and symptoms of these patients were fever 53 (67%), confusion and disorientation 38 (48.1%), headache 32 (40.5%), nausea 18 (22.7%), vomiting 16 (20.2%), neck stiffness 17 (21.5%), myalgia 9 (11.3%), seizures 33 (41.7%), generalized weakness 23 (29.1%) and tonic-clonic movement of limbs 23 (29.1%). These samples were tested with JE IgM antibody rapid test kits (Standard Diagnostics, Korea). Among the sera tested 1 sample (1.2%) was JE IgM positive. The JE positive patient was 27 year old male, from Kyar Gayak village, Down Gyi Station, Kyaung Gone Township, admitted with sign and symptoms of fever, seizures, confusion, neck stiffness, nausea, vomiting, generalized weakness and tonic-clonic movement of limbs. Case detection rate of JE among encephalitis patients in these hospitals were 4, 2, 1, 3 and 1 in 2011, 2012, 2013, 2014 and 2015 respectively, showing no apparent changes.

1.3 CHIKUNGUNYA VIRUSES

1.3.1 Clinical profile and prevalence of Chikungunya infection (2015)

During 2015, a total of 58 serum samples were collected from patients who were clinically suspected of having Chikungunya infection, admitted to the medical wards of Yangon General Hospital. These samples were tested with the Chikungunya IgM rapid test kit. Among the serum tested 14 (24.1%) were confirmed Chikungunya virus infection. The clinical signs and symptoms of chikungunya positive patients were fever 5 (35.7%), headache 6 (42.8%), altered consciousness 4 (28.6%), fits 4 (28.6%), weakness in limbs 5 (35.7%), vomiting 1 (7.1%) and skin rash 1 (7.1%). Their age ranges from 15 to 85 years. Case detection rates of chikungunya positive cases in Yangon hospitals were found to be 42, 9, 2, 3, 36 and 14 cases in 2010, 2011, 2012, 2013, 2014 and 2015 respectively.

SERVICES PROVIDED

ACADEMIC

Sr.	Name	Course	Responsibility
1.	Dr. Yin Min Htun	Workshop on Research Methodology(2015)	Facilitator
2.	Dr. Aung Zaw Latt	Workshop on Research Methodology(2015) 1 st year MMedSc (Microbiology)(UM 1) 1 st year MMedSc (Microbiology)(UM 1)	Facilitator Member of post graduate academic board of studies Supervisor

LABORATORY

Sr.	Laboratory Tests	No. of tests
1.	Anti-HBs Quantitative ELISA	2793