



## INDIAN MULTICENTRIC RABIES SURVEY- 2017

**Assembling new evidence in support of elimination  
of dog mediated human rabies from India**

### Executive Summary March 2018

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# Foreword



**Dr. Bernadette ABELA- RIDDER**

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Rabies is a neglected zoonosis estimated to cause 59,000 deaths each year: that's one person every nine minutes of every day. It is a fatal disease preventable through awareness; access to post-exposure prophylaxis (PEP) for people i.e. wound washing, high quality rabies vaccines, and rabies immunoglobulins (RIG) for severe exposures; and dog vaccination to stop disease transmission at its source. Rabies can be a measure of reach and equitable access of people to quality care that makes a clear-cut life-and-death difference. This difference can be measured. It is often shocking. It violates our sense of fairness and justice. And it compels us to act. Can rabies be the tracer to measure whether health care, veterinary and other services are reaching the poorest and most marginalized people in India?

The world has the tools and expertise to end the suffering of rabies. With a global goal of zero human rabies deaths by 2030, worldwide, countries and partners are working to make this a reality.

As a country with rich research and clinical expertise, a producer of rabies biologicals, and a country which carries around one third of the global rabies burden, India plays a key role in reaching this global target. The comprehensive, seven-state study described in this report highlights the great and necessary progress already made. Of the 529 patients surveyed at health facilities throughout the included states, all (100%) received rabies vaccinations; the majority (80.7%) had washed their wounds with soap and water, or applied local antiseptics; and almost half (46.2%) of patients with category III exposures received RIG.

Compliance with cost- and dose-saving intradermal (ID) rabies vaccination was high (85.1%), and all patients followed up after 90 days (n=450) were alive and healthy. In most states, rabies vaccines were available year-round, with stock-outs infrequent for vaccines (14%), but frequent for RIG (43%). Updates to the WHO position on rabies, such as the introduction of a 1-week ID PEP regimen, and guidance on RIG prioritisation, have potential

to improve patient compliance and access to affordable PEP. Additionally, a first generation monoclonal antibody product has recently been licenced in India and may increasingly become an alternative to RIG.

Although PEP-seeking behaviour in a community survey was high (88.9%, n=54), a broader study identified significant gaps in disease awareness. Just over half (60.5%) of 4294 individuals surveyed were aware of rabies, and less than half of dog owners had vaccinated their dogs against rabies (47.3%). Work is still needed to raise awareness of rabies disease, improve dog vaccination coverage, build confidence in health systems, and increase access to timely, affordable PEP for animal bite victims.

The learning and recommendations generated from this study are a progressive stride toward ending the burden of rabies in India. A rabies-free India would save thousands of lives, and be a huge contribution towards ending the suffering of rabies worldwide. We hope this report will highlight the great progress made in India to date, encourage India to take on the leadership in the region to build momentum for rabies elimination, and invite further commitments to see the job through. Rabies elimination is feasible: the time to act is now.

*Bernadette ABELA-RIJDER*

## Preface



**Dr. M.K. Sudarshan**

Project Lead, WHO-APCRI Survey - 2017  
Founder President & Mentor, APCRI  
Former Dean & Principal, KIMS, Bangalore

The World Health Organization once again reposing faith in Association for Prevention and Control of Rabies in India (APCRI) entrusted it to conduct a pan India rabies survey. The initial meeting between the two organizations with representatives from Government of India and others was held in December, 2016 and after necessary approvals, the work commenced in May, 2017. This Indian Multi-centric Rabies Survey, 2017 was conducted using a representative sample from the seven states of Himachal Pradesh, Bihar, West Bengal, Manipur, Kerala, Madhya Pradesh and Gujarat. Besides, the rabies free islands of Andamans and Lakshadweep were also covered. The survey duration was of nine months from May 2017 to January, 2018.

It covered the key areas of treatment seeking behaviour of dog bite victims, health centres surveys, community based surveys, assessing reasons for poor compliance to PEP, logistics, market mapping & landscape analysis of rabies biologicals, developing a draft rabies vaccination policy paper for humans, surveillance for dog bites and human rabies, introduction of human rabies monoclonal antibody, survey of rabies free islands and to prepare raw video footage and pictures of both human and animal rabies prevention, etc. About 10 experts in the field of rabies, who included medical public health experts, virologists from National Institute of Mental Health & Neurosciences and veterinarians from Veterinary College formed the project core group. In each state, the help and support from the faculty of the Community Medicine of the medical college was obtained. A well planned visit to the rabies free islands resulted in successful procurement for the first time of the brain samples of the vector (Dog in Andamans and Cat in Lakshadweep).

