INDIAN MULTICENTRIC RABIES SURVEY- 2017

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

REPORT

March 2018

Survey organization

Association for Prevention & Control of Rabies in India [APCRI]

Technical & Operational support by

World Health Organization [WHO]

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Foreword

Dr. Bernadette ABELA- RIDDER
Team Leader, Neglected Zoonotic Diseases,
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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- RIDDER

Preface

Dr. M.K. Sudarshan
Project Lead, WHO-APCRI Survey - 2017
Founder President & Mentor, APCRI
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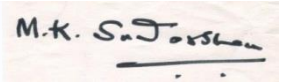
The World Health Organization once again reposing faith in Association for Prevention and Control of Rabies in India (APCRI) entrusted it to conduct a pan India rabies survey. The initial meeting between the two organizations with representatives from Government of India and others was held in December, 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.



Acknowledgements

Association for Prevention & Control of Rabies in India (APCRI) and the Project team sincerely acknowledges the help & support of the following individuals & organizations in conducting this project:

1. Dr. Bernadette Abela- Ridder, Team Leader, Neglected Zoonotic Diseases, Department of the Control of Neglected Tropical Diseases, World Health Organization (WHO), Geneva, Switzerland for entrusting this project to APCRI.
2. Dr. Lea G Knopf, Consultant, Neglected Zoonotic Diseases, Department of the Control of Neglected Tropical Diseases, World Health Organization, Geneva, Switzerland for providing all the expert guidance in conducting this project
3. Dr. Ritu Singh Chauhan, National Professional Officer - IHR, Health Security and Emergencies Team, WHO Country Office for India, New Delhi for extending all necessary help from WCO.
4. Dr. G. N. Singh, Drug Controller General of India (DCGI), Dr. Sanjiv Kumar, DDCI and Dr. Sushant Sharma, ADCI, CDSCO, New Delhi for providing permission and all the necessary help & support to conduct the meeting at CDSCO.
5. Directors of Central Research Institute (CRI) and Central Drug Laboratory (CDL), Kasuali, Himachal Pradesh for providing necessary information on RIG production and quality testing of rabies biologicals.
6. Dr. G. Gongal, Division of International Health, South - East Asia Regional Office, World Health Organization, New Delhi- Member, Technical Advisory Group (TAG).
7. Dr. Madhur Gupta, National Professional Officer, WHO Country Office for India, New Delhi & Member, Technical Advisory Group (TAG).
8. Dr. Suresh S Honnappagol, Commissioner, Department of Animal Husbandry, Dairying and Fisheries. Government of India, New Delhi for facilitating conduct of veterinary activity in survey states and rabies free islands of Andaman/Nicobar and Lakshadweep Islands.
9. Dr. Naveen Gupta, Joint Director, Division of Zoonosis, National Centre for Disease Control (NCDC), New Delhi-Member, Technical Advisory Group (TAG).
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15. Dr. Manish Kakkar, Senior Public Health Specialist, Public Health Foundation of India (PHFI), New Delhi- Member, Technical Advisory Group (TAG).
16. Dr. Pradeep K, IDSP section, NCDC, Delhi for providing surveillance data on dog bite.
17. Dr. V. Ravi, Professor of Neurovirology and Head, WHO collaborating centre for reference and research on rabies, NIMHANS, Bangalore for extending all necessary help & support in organizing initial expert consultation and stakeholder's meeting at NIMHANS, Bangalore.
18. Dr. S. Abdul Rahman, Past President, APCRI, Bangalore.
19. The Heads of the Department of Community Medicine, State Medical Investigators and the community survey team members in 7 states for conducting community survey.
20. Medical Officers and support staff of PHC/CHC/Block level hospital in 7 states for conducting health facility survey.
21. State Veterinary Investigators and field veterinarians in 4 states for conducting veterinary survey.
22. Director and staff of Department of Animal Husbandry and Veterinary Services, Andaman/Nicobar and Lakshadweep Islands for helping us to initiate laboratory surveillance on rabies.
23. The Pharmaceutical companies manufacturing/distributing rabies biologicals for providing necessary information on logistics and crucial marketing data about their products.
24. Dr. H.S. Anwith, Assistant Professor; Drs. M.P. Ramya, Nitu Kumari, A.R. Manasa, R.A. Prakruthi, Afraz Jahan, Pankaj Kumar and P. Ramu, Post-graduate students, Department of Community Medicine, KIMS, Bangalore for their technical support and assistance throughout the project in various capacities.

List of Acronyms and Abbreviations	
ADE	Adverse Drug Events
ADR	Adverse Drug Reactions
ANM	Auxiliary Nurse Midwife
APCRI	Association for Prevention and Control of Rabies in India
ARC	Anti Rabies Clinic
ARV	Anti Rabies Vaccine
ASHA	Accredited Social Health Activist
AWBI	Animal Welfare Board of India
CCV	Cell Culture Vaccine
CRI	Central Research Institute
DCGI	Drug Controller General of India
ELISA	Enzyme Linked Immunosorbent Assay
EPI	Expanded Programme of Immunization
ERIG	Equine Rabies Immunoglobulin
FI	Field Investigator
HRIG	Human Rabies Immunoglobulin
GPS	Global Positioning System
ICMR	Indian Council of Medical Research
IDRV	Intra Dermal Rabies Vaccination
IMRV	Intra Muscular Rabies Vaccine
INR	Indian National Rupee
IU/ml	International Units per milli liter
KIMS	Kempegowda Institute of Medical Sciences
NCDC	National Centre for Disease Control
NIMHANS	National Institute of Mental Health &Neuro Sciences
PrEP	Pre Exposure Prophylaxis
PCECV	Purified Chick Embryo Cell rabies vaccine
PEP	Post-Exposure Prophylaxis
PDA	Personal Digital Assistance/device
PPS	Probability proportional to size
PVRV	Purified Vero cell Rabies Vaccine
Q1	First Quartile
Q3	Third Quartile
RFFIT	Rapid Fluorescent Focus Inhibition Test
RIG	Rabies Immunoglobulin
RVNA	Rabies Virus Neutralizing Antibody
SD	Standard Deviation
SI	State Investigator
SII	Serum Institute of India
TOR	Terms of Reference
TRC	Thai Red Cross
TRS	Technical Report Series
USD	United States Dollar
WHO	World Health Organization

Glossary of Terms	
Aerophobia	Fear of air, a pathognomonic sign of rabies.
Anganwadi worker	Primary health care worker (female) in the ICDS programme.
ASHA worker	Primary health care worker at the village level.
Community dog	A dog without a single owner and cared by the community.
Confirmed case (Rabies)	A suspected human rabies case that is laboratory confirmed.
Drop out	Animal bite victims who discontinued the vaccination at any point during the recommended course (except those who discontinued vaccination after 3 doses, where the dog/cat remains healthy and alive for at least 10 days after the exposure) were considered as non-compliant/dropouts.
Exposed	A person who had a close contact (usually a bite or scratch) with a suspected/confirmed rabid animal.
Geo-scatter	A method ensuring adequate representation to the geographic diversity.
Household	A dwelling where a family or a group of people reside.
Hydrophobia	Fear of water, one of the classical pathognomonic sign of human rabies.
Indigenous treatment	A treatment received from non-allopathic systems or quacks.
Left against medical advice (LAMA)	A situation where the attendants of the human rabies case take away the patient from the hospital to home against medical advice on knowing the prognosis.
Municipal Corporation	Local self-government
Pet dog	A dog owned by an household.
Photophobia	Fear of light, a classical pathognomonic sign of human rabies.
Possibly exposed	A person who had close contact (usually a bite or scratch) with a rabies - susceptible animal in (or originating from) a rabies - infected area.
Schedules	Survey instruments used to collect information.
Stray dog	An ownerless dog, free roaming and not cared by any household in a community.
Ward	A geographical demarcation based on population in urban areas.

Executive Summary

The historic global rabies conference jointly organized by WHO, OIE, FAO and GARC held at Geneva in December 2015, set a goal of eliminating dog mediated human rabies by 2030. The 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 activity 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. The APCRI team presented the project proposal of "Assembling new evidence in support of elimination of dog mediated human rabies from India" and the terms of references, etc. were finalized.

The project work was proposed to be done in seven states representing the geo-scatter distribution across north, east, south, west, central and north-eastern 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 rabies, assessment of anti-rabies clinics and veterinary survey in four states. 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 and still pictures on human rabies prevention and animal rabies control was also prepared.

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

The project core team visited WHO, India office; Offices of IDSP, Division of Zoonosis, NRCP, Division of Epidemiology at NCDC; Director, Health, NITI Ayog; DCGI and Joint DCGI at CDSCO; ICMR; CBHI; ADG & DDG (PH), Nirman Bhawan; Animal Husbandry Commissioner; ICAR; NIHFW and NHSRC in June, 2017 and apprised about the survey and the plan of work.

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

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.

The community survey of the present study showed that, 88.9% 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, in health facility survey, all of them received vaccine, but only 46.2% received RIG because of short/ no supply.

It was found 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-IPCPEP regimen (2-2-2-0-0) needs to be considered favourably and 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.

A total of 4294 individuals were surveyed covering 1012 households in seven selected states of India. Of those surveyed, 60.5% were aware of rabies and 39.5% had never heard of rabies. 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; 69 (47.3%) 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 50.0% were provoked bites

There was no case of human rabies reported from the surveyed population.

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 hospital, 5 (10.4%) were not advised PEP. Out of the remaining 43 bite victims, 21 had category-II exposures, of whom14 (66.7%) had completed either 5 doses of intramuscular or 4 doses of intradermal vaccination and 22 had Category-III exposures , of whom, 4(18.2%) had received rabies immunoglobulin and rabies vaccination, of whom 3 (75.0%) had received ERIG and 1(25.0%) had received HRIG**.**

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

- The health facility survey included 529 animal bite cases who came for PEP at 21 health care facilities in the seven 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%) and monkey (4.5%); Only 8.7% of the biting animals were known to be vaccinated against rabies.
- Most of these bites (51.8%) were unprovoked and 65.2% of bites occurred outside the 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 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; 67.3% received IDRV 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 infiltrated with ERIG (95.5%). 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 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 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.

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.

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.

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.

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 was predominantly ID (59%) in the bigger government institutions and only IM 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 v**a**ccines (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 is bad.

d) 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 2012-2016. 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.

a) Anti rabies vaccine:

The market size of the rabies vaccines is about INR. 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, paediatricians, 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.

Due to a general shortage of some leading brands of vaccine viz. Rabipur and Vaxirab N (Zydus Cadila), other and newer brands of rabies vaccines are gaining momentum in the market.

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 INR. 83 crores.
- RIG is mostly sold by 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 is more due to issues of logistics management and in the private sector, it is mostly due to issues related to production.

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 1st December, 2017 at the Central Drugs Standard Control Organization, 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".

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 Paediatrics (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.

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 INR. 8000/- approx. (123USD) and was reduced to INR. 1970/- approx. (30 USD in February, 2018)

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

a) Andaman &Nicobar Islands: There were 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 entre 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.

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 diagnosis of 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.

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.

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.

In conclusion, it is now important to utilize the results of this survey to revamp the national rabies control programme to achieve the goal of dog mediated human rabies free India by 2030.

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.

1. Introduction

In India rabies is a neglected zoonotic disease and transmitted to humans mainly through exposure to rabid dog (97%). An estimated 20,000 humans die of rabies annually and 17.4 million animal exposures occur annually in India (WHO-APCRI National Multi-centric Rabies Survey, 2003). Rabies is almost always fatal but preventable through prompt administration of post-exposure prophylaxis. Unfortunately, access and usage to PEP is limited, where canine rabies is endemic and the incidence of dog bites is high.

Global rabies conference held in Geneva, December 2015, under the auspices of WHO, OIE, FAO and GARC has set a goal of eliminating dog mediated human rabies by 2030. WHO through its Strategic Advisory Group of Experts (SAGE) working group on rabies is tasked with reviewing the current policies on rabies vaccines and immunoglobulins and the experience and evidence from India is extremely important towards achieving the global goal of eliminating dog mediated human rabies to which India is contributing to 1/3rd of human rabies mortality.

There is a potential Global Alliance for Vaccines and Immunization (GAVI) investment into human rabies vaccine in 2018 and GAVI has rallied its partners and countries to build the evidence base to help & inform this investment decision process. India is paving the way to become a regional lead on rabies elimination and it is time to reassess the progress and impact of interventions implemented in India. The National Rabies Control Programme (NRCP) has been implemented by Government of India, Ministry of Health & Family Welfare in all the states through NCDC (Medical component) and AWBI (Veterinary component) from 12th five year plan (2012-17), with an objective to prevent the human deaths due to rabies & to prevent transmission of rabies through canine (dog) rabies control.

In this context, this project would provide new evidence on rabies vaccination policies, feasibility and impact of improving access & coverage to post-exposure rabies vaccination, health seeking behaviours, pre-exposure policies, costs and experience on delivery mechanisms throughout the country.

The World Health Organization (WHO), India office through an APW on 11thMay, 2017 assigned this task to Association for Prevention and Control of Rabies in India (APCRI) with the following terms of reference / objectives.

1.1. Terms of Reference (TOR) of the project

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.
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.

2. Methodology

The project proposal was presented by the APCRI core team at the WHO-APCRI experts consultation meeting held at NIMHANS, Bangalore on 20th December, 2016. A detailed discussion on the terms of references was made with the experts from WHO, HQ.

Photo 1: WHO-APCRI Expert consultation at NIMHANS, Bangalore

On 21st December 2016, a national technical stake holders meeting was held at NIMHANS, Bangalore comprising members from WHO, HQ; WHO India Country Office; National Center for Disease Control (NCDC) which is WHO Collaborating center for Rabies Epidemiology, New Delhi; Indian Council of Medial Research (ICMR), New Delhi; National Institute of Mental Health & Neurosciences (NIMHANS) which is a WHO collaborating center for reference & research on Rabies; Public Health Foundation of India (PHFI), New Delhi, Animal Welfare Board of India (AWBI), Chennai; Mission Rabies, Goa; representation from various other veterinary institutions and from pharmaceutical companies manufacturing rabies vaccines, rabies immunoglobulin and rabies monoclonal antibodies.

Photo 2: National technical stake holders meeting at NIMHANS, Bangalore

The APCRI core team presented the project proposal to the group and discussed in detail. In the meeting, seven states were selected for the study ensuring geo-scatter

distribution representing north, east, west, south, central and north-eastern regions of the country. They were Himachal Pradesh and Bihar (North), West Bengal (East), Manipur (North-East), Kerala (South), Madhya Pradesh (Central) and Gujarat (West). It was decided to conduct a cross sectional study adopting multi-stage sampling methodology across the seven representative states in India; with medical component in all 7 project states and veterinary component in only 4 states (Himachal Pradesh, Manipur, Kerala and Gujarat) as it was thought to be logistically feasible.

The finalised project proposal was submitted to WHO India Country Office for approval on 30th December, 2016.

A series of meetings of the core group of APCRI was held and the state investigators (Medical - 7; Veterinary - 4) from the Medical colleges and Veterinary institutions close to the survey areas in the states were identified *(Annexure - 6.1).* In each state, the state medical investigator was Professor/ Associate/ Assistant Professor from the nearest medical college. Similarly, state veterinary investigator was identified from nearby Veterinary College, i.e. Professor/Associate Professor of Public Health/Microbiology or Senior veterinarian from the disease investigation section/ unit of the state animal husbandry department, who co-ordinated the veterinary activity with a veterinary officer/ Animal Welfare Organisations.

The 1st meeting of Technical Advisory Group (TAG) was held on 11th May, 2017 at New Delhi and the experts reviewed the proposal following a presentation by the APCRI core group.

Photo 3: Technical Advisory Group (TAG) meeting held at New Delhi

Following the meeting the project was approved and the agreement for performance of work (APW) with WHO, India Country office and APCRI was signed at Delhi on 11th May, 2017.

Subsequently, a meeting of APCRI core team members along with WHO India country office software engineers was held in the Department of Epidemiology & Centre for Public

Health, NIMHANS, Bangalore on 1st & 2nd June, 2017 for developing the survey software and data management.

Photo 4 & 5: Meeting to discuss software development & data management held at NIMHANS, Bangalore

Dr. M. K. Sudarshan, Team leader, Dr. G. Sampath, then President of APCRI visited the following organizations from June 27-30, 2017 at Delhi and apprised the key officials about the survey and the plan of work i.e., 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; NIHFW and NHSRC. The apex organizations and officials at the national level were requested to provide letters of permission/approval for eliciting cooperation in the states.

Subsequently, a preliminary orientation meeting of all the 11 state investigators (Medical - 7; Veterinary - 4) was convened on 7th July, 2017 at Panjim, Goa, a day in advance of the 19th National conference of APCRI held on 8th and 9th July, 2017 at Government Medical College, Panjim, Goa. The objective of the meeting was to orient all the state medical and veterinary investigators regarding the aim, objectives and methodology of the survey, for knowing each other and to finalize the survey plans in the respective states. The meeting was attended by Dr. Bernadette Abela Ridder and Dr. Lea Knopf from WHO HQ, Geneva; Mr. Avijit Chaudhury and Ms. Swati Thakur from WHO, India country office; Dr. Simmi Tiwari and Dr. Akash Srivastava from NCDC, Government of India, New Delhi. Following the orientation meeting, the next two days, the entire team of state investigators attended the 19th Annual National Conference of APCRI.

Photo 6: Medical & Veterinary Investigators with project core team during 19th APCRICON 2017 at Goa.

As planned at Goa and after communications between the state investigators and the APCRI core team; the training of investigators on community survey (using Apps), health facility survey and veterinary survey (using paper format) was conducted in the seven states and the study was initiated by visiting the respective study areas by the project core team (Table 1). A set of predesigned, pilot tested proformas for community survey, health facility survey and veterinary survey were used to conduct the study. (Annexures 6.2, 6.3 & 6.4)

Table 1: States, Place, APCRI core team and dates of the survey work initiation

	State	Place of visit	APCRI core team	Dates
1	**Kerala** [Medical+ Veterinary]	Kottayam & Trivandrum	1. Dr. M. K. Sudarshan 2. Dr. D. H. Ashwath Narayana 3. Dr. H. S. Ravish 4. Dr. B. S. Pradeep 5. Dr.Shrikrishna Isloor	17-20 July, 2017
2	**Bihar** [Medical only]	Darbhanga & Patna	1. Dr. M. K. Sudarshan 2. Dr. Gangaboraiah	31st July to 3rd August 2017
3	**Gujarat** [Medical+ Veterinary]	Surat	1. Dr. M. K. Sudarshan 2. Dr. Gangaboraiah	9-11, August 2017
4	**Manipur** [Medical + Veterinary]	Imphal & Senapati	1. Dr. M. K. Sudarshan 2. Dr. B. S. Pradeep 3. Dr. R. Sharada	17-19, August 2017
		Senapati	4.Dr. D H Ashwath Narayana 5.Dr. N R Ramesh Masthi 6.Dr H S Ravish	30-31, October 2017
5	**West Bengal** [Medical + Raw Video & pictures footages]	Kolkata & 24 North Paraganas	1. Dr. M. K. Sudarshan 2. Dr. Gangaboraiah 3. Dr. D. H. Ashwath Narayana 4. Sri.P.H.Vishwanath	21-24, August 2017
6	**Madhya Pradesh** [Medical only]	Bhopal & Khandwa	1. Dr. M. K. Sudarshan 2. Dr. D. H. Ashwath Narayana 3. Dr. Ramesh Masthi 4. Dr. H. S. Ravish	28-30, August 2017
7	**Himachal Pradesh** [Medical + Veterinary]	Shimla	1. Dr. M. K. Sudarshan 2. Dr. D. H. Ashwath Narayana 3. Dr. Gangaboraiah 4. Dr. Ramesh Masthi 5. Dr. H. S. Ravish **6.** Dr. Shrikrishna Isloor	4-7, September 2017

The training and survey work initiation in the seven states consisted of the following activities:

Day 1	Registration + Video documentary on rabies plus discussion + Presentation of the project, an overview; Orientation to the survey work, tasks, etc. Group works and guided discussion on medical, facility and veterinary surveys (wherever planned); planning of the main surveys in the clusters, etc.
Days 2-3 or 4 as per plan	Survey in the communities /clusters, facilities, veterinary work, etc. Visits to the IDSP, NRCP, Logistics societies, ARCs, DHS, DVS, other relevant /important organizations, etc.

Photo 7: Project core team with community and health facility survey team at AIIMS, Bhopal, Madhya Pradesh

The following surveys were conducted to complete the terms of references of the project.

2.1. Community survey:

The survey was conducted with the following sub-objectives:

a) To find out the incidence of dog, cat, domestic and wild animal bites in India.
b) To assess the basic knowledge of rabies among the respondents.
c) To evaluate the level of perceived health risk associated with exposure to domestic dogs and wild animals among the survey respondents.
d) To estimate household dog density in each community based on rates of ownership as well as on rabies vaccination rates among owned dogs.
e) To describe the frequency of suspected illness or death associated with dog, cat, domestic or wild animal exposures.
f) To assess the health seeking behaviour and rates of PrEP and PEP among households.

To accomplish the above, adopting a multi- stage sampling methodology, a cross sectional study across 7 representative states in India was conducted. The stages of sampling were district/ taluka/ block/ tehsil and clusters, with the sampling unit as a household.

2.1.1. Selection of district/ taluka/ block/ tehsil and cluster in each state:

The list of districts, taluka/ block/ tehsils in the census of India 2011 database was used as sampling frame for cluster selection. Clusters were defined as villages for rural areas and wards for urban areas. Simple random sampling technique was used to select one district within the state and one taluka/ block/ tehsil within the selected district. Within each Taluka/ block/ tehsil, a minimum of 6 clusters were selected. Random numbers were generated using the "Randbetween" function of Microsoft Excel software in choosing the districts, taluka/ block/ tehsil and finally the clusters - wards & villages (Annexure 6.5). The number of rural and urban clusters selected was proportionate to the rural-urban population of that particular state (probability proportional to size - PPS sampling) (Table 2).

Table 2: Cluster details for community survey*

Name of state		**Name of district**	**Name of block**		**Number of urban: rural cluster**	**Number of households Surveyed**
			Urban	**Rural**		
1	Himachal Pradesh	Shimla	Theog	Theog	1:5	144
2	Bihar	Darbhanga	Darbhanga	Biraul	1:5	144
3	West Bengal	North 24 Paraganas	Rajarhat	Rajarhat	2:4	144
4	Manipur	Senapati	Sadar hills west	Mao Maram	2:4	147
5	Kerala	Kottayam	Meenachil	Kanjirapally	3:3	145
6	Madhya Pradesh	Khandwa	Punasa	Punasa	2:4	143
7	Gujarat	Tapi	Songadh	Valod	3:3	145
Total					**14:28**	**1012**

*Annexure- 6.5 has details of all the 42 clusters

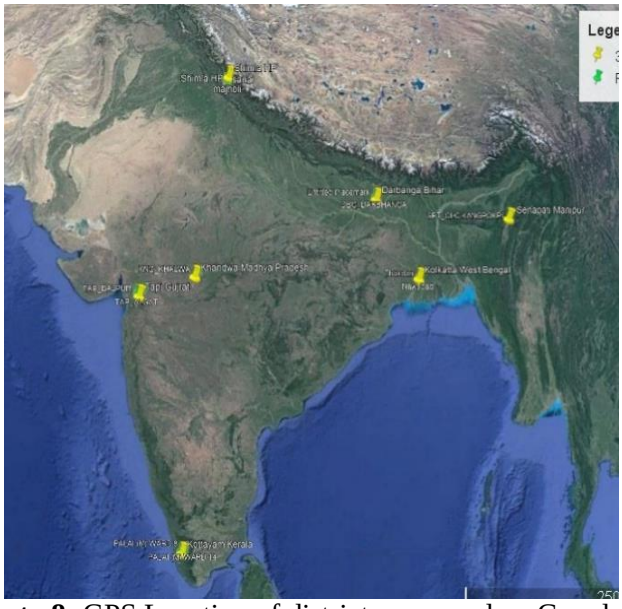


Photo 8: GPS Location of districts surveyed on Google Map

2.1.2. Sample size calculation:

As per the literature survey and following deliberations in the expert consultation and stake holders meetings at NIMHANS, Bangalore in December 2016, the incidence of animal/ dog bites was considered to be around 0.9%, and a precision of 0.4% was planned for this survey.

$$n = \frac{Z^2_{\alpha/2} P(1-P)}{d^2} \times DE$$

where Z = Value from standard normal distribution table at α = 5% (95% confidence level = 1.96); P (Prevalence) = 0.9% or 0.009;1- P=0.991; d=desired absolute precision (0.4% = 0.004). DE = Design effect (due to cluster sampling, "2"used by default).

$$n = \frac{1.96^2 \times 0.009 \times 0.991}{0.004^2} \times 2 = 4282 \text{ persons}$$

Assuming a non-response rate of about 15% in the sampled communities = 4282 X 0.15 = 642 persons. The Net Sample Size = 4282 + 642 = 4924 respondents.

- No. of individuals included in each state = 4924/ 7 states = 703 respondents.
- No. of Households (HH) surveyed in each state (703/5) = 141 HH (average of 5 persons per household).
- No. of households surveyed in each cluster =141 HH/6 cluster ~ 24 HH per cluster.

2.1.3. Selection of Households:

The WHO-EPI cluster survey methodology was used. Within each cluster, the field investigators went to centre of the village/ ward or a prominent area of the village/ward. Then, a street was selected randomly. The total number of households in that street was counted and marked. The first household on the street was selected randomly using random number table. The teams then surveyed every adjacent household in a counting series along mapped routes until 24 households per cluster were covered with every households being residents for a minimum of 6 months in the last one year. The head of household was the preferred respondent, but any adult responsible respondent in the household was also considered as an alternative. A written informed consent (or thumb impression from the illiterates with witness) was obtained from all respondents.

In this regard, all the investigators in selected states were trained for one day on the survey methodology at the state headquarters (except at Gujarat, it was at Surat). The operational aspects of the community survey were discussed in detail.

Photo 9: Manipur, Imphal: Training of the team of investigators by the project lead.

Subsequently, demonstration and installation of the specially developed software application (by WHO, India office for the survey) in their respective PDA/ android phones was done. The field investigators were given a unique ID and password for the application installed to conduct the field work using their personal digital device with a GPS receiver.

Photo 10 & 11: Training of surveyors for Community survey at Bhopal, MP & Surat, Gujarat.

A pilot study on the use of WHO software in the field including interview of a family with bite victim and family with dog was done in the nearest urban health training centre of the medical college. After the training was completed successfully, the community survey in the chosen clusters was started. After a series of field testing, software for community survey was finally used on 11th August, 2017 in a cluster in Surat, Gujarat.

2.1.4. Data collection:

Data was collected by a community survey team from the respective states. The faculty of the department of Community Medicine of a Medical College situated in the selected district or the nearest Medical College in the neighbouring district within the state formed the Community Survey team. The team consisted of Professor/ Associate Professor/ Assistant Professor supported by 2-6 field investigators who were Junior residents/ post graduates. The survey team took the support of local medical officer, ASHA, Anganwadi worker, local community and opinion leaders for the survey. Simultaneously, a backup to cover unforeseen problems with PDA, hard/ paper copy of survey information was generated.


Photos 12 & 13: Collection of data at households in Kangpoki, Manipur and Theog, Shimla

2.2. Health Facility survey

2.2.1. Selection of Health Facilities (HFs) in each Taluka/ Block/ Tehsil:

The study was conducted at 3 HFs (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 6 selected clusters in the community survey with the help of the State Medical Investigator.

2.2.2. Sample size:

$$n = \frac{Z^2_{\alpha/2}P(1-P)}{d^2} = \frac{1.96^2 \times 0.77 \times 0.23}{0.039^2} = 447$$

where Z = Value from standard normal distribution table at α = 5% (95% confidence level = 1.96); P = expected prevalence (Compliance to IDRV = 77% or 0.77); 1 – P = 0.23; d = desired relative precision (5% of 77% = 0.039).

Assuming 15% of non-response rate 447 x 0.15 = 67

Net sample size = 447 + 67 = 514 ≃ **525**

Therefore, 25 dog bite victims has to be followed at each HF, i.e., 25 X 3 HFs = 75 subjects/ state; 75 subjects X 7 states = 525 subjects.

Therefore, the study included a minimum of 25 consecutive new cases presenting to selected HF, excluding those with the history of receiving any PEP/ PrEP in the past.

2.2.3. Survey process:

In this regard, the APCRI core team along with the state medical investigator trained all the three medical officers of the corresponding health facilities from the survey area at the state headquarters (except at Gujarat, it was at Surat). The operational aspects of the health facility survey were discussed in detail.

Photo-14: Project Team Leader, discussing on health facility survey at Kottayam, Kerala (GPS coordinate using a smart compass software in the foreground)

All the medical officers were briefed to recruit animal bite cases coming for rabies post exposure prophylaxis in their respective health facilities. The medical officers were also requested to provide the information regarding the bite victims 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. In this regard, the medical officers & the respective veterinary officers (in four states) were made to discuss with each other at the training venue. After the training, the project core team as logistically feasible visited the health facilities in each state/ block to assess the facilities available at each centre and to initiate the health facility survey process. The GPS co-ordinates were recorded for each centre.

Photo 15 & 16: Project team visiting health facility & collecting information at Shimla, Himachal Pradesh

Data was collected from the respective medical officers of the selected health facility. A longitudinal study was conducted including all the animal bite victims presenting to selected health facility up to a minimum of 25 consecutive cases, excluding those who have history of previous exposure to animal bites or receiving any PEP/ PrEP. Informed consent was obtained from each study subjects after explaining the purpose of the survey, benefits

and risks in the local language. The standardized, pre-tested proforma/ questionnaires (30 hard copies was provided by the project office for each HF) was administered by the trained medical officer to collect information on the epidemiology of animal bites including host factors & environmental aspects, circumstances of bite incident, location of bite, dog ownership, patient demographics, knowledge of rabies and bite management, socio-cultural practices, cost of availing PEP (direct & indirect) and willingness to pay for availing the PEP services.

