

# Background Paper for Developing a Policy for the Use of Rabies Biologicals and Vaccination of Humans in India

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## Summary

National Rabies Control Programme, India, is in operation since 2012–2013 without much impact due to poor funding and no set policy for the rabies prevention and control. An effort was made to develop a draft policy paper which can help the Government of India to develop a national rabies vaccination policy for humans and for achieving the goal of zero dog-mediated human rabies deaths by the year 2030. A technical stakeholders meeting was held under the chairmanship of the Drug Controller General of India at New Delhi in December 2017 to discuss the problems and solutions for providing essential rabies postexposure prophylaxis (PEP). The following problems and dilemmas were identified: frequent shortages of life-saving rabies vaccines and rabies immunoglobulin for PEP; as rabies vaccines are mostly procured by the state governments that often face resource crunch and hurdles in logistics within the states; production levels of rabies biologicals in the public sector are low; and the export of rabies biologicals from the private sector needs to be critically evaluated in the context of frequent stock-outs in the domestic market and also the national vaccine security.

**Key words:** Humans, India, policy, postexposure prophylaxis, rabies

## INTRODUCTION

Rabies is almost always fatal as there is no therapy to save these hapless patients. However, the disease is practically 100% preventable with the currently available modern rabies biologicals, i.e., vaccines and immunoglobulins. About 59,000 persons are estimated to die of rabies every year globally, and dogs are the principal vectors of this disease (99%).<sup>[1]</sup> About one-third, i.e., 20,000 of human rabies deaths are from India alone, and dogs are responsible for about 97% of the disease.<sup>[2,3]</sup> In December 2015, a global conference of the World Health Organization (WHO), Food and Agriculture Organization, World Organization for Animal Health, and Global Alliance for Rabies Control gave a call for ending dog-mediated human rabies by 2030, and as a result, we are now left with about 12 years to accomplish this goal.

In India, from the States/Union Territories (UTs), rabies is reportable to the Central Bureau of Health Intelligence, Government of India, New Delhi.<sup>[4]</sup> In 2012–2013, the National Rabies Control Programme (NRCP) was launched with the National Centre for Disease Control, Delhi, as the

nodal agency for the human component, and the Animal Welfare Board of India for the animal/dog component.<sup>[5,6]</sup> The NRCP has not made any impact due to paucity of funds, etc. Besides, there is no policy paper to guide achieving the goal of rabies-free India by 2030 as part of the WHO global goal. In this context, under the WHO-funded Indian multicentric rabies survey (IMRS), 2017 conducted by the Association for Prevention and Control of Rabies in India (APCRI), it was envisaged as a term of reference to develop and provide a draft policy paper to the Director General of Health Services (DGHS), Government of India, New Delhi. This activity was done as a part of the national survey on the programmatic experiences of rabies prevention and control in the country under IMRS between July 2017 and

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DOI:  
10.4103/ijph.IJPH\_378\_19

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**How to cite this article:** Sudarshan MK, Narayana DH. Background paper for developing a policy for the use of rabies biologicals and vaccination of humans in India. *Indian J Public Health* 2019;63:S51-3.

December 2017. It was initiated after getting the clearance from the Institutional Ethics Committee, Kempegowda Institute of Medical Sciences (KIMS), Bangalore, Ref. no. KIMS/IEC/S15-2016 dated: 05.12.2016.

The APCRI is a professional, scientific society consisting of medical, public health, veterinary, and other professionals with expertise and experience in rabies epidemiology and virology, including diagnostics, program, and policy, etc. An expert group of APCRI reviewed the National Vaccine Policy, 2011 and National Health Policy, 2017, for the development of a zero draft policy paper that was finalized following discussions and deliberations into a rough draft policy paper.<sup>[7,8]</sup> This document was shared with the technical advisory group of the WHO, India, that was overseeing the project and others. The expert consultative group was formed by the APCRI and approved by the WHO-India office. Subsequently, a technical stakeholders meeting of concerned officials from the Ministry of Health of the Government of India, representatives from the pharmaceutical industry, infectious diseases hospital, Central Drugs Standard and Control Organization (CDSCO), WHO, APCRI, and others was convened under the chairmanship of the Drug Controller General of India (DCGI) at CDSCO, New Delhi on December 1, 2017.