It is sincerely hoped that the results of this survey will benefit the policy makers, planners and programme managers to improve the services for better prevention and control of rabies in India with specific reference to achieving dog mediated human rabies free India by 2030, that is in line with the global goal of WHO. In this light, it is expected that there will be a revision of National Rabies Control Programme.

## Executive Summary

The historic global rabies conference jointly organized by World Health Organization (WHO), World Organisation for Animal Health(OIE), Food & Agricultural Organization (FAO)and Global Alliance for Rabies Control (GARC) held at Geneva in December 2015 set the goal of “Eliminating dog mediated human rabies by 2030”. WHO through its Strategic Advisory Group of Experts (SAGE) working group on rabies, that reviewed the current policies on rabies vaccines and immunoglobulins, considered the programmatic experience & evidence on rabies control from India as extremely important towards achieving this global goal, as India is contributing to about one third of the global rabies burden. WHO apart from India is supporting similar studies in four other countries viz. Cambodia, Bhutan and Vietnam in Asia and Kenya in Africa.

In this context, a consultation meeting of WHO, APCRI and different stake holders for rabies control in India was held in December 2016 at National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore.



**Photo 1: National technical stake holders meeting at NIMHANS, Bangalore**

The APCRI team presented the project proposal of “Assembling new evidence in support of elimination of dog mediated human rabies from India” and the following terms of references (TORs), etc. were finalized.

1. To identify and analyse the recent data on PEP and RIG use, with emphasis on factors supporting cost-effective regimens while maintaining highest impact on public health.
2. To assemble existing data on and eventually conduct community surveys on both, dog bite incidence in humans and incidence of rabies in dogs, preferably in the same settings (or real situation in the community).

3. To determine the factors influencing the PEP seeking behaviours of individuals (community and health facility level, in different settings) who have been exposed to confirmed rabid or rabies suspected animals.
4. To identify factors contributing to poor compliance with PEP regimens (factors that influence incomplete vaccination course; cost to patient/health facility, willingness to pay for PEP, etc.).
5. To document rabies vaccine procurement, distribution and delivery mechanism in selected states of India, cost of biologicals distribution in rural and urban settings.
6. To conduct a market landscape analysis of available human and animal rabies biologicals in India; to forecast vaccine and RIG need in selected states.
7. To provide a policy paper for rabies biologicals and vaccination in humans.
8. To document operational feasibility and cost-effectiveness of the introduction of the new monoclonal antibodies in India.
9. To assess rabies free status of Andaman /Nicobar and Lakshadweep islands.
10. To report the mechanism of surveillance for dog bite and human rabies.
11. To prepare raw video footage and pictures (human & animal) on rabies prevention and control in India.

In this regard, a Technical Advisory Group (TAG) meeting was held on 11<sup>th</sup> May, 2017 at New Delhi and following a presentation by the APCRI core group, the experts reviewed and approved the proposal.



**Photo 2: Technical Advisory Group (TAG) meeting at New Delhi**

The project core team also visited WHO, India office; Offices of IDSP, Division of Zoonosis, NRCP, Division of Epidemiology at NCDC; Director, Health, NITI Ayog; DCGI and Jt. DCGI at CDSCO; ICMR; CBHI; ADG & DDG (PH), Nirman Bhawan; Animal

Husbandry Commissioner; ICAR and NHSRC in June, 2017 and apprised about the proposed survey and the plan of work.

The different activities under the project was conducted and completed in nine months from May 2017 to Jan 2018 and the activities are as follows:

The project work was done in seven states representing the geo-scatter distribution across north, east, north-east, south, central and western regions of the country. In the seven selected states of Himachal Pradesh, Bihar, West Bengal, Manipur, Kerala, Madhya Pradesh and Gujarat, the following activities were conducted viz. community survey, health facility survey, assessment of logistics of rabies biologicals, reporting surveillance for dog bites and human rabies, assessment of anti-rabies clinics and veterinary survey in four states (Himachal Pradesh, Manipur, Kerala and Gujarat). Other activities like market mapping & landscaping for rabies biologicals, preparation of background policy paper for rabies biologicals for humans, assessment of rabies free status of Andaman/Nicobar and Lakshadweep Islands, documentation of operational feasibility & cost effectiveness of introduction of rabies monoclonal antibodies were conducted. Besides, review of national and international publications for cost effective PEP regimens; and raw video footage & still pictures on human rabies prevention and animal rabies control was also prepared.