All the subjects were provided PEP as routine by the medical officer and followed up for any adverse drug reactions subsequently on days 3, 7, 14 & 28 when they came for vaccination. Any drop outs were recorded to know the compliance for completion of anti-rabies vaccination and the reasons for such drop-out were recorded. The animal bite victims who discontinued the vaccination at any point during the recommended course (except those who discontinued vaccination after 3 doses, where the dog/cat remains healthy and alive for at least 10 days after the exposure) were considered as non-compliant/dropouts. The major constraints to compliance (factors that influence incomplete vaccination course) were found out by interviewing the non-compliant bite victims or their guardians through telephone.

The respective medical officer provided the information regarding the bite victims to the veterinary team, to 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 for their health status. After that, the respective medical officers had sent all the original completed proforma/ questionnaire by speed post/ courier to the project office for entering into a password protected database.

2.3. <u>Veterinary survey</u>:

The Veterinary officer/ animal welfare organization (AWOs) coordinated with medical officer from 3 HFs in the respective states and conducted the house hold survey to get the information about the biting animals, vaccination coverage in dogs and constraints in vaccination. Once the biting dog was traced; if it is domesticated, then a collar with the number was put up on the dog (Post bite, Day 14 date marked) and signatures of 2 witness (bite victim & others) was taken. Furthermore, owner was informed to maintain and observe the dog for illness up to 14 days. If the suspected dog dies or if sick, then they have to inform the veterinary investigator to test the brain samples collected and submitted to OIE Twinned KVAFSU-CVA-Crucell Rabies diagnostic laboratory, Veterinary College, Bengaluru Lab. for confirmation of rabies. Regarding the street dogs, the available veterinary manpower or AWO involved in catching dogs were utilized. Similarly, contact tracing to recognise other unreported / unknown

human rabies exposures by the same biting dog / other dog in the community was done as operationally feasible.

The respective veterinary officers kept a copy of all the proforma/ questionnaire (for further need) and sent the original completed proforma/ questionnaire by speed post/ courier to the project office for entering into a password protected database.

Photo 17 & 18: Training of Veterinary Investigators at Shimla, HP & Quarantine facility at Pala, Kerala

2.4. 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 for articles related to PEP and use of rabies immunoglobulins both from India and other countries. The articles & reports published in peer reviewed national and international journals which were accessed from Pub Med and Google Scholar search engines and also information obtained from grey literature and from different organisations through personal overreach were utilised.

The cost-effectiveness of PEP regimens including existing approved regimens and new candidate regimens were compared from the perspective of the healthcare providers and the costs incurred by bite victims in scenarios from low to high throughput clinics. The cost data reported from previous studies were analyzed which included direct (medical) costs for rabies vaccines and RIG and their administration; indirect (non-medical) costs including transportation to and from clinics, loss of wages, food, etc. was recorded.

The following factors affecting cost effectiveness of PEP were considered:

a) Clinic throughput: Number of bite patients presenting to a clinic in need of PEP. The overall number of patients that present to a clinic depends on the PEP regimen in use, its schedule requirements and the extent to which patients comply with the regimen.

b) Vial size: Most rabies vaccines are sold in 0.5mL or 1mL vials, at equal cost, which affects the number of patients that can share the vial for ID vaccinations and the wastage of vaccine can be avoided if 1mL insulin syringes are used.

c) Patient compliance: The probability of a bite patient returning to a clinic for subsequent PEP vaccination(s). Poor compliance has consequences for vaccine use, vial sharing and the efficacy of PEP.

2.5. 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 the agency/ organization/ office responsible for logistics of rabies biologicals at the state and district levels. The pretested structured proformas (*Annexures 6.6, 6.7, 6.8 & 6.9)* were used to collect the information from the concerned officials/ personnel through an interview and perusing the relevant records. Also, visits were made to the district vaccine stores and other places. At the peripheral level, the health institutions in the 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.

Photos 19 & 20: Project Lead assessing vaccine & RIG logistics at Surat, Gujarat and Kottayam, Kerala

Photo 21 & 22: Walk in cooler in C&F agency and domestic refrigerator with temperature log and siren hood

The project team also visited the premier institutions like Central Research Institute & Central Drug Laboratory, Kasauli, Himachal Pradesh on 5th September, 2017**.** The key technical functionaries were interviewed and the relevant information was obtained.

Photo 23 & 24: Project team at Central Research Institute & Central Drug Laboratory, Kasauli, HP

Similarly, to assess the anti-rabies clinics in the survey states, the APCRI survey team visited the ARCs at the state headquarters, districts & peripheral health institutions; both in government & private sectors and in urban & rural areas. The data was collected using a pretested structured proforma/check list *(Annexure 6.10)* by interviewing the medical officer/ pharmacist/ staff nurses. Simultaneously, the facilities for wound wash, vaccine and RIG injections, cold chain, and record keeping were inspected.

2.6. To conduct a market landscape analysis of available human and animal rabies biologicals in India and to forecast vaccine & 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 (Annexures 6.11 & 6.12) were provided (in person / soft copy by email) to obtain the data. As the data requested was related to their business, some who were reluctant/ hesitant and had to be prevailed upon personally to provide the requested data. The business offices of Indian Immunologicals/ Human Biologicals, 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.

2.7. To provide a policy paper for rabies biologicals and vaccination in humans:

The team leader was delegated the responsibility of this important document. In this regard, a meeting of the technical stake holders was held on Friday, 1st December, 2017 in Central Drugs Standard Control Organization (CDSCO), at FDA Bhawan, New Delhi.

Photo 25 & 26: Technical stake holders meeting at CDSCO, FDA Bhawan, New Delhi

2.8. 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 national marketing head/ Director was personally met/ telephonically informed and the survey schedules were provided (in person / soft copy by email) to obtain the data.

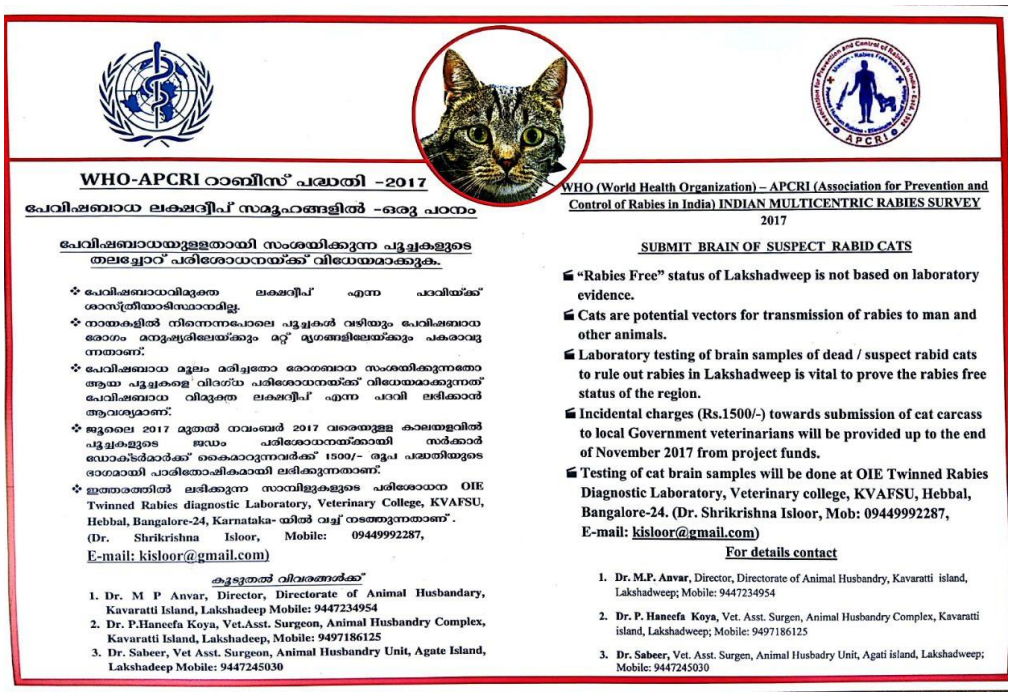
2.9. To assess rabies free status of islands of Lakshadweep and Andaman/ Nicobar:

The project team of co-investigators consisting of Drs. B. J. Mahendra (Medical) and Shrikrishna Isloor (Veterinary), Bangalore visited medical and veterinary institutions in Kavaratti and Agatti islands of Lakshadweep from June 14 -17, 2017 with the objective to establish laboratory surveillance for rabies with a view to help in working for the WHO goals of human rabies free India by 2030. They 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 sector & medical sector using the proformas *(Annexures 6.13 to 6.26).*

Photo 27 & 28: APCRI survey team at Kavaratti Islands and meeting with Lt. Governor of Lakshadweep Islands

The APCRI team briefed the Lt. Governor about the survey and prevailed upon the Administrator, Collector, Director of Animal husbandry and other veterinary officials for submission of cat brain samples to rabies diagnostic laboratory, veterinary college, Bangalore for laboratory testing as a part of continuous surveillance.

Poster was prepared both in English and local language Malayalam about the need to submit cat brain samples for diagnosis of rabies and were handed over to authorities for distribution among both medical & veterinary institution for wider dissemination.



WHO-APCRI റാബീസ് പദ്ധതി -2017

പേവിഷബാധ ലക്ഷദ്വീപ് സമൂഹങ്ങളിൽ -ഒരു പഠനം

പേവിഷബാധയുള്ളതായി സംശയിക്കുന്ന പൂച്ചകളുടെ തലച്ചോറ് പരിശോധനയ്ക്ക് വിധേയമാക്കുക.

- പേവിഷബാധാവിമുക്ത ലക്ഷദ്വീപ് എന്ന പദവിയ്ക്ക് ശാസ്ത്രീയാടിസ്ഥാനമില്ല.
- നായകളിൽ നിന്നെന്നപോലെ പൂച്ചകൾ വഴിയും പേവിഷബാധ രോഗം മനുഷ്യരിലേയ്ക്കും മറ്റ് മൃഗങ്ങളിലേയ്ക്കും പകരാവുന്നതാണ്.
- പേവിഷബാധ മൂലം മരിച്ചതോ രോഗബാധ സംശയിക്കുന്നതോ ആയ പൂച്ചകളെ വിദഗ്ധ പരിശോധനയ്ക്ക് വിധേയമാക്കുന്നത് പേവിഷബാധ വിമുക്ത ലക്ഷദ്വീപ് എന്ന പദവി ലഭിക്കാൻ ആവശ്യമാണ്.
- ജൂലൈ 2017 മുതൽ നവംബർ 2017 വരെയുള്ള കാലയളവിൽ പൂച്ചകളുടെ ജഡം പരിശോധനയ്ക്കായി സർക്കാർ ഡോക്ടർമാർക്ക് കൈമാറുന്നവർക്ക് 1500/- രൂപ പദ്ധതിയുടെ ഭാഗമായി പാരിതോഷികമായി ലഭിക്കുന്നതാണ്.
- ഇത്തരത്തിൽ ലഭിക്കുന്ന സാമ്പിളുകളുടെ പരിശോധന OIE Twinned Rabies diagnostic Laboratory, Veterinary College, KVAFSU, Hebbal, Bangalore-24, Karnataka- യിൽ വച്ച് നടത്തുന്നതാണ്.

(Dr. Shrikrishna Isloor, Mobile: 09449992287,
E-mail: kisloor@gmail.com)

കൂടുതൽ വിവരങ്ങൾക്ക്

1. Dr. M P Anvar, Director, Directorate of Animal Husbandary, Kavaratti Island, Lakshadeep Mobile: 9447234954
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WHO (World Health Organization) – APCRI (Association for Prevention and Control of Rabies in India) INDIAN MULTICENTRIC RABIES SURVEY 2017

SUBMIT BRAIN OF SUSPECT RABID CATS

- "Rabies Free" status of Lakshadweep is not based on laboratory evidence.
- Cats are potential vectors for transmission of rabies to man and other animals.
- Laboratory testing of brain samples of dead / suspect rabid cats to rule out rabies in Lakshadweep is vital to prove the rabies free status of the region.
- Incidental charges (Rs.1500/-) towards submission of cat carcass to local Government veterinarians will be provided up to the end of November 2017 from project funds.
- Testing of cat brain samples will be done at OIE Twinned Rabies Diagnostic Laboratory, Veterinary college, KVAFSU, Hebbal, Bangalore-24. (Dr. Shrikrishna Isloor, Mob: 09449992287, E-mail: kisloor@gmail.com)

For details contact

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Photo 29: Poster on creating awareness on need for laboratory surveillance of rabies in cats

Project coordinator Dr. D. H. Ashwath Narayana (Public Health) and Co-Investigator Dr. Reeta S. Mani (Neurovirologist, NIMHANS) visited medical and veterinary institutes at Port Blair, Andaman & Nicobar Islands from 19th - 22nd November 2017. A set of structured forms and questionnaires were sent to the Directorate of Animal Husbandry and Veterinary Services, and Directorate of Health Services to collect baseline information about infrastructure in medical and veterinary services, statistics on population of dogs and livestock, and rabies situation in humans and animals, prior to the visit of the team to the islands. *(Annexures 6.13 to 6.26).*

The project team visited several medical, veterinary and allied institutions and had discussions with officials and interviewed several staff members for additional information based on their relevant experience in the field.


Photo 30 & 31: Dr. D. H. Ashwath Narayana & Dr. Reeta S Mani with Directors of Veterinary services & Health services, Port Blair, Andaman & Nicobar Islands

A poster was prepared in English about need to submit dog brain samples for diagnosis of rabies and was handed over to authorities for distribution among both medical & veterinary institution for wider dissemination.

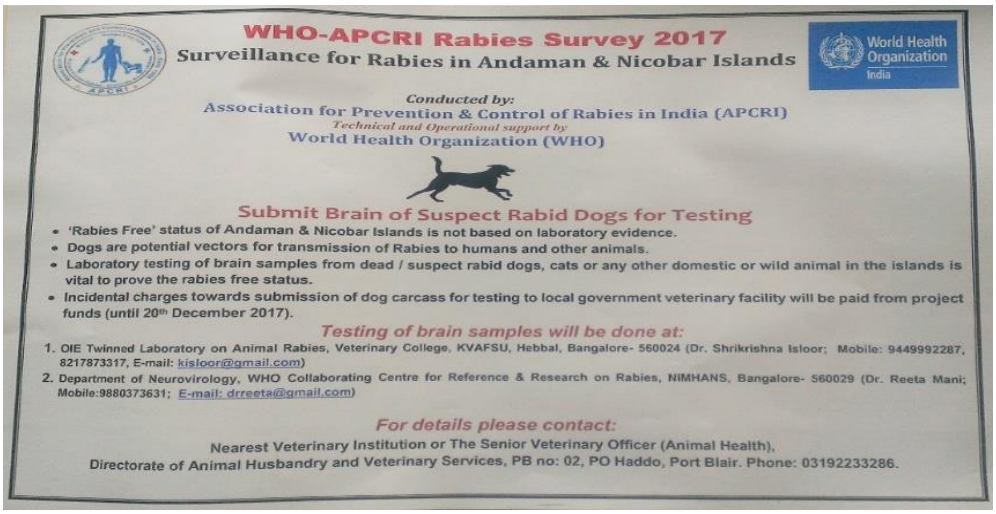

Photo 32: Poster on creating awareness on need for laboratory surveillance of rabies in dogs

2.10. To report the mechanism of surveillance for dog bite and human rabies:

An efficient surveillance system is crucial to the success of any disease control programme. Disease surveillance in India gained momentum following the outbreaks of cholera in Delhi (1988) and Plague in Surat, Gujarat (1994). From 2012, integrated disease surveillance programme (IDSP) (started as project in 2004) is in operation and it is intended to generate and detect early warning signals of impending outbreaks and help initiate an effective response in a timely manner. The programme aims to facilitate and enhance its use in health planning, management and evaluation of disease control strategies. It covers 18 diseases and conditions across all states /union territories (UTs) of India and includes dog bites as one of them. The appointment of 36 veterinary officers one for each state/union territory, is completed to cover zoonotic diseases including dog bite and human rabies under a "one health "approach.

Photo 33: Team leader collecting information at ID hospital, Patna, Bihar

The data on dog bites for the five year duration of 2012 - 2016 was obtained from the seven states mostly from the IDSP/ NRCP offices. Subsequently, the same data was obtained from the NCDC, Delhi IDSP office to know the concordance between the data of NCDC & APCRI.

To aappraise 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. (*Annexure 6.27*)

2.11. To provide the raw video footage and pictures on rabies:

A specialized agency with rabies work experience was chosen. Following discussions with the focal persons at the WHO headquarters and at the national level, both indoor and outdoor recordings were done using a professional 4K digital camera for recording of both video and still pictures/images.

2.12. Ethical approval :

Institutional ethical committee clearance was obtained from KIMS, Bangalore for the medical component of the project on 26.11.2016. Informed consent was taken from all the study subjects.

2.13 Feedback to TAG members

Dr. M. K. Sudarshan, Project Lead and Dr. D. H. Ashwath Narayana, Project Coordinator visited WHO-India office, NCDC, WHO-SEARO, ICAR and ICMR offices at New Delhi and provided feedback on progress of project and handed over the hard copy of interim report on 16-17 October, 2017. The project team also invited the members of technical advisory team for monitoring of the project.

3. Results

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

3.1.1 PEP & RIG usage in India

1) **SS Abbas et.al. (2011):**

An assessment of rabies prevention and control activity in Tamil Nadu state of India showed that, there was a gradual increase in the reporting of dog bites for PEP from 900/100,000 population (2004) to 1400/ 100,000 (2007) and simultaneously there was an increase in the consumption of anti-rabies vaccines from 400 vaccine vials/ 100,000 population (2004) to 1400 vials/ 100,000 population (2007). Hence, there was an increasing trend of utilisation of anti-rabies vaccine. The number of dog bites reported per 100,000 population in urban areas was around 5 times that reported in rural areas in 2008 & 2009.

2) **Hampton K et.al. (2015):**

A probability decision tree framework for estimating the burden of the problem for India showed that, an estimated dog bite incidence of 692.5/ 100, 000 with the probability of bite victims receiving PEP of 0.976 and an estimated 82,09,470 received PEP, thereby preventing 8,49,658 deaths due to rabies.

3) **Present study (2017):**

The community survey of the present study showed that, 88.9% had sought PEP at the health facility; among those who visited the hospitals, 10.4% were not advised PEP and only16% received RIG among category III exposures. Similarly, in health facility survey, only 46.2% received RIG because of short/ no supply.

3.1.2 Cost-effective regimens

The data from the published studies were utilised to accomplish this term of reference. The following PEP regimens for intramuscular (IM) and intradermal (ID) use have been developed/in use across the world (Table 3).

Table 3: Different PEP regimens and their approvals					
Regimen	**Schedule**	**Visit days**	**No. of days of visit**	**Total volume for complete schedule (mL)**	**Approval status**
Essen 5 dose (IM)	1-1-1-1-1	0,3,7,14,28	5	2.5 or 5	WHO;1992 & **DCGI**
Essen 4 dose (IM)	1-1-1-1	0,3,7,14	4	2 or 4	WHO 2018
Zagreb (IM)	2-1-1	0,7,21	3	2 or 4	WHO 1992
TRC (ID)	2-2-2-0-1-1	0,3,7,28,90	5	0.8	WHO 1992
Updated TRC (ID)	2-2-2-0-2	0,3,7,28	4	0.8	WHO;2005 & **DCGI**
4 site (ID)	4-0-2-0-1-1	0,7,28,90	4	0.8	Not approved
1 week, 4 site (ID)	4-4-4	0,3,7	3	1.2	Not approved
1 week, 2 site (ID)-IPC regimen*	2-2-2	0,3,7	3	0.6	WHO, 2017

DCGI = Drug Controller General (India), regulatory authority of India

* WHO, Weekly Epidemiological Record. Meeting of the Strategic Advisory Group of Experts on immunization, October 2017 – conclusions and recommendations No 48, 92, 729- 748, 2017.

Indian Studies:

1) Satapathy et.al (2012):

A hospital based study done in Berhampore, Odisha. Average daily 55-60 doses of vaccine given at ARC and cost calculated based on this average doses. IM regimen: INR 10,620/- without RIG for 59 cases @INR 180/- per dose of vaccine; ID regimen: INR 2124/- without RIG @ INR 180/- per dose of vaccine. Cost of ERIG was INR 4,255/- for all category 3 cases. Cost of IDRV + ERIG was 6,379/- per day to treat all 60 cases. It infers that IDRV using updated TRC regimen (instead of Essen IMRV) with ERIG saves 40% of the cost to the Government.

2) Sajna et.al (2014):

Study done at Government medical college, Thrissur, Kerala (n=213), Cost of IDRV/person was INR 400/- and total cost of IDRV/week was INR.82,800/-. ERIG cost per person was INR.800/- and total cost of ERIG/ week was INR 83,920/- whereas HRIG cost per person was INR 6400/- and total cost of HRIG/ week was INR 1,06,294/-. This study from Government medical college Kerala, showed that direct expenditure for ID schedule for one week was more economic burden to the Government and it will be much higher for one year. Study also emphasis on pre exposure prophylaxis to reduce cost burden.

3) Mankeshwar et.al (2014):

This study was from ARC clinic in tertiary care hospital Mumbai, Maharashtra, retrospectively done for past year 2007-2008 data to know cost effectiveness of Essen regimen and subjects were included from 1st July 2008- 30th July 2009 for updated TRC regimen. PCEC vaccine was used in the study. The cost of each vial cost around INR.230/-. 1230 subjects completed ID schedule regimen and cost was INR 2,80,600/- whereas 432

patients completed IM regimen and cost estimated was INR 7,82,230/-. Per person cost for full course IM regimen was INR.1150/- and for that of ID was INR.184/-.

4) Ravish HS et.al (2017):

A descriptive study done at both Government Hospital (where PEP is provided free of cost by ID route) & Private Medical College hospital (where PEP is provided for a cost by IM route), in Bangalore including 290 animal bite victims who completed the PEP, showed that, the total median cost incurred by the bite victims in Government hospitals was INR.585 with Q1-Q3 of INR.444-725; which included direct median cost of INR.300 and indirect median cost of INR.285; and the cost spent by the government for providing PEP free of cost was INR. 1031. Likewise, the total median cost incurred for the patients in private hospital was INR.5200 with Q1-Q3 of 4900-5701; mostly i.e., INR.3865 was spent on purchasing ARV & RIG. The study concluded that, the economic burden to the bite victims as well as for the government in the developing world was more and this is expected to rise in future due to increased population and ineffective dog population control. Hence, the study recommends for improving the availability of rabies PEP in all the government health facilities to reduce the out of pocket expenses for the poorest communities.

Studies from abroad:

5. Pannipa Chulasugandha et.al (2006):

Essen regimen: USD 64.5 – 74.5 (Range). Updated TRC regimen: When PVRV was administered: USD 33.02 – 47.25. When PCEC was administered: USD 28.75-37.25. The study concluded that in Thailand three PrEP and PEP regimens are in use and costs of both strategies, PrEP of children and PEP of exposed, become equal when the dog bite incidence is 2-30%; depending on which PEP regimens are used.

6. Hampton K et.al. (2011):

Table 4: Annual estimated cost of PEP in different countries

Country	Monthly Through put	Annual estimated cost of PEP vaccination/clinic (USD)				
		Essen 4 dose	**Zagreb**	**Updated TRC**	**4 site ID**	**One week ID**
India	>4000	>1903300	>1884800	>591500	>592950	>798100
Philippines	>600	>285500	>282700	>91200	>92200	>121300
Tanzania	15 to 400	7150-190350	7100-188500	3700-60800	4100-61500	3800-80850
Chad	30	14300	14150	5750	6350	6800

- Where PEP is provided free of charge: Zagreb (IM) and One week, 4 site (ID) are preferred.
- When travel costs are low & PEP is charged per injection: Updated TRC & 2 site (ID) are preferred.

- When travel cost are high & flat rates are charged for full course of vaccination: One week, 2 site ID is preferable (Table 4).

The study reiterates that a universal switch to ID delivery would improve the affordability and accessibility of PEP for bite victims, leading to a likely reduction in human rabies deaths, as well as being economical for health care providers in low income countries.

7. Salahuddin N et.al:

Cost of ARV by Essen IM regimen (incurred by patient): USD 27.35. Cost of ARV by Updated TRC regimen (incurred by patient): USD 5.7. Cost of ERIG/patient: USD 11.38 Cost of ARV + ERIG: USD 12 (Avg.). This study from Pakistan showed that the updated TRC ID regimen reduced the cost of vaccine to $1/5^{th}$ of Essen regimen and was recommended for institutions with large throughput.

In summary, ID regimen is cost effective and recommended for use in rabies endemic countries where financial constraints and short supply of vaccine are seen. The most recent SAGE (2017, October) recommended one week ID-IPC PEP regimen (2-2-2-0-0), which needs to be considered favourably and 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.

3.1.3. Limitations:

There were very few publications having complete information with regards to PEP & RIG use and cost-effective regimens while maintaining highest impact on public health.

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3.2. TOR 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).**

3.2.1. Community survey coverage:

The community survey was done in 7 states i.e. Himachal Pradesh & Bihar (North), West Bengal (East), Gujarat (West), Kerala (South), Madhya Pradesh (Central) and Manipur (North-East) through 7 medical colleges during August to November, 2017.

Community survey details	Urban	Rural	Total
1.States covered	-	-	7
2.Clusters surveyed	14	28	42
3.Household Surveyed	323	689	1012
4.Population surveyed	1278	3016	4294

NA- not applicable

3.2.2 Socio demographic characteristics of surveyed population:

A total of 4294 individuals were surveyed covering 1012 households. 3016 (70.2%) were living in rural settings and 1278 (29.8%) were living in urban settings. The age range of the surveyed population was < 1 year to 100 years with the median age and interquartile range being 30 (16, 45) years. Majority 2981(69.4%) of the surveyed population were in the age group of 15 to 60 years and 959 (22.3%) were in the age group of 0-14 years. 2181(50.8%) were males and 2113(49.2) were females. 2720 (63.3%) were school and pre-university educated, 568 (13.3%) were degree/diploma/ post-graduation and 1006 (23.4%) were illiterates. 1033 (24.8%) were homemakers by occupation and 816 (19.7%) were Cultivator/ Labourer (agricultural/ non-agricultural) by occupation and 1125 (27.0%) were students. 2374 (55.3%) were currently married and 1711(39.8%) were never married.

725 (71.6%) households were Hindu by religion, 193 (19.1%) households were Christians and 92 (9.1%) Muslims, 1 (0.1%) each were Sikh and Jain. Majority 915 (90.4%) had a sanitary toilet/ pit latrine in the household. 897(88.6%) lived under a finished/ rudimentary roof and least 115(11.4%) households lived under natural roof. Majority 769 (76.0%) lived in house with walls made of brick with cement/ stone/wood/ bamboo and 243 (24.0%) households lived in walls made of brick with cement. The average number of persons per household was 4.24. (Table - 5)

Table 5: Socio demographic characteristics of surveyed population				
Characteristic	**Details**	**Urban n=1278**	**Rural n = 3016**	**Total n=4294**
Age (in years)	≤14	256(20.0)	703(23.3)	959(22.3)
	15-60	916 (71.7)	2065(68.5)	2981(69.4)
	>60	106 (8.3)	248(8.2)	354 (8.3)
Gender	Male	646(50.5)	1535(50.9)	2181(50.8)
	Female	632(49.5)	1481(49.1)	2113(49.2)
Education	Illiterate	176(13.8)	830(27.6)	1006(23.4)
	Primary /High / Middle school /Pre-University College	831(65.0)	1889(62.6)	2720(63.3)
	Degree/diploma /post-graduation	271(21.2)	297(9.8)	568(13.3)
Occupation (n=4162)*	Housework	297(24.6)	736(24.9)	1033(24.8)
	Cultivator / Labourer (agricultural / non-agricultural)	94(7.8)	722(24.4)	816(19.7)
	Salaried employment/ Business	359(29.7)	429(14.5)	788(18.9)
	Non-working/unemployed	124(10.3)	260(8.9)	384(9.2)
	Student	326(27.0)	799(27.0)	1125(27.0)
	Others[$]	8(0.6)	8(0.3)	16(0.4)
Marital Status	Currently Married	711(55.6)	1663(55.1)	2374(55.3)
	Never married	497(38.9)	1214(40.3)	1711(39.8)
	Divorced/Separated/ /Widowed	70(5.5)	139(4.6)	209(4.9)
Household Information (n=1012)		**n=323**	**n=689**	**n=1012**
Religion	Hindu	205(63.5)	520(75.5)	725(71.6)
	Christian	69(21.4)	124(18)	193(19.1)
	Muslim	47(14.6)	45(6.5)	92(9.1)
	Jain	1(0.3)	-	1(0.1)
	Sikh	1(0.3)	-	1(0.1)
Toilet facility	Sanitary /Pit/Bore hole	319(98.8)	596(86.5)	915(90.4)
	No facility/Open defecation	4(1.2)	93(13.5)	97(9.6)
Material of the roof of house	Finished Roof/ Rudimentary Roof	318(98.4)	579(84.0)	897(88.6)
	Natural Roof	5(1.6)	110(16.0)	115(11.4)
Material of the wall of house	Brick with cement / stone /wood/bamboo	286(88.5)	483(70.1)	769(76.0)
	Brick with mud/ mud	37(11.5)	206(29.9)	243(24.0)

Figures in parenthesis indicate percentages.

*Details available for only 4162: Rural (n=2954) & Urban (n=1208).

$ Others include priest, helper, social worker, village chairman, ASHA, etc.

3.2.3 Socio demographic characteristics of animal bite victims:

Among the surveyed population (n=4294), 54 reported to had rabies exposure in last 1 year. The annual incidence of animal bite was 1.26 % i.e., 54 bite victims out of 4294 surveyed individuals. The annual incidence in urban and rural settings were 1.33 % (17/1278) and 1.23% (37/3016) respectively.