As a preamble, the health and rabies scenario of the country was reviewed in the meeting, and the following problems and dilemmas were identified.

### Problems and dilemmas

1. There are frequent shortages of life-saving rabies vaccines and equine rabies immunoglobulin (ERIG) for postexposure prophylaxis (PEP). The exorbitant cost and frequent stock-outs of the imported human rabies immunoglobulin are putting it beyond the reach of even higher income group
2. As secondary vaccines, rabies vaccines are mostly procured by the state governments that often face resource crunch. Besides, rabies vaccines being outside the Universal Immunization Programme system face hurdles in logistics within the states
3. The production levels of rabies biologicals in the public sector are low
4. The export of rabies biologicals from the private sector needs to be critically evaluated in the context of frequent stock-outs in the domestic area, national vaccine security, and the goal of achieving human rabies-free India by the year 2030
5. There is a frequent demand for including rabies vaccine in the routine immunization
6. The level of awareness among the medical professionals about the use of rabies biologicals, particularly for rabies immunoglobulins (RIGs) is far from satisfactory.

Simultaneously, in the meeting, the draft policy paper developed by the APCRI was deliberated on.

### The following recommendations for developing a human rabies vaccination policy, 2018 were made to facilitate developing robust policy outlines

1. A reassessment and regulation of the production, pricing, domestic distribution, export and usage of rabies vaccines, immunoglobulins, and rabies monoclonal antibodies in the country is required. The production of these life-saving biologicals in the public sector must be increased. The vaccine producers must be encouraged to obtain WHO prequalification as a measure of quality and also for exporting to UN approved agencies
2. The rabies vaccines and RIGs/rabies monoclonal antibody must be obtained by the central government and provided to the state governments/UTs as grant-in-aid under the NRCP
3. The Government of India shall consider introducing the new intradermal 1-week Institute Pasteur of Cambodia regimen (2-2-2-0-0) after conducting a multicentric study assessing safety, immunogenicity, and clinical efficacy of this regimen using all available Indian vaccines and with only wound infiltration of ERIG/human R-Mab as per the new WHO guidelines, 2018<sup>[1]</sup>
4. All government medical facilities shall provide PEP free of cost, namely rabies vaccination either by intradermal or intramuscular route and passive immunization (RIGs/rabies monoclonal antibodies)
5. With the help of professional bodies such as the Indian Medical Association, Indian Academy of Pediatrics, APCRI, and others, it is important to arrange hands on training on rabies prophylaxis to medical professionals with an emphasis on the correct use of passive immunization.

### Other related issues

These following were recommended based on the observations from the WHO-APCRI IMRS, 2017, and collective opinion of technical experts.

1. A reassessment of the burden of human rabies is urgently needed, as the current figures of 20,000 human rabies deaths and 17.4 million animal bites annually (2003) is about 15 years old
2. The facilities and care of human rabies patients in the infectious diseases hospitals must be improved.

It is planned by the APCRI to submit this draft outline policy paper to the DGHS, Government of India, to develop a rabies vaccination policy for humans to facilitate achieving dog-mediated human rabies-free India by 2030 as a part of the WHO global goal of dog-mediated human rabies-free world by 2030.

### Acknowledgments

The authors would like to thank Dr. G. N. Singh, DCGI, New Delhi, for chairing and facilitating the deliberations. The active participation of the technical stakeholders in the meeting was very valuable.

### Financial support and sponsorship

The study was financially supported by WHO, India Country Office, New Delhi.

### Conflicts of interest

There are no conflicts of interest.

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