The APCRI core team trained all the investigators on community survey (using Apps), health facility survey and veterinary survey (using paper format) in the seven states, visited the survey areas and initiated the field work .



**Photo 3: Project core team with survey team at AIIMS, Bhopal, Madhya Pradesh**



**Photo 4: Training of the investigators by the project lead at Imphal, Manipur**

The project activities were conducted by the respective investigators in all the seven states and the other activities were also done simultaneously by project core team to accomplish the terms of reference of the project.

**ToR 1: To identify and analyse recent data on PEP and RIG use, with emphasis on factors supporting cost-effective regimens while maintaining highest impact on public health.**

A review of literature was done on PEP and use of rabies immunoglobulins along with the cost-effectiveness of PEP regimens both from India and other countries. Likewise, the present study report was also considered for the analysis. In the present study, community survey showed that, 88.9% of bite victims had sought PEP at the health facility; among those who visited the health facility, 10.4% were not advised PEP and only 16% received RIG among category III exposures. Similarly, the health facility survey showed that only 46.2% received RIG because of short/ no supply.

The literature review showed that, ID regimen is cost effective and recommended for use in rabies endemic countries, where there is financial constraint and vaccines are in short supply. The most recent SAGE (2017, October) recommended one week ID-IPC PEP regimen (2-2-2-0-0) needs to be considered favourably & it is recommended to conduct a national multicentre feasibility study in India to assess its safety and immunogenicity using the locally produced/ available rabies vaccines and ERIG/RMAb in rabies exposed individuals.

**ToR 2: To assemble existing data on and eventually conduct community surveys on both, dogs bite incidence in humans and incidence of rabies in dogs in real situation in the community.**

The community survey was done by using WHO-EPI cluster survey methodology and a total of 42 clusters which includes 24 households/ cluster were surveyed. The medical college team from the 7 states conducted the survey using a specially developed software application in their PDA/ android phones.

A total of 4294 individuals were surveyed covering 1012 households in seven selected states of India. Among them, 60.5% were aware of rabies and 39.5% had never heard of rabies; only 3.7% respondents were aware about pre-exposure prophylaxis. Among those who had heard about rabies, 77.4% had perceived that risk of rabies was high from dogs. Among the households, 114 (11.3%) had owned a dog and 69 (47.3%) dogs were vaccinated.

The annual incidence of animal bite was 1.26% i.e. 54 bite victims among 4294 population surveyed. Majority (68.5%) of the bite victims were from rural settings, 68.5% of bite victims were males, 61.1% bite victims were in the age group of 15 - 60 years and 31.4% were children <14 years. 72.2% bite victims were Hindus by religion, 70.4% bite victims had

education up to school level, 40.7% of the bites had occurred at home and 50 % were provoked bites. There was no case of human rabies reported from the surveyed population.



Photo 5: Collection of data at households in Kangpoki, Manipur and Theog, Shimla

**ToR 3: To determine the factors influencing the PEP seeking behaviours of individuals (community and health facility level, in different settings) who have been exposed to confirmed rabid or rabies suspected animals.**

***a) PEP seeking behaviour of the individuals from community survey:***

Among 54 animal bite victims, 53.7% had category II exposures and 46.3% had category III exposures. 74.1% of the exposures were by dogs. 19 (35.2%) bite victims had washed the wounds with water and soap.

Out of 54 animals bite victims, 48 (88.9%) had sought PEP at the health facility. Among those, who had visited the health facility, 5 (10.4%) were not advised PEP. 43 (79.6%) bite victims received PEP, among whom 21 had category II exposures, of whom 14 (66.7%) had completed either 5 doses of intramuscular or 4 doses of intradermal vaccination and 22 had category III exposures, of whom, only 4 (18.2%) had received rabies immunoglobulin along with rabies vaccination viz. 3 (75%) had received ERIG and 1 (25%) had received HRIG.

***b) PEP seeking behaviour of the individuals who came to health facility:***

The health facility survey was conducted at 21 hospitals / health centres (Government/ Private) having anti rabies clinic providing PEP against rabies; selected randomly, that was representative of both urban and rural settings (UPHC/ PHC/ CHC & Taluka hospital) in the same Taluka/ Block/ Tehsil covering the community survey.

- The health facility survey included 529 animal bite cases who came for PEP at 21 health facilities in the project states across the country; among whom 348 (65.8%) were from rural areas and 181 (34.2%) from urban areas.