Table 6: Socio demographic characteristics of animal bite victims (n =54)

Characteristics	**Details**	**Urban n=17**	**Rural n=37**	**Total n=54**
Age in years	≤ 14	4(23.5)	13(35.2)	17(31.4)
	15-60	13(76.5)	20(54.0)	33(61.2)
	>60	-	4 (10.8)	4 (7.4)
Gender	Male	9(52.9)	28(75.7)	37(68.5)
	Female	8(47.1)	9(24.3)	17(31.5)
Religion	Hindu	10(58.8)	29(78.4)	39(72.2)
	Christian	7(41.2)	5(13.5)	12(22.2)
	Muslim	-	3(8.1)	3(5.6)
Education	Illiterate	1(5.9)	9(24.3)	10(18.5)
	Primary / Middle / High school/Pre-University College	13(76.5)	25(67.6)	38(70.4)
	Degree/Diploma/Post graduation	3(17.6)	3(8.1)	6(11.1)
Occupation	Cultivator / Labourer (Agricultural / Non-Agricultural)	4(23.5)	10(27.0)	14(25.9)
	Salaried Employment /Business	5(29.4)	6(16.2)	11(20.4)
	Housework	3(17.6)	5(13.5)	8(14.8)
	Non Working /Unemployed	-	2(5.4)	2(3.7)
	Student	5(29.5)	14(37.9)	19(35.2)
Marital Status	Currently Married	10(58.8)	21(56.8)	31(57.4)
	Never married	6(35.3)	16(43.2)	22(40.7)
	Divorced/Separated/ /Widowed	1(5.9)	-	1(1.9)
Housing standards of bite victims(n=52)*		**n=16**	**n=36**	**n=52**
Material of the roof of house	Finished Roof /rudimentary roof	16(100.0)	30(83.3)	46(88.5)
	Natural Roof	-	6(16.7)	6(11.5)
Material of the wall of house	Brick with cement / stone /wood/bamboo	14(87.5)	26(72.2)	40(76.9)
	Brick with mud/ mud	2(12.5)	10(27.8)	12(23.1)
Toilet facility	Sanitary /Pit latrine	16(100.0)	30(83.3)	46(88.5)
	No facility/Open defecation	-	6(16.7)	6(11.5)

Figures in parenthesis indicate percentages.
*Two bite victims each were in same families.

Majority 37(68.5%) of the bites victims were from rural settings and 17 (31.5%) were from urban settings. Majority 33(61.2%) of the bite victims were in the age group of 15 - 60 years, 17(31.4%) bite victims were in the age group of less than 14 year and 4 (7.4%) bite victims were elderly (>60 years old). The median age with Inter quartile range of bite victims was 35 (12, 48) years .The youngest bite victim was 3 years old and oldest bite victim was 82 years old. 37(68.5%) of bite victims were males and 17 (31.5%) were females (Table 6).

39 (72.2%) bite victims were Hindu by religion, 12 (22.2%) Christians and 3 (5.6%) Muslims. Most i.e., 38 (70.4%) bite victims were school and PUC educated and 10 (18.5%) were illiterates. 14 (25.9%) bite victims were cultivator / labourer (agricultural / non-agricultural) by occupation, 11 (20.4%) were salaried/business class and 08 (14.8%) housework. 19 (35.2%) bite victims were students. 31 (57.4%) bite victims were currently married and 22 (40.7%) were never married. Majority 46(88.5%) bite victims lived under a finished/ rudimentary roof and 6 (11.4%) lived under natural roof. Majority 40 (76.9%) bite victims lived in households with walls made of brick with cement/ stone /wood/bamboo and 12 (23.1%) bite victims lived in walls made of brick with mud/mud. Majority 46 (88.5%) bite victims had a sanitary toilet/pit latrine in the household.

The median annual income with interquartile range was INR.78,000 (1217$) (INR.32,250, INR.2,40,000).The minimum and maximum annual income of the bite victims was INR.5,000 (78$) and INR.5,00,000 (7808$) per annum.

3.2.4 Details of exposure:

Table 7: Details of exposure

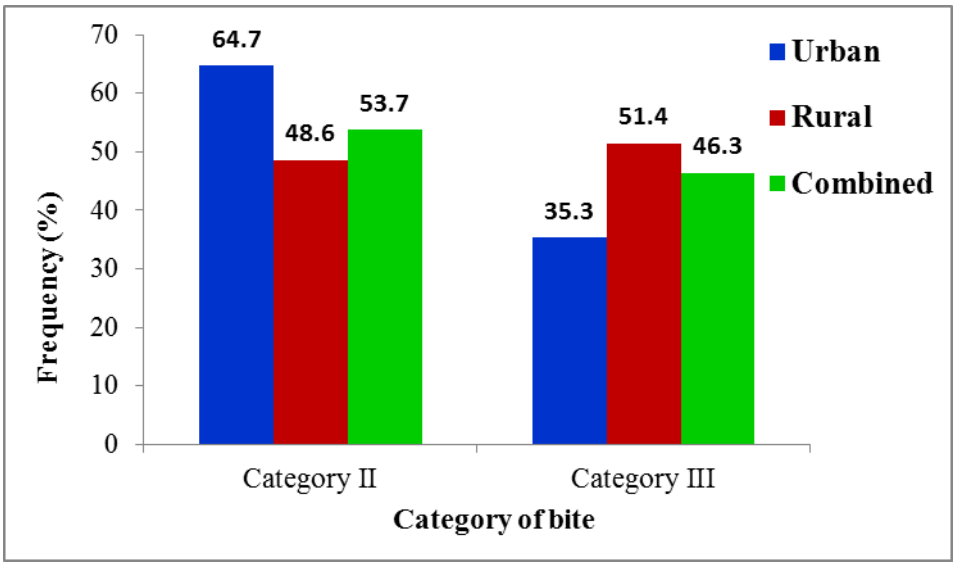
Characteristics	**Details**	**Urban n=17**	**Rural n=37**	**Total n=54**
Place of bite	Home	9(52.9)	13(35.1)	22(40.7)
	Outside home	8(47.1)	24(64.9)	32(59.3)
Nature of bite	Provoked bite	10(58.8)	17(45.9)	27(50.0)
	Unprovoked bite	7(41.2)	20(54.1)	27(50.0)
Number of bite wounds	One	11(64.7)	33(89.2)	44(81.5)
	Two	5(29.4)	2(5.4)	7(13.0)
	More than two	1(5.9)	2(5.4)	3(5.5)
Site of bite*	Leg/feet	9(52.9)	24(64.9)	33(61.1)
	Arm/forearm/hand	8(47.1)	12(32.4)	20(37.0)
	Head/face	-	1(2.7)	1(1.8)
	Buttock	-	1(2.7)	1(1.8)
Type of wound*	Abrasion	11(64.7)	20(54.0)	31(57.4)
	Puncture wound	4(23.5)	12(32.4)	16(29.6)
	Laceration	2(11.8)	7(18.9)	9(16.7)
Category of bites	Category –II[$]	11(64.7)	18(48.6)	29(53.7)
	Category –III	6(35.3)	19(51.4)	25(46.3)

Figures in parenthesis indicate percentages; *Multiple response

[$]Abrasion has been considered as category II though some may have had history of bleeding (these may not have been elicited during the survey to be classified as category-III).

Out of the 54 bite victims, 22 (40.7%) bites had occurred at home and 32 (59.3%) bites had occurred outside home. 27 (50.0%) of the victims each were provoked and unprovoked (50.0%) bites. Majority 44 (81.5%) victims had single bite wounds, 7 (13.0%) victims had two bite wounds and 3 (5.5%) had more than two bite wounds. The median number

(interquartile range) of bite wounds was 1 (1, 3). One victim had more than 10 bite wounds. In 33 (61.1%) bite victims, site of bite was leg and feet, 20(37.0%) were over the arms, forearms and hand and 1 (1.9%) each had over the head/face and buttock. 31(57.4%) bite victims had abrasion, 16 (29.6%) bite victims had puncture wounds and 9 (16.7%) bite victims had lacerations. 29 (53.7%) bite victims had category-II bites and 25 (46.3%) bite victims had category-III bites (Table - 7) (Graph 1).



Graph 1: Description of Category of bites (n=54)

3.2.5. Details of biting animal and its vaccination status:

Table 8: Details of biting animal and its vaccination status

Characteristic	Details	Urban n=17	Rural n=37	Total n=54
Biting animal	Dog	11(64.7)	29(78.4)	40(74.1)
	Pet	7(63.6)	15(51.7)	22(55.0)
	Stray	4(36.4)	14(48.3)	18(45.0)
	Cat	6(35.3)	6(16.2)	12(22.2)
	Monkey/ Ox	-	2(5.4)	2(3.7)
If Dog, Vaccination status (n = 40)*	Unvaccinated	3(27.3)	16(55.2)	19(47.5)
	Partially Vaccinated	2(18.2)	2(6.9)	4(10.0)
	Do not know	6(54.5)	11(37.9)	17(42.5)
Availability of dog for 10 days(n=40)*	Yes	6(54.5)	20(68.9)	26(65.0)
Status of dog after 10 days (n=26)	Alive	6(100.0)	20(100.0)	26(100.0)
Rabies status of biting animal	Suspect rabid	17(100.0)	37(100.0)	54(100.0)

Figures in parenthesis indicate percentage *Urban (n=11) & Rural (n=29)

Dog was the main biting animal and responsible for 40 (74.1%) of the bites followed by 12(22.2%) bites from cats and 1 (1.8%) each due to monkey and Ox. Among dogs, 22(55.0%) of the exposures was by pet dogs and 18(45.0%) exposure were due to stray dogs.

19(47.5%) dogs were unvaccinated, 4(10.0%) were partially vaccinated and 17(42.5%) dogs vaccination status was not known. 26(65.0%) dogs were available for 10 days observation and all 26(100.0%) dogs were alive after 10 days of observation (Table- 8).

31(57.4%) bite victims were bitten by single animal and 10(25.0%) bite victims had informed that they were bitten by the same animal which had bitten another victim. 13(24.1%) bite victims did not know if the same animal had bitten another victim.

Among 949 respondents information available, 4(0.4%) mentioned that they had come across people who died from an illness they got within 3 months of being bitten by an animal excluding reptiles or birds, 4 (0.4%) respondents mentioned that they had come across people who died from rabies in their family anytime in the past and 22(2.6%) out of 846 respondents mentioned that they had come across people who had died from rabies in their community anytime in the past.

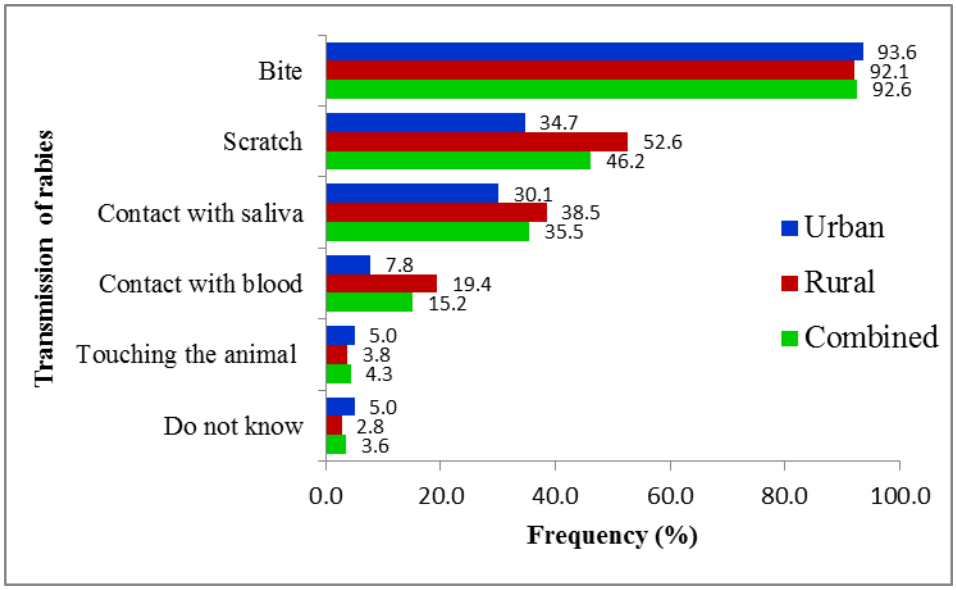
3.2.6. Awareness on rabies among respondents

Table 9: Rabies awareness among respondents (n = 1009)

Characteristics	**Details**	**Urban** n=323	**Rural** n=686	**Total** n=1009
Rabies awareness	Never heard of rabies	101(31.3)	297(43.3)	398(39.5)
	Little knowledge	128(39.6)	266(38.8)	394(39.1)
	Basic understanding	94(29.1)	121(17.6)	215(21.3)
	Extensive knowledge	-	2(0.3)	2(0.1)
Severity of Disease (n=611) [for those who had rabies awareness]		**n=219**	**n=392**	**n=611**
	Fatal	143(65.3)	298(76.0)	441(72.2)
	Recoverable	46(21.0)	49(12.5)	95(15.5)
	Mild	2(0.9)	9(2.3)	11(1.8)
	Do not know	28(12.7)	36(9.2)	64(10.5)
Transmission of rabies (n=611)* [for those who had rabies awareness]	Bite	205(93.6)	361(92.1)	566(92.6)
	Scratch	76(34.7)	206(52.6)	282(46.2)
	Contact with saliva	66(30.1)	151(38.5)	217(35.5)
	Contact with blood	17(7.8)	76(19.4)	93(15.2)
	Touching the animal	11(5.0)	15(3.8)	26(4.3)
	Do not know	11(5.0)	11(2.8)	22(3.6)

Figures in parenthesis indicate percentages
*Multiple response

398(39.5%) respondents had never heard of rabies, 394 (39.1%) respondents had little knowledge of rabies, 215 (21.3%) had basic understanding of rabies and only 2 (0.1%) had extensive knowledge of rabies (Table 9). Majority 441 (72.2%)respondents said rabies was a fatal disease and 95(15.5%) respondents said rabies is recoverable. 566 (92.6%) respondents said humans get rabies by bite, 282 (46.2%) mentioned by scratch and 217 (35.5%) contact with saliva (Graph 2).



Graph 2: Awareness on transmission of rabies (n=611)

3.2.7. Perception of rabies among respondents:

Table 10: Perceived health risk associated with animals among respondents

Animal	**Risk of rabies(n=610)** *[1=little to no risk & 5=high risk]*				
	1	**2**	**3**	**4**	**5**
Dog	34(5.6)	9(1.5)	50(8.2)	45(7.3)	472(77.4)
Cat	260(42.6)	39(6.4)	83(13.6)	92(15.1)	136(22.3)
Mongoose	405(66.4)	65(10.7)	52(8.5)	24(3.9)	64(10.5)
Rodents	383(62.8)	51(8.3)	33(5.4)	43(7.1)	100(16.4)
Monkey	324(53.1)	38(6.2)	61(10.0)	62(10.2)	125(20.5)
Bats	446(73.1)	44(7.2)	35(5.7)	37(6.1)	48(7.9)
Livestock	443(72.6)	57(9.4)	39(6.4)	39(6.4)	32(5.2)
Wild birds	472(77.4)	64(10.5)	27(4.4)	14(2.3)	33(5.4)
Snake	522(85.6)	28(4.6)	12(1.9)	9(1.5)	39(6.4)

Figures in parenthesis indicate percentage

Among the 610 respondents for whom information available on perceived risk of rabies from dogs, Majority 472 (77.4%) informed that risk of rabies was high and only 34(5.6%) respondents informed that there was little or no risk of rabies. Among the 610 respondents information available on risk of rabies from cats, Majority 260(42.6%) informed that there was little or no risk of rabies and only 136(22.3%) respondents informed that risk of rabies was high. Similarly, the perceived risk of rabies from mongoose, rodents, monkey, bats, livestock, wild birds and snake is given in Table 10.

Out of the 1006 respondents, 235(23.5%) had informed that they would wash wound with water & soap if they were bitten by a dog, that they recognise or own and 54(5.4%) respondents had informed that they would apply irritants/traditional medicine/salt, etc.

643(64.2%) respondents said that they would actively seek care at medical facility/rabies post-exposure prophylaxis and 86(8.6%) said that they would do nothing. When asked about what they will do to the dog, 285(28.5%) said would kill the dog and 227(22.7%) said would isolate the dog, 12(1.2%) said will inform concerned officials/municipality/panchayat/ veterinarian.

232 (23.2%) had informed that they would wash wound with water & soap if they were bitten by a dog that they do not recognize or own and 58 (5.8%) respondents had informed would apply irritants. 643 (63.9%) respondents said that they would actively seek care at medical facility/rabies post-exposure prophylaxis and 96 (9.6%) said would do nothing. When asked about what they will do the dog, 343 (34.3%) said would kill the dog, 98 (9.8%) said will isolate the dog, 19 (1.9%) said will inform concerned officials/ municipality /panchayat /veterinarian and 495 (49.5%) respondents said would do nothing to the dog.

160(15.9%) said that they would avoid the dog in their village which looked sick, 372(36.9%) respondents said would do nothing to the dog, 226(22.6%) respondents informed would kill the dog and 198(19.8%) said would inform veterinarian/health worker/municipality, etc.

3.2.8. Awareness and practice on rabies Pre-exposure Prophylaxis (PrEP):

Table 11: Awareness and Practice on rabies Pre-exposure Prophylaxis (PrEP)

Characteristics	**Details**	**Urban** n=322	**Rural** n=684	**Total** n=1006
Awareness of PrEP	Yes	16(4.9)	21(3.1)	37(3.7)
	3 doses of vaccine	9(56.2)	11(52.3)	20(54.1)
PrEP taken	3 doses administered	1(0.3)	2(0.3)	3(0.3)
Place of PrEP administration	Government facility	1(100.0)	1(50.0)	2(66.7)
	Private Facility	-	1(50.0)	1(33.3)

Figures in parenthesis indicate percentages

37(3.7%) respondents were aware about pre exposure prophylaxis, among them 20(54.1%) respondents mentioned 3 doses should be taken and 3(08.1%) respondents had actually taken pre exposure rabies vaccination (Table 11).

3.2.9. Health care accessibility:

Out of the 1009 respondents, 540 (53.5%) respondents had to travel 0-5kms to seek rabies PEP, 204(20.2%) respondents had to travel 6-10 kms, 134 (13.3%) had to travel 11-15 kms and 131(12.9%) had to travel more than 15 kms. The median distance travelled was 5(2,12) kms , in urban settings was 1(1,2) kms and rural settings was 7(3,15) kms. The minimum distance travelled was 0.1 kms and maximum was 65 kms.

For majority 458 (45.4%) of the respondents, the mode of transport was by bike/car/jeep/auto rickshaw, etc., 361(35.8%) travelled by bus, 186 (18.4%) mentioned by walk and least 03(0.3%) said ambulance.

Out of the 996 respondents, 542 (54.4%) respondents informed that they did not know/not aware of primary obstacle for rabies PEP, 223 (22.4%) respondents informed lack of facilities/medicines, 136(13.7%) respondents informed that there was no obstacle/nothing and 122 (12.2%) gave other reasons (fear of injection, waiting time, traditional healer, cost, can't miss work, no transport) .

3.2.10. Household dog ownership and rabies vaccination:

114 (11.3%) households had owned a dog, out of which 112(98.2%) households had pet dogs and 2(1.8%) were community dogs (Table 12). Majority 93 (83.1%) owned one dog per household and maximum number of dogs owned per household was 5. Majority 90(62.1%) of dogs were in the age group of 1-5 years,30 (20.7%) dogs were in the age group 6 years and above and least 25(17.2%) were less than one year old. The age range of the dogs was from less than one years old to 13 years old and the median age with interquartile range was 1(1,3) years.

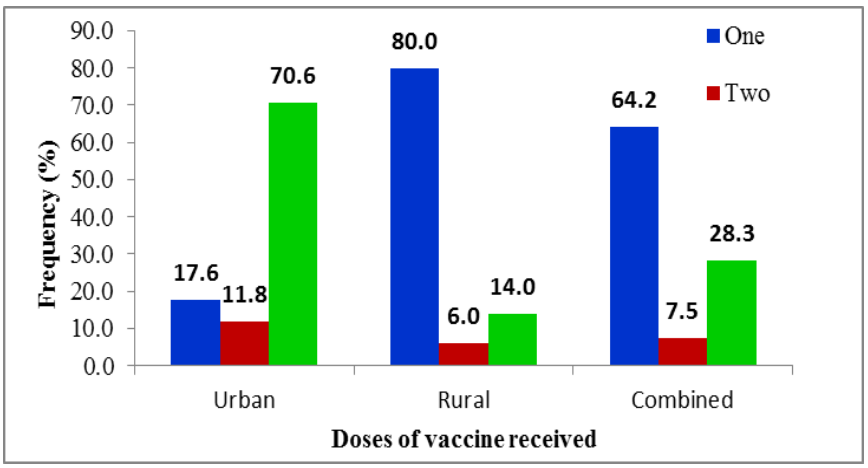
Out of 146 pet dogs among 114 households, 99 (67.8%) dogs were males and 47 (32.2%) dogs were females. All 146(100.0%) dogs were given food and water, 124(84.9%) dogs were given food, water & shelter.

69 (47.3%) of the dogs were administered rabies vaccine, 74(50.6%) of the dogs were not administered rabies vaccine and 3(2.1%) did not know. 45(65.2%) dogs had received one dose of rabies vaccine, 5(7.2%) had received two doses of rabies vaccine and 19(27.6%) dogs had received three and more doses of vaccine (Graph 3). The minimum and maximum number of rabies vaccine doses administered to the dogs was 1 and 8 respectively. The median number of rabies vaccine doses received with interquartile range was1 (1,3) doses. 3(4.3%) of the dogs were vaccinated in last one year. Only 4(5.8%) dog owners had vaccination card available with them. 66 (89.2%) mentioned not aware / no need to vaccinate/ too young/ healthy dog as reason for not getting rabies vaccine. 51(38.3%) respondents always allowed dogs to roam outside, 36(27.1%) respondents sometimes allowed dogs to roam freely outside and 46(34.6%) respondents dogs were always confined at home.

Table 12: Household dog ownership and rabies vaccination				
Characteristics	**Details**	**Urban n=19**	**Rural n=95**	**Total n=114**
Dog ownership in the households	Pet	18(94.7)	94(98.9)	112(98.2)
	Community	1(5.3)	1(1.1)	2(1.8)
Number of pet dogs in each household	One dog	17(94.4)	76(80.8)	93(83.1)
	Two dogs	1(5.6)	12(12.8)	13(11.6)
	Three and more dogs	-	6(6.4)	6(5.3)
114 households owned 146 dogs in total		**n=20**	**n=126**	**n=146**
Sex	Male	16(80.0)	83(65.9)	99(67.8)
	Female	4(20.0)	43(34.1)	47(32.2)
Type of care*	Food	20(100.0)	126(100.0)	146(100.0)
	Food,water,shelter	18(90.0)	106(84.1)	124(84.9)
	Food and water	2(10.0)	15(11.9)	17(11.6)
	Veterinary care	17(85.0)	33(26.2)	50(34.2)
Vaccination of Dog	Yes	17(85.0)	52(41.3)	69(47.3)
	No	2(10.0)	72(57.1)	74(50.6)
	Do not know	1(5.0)	2(1.6)	3(2.1)
If yes, no. of vaccine doses received	Number	**n=17**	**n=52**	**n=69**
	One	3(17.6)	42(80.8)	45(65.2)
	Two	2(11.8)	3(5.7)	5(7.2)
	Three and more	12(70.6)	7(13.5)	19(27.6)
Vaccination of dog in last one year	Yes	3(17.6)	-	3(4.3)
Vaccination card verified	Yes	4(23.5)	-	4(5.8)
If no, Reason for dog not vaccinated*		**n=2**	**n=72**	**n=74**
	Not aware/ No need to vaccinate/ Too young/ healthy dog	2 (100.0)	64(88.9)	66(89.2)
	No money/ No Time/ No transport	-	3(4.2)	3(4.0)
	No vaccine available	-	1(1.4)	1(1.3)
Dog confinement **		**n=19**	**n=114**	**n=133**
	Always allowed to roam freely outside	-	51(44.8)	51(38.3)
	Sometimes allowed to roam freely outside	6(31.6)	30(26.3)	36(27.1)
	Always confined at home	13(68.4)	33(28.9)	46(34.6)

Figures in parenthesis indicate percentages

* multiple responses possible ** Only available data was included



Graph 3: Doses of rabies vaccination in dogs (n=146)

21 (2.1%) households (n=1012) had acquired 23 new dogs in last one year, 10 (43.5%) dogs were obtained from within the community and 10 (43.5%) dogs from outside the community and 3 (13.0%) dogs no information available. Out of 114 households, 4(3.5%) dogs had given birth to 17 puppies in the past.

150(14.8%) households cared for 371 dogs in the community that they do not own. The minimum and maximum number of community dogs cared by the respondents was 1 and 12 dogs respectively. The median number with interquartile range for community dogs cared was 1(1,3). All 371 (100.0%) dogs were given food, 2(1.3%) dogs were given food, water & shelter and 1(0.6%) food water and veterinary care.

3.2.11. Dog rabies incidence:

20 (13.7%) dog deaths were observed among households with dogs (n=146). 12(60%) dogs had died due to Disease/ Illness, 2(10%) dogs had died due to age related cause and 1 (5%) dog each had died due to eaten by leopard, hit by vehicle, killed by gun shot, hurt by stone, killed for food and do not know. Among the 12 dogs that had died due to disease/illness, Majority 8(66.7%%) dogs had clinical symptoms of hyper salivation and 3(25%) dogs each had symptoms of aggression, walking with difficulty and change in dogs barking, 2(16.7%) each mentioned signs of tremors and do not know and 1(8.3%)dog had infection. Laboratory confirmation of cause of death was not done in any of the dogs.

3.2.12. Human rabies incidence:

There was no case of human rabies reported by respondents in the last one year.

3.2.13 Limitation:

1. The sample size of 4924 was calculated based on assumption of 5 persons per household with 1008 households to be surveyed. However, a total of 1012 households were surveyed and only 4294 persons were available (4.24 persons per households).
2. Due to technical problem encountered with the software at some places, the data was incomplete in some aspects.

3.3. 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.

3.3.1. Post exposure prophylaxis (PEP) seeking behaviour of animal bite victims from community survey:

Among 4294 surveyed population, 54 (1.26%) had animal bites in the last one year. The PEP seeking behaviour of the bite victims are provided in Table 13. The socio demographic profile, bite details and biting animal are provided in Table 6.

Table 13: PEP seeking behaviour of animal bite victims

Characteristic	Details	Urban n=17	Rural n=37	Total n=54
Wound care *	Water and soap	9(52.9)	10(27)	19(35.2)
	Water	3(17.6)	5(13.5)	8(14.8)
	Nothing	1(5.9)	7(18.9)	8(14.8)
	Applied irritants /consulted traditional healer	1(5.9)	7(18.9)	8(14.8)
Sought PEP at health facility	Yes	15(88.2)	33(89.2)	48(88.9)
	No	2(11.8)	4(10.8)	6(11.1)
Reason for not seeking PEP (n=3) *	Not aware/ do not know	2(33.3)	1(16.6)	3(50.0)
	No need to go to hospital	-	2(33.3)	2(33.3)
Time gap for availing PEP (n=48)$	< 1 day	13(86.6)	24(72.8)	37(77.1)
	1-2 Days	2(13.4)	5(15.1)	7(14.6)
	3 days +	-	4(12.1)	4(8.3)

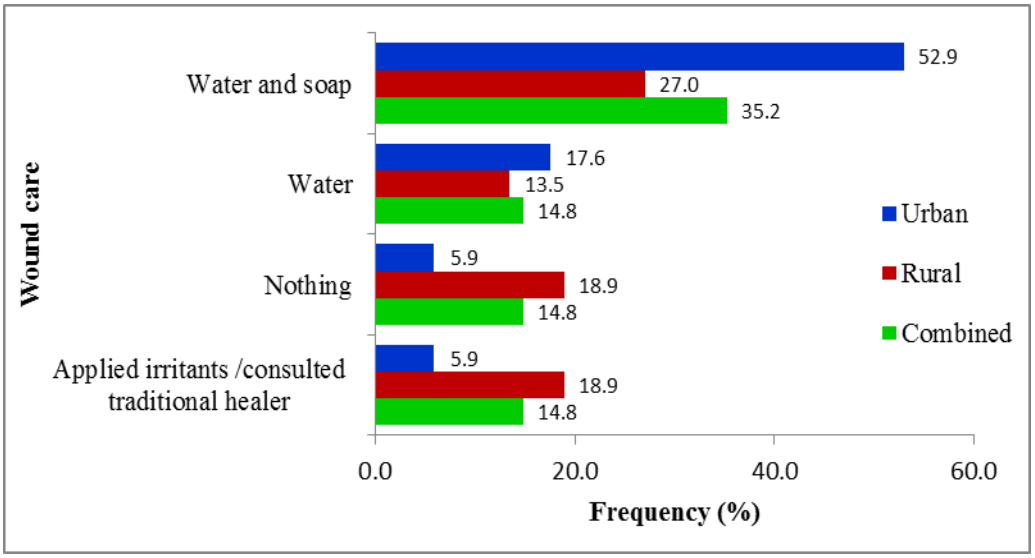
Figures in parenthesis indicate percentages

* Multiple response . $ Urban (n=15),Rural(n=33)

Among 54 animal bite victims, 19 (35.2%) bite victims had washed the wounds with water and soap and 8 (14.8%) had applied irritants (Graph 4). Majority 37 (77.1%) of the bite victims had sought PEP within 24 hours of the bite, 7(14.6%) within 1-2 days after bite and 4(8.3%) bite victims had sought care after more than two days. The median duration in hours between bite and rabies vaccination was 4 (2,10) hours and the median duration in days between bite and PEP was 2 (2,3).

29 bite victims had category II exposure, of whom 14 (48.3%) had completed either 5 doses of intramuscular or 4 doses of intradermal vaccination. Out of the 25 category III exposure victims, 4 (16%) had received rabies immunoglobulin and rabies vaccination, of whom 3 (75.0%) had received ERIG and 1 (25.0%) had received HRIG**.**

Out of 54 animals bite victims, 48 (88.9%) had sought PEP at the health facility and among those who had visited the health facility, 5 (10.4%) were not advised PEP.



