

Department of Rabies and Vaccine Quality Control

A – History

- Year started : 1909
- Evolution :
 - Dept of rabies diagnosis and research
 - Established in 1918
 - Rabies antibody testing by RFFIT as a special test was established in 1996
 - PCR for rabies diagnosis commenced in 2006
 - Dept of vaccine quality control
 - Technical evaluation of all vaccines (EPI and non EPI) for drug regulatory authority-CDDA since 1996
 - Appointed as the National Control Laboratory (NCL) for vaccines in 1998
 - Key functions of NCL
 - Lot release of vaccines since 2000
 - Testing of vaccines in certain identified situations (potency, sterility, innocuity) since 2002
- Heads of Department :

Department	Name	Period
Rabies	Dr. A. Sathasivam	1962 – 1987
Vaccine Production	Dr. Ariyawansa Jayasinghe	1975 – 1987
Rabies and Vaccines	Dr. A. Sathasivam	1987 – 1995
	Dr. Omala Wimalaratne	1996 to date

B – Services

- Services offered by the Dept of rabies diagnosis and research – It is the National Reference Laboratory for rabies diagnosis in Sri Lanka.
 - Human rabies diagnosis – ante mortem & postmortem
 - Rabies diagnosis in animals – postmortem
 - Quality assurance of decentralized rabies diagnostic laboratories
 - Assessment of rabies antibodies in serum and CSF in humans as a special test
 - Immunogenicity studies & rabies related research
 - Rabies post exposure specialized advice clinic
 - Teaching & training – medical (under graduate & post graduate) & paramedical staff
- Services offered by Dept of vaccine quality control – It is the National Control Laboratory (NCL) for vaccines and sera for human use in Sri Lanka.
 - Technical evaluation of all human vaccines for the drug regulatory authority before licensing

- Lot release of government procured vaccines
- Quality testing of vaccines – Pre registration, newly registered vaccines, following AEFI reporting, cold chain break down etc.
- Production of pharmaceuticals for laboratory use
- Specialized advice on vaccine related issues
- Teaching & training – undergraduate and post graduate medical officers and paramedical staff in vaccinology

- Type and number of laboratories:

- Rabies - Rabies diagnostic laboratory - Direct smear test for Negri bodies & Direct fluorescent antibody test (FAT) done routinely
- Immunochromatography strip test, RT-PCR & Mouse inoculation test (MIT) available
- Tissue culture laboratory - Rabies antibody detection by Rapid fluorescent focus inhibition test (RFFIT)

- Vaccine QC - Two viral vaccine laboratories - Viral vaccine quality testing
- Two bacterial vaccine laboratories - Bacterial vaccine quality testing
- Laboratory for preparation of pharmaceuticals - Pyrogen free distilled water, Sodium citrate, Normal saline for laboratory use

- Tests & Rates:

Name of test	Availability	Rates
Rabies diagnosis:		
*Detection of Negri bodies by Direct smear test	Available	Free of charge
*Detection of rabies antigen by fluorescent test (FAT)	Available	Free of charge
* Immunochromatography test (ICT)	Available (Done when indicated)	Free of charge
*PCR for rabies diagnosis	Available (Done when indicated)	Free of charge
*Mouse inoculation test for rabies diagnosis	Available (Done when indicated)	Free of charge
*Rabies antibody test using tissue culture technique	Not a routine test. Only done with recommendation by virologist	Free of charge
Vaccine testing:		
Tests for vaccine quality control	Available as the National Control Laboratory (according to vaccine testing policy)	Free of charge
<ul style="list-style-type: none"> • Sterility test • Innocuity test • Potency test • Identity and Antigen Concentration test • Mouse Weight Gain Test 		

C – Staff of the Dept of Rabies & Vaccine QC:

Name	Designation	Academic Qualification & Research Interests	Contact Information
Dr. Mrs. Omala Wimalaratne	Consultant Virologist/Vaccinologist Head of the Dept.	MBBS, Dip Medical Microbiology, MD	Tel No. 2698660
Dr. Mrs. S. Nanayakkara	Consultant Microbiologist	MBBS, Dip Medical Microbiology, MD	Tel No. 2693532-4 Ext. 131
Dr. J.S. Ishie	Medical Officer	MBBS, DFM	Tel No. 2693532-4 Ext. 131
Dr. S.M.R. Odayar	Medical Officer	MBBS, DFM	Tel No. 2693532-4 Ext. 131
Dr. P. de A. Samarawickrama	Medical Officer	MBBS, DFM	Tel No. 2693532-4 Ext. 131
Mrs. K.A.D.N. Perera	Research Officer	BSc, MSc in Applied Microbiology	Tel No. 2693532-4 Ext. 131
Mr. P.K. Jayaweera	Senior MLT	Dip in Medical Laboratory Technology	Tel No. 2693532-4 Ext. 146
Mr. S.K. Tennakoon	MLT	Dip in Medical Laboratory Technology	Tel No. 2693532-4 Ext. 146
Mr. S.P.D. Karunanayake	MLT	Dip in Medical Laboratory Technology	Tel No. 2693532-4 Ext. 434
Ms. M.K.M. Damayanthi	MLT	Dip in Medical Laboratory Technology	Tel No. 2693532-4 Ext. 434
Three laboratory orderlies and one labourer			

D – Research & Publications

- On going research projects:

1. Evaluation of an immunochromatographic assay for the diagnosis of human rabies and its application to facilitate the molecular epidemiology of rabies: A multi-centre study in Asian countries.
2. Immunogenicity study to determine the persistence of rabies neutralizing antibodies in previously immunized patients and their booster response following anti rabies vaccine(ARV) for a subsequent exposure.
3. A comparison study for diagnosis of rabies in wild animals of Sri Lanka by fluorescent antibody test (FAT) and rapid immunochromatographic test (RICT).

- Publications:

1. Kularatne S A M, Kumarasiri R P V, Pushpakumara C S K, Wijesinghe S, Bokalamulla UK, Pathirage M M K and Wimalaratne O (2008) 8 site Intradermal post-exposure antirabies vaccination for major bites. *British Travel Health Association Journal*, **XI**, 52 – 54.
2. Dodet B, Goswami A, Gunasekwa A, de Guzman F, Montalban S J, Purba W, Quiambo B, Salahuddin N, Sampath G, Tang Q, Tantawichien T, Wimalaratne O and Ahamed Ziauddin (2008) Rabies awareness in eight Asian countries. *Vaccine* -.....
3. Ferguson M, Kurane I, Wimalaratne O, Shin J and Wood D. (2007) “WHO informal consultation on the scientific basis of specifications for production and control of inactivated Japanese encephalitis vaccines for human use. *Vaccine*, **25**, 5233 - 5243
4. Gunawardena M D V M, Kannangara C I, Wimalaratne O (2007) Demographic factors and patients attitudes associated with responsible pet ownership regarding potential rabies exposure. *Journal of the Uva Clinical Society*, **2**, 28.
5. Wimalaratne O (2007) Elimination of NTV and Introduction of Intradermal Rabies Vaccination: “A Success Story From Sri Lanka”. *Infectious Diseases Journal of Pakistan*, **16**, 89.
6. Kularatne S A M, Gihan M C, Jameel A M & Wimalaratne O (2007) Outcome of skin sensitivity testing for predicting reactions to rabies equine immunoglobulin *Ceylon Medical Journal*, **52**, 149.
7. Wimalaratne O (2006) Rabies an unrecognized health priority in Asia – Introduction of intradermal rabies vaccination: A success story from Sri Lanka. *Proceedings of the 7th WHO Global Vaccine Research Forum & Parallel Satellite Symposia*, 34-36.