- Majority of the bite victims were from 15-59 years (66.7%) age group, followed by children  $\leq$  14 years (21.7%) and elderly (11.6%).
- Dog (68.6%) was the commonest biting animal followed by cat (25.3%), monkey (4.5%) and others (1.6%); only 8.7% of the biting animals were known to be vaccinated against rabies.
- Most of the bites (51.8%) were unprovoked and 65.2% of bites occurred outside home.
- Majority of the exposures were lacerations (51.9%) and abrasions (42.3%). The commonest site of bite was on lower limb (60.5%) followed by upper limb (29.7%), head, neck and face (4.7%) and trunk (4.5%).
- After the bite, only 63.5% washed their wound/s with water/ water & soap and 17.2% had applied local antiseptics; whereas 23.5% had applied irritants to the bite wound/s.
- Among the exposed, 83.6% sought PEP directly from health facility and the remaining 16.4% visited non-allopathic/ traditional healers/ consulted veterinarians/ ANMs before visiting health facility.
- The perceived risk of rabies from different biting animals and the overall knowledge, attitude and practice on prophylaxis against rabies was inadequate.

**ToR 4: To identify factors contributing to poor compliance with PEP regimens (factors that influence incomplete vaccination course; cost to patient/health facility, willingness to pay for PEP, etc.).**

All the 529 animal bite cases who came for PEP at 21 health care facilities in the project states across the country were included in the study. The medical officers of the respective health facility recruited these animal bite cases coming for post exposure prophylaxis in their respective health facilities and also provided the information regarding the bite to the veterinary team, so that, they can follow (if feasible) the biting animal (if recognized by the bite victim) to know the status of the animal and follow it up to rule out rabies in those animals. All the study subjects were followed up for 90 days to ascertain their health status. The analysis of the data captured is as follows:

- All the 529 patients were provided PEP at the respective health facilities. Majority had category III (54.4%) and category II (43.1%) exposures.
- All (100%) of them received anti rabies vaccination; among whom 67.3% received IDR V and 32.7% received IMRV.
- Among category III exposures, only 46.2% received RIG because of short/ no supply. Among those who received RIG, majority were administered ERIG (95.5%) and the

remaining 4.5% received HRIG; exclusive local infiltration of RIG was done in 56.4%, both local & systemic in 41.3% and only systemic injection in 2.3%.

- Among those who received PEP, 14.2% had mild adverse events which subsided without any complications.
- The compliance to IDRV (85.1%) was found to be significantly higher as compared to IMRV (65.9%) ( $\chi^2 = 25.76, P < 0.005$ ).

The factors influencing the incomplete vaccination course were loss of wages, forgotten dates, long distance, high cost incurred, non-availability of anti-rabies vaccine, etc.

- The total median cost incurred to the patient for availing PEP in government health facility was INR.1400 (USD 22) and the cost to health facility to provide IMRV and ERIG free of cost to the patients in each category III exposure was INR.1188 (USD 19) and only IMRV in each category II exposure was INR.640 (USD 10).
- Similarly, the cost for PEP to health facility for IDRV and ERIG for each category III exposure was INR.676 (USD 10) and only IDRV in each category II exposure was INR.128 (USD 2).
- In the private health facility, the total median cost incurred to the patient for availing PEP was INR.3685 (USD 58) for category III exposures and INR.3034 (USD 48) for category II exposures.
- All the animal bite victims in both government and private health facility opined that, the cost of availing PEP services is more and they were unwillingly paying for the treatment.

Among the study subjects, 450 (85%) were followed up for a period of 90 days after PEP to determine the clinical outcomes and all of them were found to be normal & healthy.

The veterinary team followed up 31 biting dogs which were pet/owned dogs and were confined at the respective owners' houses as logistically feasible and were kept under observation for 14 days. All of them were healthy after 14 days of confinement.

**ToR 5: To document rabies vaccine procurement, distribution and delivery mechanism in selected states of India, cost of biologicals distribution in rural and urban settings.**

The APCRI survey team visited different agencies/ organizations/ offices responsible for logistics of rabies biologicals at the state and district levels. The information was collected from the concerned officials through interview and perusing the relevant records. At the peripheral level, the health institutions in both urban and rural areas were visited and the concerned medical officers, pharmacists and others were interviewed to know the logistics of the rabies biologicals and specifically about stock outs. The project team also visited the

premier institutions like Central Research Institute (CRI) & Central Drug Laboratory (CDL), Kasauli, Himachal Pradesh. The key technical functionaries were interviewed and the relevant information was obtained.