Graph 4: Description of wound care of bite victim (n=54)

Table 14: Rabies vaccination and RIG administration to animal bite victims

Characteristics	**Details**	**Urban n=13**	**Rural n=30**	**Total n=43**
Site of vaccine administration	Deltoid	13(100.0)	27(90.0)	40(93.0)
	Gluteal	-	3(10.0)	3(7.0)
Number of Doses	1	-	4(13.3)	4(9.3)
	3	2(15.4)	6(20.0)	8(18.6)
	4	6(46.1)	12(40.0)	18(41.9)
	5	5(38.5)	8(26.7)	13(30.2)
Health Facility visited	Government	9(69.2)	26(86.7)	35(81.4)
	Private	4(30.8)	4(13.3)	8(18.6)
Category-III wounds (n=22)		**6(23.0)**	**16(77.0)**	**22(100.0)**
Rabies Immunoglobulin(n=4)#	Yes	1(16.7)	3(18.7)	4(18.2)
	ERIG	1(100.0)	2(66.7)	3(75.0)
	HRIG	-	1(33.3)	1(25.0)
Site of administration(n=4)#	Into the wound	1(100.0)	1(33.3)	2(50.0)
	Deltoid	-	2(66.7)	2(50.0)

Figures in parenthesis indicate percentages; #Urban (n=1), Rural (n=3)

Among 43 bite victims (79.6%) who received post exposure prophylaxis, 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, 4(18.2%) had received rabies immunoglobulin and rabies vaccination, of whom 3 (75.0%) had received ERIG and 1(25.0%) had received HRIG**.**

Majority 40 (93.0%) had taken vaccine in the deltoid and 3 (7.0%) had taken vaccine in the gluteal region. 35 (81.4%) bite victims had visited government hospitals for rabies vaccination and 8 (18.6%) had visited private hospitals (Table 14).

3.3.1.1: Cost analysis of post exposure prophylaxis

Among 22 category III exposures, Only 4 (18.2%) had received rabies immunoglobulin and rabies vaccination, of whom 3 (75.0%) had received ERIG and 1(25.0%) had received HRIG**.** The cost of PEP is as follows:

Table 15: Cost analysis of PEP (RIG+ARV)

Cost of RIG +ARV	**HRIG (n=1) in INR**	**ERIG (n=3) in INR**	
Direct cost			
• RIG	9901	313**	
• Rabies vaccine	IDRV (n=1)	IDRV (n=1)	IMRV (n=2)
	128*	128	Government =128 Private =1748
• Other medicine/consultation	120	-	600
Indirect cost (Travel)	2400	50	300
Total	12,549	178	3089
Cost per person	**12,549**	**491**	**1,545**

* Notional IDRV cost= INR128, ** Notional ERIG cost= INR 313, 1 USD= INR 64.03

From the Table 15, it was observed that the total cost of PEP for a person who took HRIG & IDRV was INR 12,549 (196 $); ERIG & IDRV per person was INR 491 (8 $); ERIG & IMRV per person was INR 1,545 (24 $).

Among 43 bite victims, 39 had received only anti rabies vaccination and the cost for those is as follows:

Table 16: Notional cost analysis of ARV only (n =39)

Cost of ARV	**IDRV (n=18) in INR**	**IMRV(n=21) in INR**
Direct cost		
• ARV	=128x18=2304	Government = 128 x 5 x 10=6400 Private =16885 *
• Other medicine/consultation	10	1315
Indirect cost (Travel)	6050	4960
Total	8364	29,560
Cost per person	**465**	**1,408**

*Number of bite victims=Day-0=12, Day-3=10, Day-7=10, Day-14=7,Day-28=5

From Table 16, it was observed that the notional cost of complete course of ARV per person for IDRV was INR 465 (7$) and IMRV was INR 1408 (22$)

3.3.1.2 Limitations:

1) Resurvey was done in 50 households. [Gujarat (n=2), Madhya Pradesh (n=34), Himachal Pradesh (n=6), Kerala (n=8)] as there was error in uploading data on to PDA of the community survey software.
2) Analysis was done only on data that was complete in all aspects.
3) Stray dogs were not enumerated in the survey.

References:

1. Census of India 2011. Available from www.censusindia.gov.in.
2. Training for mid-level managers (MLM) Module 7: The EPI coverage survey. Immunization, Vaccines and Biologicals. World Health Organization 2008; 1-80.

3.3.2. Post exposure prophylaxis (PEP) seeking behaviour of individuals who had been exposed to rabies suspected animals and came to health facility:

The health facility survey included 529 animal bite cases that came for post exposure prophylaxis at 21 health care facilities (14 rural and 7 urban / 18 government and 3 private) in the project states, across the country.

3.3.2.1 Socio demographic characteristics of the exposed individuals:

Table 17: Socio demographic characteristics of the exposed individuals (n = 529)

Socio demographic characteristics		Urban (n=181)	Rural (n=348)	Total (n=529)
Age	≤14	33(18.2)	82(23.6)	115(21.7)
	15-59	120(66.3)	233(66.9)	353(66.7)
	≥60	28(15.5)	33(09.5)	61(11.6)
Sex	Male	101(55.8)	217(62.4)	318(60.1)
	Female	80(44.2)	131(37.6)	211(39.9)
Educational Status	Illiterate	24(13.3)	73(20.9)	97(18.3)
	School/ Pre-university	134(74.0)	257(73.9)	391(73.9)
	Graduate/ Post-Graduate	23(12.7)	18(05.2)	41(07.8)
Occupation	Cultivator/Agricultural / Non- agricultural labourer	49(27.1)	103(29.6)	152(28.7)
	Business	18(9.9)	28(8.1)	46(08.7)
	Salaried employment	24(13.3)	31(8.9)	55(10.4)
	House work	45(24.9)	58(16.7)	103(19.5)
	Student	35(19.3)	106(30.4)	141(26.6)
	Unemployed	10(5.5)	22(6.3)	32(06.1)

Figures in parenthesis indicates percentage

Among 529 study subjects, 348 (65.8%) were from rural areas and 181(34.2%) from urban areas. Majority of the bite victims were from the age group of 15-59 years (66.7%), followed by children ≤ 14 years (21.7%) and elderly ≥ 60 years (11.6%).

Among these bite victims, 60.1% were males and 39.9% were females and many of them (73.9%) had completed schooling/ pre-university. Most of them belonged to working group such as agricultural/ non-agricultural labourers (28.7%), salaried (10.4%) and business (8.7%), followed by students (26.6%) and household work (19.5%) (Table 17).

3.3.2.2 Characteristics of the biting animal:

The study showed that majority of the biting animals were dog (68.6%) followed by cat (25.3%) and monkey (4.5%). Among the biting animals, only 8.7% were known to be vaccinated against rabies. As per the information provided by the study subjects, 29.5% of the biting animals showed some signs of suspected rabies such as aggression, hyper salivation, biting other animals and changes in dog bark; but none of the biting animal was proven to be rabid (Table 18).

Table 18: Characteristics of the biting animal (n = 529)			
Characteristics of biting animal		**Number**	**Percentage**
Biting/exposed animal	Dog **(n=363)**		
	• Pet (Owned)	112	30.9
	• Stray (Unowned)	251	69.1
	Cat	134	25.3
	Monkey	24	4.5
	Jackal	3	0.6
	Cow	3	0.6
	Mongoose	2	0.4
Vaccination status of biting animal (Dog/ Cat) (n=497)	Vaccinated	43	8.7
	Not vaccinated	235	47.2
	Don't know	219	44.1
Signs of rabies in biting animal*	Aggression	141	26.7
	Hyper salivation	5	0.9
	Biting other animal	6	1.1
	Changes in dog bark	4	0.8
	None	171	32.3
	Don't know	210	39.7
Fate of biting animal	Nothing happened	351	66.4
	Escaped	60	11.3
	Killed	8	1.5
	Isolation	1	0.2
	Don't know	109	20.6

*Multiple responses

Among the biting animals, only 31 dogs/ cats were followed-up due to logistical reasons/feasibility for 14 days by the veterinary team to know the rabid status of the biting animal. All the observed animals were healthy and alive after 14 days of quarantine.

3.3.2.3 Characteristics of Exposure:

Table 19: Characteristics of Exposure (n = 529)			
Characteristics of Exposure		**Number**	**Percentage**
Type of Exposure*	Bite	275	51.9
	Scratch	224	42.3
	Lick on wound	19	3.6
	Lick on intact skin	15	2.8
	Contact with mucous membrane	2	0.4
Site of Exposure *	Lower limb	320	60.5
	Upper limb	157	29.7
	Head, neck & face	25	4.7
	Trunk	24	4.5
	Genitals	12	2.3
Place of bite	Home	184	34.8
	Outside of home	345	65.2
Circumstance of bite	Provoked	134	25.3
	Unprovoked	274	51.8
	Don't know	121	22.9

*Multiple responses

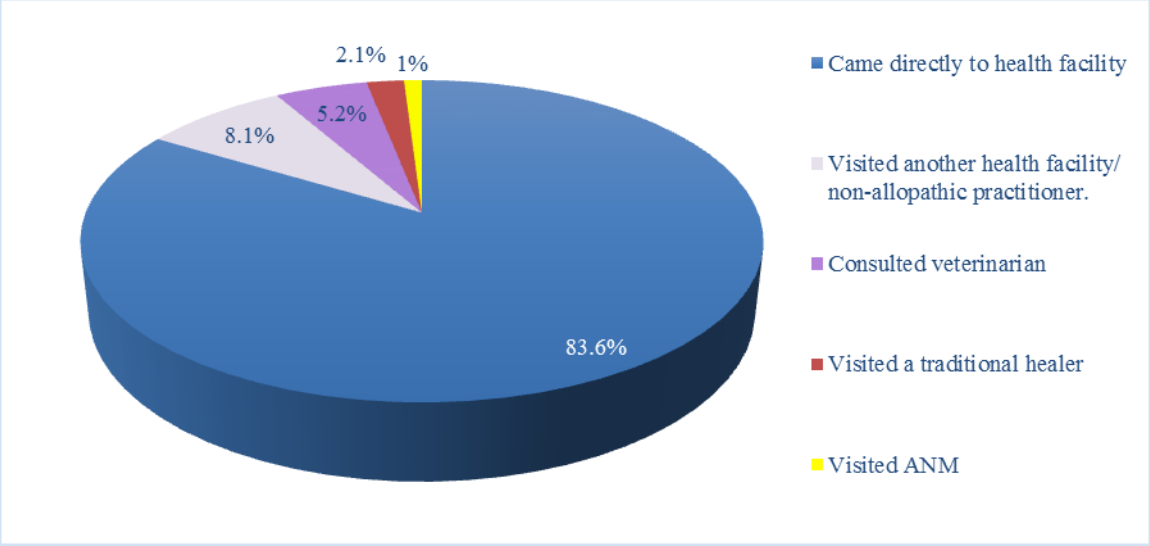
Majority of the exposures were bites/ lacerations (51.9%) followed by scratches/ abrasions (42.3%). The commonest site of bite was on lower limb (60.5%) followed by upper limb (29.7%), head, neck and face (4.7%), trunk (4.5%) and genitals (2.3%). Most of these bites (51.8%) were unprovoked and 65.2% of the bites occurred outside the home (Table 19).

3.3.2.4 Post exposure prophylaxis seeking behaviour of the exposed:

Table 20: PEP seeking behaviour of the exposed (n = 529)

Post exposure prophylaxis		**Number**	**Percentage**
Wound/s washed	Water	133	25.1
	Water & Soap	203	38.4
	No	174	32.9
	Not sure (children)	19	3.6
Local antiseptics applied	Yes	91	17.2
	No	396	74.9
	Don't know (children)	42	7.9
Irritants applied to wound/s (n=124)	Turmeric/coffee/chilli powder	73	13.8
	Plant sap/ coin	20	3.8
	Cow dung/ Mud	3	0.6
	Calcium carbonate (lime)	28	5.3
Action taken before coming to health facility	Came directly to health facility	442	83.6
	Visited another health facility / non-allopathic practitioner.	43	8.1
	Consulted veterinarian	28	5.2
	Visited a traditional healer	11	2.1
	Visited ANM	5	1.0

Among the study subjects, only 63.5% washed their wound/s with water/ soap and water and 17.2% of them had applied some local antiseptics after washing. On the contrary, 23.5% of them applied irritants such as turmeric/ coffee/ chilli powder/ plant sap/ coin/ cow dung/ mud/ lime to the bite wound/s (Table 20).



Graph 5: Action taken before coming to health facility

Among the exposed individuals, 83.6% sought post exposure prophylaxis coming directly to the health facility, the remaining 16.4% visited another health facility (non-allopathic)/ traditional healers/ consulted veterinarians/ ANMs (Table 20) (Graph 5).

3.3.2.5. Knowledge, Attitude and Practice (KAP) on prophylaxis against rabies

Table 21: Knowledge, Attitude and Practice (KAP) on prophylaxis against rabies

Knowledge, Attitude and Practice	Correct KAP	Percentage
Heard of rabies (n=529)	403	76.2
Severity of the disease (n=403)	265	65.8
Risk of transmission of rabies according to the type of exposure* (n=403)		
▪ Bite with bleeding	308	76.4
▪ Scratch without bleeding	99	24.6
▪ Contact with blood of infected	91	22.6
▪ Contact with saliva of infected	93	23.1
▪ Contact with urine/ faeces of infected	45	11.2
Practice after exposure to animals* (n=403)		
▪ Wash wound with water	119	29.5
▪ Wash wound with water and soap	141	35.0
▪ Consulting a medical doctor	145	36.0
▪ Seeking care at medical facility	145	36.0
▪ Seeking post exposure prophylaxis	145	36.0
Doses of anti-rabies vaccine for PEP (n=403)	148	36.7
Knowledge about rabies immunoglobulin (n=403)	83	20.6
Timing of vaccination against rabies (n=403)	297	73.7
Doses of anti-rabies vaccine for PrEP (n=403)	27	6.7

*Multiple responses

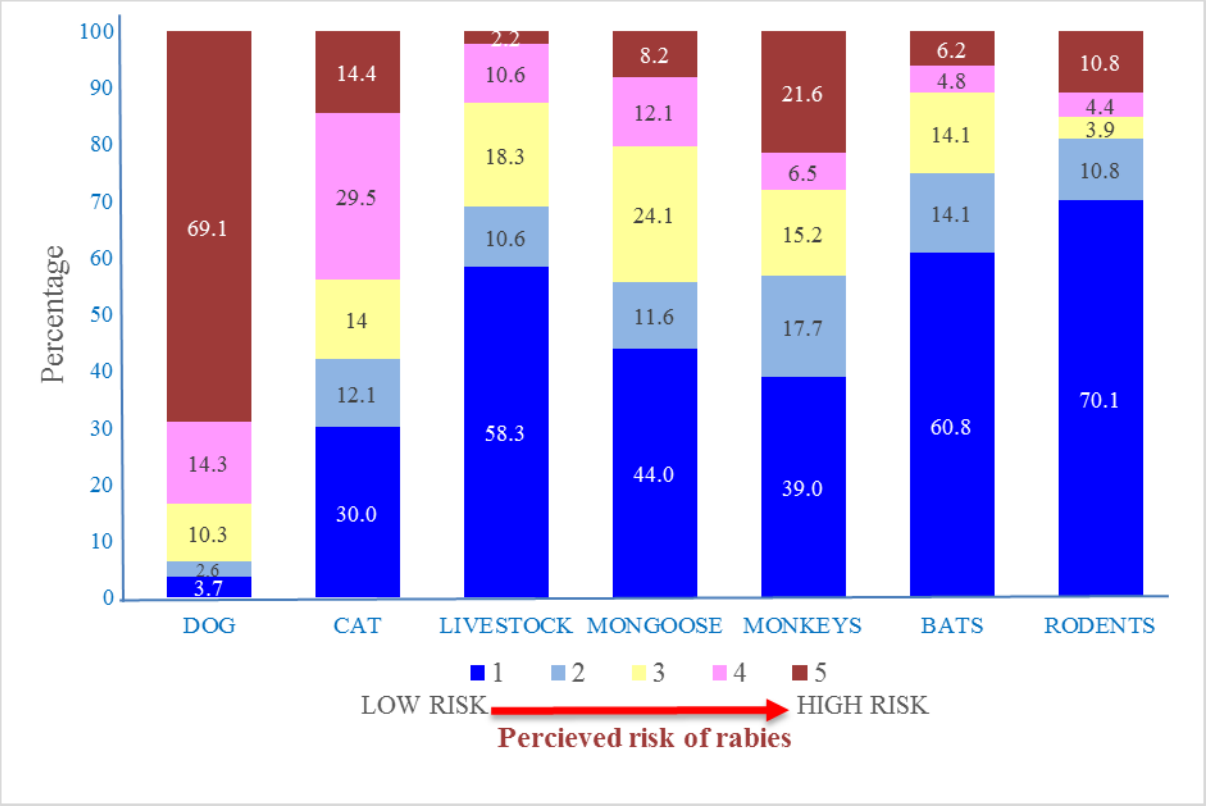
Among the 529 study subjects, 76.2% had heard about rabies; out of which 65.8% knew about the severity of the disease. The knowledge about risk of rabies transmission by type of injury/ exposure was inadequate.

The practice followed after the exposure was insufficient with regards to wound wash and seeking post exposure prophylaxis. Similarly, only 36.7% of the study subjects had knowledge about correct dose of anti-rabies vaccine for post exposure prophylaxis and only 20.6% knew that rabies immunoglobulin has to be given to all bite wounds with bleeding to prevent rabies. Most of them i.e., 73.7% of them were aware of receiving post exposure vaccination on time; but only 6.7% of them knew about pre exposure vaccination (Table 21).

3.3.2.6 Perception on rabies among those exposed

The perceived risk of rabies from different animals varied from no/ little risk of rabies to very high risk of rabies among the study subjects as shown in Table 22 & Graph 6.

Table 22: Perceived risk of rabies from different animals among the exposed					
Biting animal	**Perceived risk of rabies** 1 = No / little risk of rabies → 5 = very high risk of rabies				
	1	**2**	**3**	**4**	**5**
Dog (n=349)	13 (3.7%)	9 (2.6%)	36 (10.3%)	50 (14.3%)	241(69.1%)
Cat (n=257)	77 (30.0%)	31 (12.1%)	36 (14.0%)	76 (29.5%)	37 (14.4%)
Livestock (n=235)	137 (58.3%)	25 (10.6%)	43 (18.3%)	25 (10.6%)	5 (2.2%)
Mongoose (n=232)	102 (44.0%)	27 (11.6%)	56 (24.1%)	28 (12.1%)	19 (8.2%)
Monkeys (n=231)	90 (39.0%)	41 (17.7%)	35 (15.2%)	15 (6.5%)	50 (21.6%)
Bats (n=227)	138 (60.8%)	32 (14.1%)	32 (14.1%)	11 (4.8%)	14 (6.2%)
Rodents (n=231)	162 (70.1%)	25 (10.8%)	9 (3.9%)	10 (4.4%)	25 (10.8%)



Graph 6: Perceived risk of rabies from different animals among the exposed

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

All the 529 animal bite cases were provided post exposure prophylaxis at the respective health facilities. The following are the details of PEP provided compliance to vaccination by different routes in different settings; factors that influence incomplete vaccination course and cost incurred to patient / health facility.

3.4.1 Post exposure prophylaxis provided at the health facility:

3.4.1.1 Details of post exposure prophylaxis

Table 23: Post exposure prophylaxis provided at the health facility (n = 529)			
Post exposure prophylaxis		**Number**	**Percentage**
WHO exposure category	I	13	2.5
	II	228	43.1
	III	288	54.4
Anti - rabies vaccine			
Route of administration	**IM**	173	32.7
	ID	356	67.3
Brand of ARV	Abhayrab (PVRV)	359	67.9
	Rabipur (PCECV)	128	24.2
	Vaxirab N (PCECV)	42	7.9
Rabies Immunoglobulin: Category III exposures (n=288)			
Administered	Yes	133	46.2
	No	155	53.8
Type & brand (n =133)	**HRIG:** Berirab P	4	3.0
	PlasmaRab	2	1.5
	ERIG: Equirab	112	84.2
	Premirab	15	11.3
Site of administration (n =133)	Exclusive local infiltration	75	56.4
	Local & systemic	55	41.3
	Only systemic injection	3	2.3
Other treatment given* (n = 529)	Wound irrigation	207	39.1
	Wound dressing	127	24.0
	Tetanus toxoid	379	71.6
	Antibiotics	149	28.2
	Pain medication	128	24.2
	Admission to hospital	10	1.9
	Suturing	6	1.1

*****Multiple responses

The present study showed that majority of the exposed individuals coming to health facility had category III exposures (54.4%), followed by category II exposures (43.1%).

All the study subjects received anti rabies vaccination; among them 67.3% received by intradermal route and 32.7% by intramuscular route. Since all 13 Category I exposures were apprehensive about the animal exposure, they were also provided anti rabies vaccination.

Among the category III exposures, only 46.2% individuals were infiltrated with rabies immunoglobulin, because of short/ no supply & severity of the wounds; majority with equine rabies immunoglobulin (95.5%) and only 4.5% with human rabies immunoglobulin. Rabies immunoglobulin was infiltrated exclusively local in 56.4%; both local & systemic in 41.3% and only systemic injection in 2.3% (Table 23).

3.4.1.2 Adverse drug events following post exposure prophylaxis:

Table 24: Adverse drug events following post exposure prophylaxis (n = 529)

Adverse drug events	**Number**	**Percentage**
Yes	75	14.2
No	454	85.8
Type of adverse drug events*		
Pain	34	6.4
Itching	34	6.4
Redness	32	6.1
Swelling	15	2.8
Headache	8	1.5
Bodyache	8	1.5
Numbness	5	0.9
Nausea	5	0.9
Malaise	4	0.8
Rash	3	0.6
Fever	3	0.6
Joint pain	1	0.2

*Multiple responses

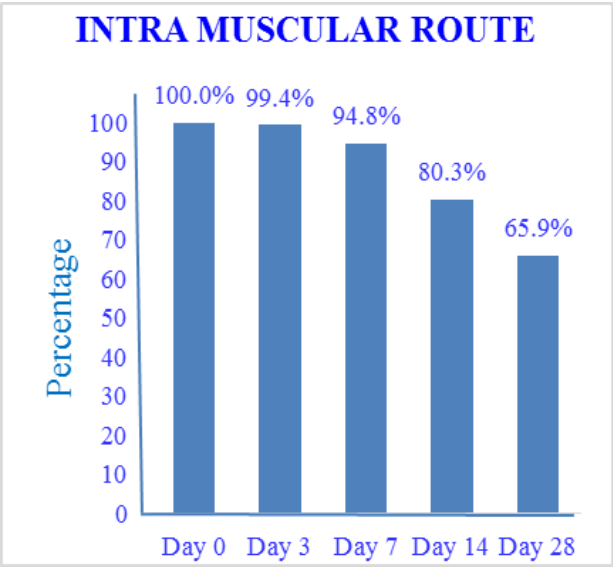
Among the individuals who received post exposure prophylaxis at the health facility, 14.2% had minor adverse drug events viz. pain, numbness, itching, redness, rash, headache, body ache, malaise, nausea and fever which subsided with/ without medication (Table 24).

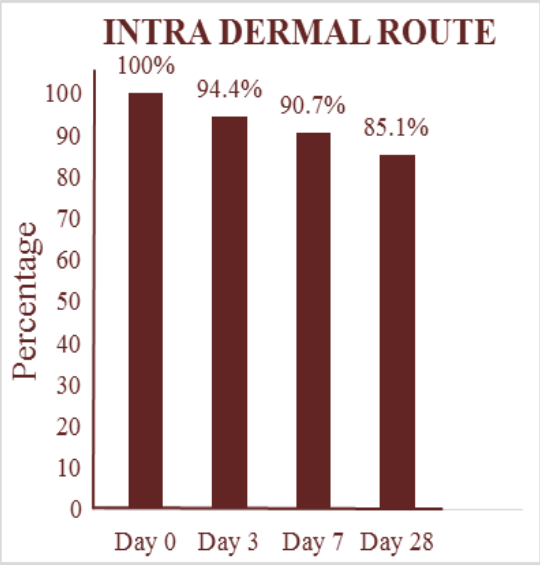
3.4.1.3. Compliance to post exposure vaccination among the bite victims

Table 25: Compliance to post exposure vaccination among bite victims (n = 529)

Vaccine schedule	**Intramuscular vaccination Essen Regimen (n =173)**		**Intradermal vaccination Updated TRC (n = 356)**	
	Number	**Percentage**	**Number**	**Percentage**
Day 0	173	100	356	100
Day 3	172	99.4	336	94.4
Day 7	164	94.8	323	90.7
Day 14	139	80.3	NA*	NA*
Day 28	114	65.9	303	85.1

***** NA=Not applicable, since there is no day 14 dose for intradermal rabies vaccination



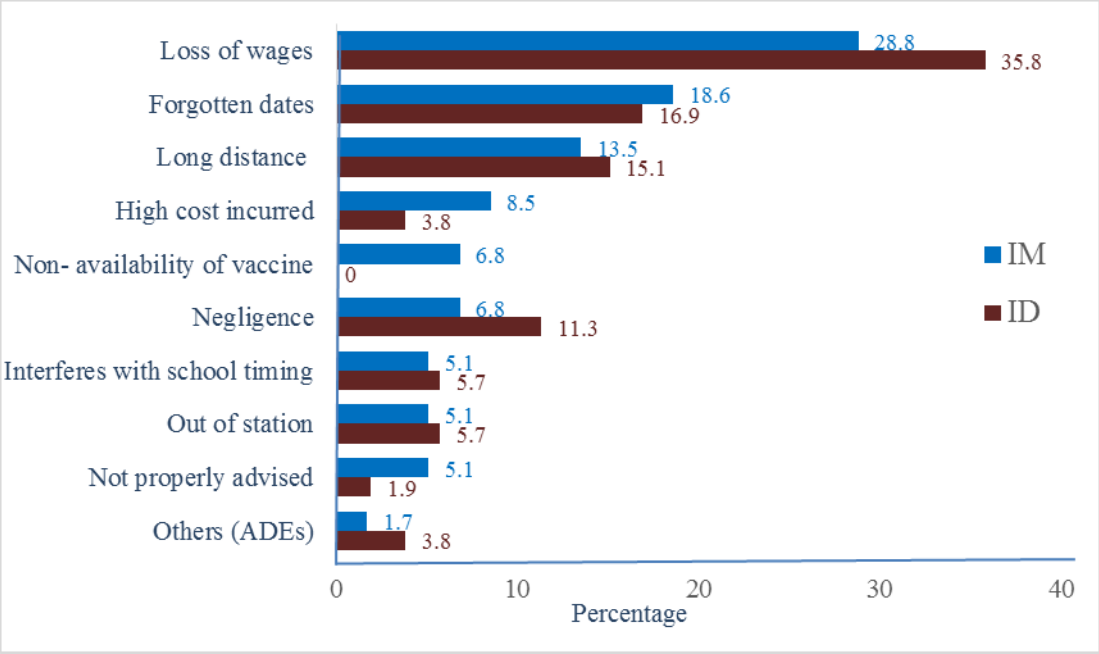


Graph 7 & 8: Compliance to post exposure vaccination by different routes

The compliance rate for full course of intramuscular rabies vaccination (IMRV) was 65.9% and that for intradermal rabies vaccination (IDRV) was 85.1% (Table 25; Graph 7 & 8). The compliance to intradermal route was found to be higher as compared to intramuscular route and the difference was found to be statistically significant ($\chi^2 = 25.76$, $P < 0.005$).

Table 26: Factors contributing to poor compliance/ incomplete vaccination

Contributing factors	**Intramuscular vaccination Essen regimen (n = 59)**		**Intradermal vaccination Updated TRC (n = 53)**	
	Number	Percentage	Number	Percentage
Loss of wages	17	28.8	19	35.8
Forgotten dates	11	18.6	9	16.9
Long distance	8	13.5	8	15.1
High cost incurred	5	8.5	2	3.8
Non- availability of vaccine	4	6.8	0	0
Negligence	4	6.8	6	11.3
Interferes with school timing	3	5.1	3	5.7
Out of station	3	5.1	3	5.7
Not properly advised	3	5.1	1	1.9
Others (ADEs)	1	1.7	2	3.8



Graph 9: Factors contributing to incomplete vaccination

The factors influencing the incomplete vaccination course were loss of wages, forgotten dates, long distance for health facility, high cost incurred, non-availability of vaccines, negligence, interference with school timings, out of station and not properly advised (Table 26 & Graph 9).