8. Folb P I, Bernatowska E, Chen R, Wimalaratne O et al (2004) Global Alliance for vaccines. A global perspective on vaccine safety and public health. *American Journal of Public Health*. **94**, No.11, 1926-31.
9. Susilakanthi Nanayakkara, Jean S Smith, Charles E Rupprecht (2003) Rabies in Sri Lanka: Splendid Isolation. *Emerging Infectious Diseases*. **9**, No.3; 368 – 371.
10. Gunathilake M, Wimalaratne O & Perera K A D N. (2003) Persistence of antibody titres in adult dogs and puppies following anti-rabies immunization. *The Ceylon Journal of Medical Science*, **46**, 67 – 71.
11. Perera K A D N & Wimalaratne O. (2001) A study to determine the potency and thermal stability of live measles vaccine used in the Expanded Programme on Immunization. Abstract/Annual Academic Sessions, Sri Lanka College of Microbiologist.
12. Patabandige C G U A, Fernando W S A & Wimalaratne O (2001) The existence of rabies in mongoose and domestic rats. Abstract/Annual Academic Sessions, Sri Lanka College of Microbiologist.
13. Arai Y T, Takahashi H, Kameoka Y, Shino T, Wimalaratne O & Lodmell D L (2001) Characterization of Sri Lankan rabies virus isolates using nucleotide sequence analysis of nucleoprotein gene. *Acta Virologica*, **45**, 327-333.
14. Nanayakkara S, Wimalaratne O, Liyanage A D, Perera D. (2000) An immunogenicity study to compare two accepted intradermal rabies post exposure therapy in healthy adults. Abstract/Annual Academic Sessions, Sri Lanka College of Microbiologist.
15. Gunathilake M, Wimalaratne O & Perera K A D N. (2000) Does one dose of antirabies vaccine produce a protective antibody level in domesticated canines? A preliminary study. *Abstract/The Sri Lankan Veterinary Journal*, **47**, 60.
16. Wimalaratne O (2000) Non EPI vaccines in the prevention of infectious diseases. *Galle Medical Journal*, **2**, 7 -12.
17. Perera M A L R, Harischandra P A L, Wimalaratne O & Damboragama S N (2000) Feasibility of canine oral rabies vaccination in Sri Lanka – A preliminary report. *Ceylon Medical Journal*, **45**, 61-64.
18. Wimalaratne O & Kodikara D S (1999) First reported case of elephant rabies in Sri Lanka *Veterinary Record*, **January 23rd**, 987.
19. Wimalaratne O., Nanayakkara S., Perera D. (1998) Immunogenicity study of rabies pre-exposure vaccination given Intra-dermally & Intra-muscularly. Abstract / 111th Anniversary Sessions, Sri Lanka Medical Association.
20. Jaijaroensup, Lang J, Wimalaratne O, Samaranwataya P et al. (1998) Safety and immunogenicity of purified vero cell rabies vaccine given intramuscularly and intradermally. *Vaccine*, **16**, 1559 -1562.

21. Kositprapa C, Wimalaratne O, Chomchey P et al (1998) Problems with post-exposure management: A survey of 499 public hospitals in Thailand. *Journal of Travel Medicine*, **5**, 30 -32.
22. Wimalaratne O (1997) Is it necessary to give post-exposure treatment after rodent bites? *Ceylon Medical Journal*, **42**, 144.
23. Wimalaratne O, Nanayakkara S (1997) First reported case of rabies in a horse in Sri Lanka (Letter) *Ceylon Medical Journal*, **42**, 106.
24. Sathasivam A & Perera K A D N (1994) Preliminary studies on preparation of monovalent antivenom to Sri Lankan Cobra venom. Abstract/Annual Academic Sessions, Sri Lanka College of Microbiologist.
25. Sathasivam A & Perera K A D N (1993) Preliminary studies on preparation of monovalent antivenom to Sri Lankan Russell's Viper venom. Abstract/Annual Academic Sessions, Sri Lanka College of Microbiologist.
26. Sathasivam A & Perera K A D N (1992) Preliminary studies on Sri Lankan poisonous snake venom. Abstract/Annual Academic Sessions, Sri Lanka College of Microbiologist.