**a) Logistics of supplies (including cold chain) from the producer to the end user:**

Currently, there is a limited supply (due to production issues) of two major brands of rabies vaccines viz. Rabipur & Vaxirab N and as a result, other brands have taken these market slots. When a particular brand of rabies vaccine was not available in the market, it was substituted by the available brand of rabies vaccine thus ensuring continuous and uninterrupted supply of rabies vaccines to the patients.



**Photo 6: Assessing Vaccine/RIG logistics in Government (CHC) (left) and Private (stockist) (right)**

**b) Procurement of rabies biologicals:**

In most of the surveyed states, the rabies vaccines are available throughout the year due to fear of public hue and cry as non-availability of rabies vaccines in public hospitals becomes a subject of legislative debates both at the state/province and central level/ Government of India. Rabies immunoglobulins were sparingly used /scarce in survey states except in the states of Gujarat, Kerala and Himachal Pradesh. The Pharma houses and the drug logistics societies squarely blame the medical profession for not raising the demand for RIGs in the government sector. Procurement of ARV & RIG is by the respective state/ provincial governments, mostly through drug logistics societies established for the purpose. The forecasting of vaccine demand is based on the current consumption levels plus about 10% buffer stock in the Government.

**c) Assessment of ARC in surveyed states:**

- The wound wash facility was deficient in many ARCs (54%).
- The route of administration of rabies vaccine was predominantly intradermal (59%) in the bigger government institutions and only intramuscular in the private sector. The stock out

of vaccine was occasional/sometimes in the government sector (14%) and never in the private sector.

- The use of RIG in the government (34%) and private sectors (20%) need improvements.
- The stock outs of RIG are more frequent (43%) than that for vaccines (14%).

The logistics of rabies biologicals was good in the states of Gujarat, Kerala and HP and satisfactory in West Bengal, whereas it was not satisfactory in MP& Bihar. The situation in Manipur was bad.

**c) CDL & CRI, Kasauli, HP:**

There was a gradual increase in the number of batches of rabies vaccines being tested at CDL during a five-year period of 2012-16. This reflects on the trend of increasing demand/consumption of rabies vaccines in the country. None of the batches of the rabies vaccines and RIG provided by the manufacturers failed the quality test at the CDL.

There is a gradual decline in the production of ERIG at CRI and it is attributed to issues related to the institute building renovation and lack of demand for the product from the public institutions as it is not supplied to private sector.

**ToR 6: To conduct a market landscape analysis of available human and animal rabies biologicals in India; to forecast vaccine and RIG need in selected states.**

All the producers and importers of rabies biologicals were informed about this survey, its objectives and their cooperation was sought to provide the required data. Subsequently the national marketing heads/ directors were personally met/ telephonically informed and the survey schedules were provided (in person / soft copy by email) to obtain the data. The business offices of Indian Immunologicals Ltd/Human Biologicals Institute, Bharath Biotech International limited and VINS Biopharma, Hyderabad were personally visited by the project team and the data was obtained. The data received was cross validated with the information from the seven survey states as feasible/ relevant.

The following data was obtained regarding the market landscape:

**a) Anti rabies vaccine:**

- The market size of the rabies vaccines is about Rs. 125 crores. The sales of ARV in terms of value (in crores) was highest in trade (71.6%) and 28.4% in institutions. The prescription market for ARV usage (include GPs, pediatricians, physicians, surgeons, doctors in the both private and some government hospitals/health centres where vaccines are not stocked/ not available) constitutes the largest market share.

- ARV used for intramuscular route was 34%, intradermal route was 34% and used either by IM/ID was 32%. The rabies vaccines are exported to countries of Asia and Africa and the proportion varies from 2 – 16 % depending on the producer.

**b) Rabies immunoglobulin:**

- The ERIG market is about 80-90 % in Government sector and 10-20% in Private sector. The current market value is about Rs. 83 crores.
- RIG is mostly sold through tenders mainly in government sector. There are frequent stock outs of RIGs both in private and government sectors. The demand in the private sector is limited mostly due to fear of reactions and the tedious process of wound infiltration.
- Besides, the ERIGs are exported and its share/ quantum range from 1 to 50% between the producers.
- The stock outs of rabies biologicals, in the government sector was more due to issues of logistics management and in the private sector, it was mostly due to issues related to production.