3.4.1.4. Cost Incurred for post exposure prophylaxis

Table 27: Cost incurred for post exposure prophylaxis at the Government health facility

Cost of PEP (INR)	**Day 0** Median (Q3-Q1)	**Day 3** Median (Q3-Q1)	**Day 7** Median (Q3-Q1)	**Day 14** Median (Q3-Q1)	**Day 28** Median (Q3-Q1)	**Total** Median Q3-Q1)
Direct Cost (INR)						
Anti rabies vaccine	0*	0*	0*	0*	0*	0*
Rabies Immunoglobulin	0*	0*	0*	0*	0*	0*
Hospital Charges	3 (2-200)	2 (2-118)	2 (2-77)	2 (2-77)	2 (2-77)	3 (2-10)
Other Medicines & disposables	165 (150-200)	0	0	0	0	165 (150-200)
Total	170 (87-200)	2 (2-118)	2 (2-77)	2 (2-77)	2 (2-77)	182 (80-200)
Indirect Cost (INR)						
Travel for the patient & attendants	50 (30-74)	50 (30-74)	50 (30-70)	50 (50-80)	50 (28-60)	250 (150-358)
Food for the patient & attendants	40 (20-100)	40 (20-100)	40 (20-100)	0 (0-30)	40 (20-60)	160 (80-390)
Loss of wages for the patient & attendants	200 (200-400)	200 (185-350)	200 (200-350)	0 (0-200)	200 (200-400)	800 (785-1700)
Total	260 (250-420)	260 (250-420)	260 (250-420)	50 (0-200)	260 (250-420)	1250 (900-1800)
Grand Total	445 (350-520)	325 (250-400)	325 (250-400)	90 (50-120)	325 (250-400)	1400 (1180-1584)

*Provided free of cost by the Government health facility

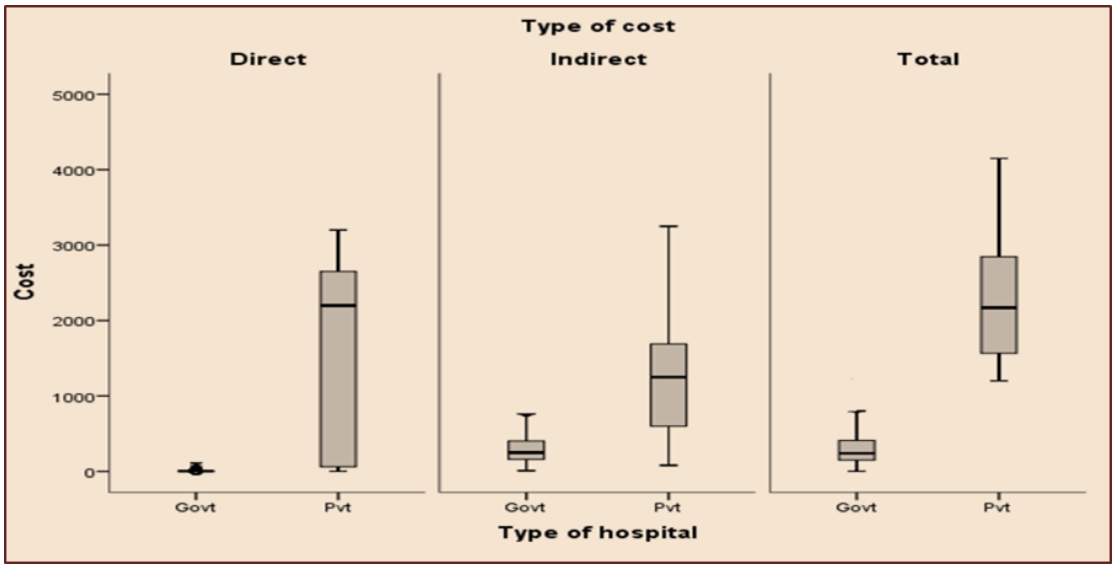
The total median cost incurred to the patients for availing post exposure prophylaxis in the government health facility, where both anti rabies vaccine & rabies immunoglobulin were provided free of cost was INR. 1400 (USD 22) with inter - quartile range of INR.980-1584.

The expenditure made by the government health facility for providing both anti rabies vaccine & rabies immunoglobulin was also estimated. The cost for providing intramuscular Essen regimen was calculated for 5 doses of vaccine and equine rabies immunoglobulin for all category III exposures [the amount of rabies immunoglobulin required is 1 vial (5 ml) for children $\leq$ 14 years and 2 vials (>5–10 ml) for adults]. The respective state government purchases the rabies biologicals by the lowest bidding procedure and as per the information available, the average cost of vaccine purchased in study states was INR.128/ dose (USD 2 @ 1 USD = INR. 63.5) and rabies immunoglobulin was INR. 313/ vial (USD 5 @ 1 USD = INR. 63.5) (Annexure 4.28 & 4.29). Hence the health facility will be spending INR.640 for 5 doses of vaccines and INR. 548 for equine rabies immunoglobulin (considering $1/4^{th}$ of the bite victims as children as per the survey results). Therefore, the total cost for post exposure prophylaxis spent by the government health facility for intramuscular vaccination and equine rabies immunoglobulin for each category III exposure was about INR.1188 (USD 19) and for each category II exposure was INR.640 (USD 10).

Similarly, the estimated cost for providing intradermal rabies vaccination by Updated TRC regimen was calculated. The total amount of vaccine required for complete course of post exposure prophylaxis per person was around 1 ml (0.2 x 4 doses = 0.8 ml $\simeq$ 1 vial including wastage). Hence the government will be spending INR.128 for anti-rabies vaccine and INR. 548 for equine rabies immunoglobulin. Therefore, the total cost for post exposure prophylaxis spent by the government health care for intradermal vaccination and equine rabies immunoglobulin for each category III exposure was about INR.676 (USD 10.5) and for category II exposure was INR. 128 (USD 2) (Table 27).

Table 28: Cost incurred for post exposure prophylaxis at the private health facility						
Cost of PEP (INR)	**Day 0** Median (Q3-Q1)	**Day 3** Median (Q3-Q1)	**Day 7** Median (Q3-Q1)	**Day 14** Median (Q3-Q1)	**Day 28** Median (Q3-Q1)	**Total** Median (Q3-Q1)
Direct Cost (INR)						
Anti rabies vaccine	325 (325-350)	325 (325-350)	325 (325-350)	325 (325-350)	325 (325-350)	1625 (1625-1750)
Rabies Immunoglobulin	651 (465-930)	**0**	**0**	**0**	**0**	651 (465-930)
Hospital Charges	160 (40-200)	160 (40-200)	160 (40-200)	160 (40-200)	160 (40-200)	750 (180-920)
Other Medicines	195 (150-215)	**0**	0	**0**	**0**	195 (150-215)
Total	1150 (560-1610)	485 (365-550)	485 (365-550)	485 (365-550)	485 (365-550)	3104 (1180-3662)
Indirect Cost (INR)						
Travel for the patient & attendants	50 (30-74)	50 (30-74)	50 (30-70)	50 (50-80)	50 (28-60)	250 (150-358)
Food for the patient & attendants	40 (20-100)	40 (20-100)	40 (20-100)	0 (0-30)	40 (20-60)	160 (80-390)
Loss of wages for the patient & attendants	200 (200-400)	200 (185-350)	200 (200-350)	0 (0-200)	200 (200-400)	800 (785-1700)
Total	260 (250-420)	260 (250-420)	260 (250-420)	50 (0-200)	260 (250-420)	1250 (900-1800)
Grand Total	1452 (1095-1812)	646 (405-750)	665 (483-750)	490 (352-610)	665 (483-750)	3685 (2433-4115)

In the private health facility, the total median cost incurred to the animal bite victims for availing post exposure prophylaxis with intramuscular rabies vaccination and equine rabies immunoglobulin in category III exposures was INR.3685 (USD 58) with inter-quartile range of INR.2433-4155. Similarly, for category II exposures it was INR. 3034 (USD 48) with inter-quartile range of INR.2433-3755 (Table 28).



Graph 10: Box & Whisker diagram for cost incurred (in INR) to the patients

In the present study, 450 dog bite victims were followed up for a period of 90 days after post exposure prophylaxis to determine the clinical outcomes following suspected rabies exposures. All of them were found to be normal & healthy.

3.4.1.5 Limitation*:*

The health survey at Manipur could not be done, since the dog bite cases were rarely reported and the rabies immune-biologicals (both anti rabies vaccine and rabies immunoglobulin) were sparsely supplied. Therefore, to accomplish the sample size, 3 of the survey states viz. Kerala, West Bengal and Bihar had recruited extra animal bite cases.

3.4.2.Veterinary survey:

Overall, 31 domesticated biting dogs were confined at the respective owners' houses. Among them 68 % of the dogs were adults, 78% (23/31) were male dogs, 87 % (27/31) were neutered, 58 % (18/31) were not immunized against rabies.

1) Kerala: 22 domesticated dogs had bitten persons who received PEP. All 22 dogs were confined to the respective owners' house and observed for 14 days. None of these dogs showed any clinical manifestation of rabies. Besides, five stray dog bites were reported, of which 2 dogs were killed by the public and the carcasses were buried and the remaining 3 stray dogs could not be traced.

2) Gujarat: A domesticated biting dog was caught in Valod and maintained for 14 days at the owner's residence itself. Furthermore, 30 stray dog biting incidents were reported from Valod, but these stray dogs could not be traced.

3) Manipur: No dog bite incidents in humans were brought to the notice of the veterinary investigator and hence no dogs were caught / quarantined.

4) Himachal Pradesh: 8 biting domesticated dogs were confined at their respective owners' house for 14 days observation and were found healthy. Further, there were two cat bites reported and they were also confined at the owners' residence.

All the domesticated dogs which were kept under observation were found healthy after 14 days of confinement. There were no reports of death of any stray dogs during the study period. Hence, it is presumed that these biting stray dogs may not be rabid.

3.4.2.1 Limitation:

The reluctance of dog owners to provide details of the biting dogs and difficulty to catch stray dogs due to hilly terrain were the constraints faced by the Veterinary investigators.

3.5 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.

3.5.1. Use of rabies biologicals in the seven survey states.

The summary on the use of the rabies vaccines and immunoglobulins in the seven survey states is given vide below (Table 29) and Annexures 6.28 & 6.29.

Table 29: Use of rabies vaccines & immunoglobulins in the seven survey states – A summary

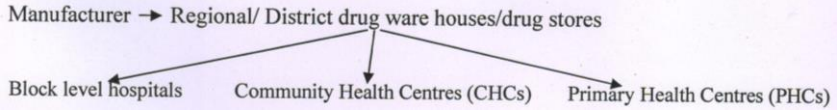
Sl. No.	State	Vaccine	RIGs
1.	Bihar	Government: Majority use IM route, Few centres use ID, AbhayRab. Private sector: IM route and all brands used	Government: ERIG used sparsely. Private sector: HRIG in high income groups
2.	Gujarat	Government: IM route used in PHCs & CHCs, Abhayrab (0.5ml) for IM use. ID route used in district hospitals and higher-level hospitals, Rabipur (1.0ml) for ID use Private sector: IM route and all brands	Government: Predominantly HRIG, ERIG sparingly used. Private sector: HRIG in high income groups. Others referred to Government centres
3.	Himachal Pradesh	Government: ID Route only, AbhayRab, Vaxirab-N and Rabipur. Vaccine available in all Govt.centers Private sector: IM route and all brands used	Government: ERIG available from CHC level. Approx. 3000 patients receive RIG every year Private sector: HRIG in high income groups
4.	Madhya Pradesh	Government: Both IM and ID routes used Private sector: IM route and all brands used	Government: ERIG used sparsely Private sector: HRIG in high income groups
5.	Manipur	Government: Local purchase by the Govt. from local market (when rabies outbreaks are reported) Vaccine made available at district hospital .IM route used. No data on quantity used. No system for vaccine procurement and delivery. Private sector: IM route and all brands used	Government: RIG used occasionally Private sector: HRIG in high income groups
6.	West Bengal	Government: ID route used, Vaccine available at PHC level also. Supplies are based on utilization certificate submitted Private sector: IM route and all brands used	Government: ERIGs used; Supplies are based on utilization certificate submitted. Private sector: HRIG in high income groups
7.	Kerala	Government: ID route used in higher centres i.e. District and above & IM route in peripheral centres. Private sector: IM route and all brands used	Government: ERIG used in bigger centres. HRIG in SST positive cases. Private sector: HRIG in high income groups

3.5.2. Logistics of supplies (including cold chain) from the producer to the end user.

3.5.2.1. Government sector:

The manufacturer supplies the rabies biologicals (vaccine and/or RIGs) in refrigerated van by surface transport to the designated places in the states i.e. usually the drug ware houses at the regional or district levels. The vaccines are stored in the walk-in coolers/ cold rooms and the temperature log is maintained. The rabies vaccines are kept along with other EPI vaccines. But no designated area was marked for rabies biologicals.

From the regional/district ware houses/ stores, the rabies biologicals are supplied in cold boxes (with ice packs) to the peripheral institutions using regular jeeps /vans and the travel time may take on an average about 1-6 hours by road. The vehicle mostly belongs to the health institution that sends the pharmacist/health person to pick up the rabies biologicals. At the health centre level, the rabies biologicals are stored separately in a domestic refrigerator at 2-8 degree Celsius with other non- EPI vaccines and drugs. The EPI vaccines are stored separately in designated ice-lined refrigerators (ILRs) and the deep freezers are used to prepare the cold packs needed for vaccine carriers and cold boxes. At the health centres, at the time of vaccinating the bite victims, the vaccines/ RIGs are kept in the vaccine carrier/ ice pack depending on the ambient temperature.



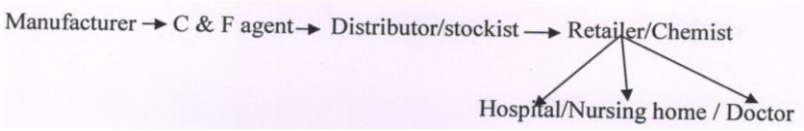
Flow diagram of logistics of rabies vaccines/RIGs in government sector

There are adequate cold chain equipments and temperature log systems in place and these are not areas of concern. The health staffs are well trained in cold chain management and vaccine/ RIG handling mainly from their work experience in EPI and Polio eradication programme. To conclude, the cold chain is robust and the rabies biologicals are well handled to safe guard their potency and sterility

3.5.2.2. Private/trade sector:

From the manufacturer the vaccines/ RIGs are transported to the clearing and forwarding (C&F) agents at the state capital. In bigger states, besides the state capitals additional C&F agents are present at more cities. From the manufacturers' vaccines/ RIGs reach the C&F by air cargo / refrigerated van depending on the distance. At the C&F vaccines/RIGs are stored in the walk-in-coolers [WICs] with temperature log maintained by cobalt device that in case of any cold chain failure sends text / voice message to the mobile phone of the C&F agent for corrective action. In some instances, it may be sound alarm alert in case of cold chain failure for corrective action. However, as the WICs are provided with UPS (uninterrupted power supply) and consequently instances of cold chain failure are rare. The C&Fs are periodically supervised by not only the auditors of the manufacturer but also by the regulatory authorities viz. State drugs controller. From the C&F agencies, the rabies vaccines/ RIGs are transported to stockists/ distributors in thermacol boxes or vaccine carrier/ cold bags with ice packs for short distances of travel of 2-4 hours using Omni vans/ goods auto, etc. For longer distances, it is sent overnight through special transport logistics/

courier/ cargo services by road with same cold packing arrangements. All related communications are made by E-mail and using telephones/ Mobile phones.



Flow diagram of logistics of rabies vaccines/RIGs in private sector

At the stockist/ distributor level in metros and bigger cities, the vaccines/RIGs are stored in the walk-in-cooler depending on the volume and geo-area coverage. From stockist /distributor to the retailers /chemists and druggist shops the vaccines /RIGs are transported in 2- 4 hours using cold carry bags with icepacks by delivery personnel using two wheelers. In case of smaller stockists/distributors sometimes arrangement is made for delivery of the vaccine/RIG stocks in cold chain from the C&F [in the name of the stockist] directly to the hospital/ nursing home / doctor. The retailer/ druggist and chemist store the vaccines/ RIGs in domestic refrigerators with UPS and mostly dispense the vaccines to the patients / practitioners directly in hand for immediate administration in 1-2 hours maximum. At all levels, the rabies biologicals are stored with other drugs and vaccines that need cold chain and there is no designated space for the rabies biologicals. Overall, there is a good system of communications, cold chain and logistics of rabies biologicals in most of the private sector.

It was noticed that when a particular brand of rabies vaccine was not available, it was substituted by the available brand of rabies vaccine thus ensuring continuous and uninterrupted supply of rabies vaccines. Currently, there is a limited supply (due to production issues) of two major brands of PCEC rabies vaccines (Rabipur & Vaxirab N) and as a result other brands have taken these market slots. The market demand is usually assessed by the manufacturer through their network of marketing personnel and accordingly based on the present production levels the C&Fs are supplied with the quantum of vaccines. Because of limited supplies, there is rotation of brands of vaccines at stockist levels and the substitute brand is invariably accepted by retailer/ hospital/ practitioner. This situation is an exception. Otherwise in a normal supply situation, to push the vaccines from top to the periphery, schemes such as 1 unit of vaccine free for 10 units of purchase are offered as an incentive by some manufacturers. The marketing personnel in the pharmaceutical companies are also given time bound targets of rabies vaccines sales vis-a-vis payment of incentives, assessing their performance, etc.

In most parts of the country, it was noticed that stock outs of rabies vaccines was rare as some (brand of) rabies vaccine was always available. However, the same was not true of

RIGs. There was poor/ virtually no demand for ERIGs and the HRIG, being expensive was used in smaller quantities in bigger cities/metros. Interestingly, stock outs of HRIG, though an imported product was rare.

3.5.3. Estimation of the demand and procurement of rabies biologicals in the states:

The annual requirement of vaccines is usually based on the consumption levels of the current year viz. April to March plus an additional quantum of about 10 % as buffer is added. This is usually worked out by the institutions and the consolidated report is submitted in most of the instances by the district health/medical officer to the state drug logistics society/ medical services corporation. Subsequently the consolidated annual quantum is purchased through a public E-tender notification issued on the website of the society/corporation. Both rabies vaccine & equine rabies immunoglobulin have been brought under the drug price control (DPC) by the Indian government. The MRP (cost to the customer) of one vial of rabies vaccine is around INR.325.00 (USD 5) and that of ERIG is around INR 476.00 (USD 7). However, the rates at which the individual state governments procure rabies vaccine or rabies immunoglobulin may vary from state of state.

Sometimes the quantum is divided among 2-3 companies to avoid monopolization and ensure good competition. The successful bidder(s) Pharma house/s supply the approved quantity directly to the regional/ district drug ware houses. This result in different brands of vaccines getting supplied to the hospitals simultaneously or some times when one company fails the other company is asked to supply to avoid stock outs. When stock outs occur, not uncommon, the institutions or the district level officer /designated officers to avoid public outcry are authorised to buy the vaccines from the local open market at the pre-approved rates/ rate contract (RC) list.

In some instances, it was found that the state authorities approve the rates and notify and the designated officers viz. At the district levels, medical college hospitals, bigger hospitals are permitted to procure directly from the Pharma houses. Lastly, animal bites more so from stray dogs affecting the poor often results in public hue and cry and as rabies is practically 100% fatal, non-availability of rabies vaccines in public hospitals has become subject of legislative debates both at the state/province and central level/ Government of India. As a result, in most of the states the vaccines are available in most parts of the year.

About equine rabies immunoglobulins, except in the states of Gujarat, Kerala and Himachal Pradesh, in other states it was sparingly used/ scarce. The medical doctors are reluctant to use the ERIGs for unfounded fear of reactions, time consuming skin sensitivity test (needed as per drugs and cosmetics act, as it is in the product insert that is contrary to the

recommendations of WHO and Government of India) and the cumbersome procedure of wound infiltration. As a result, about 5% of the cases received RIGs. The Pharma houses and the drug logistics societies squarely blame the medical profession for not raising the demand for RIGs in the government sector. The public is also ignorant about the need for life saving RIGs and this has resulted in the current situation.

The human RIGs are imported, costly and it was procured by the Government only in the states of Gujarat (predominant use) and Kerala (occasional use). Otherwise its use is limited to mostly private sector, in metro and bigger cities and the beneficiaries invariably belonging to higher income group.

3.5.4. Assessment of anti-rabies clinics in the survey states

The APCRI survey team visited the ARCs at the state headquarters, districts & peripheral health institutions; both in government and private sectors in urban & rural areas

Table 30 : Distribution of the surveyed ARCs in the seven states

Characteristic	**Urban**	**Rural**	**Total**
Government	18	09	27
Private	08	None	08
Total	**26**	**09**	**35**

The majority of the animal bite victims are invariably from the lower echelons of the society and they mostly visit the government facility where rabies PEP is provided free of cost. However, only one government institution in the surveyed states was charging a fee for the vaccine. The wound wash facility was deficient in many ARCs (54%); the route of administration was predominantly ID (59%) in the bigger government institutions and only IM 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 individual case record forms may be introduced under the NRCP for better surveillance of the PEP in bite victims (Table 31).

In summary, in Government sector in the bigger centres where the case load is more it is predominantly ID route and in smaller and peripheral centres where the case load is less it is IM route. The logistics of rabies vaccines was good in the states of Gujarat, Kerala and HP and satisfactory in West Bengal and not satisfactory in MP& Bihar. The situation in Manipur is bad. The same is true for rabies immunoglobulins too.

Lastly , in some places like the remote, rural, hilly and tribal areas where power cuts are common and there are no UPS/ Generator /power backups, the break in the cold chain is

an issue at the retailer/ drugs and chemists level in the private sector . Thus, contrary to the popular belief, the logistics and cold chain is generally better in the Government sector than private sector.

Table 31: **Appraisal of anti - rabies clinics in seven states of India**

Sl. No	Details/State		HP (n=09)	Bihar (n=04)	WB (n=06)	Manipur (n=03)	Kerala (n=02)	MP (n=06)	Gujarat (n=05)	Total (n=35)
1	**Area**	Urban	06	04	05	03	01	04	03	**26**
		Rural	03	00	01	00	01	02	02	**09**
2	**Type**	Government	06	03	04	02	02	06	04	**27**
		Private	03	01	02	01	00	00	01	**08**
3	**Location**	Independent	01	02	01	00	00	01	00	**05**
		Easy accessibility	09	04	06	03	02	06	05	**35**
4	**Staff**	Medical Officer	09	04	06	03	02	06	05	**35**
		Paramedics	09	04	06	03	02	06	05	**35**
5	**ARC facilities**	Running tap water (Yes)	07	03	06	03	02	05	04	**30**
		Wound wash facility (Yes)	04	03	04	01	02	03	02	**19**
		Antiseptics used (Yes)	09	04	05	02	02	05	05	**32**
		Continuous power supply (Yes)	09	04	06	03	02	06	05	**35**
		AC (Yes)	02	00	02	00	00	01	01	**06**
6	**Cold chain facilities**	Domestic refrigerator (Yes)	09	04	05	03	02	06	05	**34**
		ILR (Yes)	05	02	03	00	00	04	03	**17**
		Deep freezer (Yes)	03	01	03	00	00	04	02	**13**
		Temperature log (Yes)	05	03	04	01	02	04	03	**22**
7	**Cases**	New cases of animal bite/ month	136	510	402	250	420	351	210	**298**
8	**Vaccines available**	Rabipur	01	00	04	02	00	01	03	**11**
		Abhayrab	05	04	02	00	02	05	02	**20**
		Vaxirab-N	03	01	01	01	00	00	00	**06**
		Zoonovac-V	00	00	01	00	00	00	00	**01**
		Other PVRV	01	00	00	01	00	00	00	**02**
	Route of administration	IM	03	04	02	03	00	04	03	**19**
		ID	06	00	04	00	02	02	02	**16**
	Cost/dose	Free	05	03	04	02	02	06	04	**26**
		Charged	04	01	02	01	00	00	01	**09**
	Vaccine stock outs	Government	00	00	00	01	00	03	01	**05**
		Private	00	00	00	00	00	00	00	**00**
9	**RIGs available (Yes)**	ERIG	06	02	02	00	02	00	00	**12**
		Equirab	00	01	00	00	00	00	00	**01**
		Premirab	04	01	00	00	00	00	00	**05**
		CRI-K	02	00	00	00	00	00	00	**02**
		Vinrig	00	00	02	00	02	00	00	**04**
		HRIG	00	02	01	00	00	01	03	**07**
		Berirab-P	00	02	01	00	00	01	00	**04**
		Plasmarab	00	00	00	00	00	00	03	**03**
	RIG: Route of administration	Local	06	02	03	00	02	01	03	**17**
		Systemic	01	02	03	00	02	01	03	**12**
	Cost	Free	06	00	02	00	02	01	03	**14**
		Charged	00	02	01	00	00	00	00	**03**
	RIG Stock out	Government	00	03	01	02	00	04	01	**11**
		Private	00	00	02	01	00	00	01	**04**
10	**Records maintained**	OP register (Yes)	09	04	06	03	02	06	05	**35**
		ART register (Yes)	05	02	04	01	02	03	04	**21**
		ART case form (Yes)	00	00	04	00	02	00	00	**06**
		Stock register (Yes)	06	03	04	03	02	02	04	**24**

3.5.5. Limitation:

At the state level, about 6-9 man days were spent by the APCRI project team in visiting the offices, hospitals, health centres, antirabies clinics, pharmacies, etc. in both government and private sector for obtaining the desired information. In the absence of a formal letter of support/ introduction to the APCRI survey team from Government of India, most of the information was collected using personal and professional standing of the investigators and in some instances there was outright refusal, denial, etc. In each survey state, in addition to the state capital only one district was visited and hence the sample was purposive and not of sufficient size.

3.5.6. Visit to CDL and CRI, Kasauli, Himachal Pradesh

A team of project lead and coordinator visited the above premier institutions during the survey work in Himachal Pradesh**.** The key technical functionaries were interviewed and the relevant information was obtained.

3.5.6.1 Central Drugs Laboratory (CDL)

This is a NABH accredited and WHO audited laboratory established by Government of India under the Central Drugs Standard Control Organization (CDSCO) to monitor the quality of drugs in India. The survey team was interested to know the quality control checks imposed by the organization on the rabies vaccines and immunoglobulins in the country. It was noted that the samples are received from both the manufacturers and from the field from the drugs inspectors. The survey team obtained the following data about the rabies vaccines and immunoglobulins from the institute.

Table 32: Central Drugs Laboratory, Kasauli, Himachal Pradesh: Quality control testing of rabies vaccines and immunoglobulins (in batches): 2012 - 2016

Rabies biologicals	**2012**	**2013**	**2014**	**2015**	**2016**	**Trend/ Remarks**
Rabies Vaccine	495	420	649	618	618	Increase
ERIG / ARS	74	77	78	80	84	Increase
HRIG	-	2	-	-	-	Occasional
RMab*	01	-	-	-	-	New Product

Source: CDL, Kasauli, HP, Sept.2017. * 3 batches were tested in 2017

It may be noted that there is a gradual increase in the number of batches of rabies vaccines being tested during a five-year period of 2012-2016. This reflects on the trend of increasing demand/consumption of rabies vaccines in the country. Regarding RIGs, as it is a blood derivative and considered lifesaving, it is not mandatory for routine testing. Even here there is a gradual increase in the number of batches being tested. It is interesting to note that one batch of rabies monoclonal antibody was tested in 2012 and another 3 batches were

tested in 2017 and the product was launched in November, 2017 by Serum Institute of India Private Limited, Pune.

It is heartening to note that during this five-year period none of the batches of the rabies vaccines and RIG provided by the manufacturers failed the quality test at the CDL.

3.5.6.2 Central Research Institute

This is a premier public institution in the country that manufactures vaccines and sera. Presently it produces ERIG and the details are as follows.

Table 33 : Production of Equine Rabies Immunoglobulin/ Anti-Rabies Serum (in vials) 2012 – 2017 period (April to March)

2012-13	2013-14	2014-15	2015-16	2016-17	Trend/Remarks
40,662	42,600	42,775	29,189	22,955	Decrease

Source: Central Research Institute, Kasauli, Himachal Pradesh, Sept. 2017

Interestingly, there is a gradual decline in the production of ERIG 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 (Table 33).

3.6. 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.

3.6.1. Rabies Vaccines (humans)

The currently available rabies vaccines (6 plus) are indigenously produced in the state supported cooperative sector (Indian Immunologicals/ Human Biologicals Institute) (1) and Private sector (5 plus). There is no vaccine produced in the state / Government sector. A very small quantity of rabies vaccine is occasionally imported, mostly from China and that is more during exigencies and profit reasons. All vaccines are cell culture derived and no embryonated egg rabies vaccines or nerve tissue derived vaccines are produced/ available in the country.

3.6.1.1. Types of vaccines:

Broadly two types of cell culture rabies vaccines are available

1. Purified Chick Embryo Cell Vaccine (PCEC): Rabipur &Vaxirab-N
2. Purified Vero Rabies Vaccine (PVRV): Verorab/Abhayrab/ Indirab/ Rabivax-S/ Zoonovac / BeRab/SureRab/XP-Rab

3.6.1.2. Compositions of some popular brands:

The compositions of the three popular brands are vide below -

i. Purified Chick Embryo Cell Vaccine (PCEC)

Rabipur: Marketed by: GSK; MRP: INR 319/-; Presentation: One vial containing lyophilized vaccine along with diluent, accompanied with syringe and needle (25G); Dose–1 ml; Strain used: Flury LEP strain; Mode of Administration: IM/ ID use; Stabilizers: Polygeline & Potassium-L-Glutamate; Antibiotics:Neomycin, Chlortetracycline, Amphotericin B; Expiry period: 4 yrs. This is a WHO prequalified vaccine.

Vaxirab-N: Manufacturer: Zydus Cadila; Marketed by: Zydus Fortiza; MRP: INR. 325/-; Presentation: One vial of lyophilized vaccine, one pack of 1 ml sterile water for injection, one 2 ml disposable syringe & needle; Dose – 1 ml; Strain used: Pitman Moore strain; Mode of Administration: IM/ ID use; Stabilizers: Gelatin, Human Albumin & Sucrose; Antibiotics: none mentioned in insert; Expiry period: 2 years

ii. Purified Vero Cell Rabies Vaccine (PVRV) – Abhayrab

Manufacturer: Indian Immunologicals Ltd; MRP: INR 325/-; Presentation: One vial containing lyophilized vaccine along with diluent, accompanied with syringe and needle (25G); Dose – 0.5 ml/1 ml; Strain used: Rabies Virus (L. Pasteur 2061/Vero strain propagated in Vero Cells); Mode of Administration: IM/ID use; Stabilizers: Human Serum Albumin, Maltose; Preservative: Thiomersal; Antibiotics: Neomycin, Kanamycin and Polymyxin – B sulphate; Expiry period: 3 years

The details are as follows:

Table 34: Rabies Vaccines for humans in India							
Brand/ Company	**Dose vol.**	**Strain used**	MRP	**Antibiotic**	**Stabilizers**	**Expiry period**	**Precautions**
Rabivax-S SIIL	1 ml	Pitman Moore	325	None	Human albumin	3 years	None
Rabipur GSK	1 ml	Flury LEP	319	Neomycin	Polygeline	4 years	Hypersensitivity to egg proteins
XP-Rab Ranbaxy	0.5 ml	Pitman Moore	319	Neomycin	Human albumin Maltose	3 years	Hypersensitivity to neomycin
Indirab Bharat Biotech	0.5 ml	Pitman Moore	315	Neomycin	Human albumin Maltose	3 years	Hypersensitivity to neomycin
Abhayrab Human Biologicals	0.5 ml	Pitman Moore	325	Neomycin	Human albumin Maltose	3 years	Hypersensitivity to neomycin
Vaxirab-N; Zydus Cadila	1 ml	Pitman Moore	325	None	Cysteine Gelatin	2 years	Hypersensitivity to avian proteins
Zoonavac; Mktd. By BSVL	0.5 ml	Pitman Moore	325	Neomycin	Human albumin Maltose	3 years	Hypersensitivity to neomycin
BE Rab; Mktd. By BE Pharma	0.5 ml	Pitman Moore	325	Neomycin	Human albumin Maltose	3 years	Hypersensitivity to neomycin

3.6.1.3. All India geographical distribution of sales of rabies vaccines:

The sales were highest in the north region followed by south and other regions.

Table 35: Geographical distribution of sales of rabies vaccines [August, 2017]			
Sl.No.	**Area / State / Union Territory**	**Vials (in 000s)**	**Value in INR (Crores)**
A. Institution			
I.	**North**		
	Delhi	15.46	0.37
	Haryana	95.71	2.35
	Punjab	170.10	4.16
	UP East	24.60	0.60
	Uttarakhand & UP West	146.20	3.63
	Sub total	**452.07**	**11.11**
II.	**East**		
	Bihar	41.30	1.03
	Chhattisgarh	33.11	0.82
	Jharkhand	22.03	0.54
	Kolkata	47.10	1.16
	Odisha	6.16	0.16
	West Bengal rest	108.88	2.77
	Subtotal	**258.58**	**6.48**
III.	**North East**	**134.63**	**3.27**
IV.	**Central**		
	Madhya Pradesh	62.36	1.54
	Vidarbha	13.82	0.34
	Sub total	**76.18**	**1.88**
V.	**South**		
	Andhra Pradesh	13.76	0.35
	Karnataka	230.77	5.80
	Kerala	10.11	0.25
	Tamil Nadu	25.06	0.61
	Telengana	17.13	0.42
	Sub total	**296.83**	**7.43**

VI.	**West**		
	Gujarat	57.00	1.43
	Marathwada	26.43	0.65
	Mumbai	80.65	1.95
	Rajasthan	43.09	1.07
	Subtotal	**207.17**	**5.1**
	Total	**1425.46 (29.4%)**	**35.27 (28.4%)**
B. Trade (All India)		**3417.31 (70.6%)**	**89.14 (71.6%)**
Grand Total		**4842.77**	**124.41**

According to another source of information (Official communication), the distribution of the rabies vaccines procurement/ business in 2017 (as of 11th Dec.) according to the route of administration was as follows:

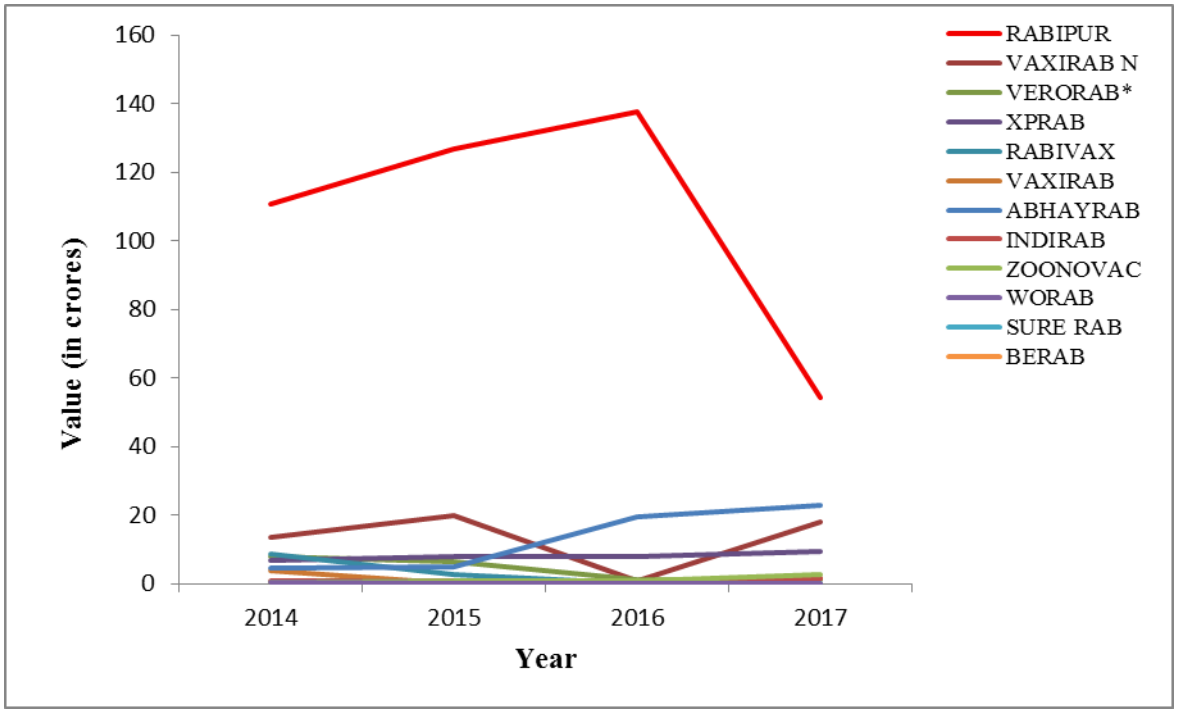
Table 36: All India distribution of the rabies vaccines according to route of administration	
Intramuscular (IM)	47, 94,713 vials (34%)
Intradermal (ID)	48, 65,285 vials (34%)
Intramuscular/Intradermal (IM/ID)	43, 96,638 vials (32%)
Total	1,40,56,636 vials (100%)

The IM market, that is private/ trade sector as per pharma houses, was about 1/3rd of the total ARV market in the country. The remaining 2/3rd is by ID (Govt.) and ID/IM (Govt. /Pvt.).

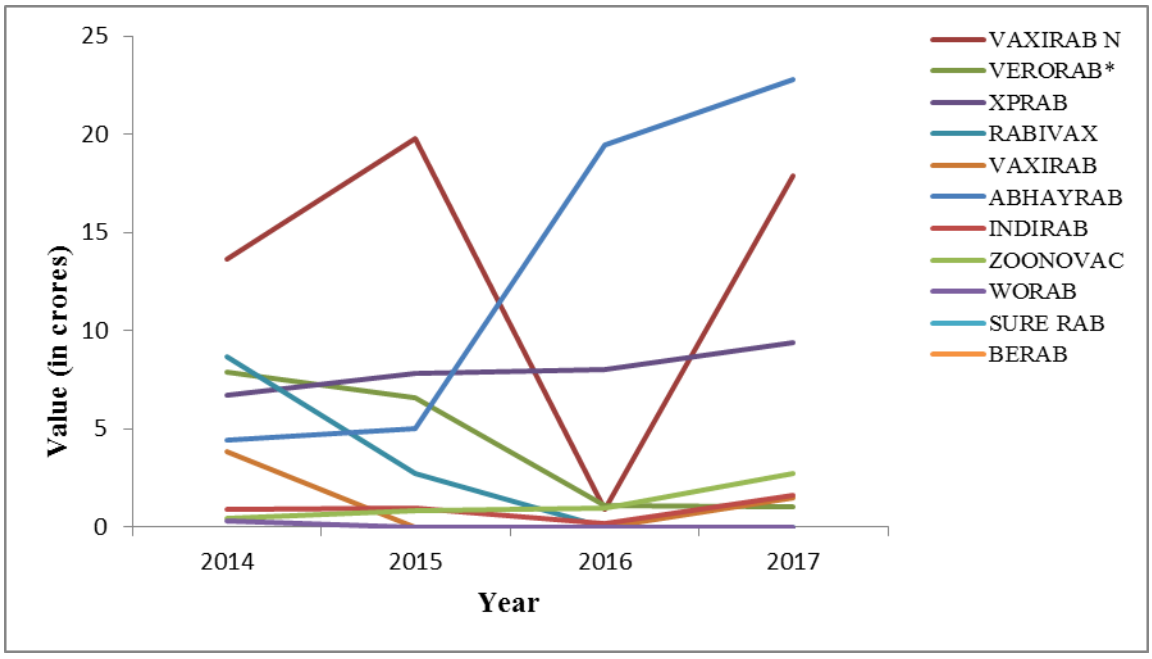
3.6.1.4. Market trends of brands of rabies vaccines:

In short due to issues in production, the market leader Rabipur (PCEC, GSK/Chiron Vaccines], is showing a decline and there is a slow ascend of Abhayrab, produced by Human Biologicals Institute that is established by National Dairy Development Board, a Government of India initiative. Due to a general shortage of some leading brands of vaccine viz. Rabipur and Vaxirab N (Zydus Cadila) other and newer brands of rabies vaccines are gaining momentum in the market.

a) Trends of total value of brands over 4 years



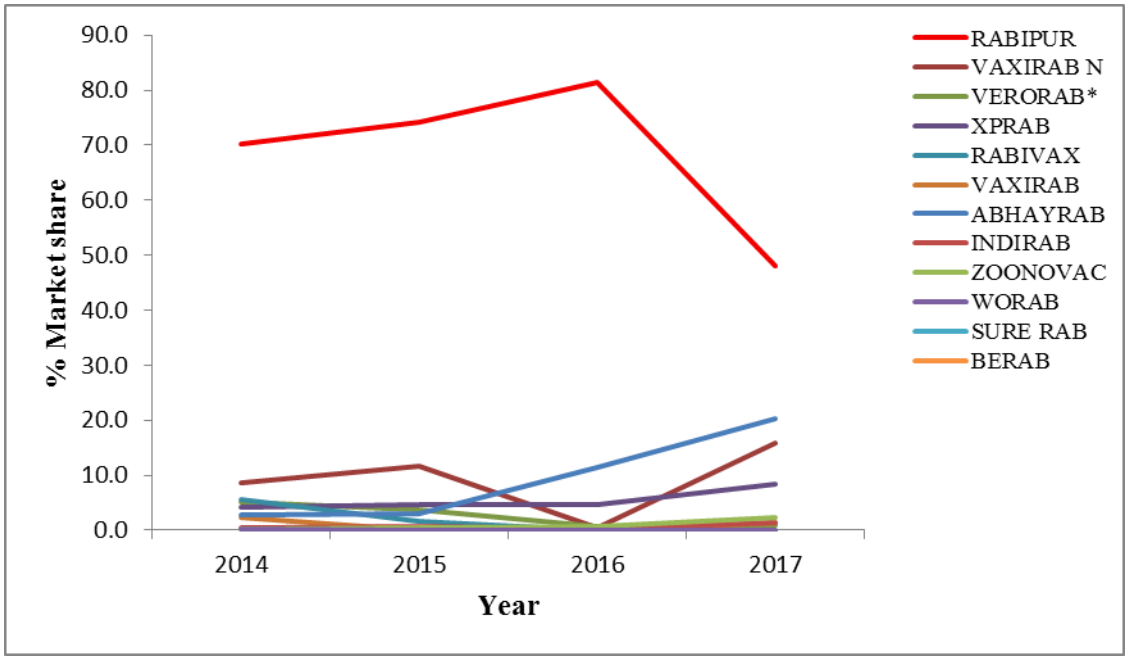
Graph 11A: Trend of total value of the brands over 4 years (All vaccines)



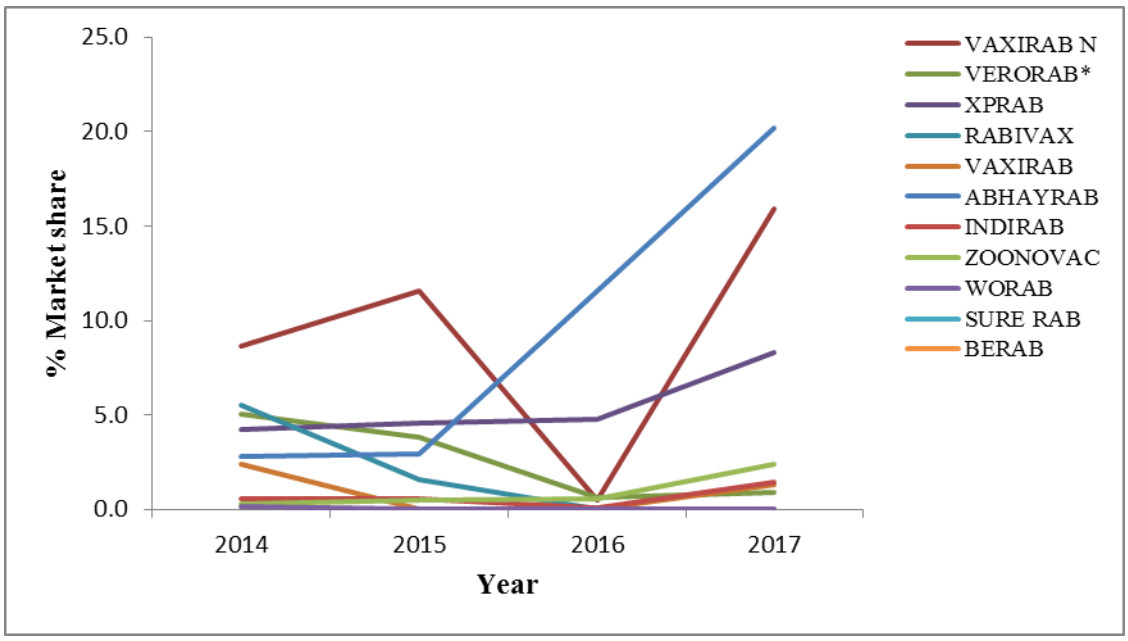
Graph 11B: Trend of total value of the brand over 4 year without Rabipur

**Verorab: One of the WHO prequalified vaccine presently not available in the country*

b) Market share of the brands over 4 years



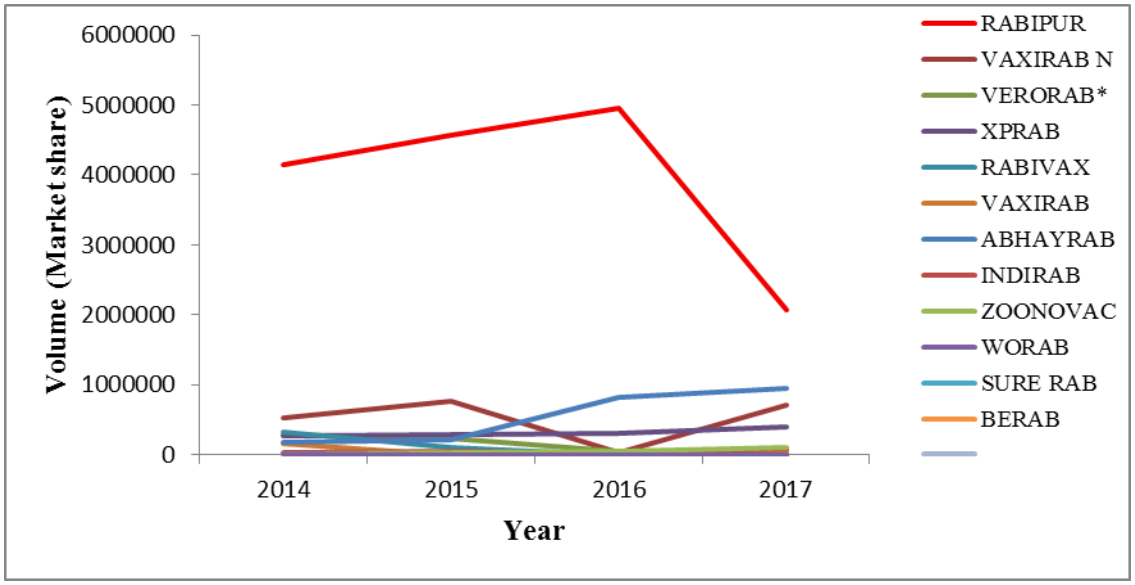
Graph 12A: Trend in market share of the brand over 4 years (All vaccines)



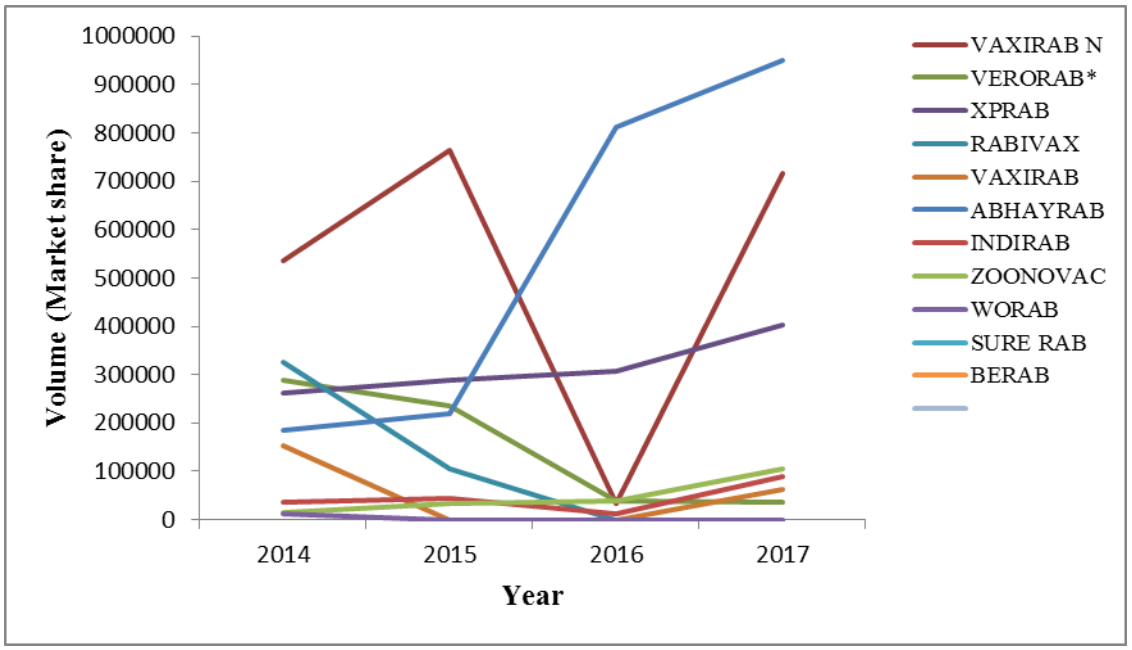
Graph 12B: Trend in market share of the brand over 4 year without Rabipur

**Verorab: One of the WHO prequalified vaccine presently not available in the country*

c) Total volume sales of the brand over 4 years



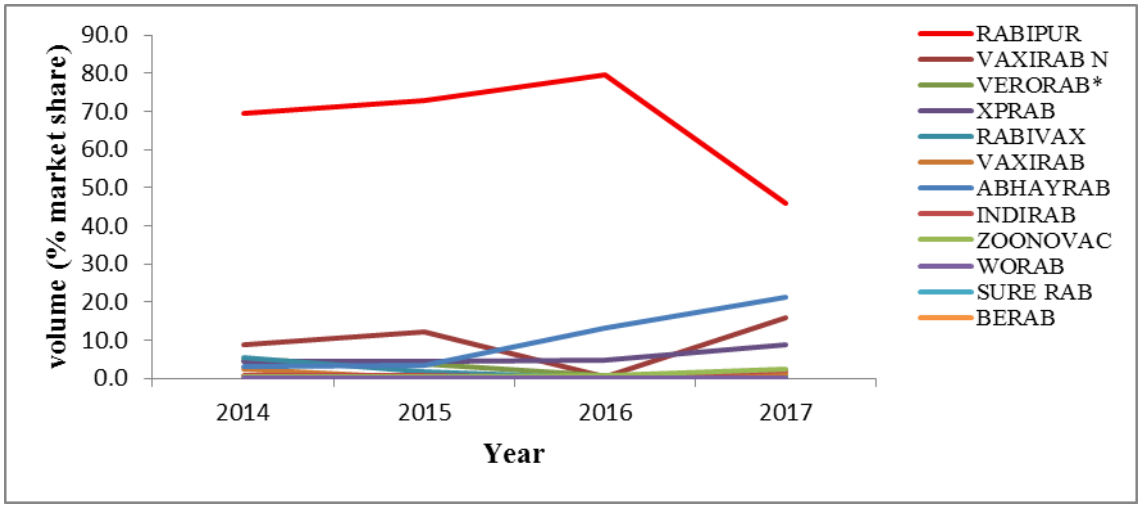
Graph 13A: Trend of total volume sales of the brand over 4 years (All vaccines)



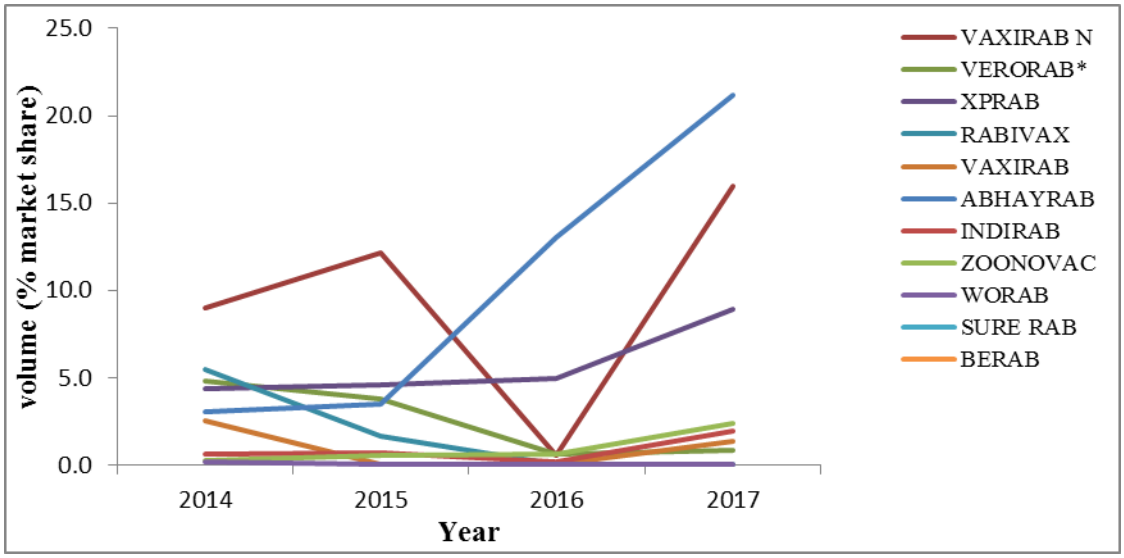
Graph 13B: Trend of total volume sales of the brand over 4 year without Rabipur

**Verorab: One of the WHO prequalified vaccine presently not available in the country*

d) Market volume share of the brands over 4 years



Graph 14A: Trend of volume market share of the brands over 4 years (All vaccines)



Graph 14B:-Trend of volume market share of the brands over 4 year without Rabipur

**Verorab: One of the WHO prequalified vaccine presently not available in the country*

3.6.1.5. Information about rabies vaccines from Government of India and the producers

As a beginning exercise of this activity following a desk review, the following information from the central government and the producers was obtained.

Table 37: Production of rabies vaccines in both public and private sectors in India (100,000 doses): 2014-16 (2 years period)

Institution	Installed	Production		Demand		Supply		Achieved %	
Year	Capacity	2014-15	15-16	2014-15	15-16	2014-15	15-16	2014-15	15-16
1.PUBLIC SECTOR									
PII, Coonoor	02	Nil	Nil	Nil	Nil	Nil	Nil	NA	NA
HBI	120	54.22	66.7	NA	-	65.6	60.50	NA	NA
2.PRIVATE SECTOR									
Chiron Behring	150	72.36	87.18	73.12	86.99	73.12	86.99	100	100
Sanofi Pasteur	20	06.66	06.66	10.44	10.44	10.44	10.44	100	100
Bharat Biotech	120	90.00	90.00	35.20	35.20	35.20	35.20	100	100
Cadila Health	84	18.77	42.00	18.25	14.51	18.25	14.51	100	100
SIIL, Pune	40	04.60	04.60	NA	NA	NA	NA	NA	NA
TOTAL	**536**	**246.61**	**297.14**	**137.01**	**147.14**	**202.61**	**207.64**	-	-
Ind Immunol. (Veterinary vaccine)	60	80.99	80.99	-	-	77.99	77.99	NA	NA

Source: Government of India, Central Bureau of Health Intelligence, National Health Profile, March, 2017, Nirman Bhawan, New Delhi plus individual Pharma houses

It may be noted that in the public sector, for human vaccines, the installed capacity was 22.8% and the production was about 22.5%.

3.6.1.6. Type of rabies vaccine market:

The market is broadly categorized as follows:

1. Prescription market – Comprising of General Practitioners (MBBS & Others); Physicians in Government and private Corporate Hospitals.

2. Dispensing market – General Practitioners; Pediatricians & doctors in Government hospitals, nursing homes, specialized anti-rabies clinics, corporate hospitals & others

3. Tender market – Government hospitals and some/large private hospitals.

The vaccines are mostly administered by ID route in Government sector free of cost to the patient and by IM route in private sector for a fee payable by the patient. The approximate cost varies from INR. 400/- to INR. 600 per dose (USD 6 to 9 approximate)

Pediatricians. Many pediatricians dispense rabies vaccines or order from a nearby Stockist/ distributor chemist /drug shop when a case of animal bites reports. Because of the rapport of the pediatricians with the parents of the children, now Pharma houses are targeting them to promote pre-exposure rabies vaccination (PrEP).

General Practitioners (GPs). As dog bites results in wounds, the victim invariably reports to a GP. The GPs usually stock the rabies vaccines or procure from a nearby drug shop depending on the number of cases seen, affordability of the patients, facility to keep a

refrigerator, etc. The GPs are generally targeted by the Pharma houses for promoting the rabies vaccines in both urban and rural areas.

Private/ corporate hospitals/ nursing homes: In the metro and large cities, corporate and private hospitals are now a popular and growing segment for emergency medical care for convenience and invariably have an in-house chemist storing rabies vaccines. In the smaller cities, the nursing homes (smaller private hospitals owned and run by a doctor) offer antirabies treatment thus constituting a significant chunk.

Government hospitals: Procure the rabies vaccines through tenders and during exigencies purchase from the local market. The state or provincial government procures the vaccines for all the government hospitals through an agency specially created for procuring drug, vaccines, etc. known as drugs logistics society/ corporation/ medical services corporation, etc**.** This constitutes a significant portion of the market share for the Pharma houses.

It must be noted that the prescription market constitutes the largest market share and the stake holders are diverse. The main segments include GPs, pediatricians, physicians, surgeons, doctors in the both private and some government hospitals / health centres where vaccines are not stocked/ not available.

3.6.1.7. The market size and value:

The market in terms of its size and value is as follows.

Table 38: Market value and size of rabies vaccines in India

BRAND	TYPE	COMPANY	Market Value AUG 16	Market Value AUG 17	Market Value GR AUG 17	Market Unit AUG 16	Market Unit AUG 17	Market Unit GR AUG 17
Abhayrab 1 mL	PVRV	IIL	29.2	59.0	102.0	1121.6	2272.3	102.6
Rabipur 1 mL	PCEC	GSK LTD.	103.2	30.1	-70.8	3684.7	1144.9	-68.9
Vaxirab 1 mL	PCEC	Zydus Cadila	7.5	16.3	189.2	281.3	659.4	222.0
Zoonovac-V 1 mL	PVRV	BSVL	1.2	9.7	723.0	43.2	376.9	771.8
Xprab 0.5 mL	PVRV	Sun Pharma	13.0	8.8	-32	504.5	368.2	-27.0
Indirab 0.5 mL	PVRV	BBIL	0.2	0.5	180.4	7.4	20.8	181.0
Total Market			**154.3**	**124.4**	**-19.7**	**5667.0**	**4842.8**	**-14.5**

[MAT value in Rupees crores; Units in 000s]

The market size of the rabies vaccines is about INR. 125 crores as per the pharmaceutical market research agencies. i.e. PHARMATRAC/AWACS (Aug.2017) There is a de-growth due to severe product shortages resulting in Rabipur (GSK) vaccine losing the number one status. Currently the market is dominated by Abhayrab (48% market share) followed by Rabipur (24%). The dispensing market is a significant portion of the market and

it is generally the preferred target by the Pharma houses. The information about the tender business is kept confidential and not easily shared.

The survey results showed that as the rabies vaccines are procured by the state or provincial governments the scenario of their availability was varied from 24X7 availability viz. Gujarat and Kerala to occasional supplies viz. Manipur and Bihar.

Besides the rabies vaccines are exported to countries of Asia and Africa and the proportion varies from 2 – 16 % depending on the producer. However, all the producers did not share the information despite many attempts.

6.6.1.8. SWOT analysis:

The results of the swot analysis done in general for rabies vaccine by the core project team is vide below**:**

Strengths:

1. The indigenous production.
2. Capacity to upscale.
3. Good logistics i.e. transport, Cold chain, Communications, etc.

Weakness:

1. Except one producer none have WHO prequalification
2. R&D
3. Total absence of vaccine production in the Government sector

Opportunity:

1. To promote pre-exposure vaccination for special groups
2. Inclusion of PrEP in the national immunization schedule in the due course

Threats:

1. Profitability of export market leading to neglect of domestic need/demand.
2. Dependence on private sector

A company-wise SWOT analysis done through the respective marketing departments using a structured questionnaire gave the following results:

Table 39: SWOT Analysis of Pharmaceutical companies producing rabies vaccines in India

No.	COMPANY	STRENGTHS	WEAKNESSES	OPPORTUNITY	THREAT
1	HBI	Marketing network	R&D	Spurt in demand	Aggressive competition
2	CPL	Innovation ; collaboration ; Domestic network	Reach ; Productivity	Adult vaccination drive	Aggressive competition
3	SIIPL	Global & UN sales ; Domestic reach	Failure to create awareness of product	Spend more for convenience	Competitors – fast pace growth; unethical gift practices; Drug price control orders (DPCO)
4.	BSVL	Products range; Local reach & Exports	Production ; Forecasting	Upcountry market	NPPA (National Pharmaceutical Pricing Authority
5	ZCH	Good yield ; Cold chain logistics + Domestic reach	Institutions sales ; Supply gap management	Patient outreach ; short course regimens	Aggressive competitors
6.	GSK	WHO prequalified ; Global supply and domestic trade & wide reach; Brand recall .	Production ; Connect with General practitioners	Clinical trials ; R&D	Aggressive market competition ; NPPA/DPCO

Note: HBI = Human Biologicals Institute (Abhayrab; PVRV 1mL for ID & 0.5mL for IM); CPL = CPL Biologicals Pvt. Ltd. (G protein vaccine); SIIPL = Serum Institute of India (Rabivax –S; 1 mL PVRV for IM & ID); BSVL = Bharat Serums and Vaccines Limited (Zoonovac; PVRV 0.5mL for IM); ZCH = Zydus Cadila Health Care (Vaxirab N, PCEC, 1mL for IM & ID); GSK = Smith Kline Beecham (Rabipur, PCEC=1mL; IM & ID)

In the global context, it is important that the companies go in for WHO prequalification that guarantees international quality and entitles them for supplying to UN agencies like UNICEF, and others like GAVI, etc.