**c) ARV for animals:**

Sales of ARV for animals was more in North (32%), followed by South (24%), East & West (18% each) and Central 8%.

**ToR 7: To provide a policy paper for rabies biologicals and vaccination in humans.**

At a meeting of technical stake holders held on 1<sup>st</sup> December, 2017 at the Central Drugs Standard Control Organization (CDSCO), FDA Bhawan, New Delhi, a draft policy paper for submission to the Director General of Health Services (DGHS), Government of India, New Delhi was prepared in the context of goal of “Dog-mediated human rabies free world / India by 2030”.



**Photo 7: Technical stake holders meeting with DCGI, at CDSCO, FDA Bhawan, New Delhi**

The following recommendations were made to facilitate developing robust policy outlines by DGHS:

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 lifesaving biologicals in the public sector must be increased. The vaccine producers must be encouraged to go in for WHO prequalification as a measure of quality and for exports to UN approved agencies.
2. The rabies vaccines and rabies immunoglobulins/ rabies monoclonal antibody must be obtained by the central government and provided to state governments/Union Territories as grant-in-aid under the national rabies control programme.
3. All government medical facilities shall provide post exposure prophylaxis free of cost viz. rabies vaccination either by intradermal or intramuscular route and passive immunization (rabies immunoglobulins/ rabies monoclonal antibodies).
4. With the help of professional bodies like Indian Medical Association (IMA), Indian Academy of Pediatrics (IAP), Association for Prevention and Control of Rabies in India (APCRI) and others, it is important to arrange hands on training on rabies prophylaxis to medical professionals with emphasis on correct use of passive immunization.
5. A reassessment of the burden of human rabies is urgently needed as the current figures of 20,000 human rabies deaths & 17.4 million animal bites annually (2003) is about 15 years old.
6. The facilities and care of human rabies patients in the infectious diseases hospitals must be improved.

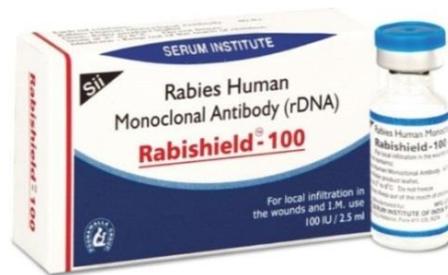
**ToR 8: To document operational feasibility and cost-effectiveness of the introduction of the new monoclonal antibodies in India.**

The producer of rabies monoclonal antibody, Serum Institute of India private limited, Pune was informed about this survey, its objectives and their cooperation were sought to provide the required data. Subsequently, the marketing head and team was personally met/ telephonically informed and the survey schedules were provided to obtain the data.

Human R-MAbs (Rabishield) is now produced in India by Serum Institute of India Private Limited, Pune by rDNA technology which overcomes all the limitations associated with the production of RIGs. It is duly acknowledged by the SAGE, WHO, September, 2017; approved by Drugs Controller General of India (DCGI) and available from November 2017 in the market. Serum Institute of India has an installed production capacity of 5 million vials/year. The R-MAb usage for PEP is operationally feasible as mechanism of action & administration is similar to RIG. R-MAbs will be a better product for passive immunization

compared to ERIG/HRIG as the required dosage will be much smaller quantity and sufficient enough to infiltrate all animal bite wounds with no wastage that is in line with recent WHO recommendation. Lastly, R-MAb as a new product in the market requires a strong post-marketing surveillance (PMS).

The launch price of the product (per vial) in November, 2017 was Rs. 8450/- approx. (130USD) and was reduced to Rs. 1970/- approx. (30 USD) in February, 2018.



**Photo 8: Rabies Human Monoclonal Antibody: Rabishield**

**ToR 9: To assess rabies free status of Andaman /Nicobar and Lakshadweep islands.**

The project team visited both the islands to collect the data and initiate laboratory surveillance for rabies. The project team conducted a series of interactive sessions with the medical and veterinary professionals, explaining the objective of this survey and the need for their participation in this event of national importance. The method of collection and transportation of brain samples were demonstrated to the veterinarians and para-veterinarians. The information was collected from both veterinary & medical sector using the proformas.

**Andaman & Nicobar Islands:** There was no human/animal rabies cases reported in the past. Laboratory surveillance for diagnosis of rabies in dogs was initiated and four dog brain samples were tested negative for rabies by PCR at WHO collaborating centre for reference & research on Rabies, NIMHANS, Bangalore. The same samples were cross validated by lateral flow assay at Veterinary college, Bangalore and found negative for rabies.