3.6.2. Rabies immunoglobulins (RIGs):

3.6.2.1: Type of RIGs

The currently available RIGs are of two types :

i. Equine (ERIG) (indigenously produced) – Equirab; VINRIG and Premirab

ii. Human (HRIG) (all imported) – Berirab-P and Plasmarab.

All ERIGs are indigenously produced whereas all HRIGs are imported. The ERIGs are also exported. The ERIGs are provided mostly free of cost in the government hospitals and their usage in the private sector is limited due to time consuming skin sensitivity test, fear of anaphylaxis amongst medical professionals, cumbersome procedure of infiltrating the wounds and hence in many instances the cases are referred to the government hospitals. The HRIGs are mostly provided for a fee (HRIG cost plus administration charges) which is beyond the reach of even the middle-income group and only the rich can afford. Only in the survey state of Gujarat it was provided free of cost in the Government hospitals and in cases of adverse events to ERIG in a limited way in Kerala state. This is a product that is mostly used in the corporate hospitals and private hospitals that are visited by the rich and high-income group.

3.6.2.2. Composition of rabies immunoglobulins (RIGs)

The composition of different brands of RIGs is given below.

Equirab: Equine Rabies Immunoglobulin (BSVL): Manufacturer: Bharat Serums & Vaccines Ltd ; Marketed by: BSVL; MRP: INR 476/-; Presentation: Vial containing 5 ml of 300 IU/ml, total 1500 IU per vial; Dose – 40 IU/kg Body weight; Source: Equine (Horses) ; Mode of Administration: IM/SC use only; Stabilizers: Glycine; Expiry period: 2 years.

Premirab: Equine Rabies Immunoglobulin (Premium Serums and Vaccine Private Limited): Each ml of Rabies Anti Serum neutralizes not less than 300 I.U. ; 1500 IU in 5 mL vial ; Exports 200IU per mL and 1000IU in 5 mL vial ; Preservative Phenol/Cresol I.P. ≤ 0.25 % w/v; Cost of vial .Price INR. 630/- per vial.

VINRIG - Equine Rabies immunoglobulin (VINS Bioproducts Limited): Each ml of Rabies Anti Serum neutralizes not less than 300 I.U. ; 1500 IU in 5 mL vial ; Exports 200IU per mL and 1000IU in 5 mL vial ; Cresol I.P. < 0.25% v/v as a preservative. ; Glycine I.P.; 0.0225 g/ml ; Sodium Chloride I.P. – 0.009 g/ml ; Water for injection I.P. – q.s. Price INR. 476/- per vial.

Berirab-P: Human Rabies Immunoglobulin (BSVL): Manufacturer: Behring AG, Germany; Marketed by: BSVL; MRP: Rs 5290; Presentation: Vial containing 2 ml of 150 IU/ml, total 300 IU per vial; Dose – 20 IU/kg body weight; Source: Humans; Mode of Administration: IM use only; Stabilizers: Glycine; Expiry period: 3 years

Plasmarab- Human Rabies Immunoglobulin: Manufacturer: Kamada Ltd; Marketed by: Trigenesis Lifesciences Pvt. Ltd;. MRP: Rs 6579. Presentation: Vial containing 2 ml of 150 IU/ ml, total 300 IU per vial Dose – 20 IU/kg body weight; Source: Humans; Mode of Administration: IM use only; Stabilizers: Glycine; Expiry period: 2 years

The shelf life of HRIGs are shorter; besides as they are imported some more time is lost in the process of procedures of import thus sometimes leaving only six months shelf life in the market. As these are very expensive and thus are mostly available in metro and large cities and have become the product for the rich.

The current scenario of indigenous production of ERIG is as follows:

Table 40: Current scenario of indigenous production of ERIG

Product/ Company	**Installed capacity (vials) per Year**	**Current Production (vials) per Year**
Equirab (BSVL)	14,00,000	5,72,001 (2016)
Premirab (Premium Serums)	3,00,000	2,94,636
VinRiG (VINS Biopharma)	25,000,00	6,00,000
Abhay RIG*	100,000	12,738
ARS (CRI,Kasauli ,HP)*	40,000	22,955(2017)
Total	43,40,000	15,02,330

*G = Government

The installed capacity and the production in Government are 3.2 % and 2.3% respectively showing a poor performance in this area.

3.6.2.3. Type of RIG market:

The market can be broadly categorised into three types:

i. Prescription market: Physicians and surgeons, doctors in government and private/corporate hospitals.

ii. Dispensing market: Specialized anti-rabies clinics; corporate hospitals and private hospitals

iii. Tender market: Government and Private Hospitals

Paediatricians: Though qualified and competent many are reluctant to use ERIGs. Some use HRIGs in those who can afford and when the number of wounds is few and easy to infiltrate.

General Practitioners: They are not very clear about the concept of use of RIGs and mostly confine to vaccines. Some refer their cases for RIG to speciality antirabies clinics in metro and large cities**.**

Government hospitals: The maximum use of ERIGs takes place here as it is provided free of cost/nominal cost to the patient. Hence, the doctors from the private sector and from the peripheral rural health centres refer the dog bite cases after administering the vaccine.

Corporate /private hospitals: As these are visited by those from higher income group, the HRIGs are mostly used here.

Nursing homes: In smaller cities and on the suburbs of bigger cities, the RIGs are used based on the affordability of the patient and the professional competence of the medical doctor.

The prescription market has a great share and like for vaccines the stake holders are diverse.

3.6.2.4: The market size and value:

The RIGs available & their market share in India are as follows:

Table 41: Rabies Immunoglobulins in India

BRAND	TYPE	COMPANY	Market Value AUG 16	Market Value AUG 17	Market Value GR AUG 17	Market Unit AUG 16	Market Unit AUG 17	Market Unit GR AUG 17
Berirab P; 300 IU Inj 2 mL	HRIG	BSVL	4.7	4.9	5.7	9.5	10.6	11.3
Plasma Rab; 300 IU Inj 2 mL	HRIG	Plasmogen	NA	NA	NA	NA	NA	NA
Equirab; 1500 IU Inj 5 mL	ERIG	BSVL	1.1	2.1	98.0	30.0	58.7	95.9
Abhayrig; 1500 IU Inj 5 mL	ERIG	IIL	2.0	0.5	-73.9	42.1	10.8	-74.5
Berirab P; 300 IU Inj 2 mL	HRIG	Zydus Cadila	1.0	0.7	-34.4	2.0	1.5	-27.2
Premirab; 1500 IU Inj 5 mL	ERIG	Premium Serums	NA	NA	NA	NA	NA	NA
VINRIG; 1500 IU Inj 5 mL	ERIG	VINS Biopharma	NA	NA	NA	NA	NA	NA
Total Market	RIG	ALL	8.8	8.2	-6.2	83.6	81.6	-2.6

(Market Value in INR crores, Units in 000s) (Source: PHARMATRAC AUG '17)

The ERIG market is about 80-90 % to 10-20% in Government to Private sectors respectively. The current market value is about INR. 83 crores. However, these figures do not include the supplies to the government that is not shared easily. However, there are frequent stock outs both in private and government sectors. The manufacturers blame the medical profession for not raising the demand in the government supplies for the drug logistics corporations to call for tenders. 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.

3.6.2.5. SWOT ANALYSIS

Strengths:

1. The indigenous production (ERIG)
2. Capacity to upscale
3. Good logistics i.e. transport, Cold chain, Communications, etc.

Weakness:

1.Import dependant (HRIG)

2.Short shelf life and frequent stock outs (HRIG)

Opportunity:

1. To create professional awareness about complete PEP, including RIG in all category III exposures, as a lifesaving measure.

Threats:

1. Export of ERIG Vis-a - Vis national vaccine security.

2. Stoppage of import of HRIG that is lifesaving and preferred by the high income group/rich.

3.6.3. Rabies monoclonal human antibody (RMAb)

The Serum Institute of India private limited, Pune; a 50 year old private pharmaceuticals and the world's largest producer of vaccines, launched the first global RMAb (Rabishield) in November, 2017 in India. The product is patented in India and was developed in association with Massachusetts Biologicals Ltd., USA. It is a monoclonal antibody against rabies G protein and is produced by recombinant DNA technology on Chinese hamster ovary [CHO] cells. This antibody, showed strong neutralizing activity in vitro against a panel of geographically diverse rabies isolates viz. raccoons (N America); dogs (Sri Lanka); ten isolates from dogs, cat and calf (India) and bats (USA).

3.6.3.1 Composition of Rabishield:

Each mL contains: Rabies Human Monoclonal Antibody- 40IU; Citrate Buffer 20 mM ; Sodium Chloride-150mM; Polysorbate 80- 0.025% (w/v) Stability**.** Shelf life of three years at the recommended storage temperature of 2 to 8 degree Celsius. Cost. INR. 1970/- (approx.) per vial.

3.6.3.2 RMAb market:

The Rabishield (RMAb) is just launched and expected to make inroads into the RIG segment. It is a competitor to HRIGs and expected to stop the import of HRIGs in the due course of time. It would be premature to make any estimates, predictions and projections. Serum Institute of India has an installed production capacity of 5 million vials/ year.

3.6.3.3. SWOT Analysis

The results of the SWOT analysis done by the core project team is vide below:

Strengths:

1. The indigenous production of world's first human RMAb.
2. Capacity to upscale.
3. Good logistics i.e. transport, Cold chain, Communications, etc.
4. Proven safety and efficacy in Indian subjects.

Weakness:

1. Not a cocktail of MABs as is the popular demand.
2. Costlier than Equine RIGs.
3. Virtual lack of awareness amongst medical profession .
4. As a new product there will be natural hesitation to accept quickly.

Opportunity:

1. Potential to replace the HRIGs and thus prevent their import.
2. Growing demand stimulates up scaling and industrial scale of production.

Threats:

1. Some more brands of RMAb are in the pipeline of launch.
2. Low cost highly purified ERIGs.

3.6.4. Market demand and forecasting:

Lastly, about forecasting the vaccine and RIG demands, reiterating the observations from the chapter on logistics, in the government, procurement of vaccine is done by the respective state/ provincial governments, mostly through drug logistics societies established for the purpose. The procurement of ERIG is irregular, occasional and done by only a few states on continual basis. The HRIG is procured for selective/limited/restricted use by some state governments. The forecasting of vaccine demand is based on the current consumption levels plus 10% buffer stock in the Government.

In the private sector, the marketing personnel of the vaccine/ ERIG producer/ HRIG importer periodically provide to the manufacturer an estimate of the market demand that is accordingly supplied to the C& F agents for further downward distribution up to retailer level. The stock outs of rabies vaccines and RIGs, in the government is more due to issues of logistics management; in the private sector it is mostly due to issues related to production. The stock outs of rabies vaccines in the private sector is rare and of ERIG and HRIG occasional.

3.6.5. Limitation:

The pharmaceutical companies were reluctant to provide the requested information as it involved their businesses and considered confidential. In this context, the information obtained is not comprehensive and complete**.**

3.6.6. Veterinary/ Animal rabies vaccines:

The currently available animal rabies vaccines in India are Anirab H, Defensor 1, Megavac R, Rabdomun, Defensor-3, Nobivac Rabies, Rabivac -vet, Raksharab and others. These are used both for pre-exposure and post-exposure prophylaxis. The major and popular indigenous manufacturer is Indian Immunologicals, Hyderabad, a Government supported initiative. The utilization of the Raksharab vaccine state wise and zone wise is as follows:

Following are the details of animal rabies vaccine supply from Indian Immunologicals Ltd., Hyderabad during 2015 -2016.

Table 42 : Zone wise sales of animal rabies vaccine, 2015-16

Zone	Sales volume in doses	(%)
North	1,14,6000	31%
East	6, 93,000	18%
South	920000	25%
Central	291400	8%
West	690000	18%
Total	**3,74,0400**	**100%**

Table 43: State wise sales of animal rabies vaccine, 2015-16

Punjab	320000
Uttar Pradesh	310000
Haryana	300000
Delhi	90000
Uttarakhand	80000
Himachal Pradesh	30000
Chandigarh	16000
West Bengal	430000
Orissa	100000
Chhattisgarh	20000
Bihar	20000
Jharkhand	13000
North East	150000
Maharashtra	410000
Rajasthan	210000
Gujarat	70000
Madhya Pradesh	251400
Karnataka	250000
Andhra Pradesh	210000
Tamil Nadu	200000
Telangana	170000
Kerala	90000
Total	**3,74,0400**

The consumption of animal rabies vaccine was highest in the region of north followed by south and others. The pet vaccination in India is still not satisfactory and needs vast improvements.

3.7. TOR 7: To provide a policy paper for rabies biologicals and vaccination in humans

A meeting of the technical stake holders was held on Friday, 1st December, 2017 in Central Drugs Standard Control Organization (CDSCO), at FDA Bhawan, New Delhi and was attended by the following:

1. **Dr. G.N. Singh,** Drugs Controller General of India (DCGI), CDSCO, Government of India, New Delhi.
2. **Dr. G. Gongal,** WHO Health Emergency Programme, WHO SEARO, New Delhi.
3. **Dr. Ritu Singh Chauhan**, National Professional Officer – IHR, WHO country office for India, New Delhi.
4. **Dr. Inder Parkash,** DDG (Public Health), DGHS, Government of India, Nirman Bhawan, New Delhi.
5. **Dr. Ashok Kumar,** Assistant Director General (Animal Health), Indian Council of Agricultural Research (ICAR), New Delhi
6. **Dr. Sanjiv Kumar,** Deputy Drugs Controller of India, CDSCO, New Delhi.
7. **Dr. Sushant Sharma,** Assistant Drugs Controller of India, CDSCO, New Delhi.
8. **Dr. M. K. Sudarshan,** Founder President, APCRI & Mentor, WHO-APCRI Project Lead, Bangalore.
9. **Dr. D. H. Ashwath Narayana,** President, APCRI & WHO-APCRI Project Coordinator, Bangalore
10. **Dr. Sumit Poddar,** Secretary General, APCRI, Kolkata
11. **Dr. Hemant Gohil,** Senior Medical Officer, ID Hospital, Delhi
12. **Dr. G. S. Reddy,** Senior Vice-President (Manufacturing), Indian Immunologicals Ltd, Hyderabad
13. **Dr. Bhagwat Gunale,** Deputy Medical Director, Serum Institute of India, Pune
14. **Mr. Adeet Gosh,** Vice President (Marketing), Bharath Serums & Vaccines Ltd (BSVL), Mumbai.
15. **Mr. Nitin Deshpande,** Consultant, Premium Serums & Vaccines Ltd., Mumbai.
16. **Mr. Nikhil Sharma,** Deputy General Manager, VINS Biopharma Ltd., Hyderabad.

Dr. G.N. Singh, Drugs Controller General of India (DCGI), CDSCO, Government of India inaugurated the meeting and stressed on the need for the rabies vaccine & RIG manufacturers to apply for WHO prequalification.

Dr. M. K. Sudarshan, Founder President, APCRI & Mentor, WHO-APCRI Project Lead, chaired the meeting and made a presentation on WHO-APCRI Rabies project and Rabies vaccination policy paper.

The draft rabies vaccination policy paper developed under the project was provided to the participants in advance of the meeting and the same was deliberated and finalized as follows:

3.7.1. Aim

To provide a draft policy paper to the Director General of Health Services (DGHS), Government of India, New Delhi to develop a national rabies vaccination policy in the context of the "Global goal of dog-mediated human rabies free world/ India by 2030".

3.7.2. Introduction

India is a country in South Asia, that is seventh largest by area and second most populous with over 1.2 billion people and the largest democracy in the world. The country has a federal political structure and functions with multi-party system. There are 29 states and 07 union territories with 707 districts. The urban and rural divide is 40:60. It is the world's fourth largest economy and with a life expectancy at birth of about 68 years. The overall literacy rate is about 73%.

3.7.3. Health facilities

There are 462 medical colleges & hospitals; 14,379 tertiary care hospitals; 5510 secondary health centres and 23,354 primary health centres offering primary and secondary medical care. Others like railways, defence services, employees' state insurance corporation, central government health scheme and other hospitals also cater to the medical needs of separate organized groups of populations. All these centres provide rabies prophylaxis.

3.7.4. The context

The recent national health policy, 2017 aims to inform, clarify, strengthen and prioritize the role of Government in shaping the health systems. It recognizes the interrelationship between communicable disease control programmes and public health system strengthening. Under integrated disease surveillance programme, the policy advocates the need for districts to respond to communicable disease priorities of their localities. For disease surveillance, all clinical establishments would be encouraged to notify disease and provide information of public health importance. In line with the national vaccine policy, 2011; the national health policy recommends commissioning more research and development for manufacturing new vaccines, including vaccines against locally prevalent diseases. It recommends more public sector manufacturing units; uninterrupted supply of quality vaccines and increasing the installed capacity of anti-sera manufacturing public sector units.

In this backdrop, as a logical extension of broader national health policy, 2017 and national vaccine policy, 2011; a national rabies vaccination policy, 2018 for human needs to be formulated to achieve the goal of dog - mediated human rabies free India by 2030.

3.7.5. Problem of Rabies

Rabies is a viral zoonotic disease that is almost always fatal both in humans and animals; but is preventable too. Globally the annual estimated human rabies mortality is about 60,000 persons of which 20,000 i.e. one–third is occurring in India alone. The principal vector is the dog (97%) and others include cat (2%); monkeys and wild animals like jackals, foxes, mongoose, etc. (1%). There are an estimated 15 million pet dogs and 25-30

million stray dogs, resulting in a pet dog: stray dog ratio of about 1:2. An estimated 17.4 million animal bites are estimated to occur annually and about 5 million post exposure rabies prophylaxis is provided annually in India.

Rabies is a disease of low public health priority, affecting mostly the poor. A pilot project on rabies prevention and control was implemented by Government of India (2007 – 2012) through National Centre for Disease Control (NCDC). Based on its experience, under the 12th five year plan, national rabies control programme (NRCP) is now implemented (2012-2017) in all the states with a "one health" approach through NCDC and Animal Welfare Board of India. But, the allotted budget is a meagre amount of INR. 50 crores; and is yet to take off to make any desired impact.

3.7.6. Rabies biologicals

There are 6 vaccine producers in the country [1 public sector – HBI/IIL, Hyderabad (Abhayrab) & 5 private sector – GSK/ Chiron (Rabipur), Zydus Cadila (Vaxirab N), SIIL (Rabivax- S), BBIL (Indirab), BioMed (SureRab) with an installed capacity of 53.6 million doses [public sector 12.2 million doses (22.8 %) & private sector 41.4 million doses (77.2%)]. There are about 10 brands of rabies vaccines viz. purified chick embryo cell (PCEC) vaccine – 2 and purified verocell rabies vaccine (PVRV) – 8. Currently these are used for PEP/ as secondary vaccines (out of routine or National/ Universal immunization) to provide post exposure prophylaxis (PEP) to rabies exposed individuals. Presently one intramuscular Essen regimen (5 doses, one dose each given on days 0,3,7,14 & 28) and one intradermal Updated TRC regimen (4 doses, one dose of 0.1 mL X 2 sites given on days 0,3, 7 & 28) are approved and used in the country.

There are 5 producers of equine rabies immunoglobulin (ERIG), 2 public sector and 3 private sector with a total installed capacity of 4.3 million mL; public sector 0.14 million mL (3.2%) & private sector 4.2 million mL (96.8 %). A rabies monoclonal antibody (RMAb, human) is now indigenously produced in the private sector with an installed capacity of 4 million vials and available in the market from November, 2017. Besides, 2 brands of human rabies immunoglobulin are imported. The rabies vaccines from both government & private sector and ERIG from the private sector is exported to mostly rabies endemic countries in Asia and Africa.

3.7.7. Problems and Dilemmas

1. There are frequent shortages of life saving rabies vaccines and ERIG for PEP. The exorbitant cost and frequent stock outs of the imported HRIG is 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 UIP 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 & the goal of achieving human rabies free India by 2030.

5. There is a frequent demand for including rabies vaccine in the routine immunization.

6. The level of awareness amongst the medical professionals about the use of rabies biologicals, particularly for RIGs is far from satisfactory.

3.7.8. Recommendation for developing policy outlines

In the context of the above, the following recommendations are 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 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 Paediatrics (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.

<u>Other related issues</u>:

These are recommended based on the observations from the survey 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 fifteen years old.

2. The facilities and care of human rabies patients in the infectious diseases hospitals must be improved.

3.7.9. Conclusion

These measures will certainly help in reducing the burden of human rabies and help in achieving the goal of dog-mediated human rabies free India by 2030.

The meeting was closed following a formal vote of thanks by Dr. M. K. Sudarshan.

3.7.10.Limitations

APCRI is a registered scientific society and a non-governmental organization. Hence, the above paper may be used as a draft / background document by the government in future, whenever a formal policy paper is evolved.

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

Currently equine rabies immunoglobulin (ERIG) and human rabies immunoglobulin (HRIG) are used in the country to provide immediate passive immunity in animal bite victims. There are 5 brands of ERIG produced indigenously and marketed in India. The ERIG administration is associated with small risk of serious allergic reactions including anaphylaxis and as per Indian drug regulations, skin sensitivity test (SST) has to be performed before administration of full dose. On an average, each vial of ERIG costs about INR. 500 (US $ 7) for 5 mL vial containing 1500 IU having potency of 300 IU/mL. Similarly, there are 2 brands of human rabies immunoglobulin (HRIG) being marketed in India which are imported and there is no indigenous production. Even with HRIG there is a rare risk of transmission of potential infectious diseases as it is derived from human blood and limitation of production capacity. Compared to ERIG, HRIG is very expensive and costs about INR. 6000 (US $ 90) for 2mL vial containing 300 IU and potency of 150 IU/mL.

The usage of rabies immunoglobulins (RIG) is very low (upto 10%) in India due to 1) Lack of awareness both among professionals and public 2) Non-availability of RIGs in most parts of the country 3) Non-affordability of RIGs (HRIGs in particular) by majority of the bite victims 4) Trained manpower deficit 5) Professional apathy 6) Case load (Time constraint) & cumbersome procedure and 7) Fear of anaphylaxis among professionals (ERIG).

Recently, a human rabies monoclonal antibody (human RMAb) was developed by Serum Institute of India private limited, Pune in collaboration with and following technology transfer from Mass Biologics, University of Massachusetts Medical School, USA. The rabies monoclonal antibody (R-Mab) is being manufactured in Chinese hamster ovary (CHO) cells by recombinant technology and this contains IgG1 monoclonal antibody that binds to the ectodomain of the G glycoprotein. Studies has shown that R-Mab neutralizes a wide variety of terrestrial and bat isolates of rabies virus worldwide including all rabies virus isolates in India. This R-Mab is produced by rDNA technology which overcomes all the limitations associated with RIGs.

Monoclonal antibodies are made from identical immune cells that are clones (genetically identical cells) of a parent cell. Such antibodies are identical and have monovalent affinity for the targeted molecule/ antigen. They bind to the same epitope or part of the antigen or virus. This is in contrast to polyclonal antibodies which are present in HRIG and ERIG and bind to different antigens.

The advantages of Monoclonal antibodies are: 1) High purity 2) Highly potent 3) Reproducible and reliable results 4) Excellent batch to batch consistency 5) Can be produced in high quantities.

SII-R-Mab (Rabishield) has been approved by Drug Controller General of India (DCGI) for marketing and the dose is 3.33 IU/kg body weight with potency of 40 IU/mL and available as 100 IU/2.5 mL vial. The cost of R-MAb is INR. 1970=00 (USD 30) maximum retail price (MRP) per 2.5 mL vial. Serum Institute of India has an installed production capacity of 5 million vials/ year.

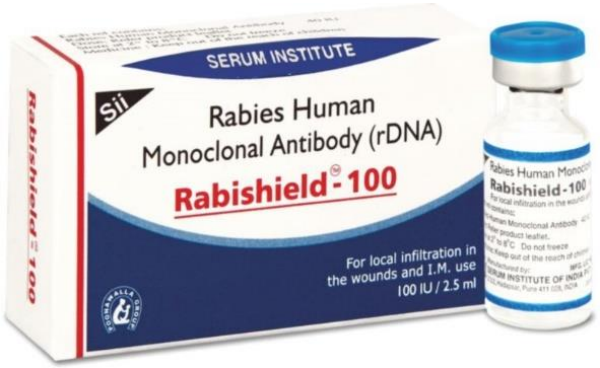

Photo 34: Rabishield-100 (Potency @ 40 IU per mL in a 2.5 mL vial)

3.8.1. Composition

Each mL contains:

Rabies Human Monoclonal Antibody	40 IU
Citrate Buffer	20 Mm
Sodium Chloride	150 mM
Polysorbate80	0.025% (w/v)

Rabishield is stable for shelf life of 3 years and recommended to store at 2-8^0 C.

Dose calculation for the patient (in mL) = 3.33 IU x Body Weight in kg / 40 IU (0.0833mL per kg body weight).

3.8.2. Comparison with ERIG and HRIG

Table 44: Comparison of Rabishield with ERIG & HRIG

Product	Recommended Dose	Formulation concentration	Dose in IU for Average 75 kg adult	Dose in mL for average 75 kg adult
ERIG	40 IU/kg	300 IU/mL	3000	10 mL
HRIG	20 IU/Kg	150 IU/mL	1500	10 mL
Rabishield	3.33 IU/Kg	40 IU/mL	250	6.25 mL

The R-MAb usage for PEP is operationally feasible as mechanism of action & administration is similar to RIG. However, there is a need to create awareness about availability of R-MAb as a novel, advanced product for passive immunization over RIG. There is a need to establish R-MAb infiltration centres (both in private & Government sectors) in bigger towns & cities. An effort will be made to conduct continuing medical education (CME) and hands on training programmes for professionals on R-MAb infiltration through APCRI.

R-MAb will be a better product for passive immunization compared to ERIG/ HRIG as required dosage will be much small quantity sufficient enough to infiltrate all animal bite wounds with no wastage that is in line with recent WHO recommendation. There is no need for test dose and can be infiltrated directly into the wound(s) within few minutes, saving the time of attending physician. However, 1) Multi-centric studies of R-Mab with IM / ID route of vaccine administration and 2) Post marketing pharmaco-vigilance studies (PMS) has to be done with this new R-MAb for wider acceptance.

Table 45: Comparison of cost (INR) of ERIG, HRIG with R-MAb for different age group

Type of product	Child < 30 kg	Adult <60 kg	Adult > 60 kg
ERIG	500 (USD 7)	1000 (USD 14)	1500 (USD 21)
HRIG	12,000 (USD 175)	24,000 (USD 350)	36,000 (USD 525)
Rabishield (R-Mab	1970 (USD 30)	3940 (USD 60)	5910 (USD 90)

The launch price of the product (per vial) in November, 2017 was INR. 8450/- approx. (130 USD) and was reduced to INR. 1970/- approx. (30 USD in February, 2018), which is now only 4 times expensive than ERIG but 6 times cheaper than HRIG. For wider usage both in private & Government health facility, the SII has to make Rabishield affordable and price reduced to less than ERIG at least in near future.

3.8.3 Introducing RMAb to the market

Serum Institute of India Pvt. Ltd., Pune launched Rabishield on 31st October 2017 at Mumbai, India. A series of launches & clinical meetings are being conducted in several state capitals like Delhi, Jaipur, Ahmadabad, Lucknow, Hyderabad, Mumbai, Kolkata, Bangalore, Cochin and Chennai. In most of these places, clinical meetings are stand alone or meetings in association with the Indian Academy of Paediatrics (IAP)/ Indian Medical Association (IMA). The participants are general physicians, surgeons, paediatricians and doctors attached to Corporate and Government hospitals who deal with cases of potential rabid animal exposures. These launch meetings will be followed-up with small CME programs in the top 30 cities of India. These CMEs would be addressed by rabies experts or Key opinion leaders

(KOLs) and we would be targeting small groups of up to 30 doctors. After the CME, a video documentary on Rabies and its prevention is being shown to the doctors.

In the subsequent phase, SIIL would be conducting round table meetings with the aim to organize up to 200 meetings in various cities and Class B towns to increase awareness about Rabies and its prevention. SIIL has produced video film on PEP: 20 minutes, 5 minutes, 3 minutes & 1 minute and use these to create awareness on rabies using various social media channels like face book, Instagram, Twitter and WhatsApp. Short videos on rabies would also be uploaded on to YouTube to create public awareness.

Lastly, human RMAb in the due course of time is expected to replace the HRIG that is a fully imported product. For the present, as a new product in the market a strong post-marketing surveillance (PMS) is the need of the hour.

3.8.4. Other RMAb

Another R-Mab (murine monoclonal antibody) a cocktail is being developed by Zydus Cadila Health Care Ltd, Ahmadabad and is due to undergo Phase III trial this year.

3.9. TOR 9: To assess rabies free status of islands of Lakshadweep and Andaman/Nicobar

3.9.1. Islands of Lakshadweep:

The population of the islands is about 86,000 (2017). Lakshadweep islands are free from dogs based on the preliminary official communication, interactions with the medical & veterinary professionals, administrators, local public, animal owners and the personal physical survey in Kavaratti and Agatti islands. This is attributed to majority of the population being Muslim and restrictions imposed by the authorities for bringing dogs into the islands at the limited entry points. Cats are the only potential vectors of rabies in Lakshadweep. However, the cats are not included in the livestock census. As for cat population is concerned, the Director of Animal Husbandry, District Veterinary Officer, Veterinary Assistant Surgeons and Veterinary Inspectors were of the opinion that there could be about 5000 cats put together in all the inhabited islands with approximately 4500 community / stray cats and 500 domesticated.