**Photo 9: APCRI survey team at rabies free Islands of Lakshadweep (left) and Andaman/Nicobar (right)**

**b) Lakshadweep islands** are free from dogs; cats are the only potential vectors of rabies. No rabies was reported in human beings or animals in the past. Laboratory surveillance for rabies in cats was initiated and five cat brain samples were tested negative for rabies by direct fluorescent antibody test (DFA) & Lateral flow assay at OIE twinned rabies diagnosis laboratory, Veterinary College, Bangalore. The same samples were cross validated by PCR at NIMHANS, Bangalore and were also found negative for rabies.

**ToR 10: To report the mechanism of surveillance for dog bite and human rabies.**

Presently, Integrated Diseases Surveillance programme (IDSP) does not report human rabies. As a result, the system of collection of data on human rabies from the states/UTs is irregular, inconsistent and mostly incomplete. Now under the national rabies control programme (NRCP) efforts are being made to establish linkage with the infectious diseases (ID) hospitals and strengthening surveillance of dog bites and human rabies through IDSP using modified P form.

To appraise the human rabies in the survey states, the APCRI team visited the isolation/ infectious diseases (ID) hospitals/wards at the state headquarters (except in Gujarat, it was at the regional level at Surat) and analysed the in-patient medical case records from the medical records department (MRD) using a pretested structured proforma developed for the purpose.



**Photo 10: Team leader collecting rabies surveillance information at ID hospital, Patna, Bihar**

**a) Dog bites:** The concordance (between the data of IDSP& APCRI survey) was seen only in 43% (12/28) of instances thus calling for better/ improvement of consistency in the reporting system. Amongst the states, Gujarat and Kerala reported a higher incidence rates signifying good surveillance, treatment availabilities, etc.

**b) Human rabies:** There is poor surveillance of human rabies in the states and its reporting to the central government. There is a decline in the incidence of human rabies reported to the

isolation hospitals across the states vis-a-vis reasonably stable PEP services during 2012-2016. To further reduce the human rabies burden it is important to accelerate the services of rabies PEP in the states.

**c) Appraisal of human rabies in the survey states:** At the isolation/ infectious diseases hospitals, the sentinel centres for human rabies, majority of cases were from rural areas (77%), males (83%) and adults (74%). The most common biting animal was dog (83%), the bites were more on the head (12%) and some (27%) had received few doses of ARV.

**ToR 11: To prepare raw video footage and pictures (human & animal) on rabies prevention and control in India.**

A specialized agency with rabies work experience was chosen for this purpose. Following discussions with the focal persons at the WHO headquarters and at the national level, both indoor and outdoor recordings were done. Video recording & still pictures of human rabies prevention and animal rabies control (both indoor and outdoor) were done using a professional 4K digital camera at Bangalore, Goa and Kolkata. The recordings were segregated into different folders and provided to WHO Country office in a hard disk.



**Photo 11: Video recording at a household level in a urban community at Kolkata, West Bengal**

## Conclusions

The following conclusions were derived from the study on assembling new evidence in support of elimination of dog mediated human rabies from India.

1. Intradermal rabies vaccination is cost effective for use in rabies endemic countries where there is financial constraint and vaccines in short supply. One week ID - IPC PEP regimen (2-2-2-0-0) may be considered as it is cost and dose sparing with reduced number of visits.
2. The annual incidence of animal bite from the community survey was found to be 1.26 %.
3. The PEP seeking behavior and perceived risk of rabies from the biting animal was inadequate, with some of them sought the PEP from non-allopathic/ traditional healers.
4. Most of the animal bite victims reported to health facility had category III exposures (54.4%) and the use of RIG among them was low.
5. The compliance to IDRV (85.1%) was found to be significantly higher as compared to IMRV (65.9%) ( $P < 0.005$ ). The factors influencing the incomplete vaccination course were loss of wages, forgotten dates, long distance, high cost incurred, non- availability of anti-rabies vaccine and negligence. The overall cost incurred by both the bite victims and the health facility is more for a developing country.
6. The rabies vaccine procurement, distribution and delivery mechanism is not universal and the PEP facilities available at the anti- rabies clinics are inadequate.
7. The sales of rabies vaccine is higher in trade (71.6%) than in institutions (28.4%); whereas the ERIG market is more in Government (80-90 %) than in Private sector (10-20%).
8. A background draft policy paper is prepared in context of “dog-mediated human rabies free India by 2030” for submission to the DGHS, Government of India for favourable consideration.
9. Rabies monoclonal antibodies usage for PEP is operationally feasible as mechanism of action & administration is similar to RIG and the required dosage will be smaller quantity as compared to RIG and sufficient enough to infiltrate all bite wounds with no wastage.
10. Andaman/ Nicobar and Lakshadweep islands are free from rabies, as it was proved by initiating laboratory surveillance for diagnosis of rabies in dogs & cats; where the brain samples were tested negative for rabies.
11. The concordance on dog bite data between Integrated Diseases Surveillance Programme & APCRI survey was seen only in 43%. There is a decline in the number of human rabies in the isolation hospitals across the states vis-a-vis reasonably improved PEP services.
12. A comprehensive raw video footage & pictures on prevention of human rabies and control of animal rabies was accomplished.

## Recommendations

Based on the results of the survey, the following recommendations are made to facilitate achieving the goal of dog mediated human rabies free India by 2030.

1. Intradermal rabies vaccination has to be implemented throughout the country. A national-multicentre feasibility study on 1 week ID - IPC PEP regimen (2-2-2-0-0) to assess its safety and immunogenicity using locally produced/available rabies vaccines and ERIG/RMAb in rabies exposed individuals' needs to be conducted.
2. Regular health education on prevention and control of rabies has to be given to the community by health workers and mass media to improve the PEP seeking behaviours. Similarly, the health care personnel should be trained to follow WHO guidelines for categorization of exposures and providing appropriate PEP by means of CME programs, conferences, workshops, technical films, hands on training in IDRV & RIG use, etc.
3. Complete PEP services including RIG/RMAb have to be provided free of cost by the Government and support from an international agency like GAVI may be obtained to scale up the services.
4. Vaccine & RIG procurement, distribution and delivery mechanism has to be further improved by universal delivery mechanism similar to UIP vaccines by the central government.
5. The availability of vaccine and RIG has to be improved by creating vaccine security and providing more funds under NRCP for providing free of cost to exposed individuals.
6. Rabies human monoclonal antibody can be widely used after a strong post marketing surveillance (PMS).
7. To ensure continuous laboratory surveillance of both animal and human rabies in historically rabies free Andaman/ Nicobar and Lakshadweep islands.
8. The surveillance mechanism of dog bites and human rabies needs to be geared up by providing a simple structured format from IDSP/ NRCP, to facilitate uniform transmission of correct & complete desired information on a weekly basis from ID hospitals to begin with.
9. The background draft policy paper for rabies biologicals and vaccination in humans developed under this project may be accepted by the DGHS, and subsequently GOI formulate the national rabies vaccination policy, 2018 to achieve the goal of dog-mediated human rabies free India by 2030.

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**Together we can eliminate rabies by 2030**

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## About APCRI

**APCRI** was founded in the year 1998 with a vision to **make India Rabies Free by 2020**. Since then, it has evolved into a national organization that is one of the most vibrant scientific societies in the field of with a strength of 750 life members. APCRI serves as a platform that brings together the best minds in the country comprising of medical professionals, public health personnel, veterinary doctors and others for Advocacy, Research & Information dissemination about prevention & control of Rabies.

APCRI led by an excellent team of experts and dedicated people is actively involved in organizing conferences, continuing medical education (CME), symposia, lectures, trainings, scientific publications, book releases, etc. and has a pan India representation.

APCRI has its own official indexed and peer reviewed journal on prevention and control of rabies that is published biannually.

APCRI, with the technical and financial assistance from World Health Organization (WHO) undertook the landmark national multi-centric rabies survey to assess burden of rabies in India during 2002 - 2004. In, 2017-18, it again completed another Indian multi-centric rabies survey to assess programmatic experiences on rabies in India with financial assistance from WHO.

### Aims and Objectives

The Vision of APCRI now is to make **India Rabies Free by 2030** in line with the global WHO mandate. We strive to achieve this through the following aims and objectives:

1. To re-estimate the burden of rabies in India and support rabies surveillance in humans.
2. To work for an effective control of rabies in dogs.
3. To ensure lifesaving rabies post-exposure prophylaxis free for all.
4. To conduct trainings & campaigns; produce & disseminate educational material for medical, veterinary and other professionals and also for lay people on rabies
5. To work in liaison with Governments and non-governmental organizations for prevention and control of rabies.
6. To offer consultancy, professional advisory services and play the advocacy role to Government and non-governmental organizations.