As per the available records and the local officials there are no pigs, foxes, jackals, mongoose and other wild animals. No rabies was reported in human beings or animals in Lakshadweep in the past as per the records available either in the medical or veterinary hospitals in both Kavaratti and Agatti islands. No rabies vaccines and rabies immunoglobulins are available either in the pharmacy shops in the market or government medical and veterinary hospitals. The APCRI team briefed the Lt. Governor about the survey and prevailed upon the Administrator, Collector, Director of Animal husbandry and other veterinary officials for submission of cat brain samples to rabies diagnostic laboratory, veterinary college, Bangalore for laboratory testing.

Five cat brain samples from Lakshadweep Islands (3 from Kavaratti and 2 from Agatti) were tested by direct fluorescent antibody test (DFA) & Lateral flow assay at OIE reference laboratory, Veterinary College, Bangalore were found Negative for Rabies.

Two samples were cross validated by PCR at NIMHANS, Bangalore and found Negative for Rabies.

3.9.2. Islands of Andaman & Nicobar

Andaman and Nicobar Islands, a Union Territory of India, is an archipelago consisting of about 600 islands located in the Bay of Bengal. The entire urban population of about 108,058 (28%) inhabitants live in Port Blair, the capital town (2011 census).

Though the islands have been known to be historically free from human and animal rabies, credible evidence in the form of laboratory surveillance is lacking. Therefore, the main objective of this visit was to re-assess the rabies free status and highlight the need to establish laboratory surveillance for canine rabies in the islands, towards achieving the WHO goal of human rabies free India by 2030.

Table 46: Visit to Medical/Veterinary Institutes in Andaman & Nicobar Islands		
Name of Institute / Place, Port Blair		**Date(s) visited**
Veterinary		
1	Directorate of Animal Husbandry and Veterinary Services	20-21st November 2017
2	Central Island Agricultural Research Institute (CIARI-ICAR), Garacharma	20th November 2017
3	Animal Diseases and Diagnostic Laboratory [ADDL]	20th November 2017
4	Veterinary Hospital**,** Garacharma	20th November 2017
5	Veterinary Hospital**,** Junglighat	21st November 2017
6	Dog sterilization centre (Friendicoes-SECA), Dollygung	21st November 2017
7	Private veterinary practioner (1), Garacharma	20th November 2017
Medical		
8	Directorate of Health Services	20th November 2017
9	Regional Medical Research Centre (RMRC), ICMR	21st November 2017
10	G.B Pant Hospital	21st November 2017
11	Naval Hospital (INHS Dhanvantri)	20th November 2017
12	Private hospitals/clinics (3)	21-22nd November 2017
Others		
13	Seaport	20th November 2017
14	Airport	20th November 2017
15	Biological Park, Chidiyatapu (Zoo)	20th November 2017
16	Medical stores/pharmacies (8)	19-22ndNovember 2017

Results (Salient points):

1. No human rabies cases have been reported in the islands based on official records from the Directorate of Health services, and interactions with doctors in public and private hospitals/clinics in the islands.

2. About 381 dog bite cases were seen and treated in various government hospitals in Port Blair in the last 10 years (2007-2017).

3. It is evident from official records of Veterinary hospitals and interaction with many Government and Private veterinarians, that no cases of rabies in dogs (or any other animals) have been reported in the past in the islands.

4. Dogs are the major potential vectors of rabies in the islands. There are about 27,000 dogs in the islands (2012 animal census). The animal birth control (ABC) programme for stray dogs is carried out by the municipality and animal husbandry department, through a non-governmental organization (NGO) Friendicoes-SECA.

5. Other animals seen on the island are cats, goats, pigs and cattle. However, as per the available records there are no sheep, horses, foxes, wolves, jackals or mongoose on the islands. Several species of bats (about 25 species) are found on the islands.

6. Anti-rabies vaccination (ARV) for stray dog population is not done. Pet owners get their dogs vaccinated; however, there is no licensing of pet dogs. There is no data available on the number of pet dogs in the islands. No data on dog death statistics and the causes is available.

7. Interviews and discussions with officials at the seaport and airport (cargo hold) revealed that since travel by sea from mainland to the islands takes about 3-4 days or more, it is not conducive for transport of pets and is no longer used. Only inter-island transport of animals, mainly livestock is carried out by sea route. Air transport is the preferred route and notably, several pet dogs are imported from mainland, by dog breeders, defence personnel and public officials deputed/posted to the islands. Though, several private airlines operate flights to Port Blair, primarily from Chennai and Kolkata, Air India is the preferred carrier to transport pets, especially for defence personnel and other government employees. However, there are no strict guidelines to ensure that the pet is vaccinated and adequately protected against rabies during entry into the islands. The number of pets being imported appears to have risen due to increased migration of people into the islands; however, there are no official records pertaining to the number of pets imported from mainland into the islands. Quarantine of animals imported without vaccination / signs of rabies or any other illness into the islands is not practiced.

8. Rabies immunoglobulin and anti-rabies vaccines for humans are not available in any public or private hospitals. Discussions with doctors in government hospitals as well as 3-4 private practitioners in Port Blair revealed that both ARV and RIG are not routinely prescribed for post-exposure prophylaxis following animal bites on the island. However, only one private pharmacy/chemist & druggist shop stocks rabies vaccine (Zoonovac-V) and dispenses it following a medical prescription to travellers/ individuals exposed to dogs/ cats in the island or individuals who are exposed to animal bites in the mainland and seek PEP. The Naval hospital (INHS Dhanvantri), Port Blair maintains a stock of ARV (Indirab) for use in defence personnel.

9. Anti-rabies vaccine (ARV) for dogs (Rabies Vet) is available with a private veterinary practitioner. Limited stocks of ARV (Rabies Vet, manufactured & marketed by Bio Med) were procured by the animal husbandry department for vaccination of pet dogs recently.

10. Significantly, World Rabies Day (28th September) is being observed every year from 2013 by the Animal Husbandry and Veterinary Services department, and activities to increase awareness about rabies free status of the island are carried out.

Recommendations/Action taken:

1. The visiting project team prevailed upon the veterinary officials for ensuring the submission of dog brain samples (obtained post-mortem from dogs which succumb due to disease or natural causes) to Rabies Diagnostic Laboratory, Veterinary college or NIMHANS, Bangalore for laboratory testing either by FAT or RT-PCR. Posters containing above information were handed over to Veterinary officials for wider dissemination among veterinary and other institution.
2. Standard operating procedures (SOP) for collection and transport of brain samples were explained to the veterinary officials and copies of the same were also handed over to them.
3. CIARI-ICAR and RMRC (ICMR) have facilities to initiate laboratory testing for rabies (fluorescent microscope/PCR/biosafety cabinets) and officials at these institutes have offered co-operation and support in rabies surveillance. To ensure continual rabies free status of the islands, the Government should initiate laboratory surveillance for rabies through ICAR and ICMR at Port Blair. Initially a few staff members from these institutes can be trained in rabies diagnostic techniques at the Department of Neurovirology, WHO Collaborating Centre for Reference & Research in Rabies, NIMHANS, Bangalore.
4. Compulsory pet licensing, registration and mandatory rabies vaccination of pets should be implemented. Census of stray dogs should be carried out regularly and ARV should be considered for stray dogs as well.
5. The import/entry of animals (through air and sea routes) should be strictly monitored. Submission of documented evidence for vaccination against rabies and adequate protection (by estimation of rabies neutralizing antibody titres in approved laboratories) should be made mandatory and strictly verified for all pets being imported into the islands. Quarantine facilities are required near entry-points. The implementation can be facilitated at the earliest through the recently proposed Act 'Andaman & Nicobar Prevention and Control of Infectious and Contagious Diseases in Animals (check post and quarantine, manner of inspection) rules, 2017'.

Four dog brain samples from Andaman & Nicobar Islands were tested by PCR at WHO collaborating centre for reference & research on Rabies, NIMHANS, Bangalore were found Negative for Rabies.

Same samples were cross validated by Lateral flow assay at Veterinary college, Bangalore and found Negative for Rabies.

3.10. TOR 10: To report the mechanism of surveillance for dog bite and human rabies

Presently 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.

3.10.1. Dog bite:

Dog bites for the five year duration of 2012 to 2016 was obtained from the seven states mostly from the IDSP/NRCP offices. Subsequently, the same data was obtained from the NCDC, Delhi IDSP office. The concordance (between the data of NCDC & APCRI) was seen only in 43% (12/28) of instances thus calling for better / improvement of consistency in the reporting system.

Table 47: State wise annual incidence of dog bites in India: 2012-2016 [5 year period]

STATE	Census 2011 Population	Reported dog bites									
		2012		2013		2014		2015		2016	
		IDSP	APCRI	IDSP	APCRI	IDSP	APCRI	IDSP	APCRI	IDSP	APCRI
Himachal Pradesh	6,856,509	12683	12683	11412	11412	13880	13880	23909	23582	34975	34975
Bihar	104,099,061	414344	703925	418911	419503	622333	401291	268600	262776	398284	341065
West Bengal	91,276,115	224512	186896	257378	212455	284748	251203	331989	268727	401511	407393
Manipur	2,721,756	498	498	1728	1728	1568	1568	4450	7337	3020	2708
Kerala	33,406,061	106722	NA	116457	62,280 From April	146803	119191	149201	125385	129089	135217
Madhya Pradesh	72,626,809	94274	94274	127467	127467	223315	223315	229825	229825	196515	196515
Gujarat	60,439,462	319824	NA	305332	NA	333246	NA	362033	NA	376183	NA
Total	**37,14,25,773**	**1172857**	**998276**	**1238685**	**834845**	**1625893**	**1010448**	**1370007**	**917632**	**1539577**	**1117873**

Note: APCRI denotes for data obtained from the states by the WHO-APCRI survey team; IDSP stands for the data obtained from the IDSP office, NCDC, New Delhi. NA-Not available

3.10.1.1. Hospital incidence rates of dog bites from the states

The information obtained from the government hospitals under IDSP was used to work out the annual incidence rates of dog bites for the five year period of 2012-2016, using the 2011 census population of the respective state. The hospital incidence rates show to some extent the bite load in an area/ community; it also reflects on the availability of rabies vaccines in the hospitals as cases come only to avail anti-rabies treatment that is offered mostly free of cost. It must be noted that it does not reflect the true incidence of dog bites in a community as it does not cover private hospitals, self-treatments, etc. Overall there was a steady increase in reporting of dog bite cases (0.26 to 0.39) during this five year period. Amongst the states, Gujarat and Kerala reported a higher incidence rates signifying good surveillance, treatment availabilities, etc. The scenario was poor in Manipur, where the dog

bite incidence is low and it could be possibly due to the practice of dog meat consumption, poor rabies vaccine supplies, etc.

Table 48: Hospital incidence rates (%) of dog bites from the states based on the IDSP reports

State /Year	2012	2013	2014	2015	2016
Himachal Pradesh	0.18	0.17	0.20	0.35	0.51
Bihar	0.40	0.40	0.60	0.26	0.38
West Bengal	0.25	0.28	0.31	0.36	0.44
Manipur	0.02	0.06	0.06	0.16	0.11
Kerala	0.32	0.35	0.44	0.45	0.39
Madhya Pradesh	0.13	0.18	0.31	0.32	0.27
Gujarat	0.53	0.51	0.55	0.60	0.62
Total	**0.26**	**0.28**	**0.35**	**0.36**	**0.39**

3.10.2. Human Rabies

Presently information from the states is sent periodically to the Central Bureau of Health Intelligence (CBHI), New Delhi through the NRCP officer or from a designated officer from the states. The information is collected mostly from the ID hospitals/ wards in the states. WHO-APCRI survey team during its visits to the states collected the information about human rabies from the isolation hospital/ ward of the state capital (except in Gujarat, it was from Surat) and the same was cross tabulated against the CBHI data.

Table 49: State wise annual incidence of human rabies in India: 2012-2016 [5 year period]

State	2012		2013		2014		2015		2016	
	CBHI	APCRI	CBHI	APCRI	CBHI	APCRI	CBHI	APCRI	CBHI	APCRI
HP	02	03	00	02	01	03	02	02	00	00
Bihar	00	93	00	86	00	69	01	82	04	58
WB	80	36	57	55	52	50	47	42	47	52
Manipur	00	01	00	17	00	17	00	08	00	01
MP	03	11	09	13	02	14	11	11	00	NA
Gujarat	07	15	03	14	00	13	08	12	01	11
Kerala	07	13	08	11	05	10	07	10	02	05
Total	**99**	**172**	**77**	**198**	**60**	**176**	**76**	**167**	**54**	**127**

Despite, the WHO-APCRI survey team visiting only one facility in each state i.e. isolation hospital/ward in a hospital at the state capital (except in Gujarat it was Surat city) it was found that except in three instances there was gross under reporting of the disease from the states. A single visit to a isolation hospital/ ward in the state capital (except in Gujarat) resulted in identifying more than twice (366 cases of CBHI vis-a-vis 840 cases of APCRI survey) the number of human rabies cases from the state. This summarizes the current scenario of poor human rabies surveillance in the states and its reporting to the central government. Also this data is institution based/ passive surveillance, has inherent limitations

of iceberg phenomenon of a disease in a community/ population as compared to an active community based surveillance that was undertaken by WHO-APCRI survey, in 2003.

In this context the new initiative under the national rabies control programme (NRCP) to establish linkage with the infectious diseases (ID) hospitals to improve human rabies surveillance through IDSP using modified P form is a welcome move.

Lastly, the data obtained from the IDSP (dog bite incidence from the government hospitals providing PEP) was linked to human rabies incidence (from the Isolation hospitals of the state capitals in the government) from the states for epidemiological evaluation.

Table 50 : Hospital incidences of dog bites and human rabies from seven survey states during 2012- 2016 (5 year period)

Year/ Surveillance	**2012**	**2013**	**2014**	**2015**	**2016**
Dog bite incidence (%)	0.26	0.28	0.35	0.36	0.39
Human rabies	172	198	176	167	127

It is well known that good PEP services reduce the rabies burden in a population. It can be seen that, there is a decline in the incidence of human rabies in the isolation hospitals across the states vis-a-vis reasonably improved 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.

References:

1. Government of India, Directorate General of Health Services, Joint monitoring mission report, integrated disease surveillance programme, WHO country office for India, 2015, New Delhi.

2. Government of India, National health profile, Central Bureau of Health Intelligence, Ministry of Health and Family Welfare, 2017, New Delhi

3. National Centre for Disease Control, Integrated disease surveillance programme, New Delhi, October, 2017 [official communication]

3.10.3. Appraisal of human rabies in the survey states

The record keeping was far from satisfactory and in one instance the records were not traceable in a medical college hospital. Despite the time constraint of the field work duration in the survey, still a serious effort was made to obtain the records from the MRD/ ward and these were analysed at those places using a simple tally method. The results are vide below.

Table 51: Analysis of Human rabies admitted for 2016 in seven states									
Characteristic	***States***	***HP***	***Bihar***	***WB***	***Manipur***	***Kerala***	***MP***	***Gujarat***	***Total***
	Total cases	00	53	43	01	01	-	01	**99**
Area	*Urban*	-	05	14		01		01	**21**
	Rural	-	48	29					**77**
	NR/NK	-			01				**01**
Sex	*Male*	-	48	34		01			**83**
	Female	-	05	09				01	**15**
	NR/NK	-			01				**01**
Age	*Adult*	-	36	36	01	01			**74**
	Child(≤14yrs)	-	17	07				01	**25**
Animal	*Dog*	-	46	35		01		01	**83**
	Cat	-	01						**01**
	Wild Animal	-	04	03					**07**
	NR/NK	-	02	05	01				**08**
Bite site	*Head*	-	05	06				01	**12**
	Trunk	-	01						**01**
	UL	-	06	01					**07**
	LL	-	03	03					**06**
	Groin	-		01					**01**
	UK/NR	-	38	32	01	01			**72**
ARV	*Received*	-	11	15				01	**27**
	Not Received	-	24	12		01			**37**
	NR/NK	-	18	16	01				**35**
RIG	*Received*	-		05					**05**
	Not Received	-		20		01		01	**22**
	NR/NK	-	53	18	01				**72**
Outcome	*Died*	-	06	43	01	01		01	**52**
	LAMA	-	47						**47**
	NR/NK	-							

Majority of cases were from rural areas (77%), males (83%) and adults (74%). The most common biting animal was dog (83%), the bite being more on the head (12%) and some (27%) had received few doses of ARV. The documentation of information of the patient was poor in the wards by the medical officers. As a result a detailed analysis could not be done. Hence, under National Rabies Control Programme (NRCP) it would be worthwhile introducing a simple structured format to facilitate uniform recording of correct and complete desired information.

In conclusion, the surveillance of dog bites and human rabies needs to be vastly improved. But this would be time consuming; pain staking and sustained long term efforts are needed under IDSP/NRCP. But to plan further interventions, it would be worthwhile to conduct a special disease survey/surveillance, in 2018 (on the lines of WHO-APCRI survey

done in 2013) for immediate estimation of the burden of human rabies in the country. This is for the consideration of Government of India/ World Health Organization.

3.10.4. Limitation:

APCRI is a registered scientific society and a non-governmental organization. In the absence of a formal letter of authorization/ introduction from Government of India for APCRI to obtain the desired information from the offices of the government, the project team members from APCRI obtained the same using their personal and professional standing.

3.11. TOR 11: Providing raw video footage and pictures on prevention of rabies

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 using a professional 4K digital camera for recording of both video and still pictures/images. The identified areas included rabies prophylaxis both in the animals and humans and all activities related to prevention and control of rabies. The team recorded these at Bangalore, Goa and Kolkata from both medical and veterinary sectors. The recordings were segregated into different folders and were provided in a hard disk to WHO India Country Office.

Photo 35: Video recording at a household level in a urban community at Kolkata, West Bengal

4. 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 disease surveillance programme (IDSP) & 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.

It is now important to utilize the survey results to revamp the national rabies control programme to achieve the goal of dog mediated human rabies free India by 2030.

5. 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.

6. Annexures

Annexure-6.1: State Medical and Veterinary Investigators			
1	**Dr. Anmol Gupta**	Himachal Pradesh- State Medical Investigator	HoD of Community Medicine, IGMC, Shimla
2	**Dr. Uppinder Sharma**	Himachal Pradesh- State Veterinary Investigator	Assistant Director, Animal Husbandry Department, District Una
3	**Dr. Chittaranjan Roy**	Bihar- State Medical Investigator	HoD of Community Medicine, Darbhanga Medical College, Laheriasarai, Darbhanga-846003
4	**Dr. Dipankar Mukherjee**	West Bengal- State Medical Investigator	Assistant Professor of Community Medicine, KPC Medical college, Kolkata
5	**Dr. Longiam Usharani Devi**	Manipur- State Medical Investigator	HoD of Community Medicine, Jawarlal Nehru Institute of Medical Sciences, Imphal
6	**Dr. Ibotombi Singh**	Manipur – State Veterinary Investigator	PI & I/C Disease Investigation Laboratory, Directorate of Vety. & AH Services Manipur, Imphal-795001
7	**Dr. M. Geetadevi**	Kerala- State Medical Investigator	Assistant Professor of Community Medicine, GMC, Kottayam
8	**Dr. Swapna Susan**	Kerala- State Veterinary Investigator	Disease Investigation officer, Chief Disease Investigation Office, Department of Animal Husbandry, Palode, Thiruvananthapuram-695562
9	**Dr. Arun Kokane**	Madhya Pradesh- State Medical Investigator	HoD of Community Medicine, AIIMS, Bhopal
10	**Dr. Abhay Kavishvar**	Gujarat- State Medical Investigator	Associate Professor of Community Medicine, GMC, Surat
11	**Dr. Irshad Kalyani**	Gujarat- State Veterinary Investigator	Professor and Head, Department of Microbiology, Veterinary college, Navsari Agricultural University, Eru Char Rasta, At & Po Eru Ta - Jalalpore, Navsari, Gujarat 396 450

Annexure-6.2 Community Survey- Proforma (Data was collected using android mobile phone with Apps developed by WHO- India Office

EPIDEMIOLOGIC EVALUATION OF ANIMAL BITES AND RABIES EXPOSURES IN THE COMMUNITY

ADULT CONSENT FORM (AGE 18 or OVER)

SECTION 1: INTERVIEW INFORMATION			
Respondent ID			
Interviewer Name _____			
Date of interview: DAY	**MONTH**	**YEAR**	

Why is this study being done?

The WHO - APCRI are researching diseases that are transmitted by animals to people. We are asking you to participate in a survey.

What will happen in this study?

We will ask you questions about your experiences with dogs and other domestic and wild animals and your knowledge about diseases that you can get from animals. If you choose to be in this study, we will ask you questions for about 30 min.

Why me?

Your household has been randomly selected as a potential participant because you live in an area where you may come into contact with sick dogs or other animals in your day-to-day activities.

What are the risks?

There are NO risks for being in the study. We are only asking for information about your experiences and knowledge. Your participation is completely voluntary.

Will anything good happen to me?

You may not get any direct benefit from being in this study, but you will help us know more about animal bite injuries and diseases in your community. Information obtained from this study may help the Ministry of Health to prevent and treat illnesses caused by animals, particularly in your community.

What about privacy?

The information we collect in this study is confidential. To protect your privacy, all the information collected in this project will be kept in locked computer files. Only authorized persons involved in the survey can view your responses.

If you have questions

You can call Interviewer name_____, phone number_____, affiliation with questions or worries about the study. If you have questions about your rights as a participant in this study, you can call [give the State Investigator / Local ethics committee contact number].

What happens if you don't take part or want to stop?

You are free to join the study or not to join. You may leave the study or refuse to answer a particular question, at any time, for any reason. Nothing will happen to you if you decide not to join or to drop out.

Agreement

This study has been explained to me. I have had a chance to ask questions. Any questions I had were answered. I can choose to be in this study. I can drop out of the study at any time. I will receive a copy of this form. I am 18 years of age or older and I agree to join the study,

Name/Signature: _____

Date: _____

(SPACE FOR THUMBPRINT IF NEEDED)

(If participant is illiterate, you will need thumbprint and signature of witness below*)

***Witness:** _____

Date: _____

For Community survey: Contact details of coordinators	
Dr. N. R. Ramesh Masthi Co-Investigator & Associate Professor of Community Medicine, KIMS, Bangalore-70 **Mobile:** 09845759992 **E-mail:** ramesh.masthi@gmail.com	**Dr. Gangaboraiah** Project Statistical Consultant & Former Professor of Statistics, KIMS, Bangalore-70 **Mobile**:09845128875 **E-mail:** gbphdstats@gmail.com
For Survey app. Only : Contact details of coordinators	
Dr. B. S. Pradeep Project- Epidemiologist & Additional Professor of Epidemiology NIMHANS, Bangalore-560029 **Mobile:** 09845452250 **E-mail:** doctorpradeepbs@gmail.com	**Dr. H. S. Anwith** Project- Data Manager & Assistant Professor of Community Medicine KIMS, Bangalore-70 **Mobile:** 09844467237 **E-mail** : anwith2006@gmail.com

STUDY ID: ☐☐☐☐☐

SECTION I: INTERVIEW INFORMATION

Household number..... ☐☐

State:_____ ☐☐

District: _____ ☐☐☐

Taluka: _____ ☐☐☐☐☐

Cluster Name:_____ ☐☐☐☐☐☐

Address

House number/Name:_____ Street Name:_____

Landmark:_____ GPS :N_____E_____

Land Phone: ☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐

Mobiles : ☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐

Locale: Rural.....1 Urban.....2

Name of the Medical College:_____

Name of the State Investigator:_____

Name of the field investigator 1 :_____

Name of the field investigator 2 :_____

Date of Study: DAY ☐☐ MONTH ☐☐ YEAR ☐☐☐☐

Did you participate in this study previously? YES.....1 → STOP CONDUCTING INTERVIEW → RESULT

NO.....0 PROCEED WITH CONSENT →

Consented for Study (Yes=1, N0=0)..... ☐

Have you or your family stayed in this locality for more than six months? (Yes=1, N0=0)…….. ☐

Stop interview if response is NO = 0 → RESULT

Result*..... ☐

***RESULT CODES:** INTERVIEW COMPLETED= 1; INTERVIEW PARTIALLY COMPLETED= 2
RESPONDENT WAS A DUPLICATE= 3

SECTION II - SOCIO- DEMOGRAPHIC PROFILE

No.	QUESTIONS AND FILTERS	*CODING CATEGORIES*	SKIP
01	Name of the informant:	_____	
02	What is your age? **(In completed years)**	AGE IN COMPLETED YEARS..... ☐☐ DON'T KNOW.....98	
03	What is your sex?	MALE .....1 FEMALE 2	
04	What is your religion?	HINDU .....01 MUSLIM .....02 CHRISTIAN.....03 BUDDHIST.....04 SIKH.....05 OTHERS**(SPECIFY)**_____96	
05	Can you read and write a letter in any language?	NOT AT ALL.....1 WITH DIFFICULTY.....2 EASILY.....3	
06	What is your current marital status?	CURRENTLY MARRIED.....1 MARRIED, NOT LIVED WITHSPOUSE.....2 WIDOWED.....3 DIVORCED.....4 SEPARATED.....5 DESERTED.....6 NEVER MARRIED.....7	
07	Occupation	CULTIVATOR.....01 AGRICULTURAL LABOURER.....02 NON-AGRICULTURAL LABOURER.....03 BUSINESS.....04 SALARIED EMPLOYMENT.....05 HOUSEWORK.....06 STUDENT.....07 NOT WORKING/UNEMPLOYED.....08 OTHER**(SPECIFY)** _____96	
08	How many persons live in your household?	NUMBER: ..... ☐☐	

Individual details of members of the household										
Sl No	**8A** Name	**8B** Age	**8C** Sex M F	**8D** Relationship with the informant	**8E** Education	**8F** Marital status CM W D NM	**8G** Occupation	**8H** Annual Income in INR.	**8I** Ever bitten by an animal in the **past one year?**	**8J** Number of bites if yes to Q.8I
1			1 2	SELF	0 1 2 3 4 5 6	1 2 3 4		Atleast 6 boxes for PDA	If 2.no → 9	
2			1 2		0 1 2 3 4 5 6	1 2 3 4				
3			1 2		0 1 2 3 4 5 6	1 2 3 4				
4			1 2		0 1 2 3 4 5 6	1 2 3 4				
5			1 2		0 1 2 3 4 5 6	1 2 3 4				

6			1 2		0 1 2 3 4 5 6	1 2 3 4				
7			1 2		0 1 2 3 4 5 6	1 2 3 4				
8			1 2		0 1 2 3 4 5 6	1 2 3 4				

CODE FOR Q 8D: Wife/husband=01,Son/daughter =02Son-in-law/Daughter-in-law =03, Grandchild =04, Father =05, Mother = 06, Mother-in-law =07 Father-in-law =08, Brother/sister =09, Brother-in-law/ sister-in-law =10,Niece/nephew =11, Other relative =12,Adopted/foster child=13, Not related=14

CODE FOR Q 8E: Illiterate=0 Primary =1 Middle school =2 High school =3 Pre University College (Class 11 and 12) =4 Degree/Diploma =5 Post-Graduation and Above =6

CODE FOR Q 8F: Currently married (CM)=1,Widowed(W)=2,Divorced/Separated/Deserted(D)=3, Never married(NM)=4

CODE FOR OCCUPATION Q 8G: Cultivator =01 Agricultural Labourer=02 Non-Agricultural Labourer=03 Business=04 Salaried Employment=05 Housework=06 Student=07 Not Working/Unemployed=08 OTHER**(SPECIFY)** _____96

CODE FOR EVER BITTEN BY ANIMAL Q 8I: Yes = 1 No = 2

SECTION III - SOCIO-ECONOMIC CLASSIFICATION:

No.	QUESTIONS AND FILTERS	*CODING CATEGORIES*	SKIP
9	Type of toilet facility available	SANITARY WATER SEAL.....01 PIT LATRINE .....02 NO FACILITY.....03 OTHERS **(SPECIFY)** _____96	
10	What is the material of the roof of your house? **(INTERVIEWER ASSESS)**	NATURAL ROOF **(THATCH)**.....01 RUDIMENTARY ROOF **(TIN/ALUMINUM/ASBESTOS)**.....02 FINISHED ROOF **(CEMENT / TILED)**..03 OTHERS **(SPECIFY)** _____96	
11	What is the material of the wall of your house? **(INTERVIEWER ASSESS)**	Mud .....01 Brick with mud.....02 Brick with cement.....03 Stone with cement.....04 OTHERS **(SPECIFY)** _____ 96	
12	Does your family currently own any dogs?	YES.....1 NO.....0 →	**15**
12a	How many?	NUMBER..... ☐☐	
13	Type of dog ownership **MARK ALL THAT APPLY**	PET.....1 COMMUNITY.....2 STRAY.....3	

		DOG 1	DOG 2	DOG 3	DOG 4	DOG 5	
13a	What type of care do you provide for your dogs)? (MARK ALL THAT APPLY)	☐☐	☐☐	☐☐	☐☐	☐☐	
13b	What is the age of the dog? (in completed years) (If age less than 1 year mark as 00)	☐☐	☐☐	☐☐	☐☐	☐☐	
13c	What is the sex of this dog?	☐	☐	☐	☐	☐	
13d	Whether this dog has **ever** been vaccinated against rabies?	YES.1 NO.0 →	YES.1 NO..0 →	YES.1 NO..0 →	YES.1 NO..0 →	YES.1 NO..0 →	i
		DK.98 →	DK.98 →	DK.98 →	DK.98 →	DK.98 →	j
13e	How many doses of rabies vaccine has this dog received?	☐☐	☐☐	☐☐	☐☐	☐☐	
13f	Vaccination card verified	YES.1 NO..0 →	YES.1 NO..0 →	YES.1 NO..0 →	YES.1 NO..0 →	YES.1 NO..0 →	j
13g	Photo documentation sent take photo documentation and send both hard and soft copy	YES.1 NO..0	YES.1 NO..0	YES.1 NO..0	YES.1 NO..0	YES.1 NO..0	

13h	Has this dog received rabies vaccine in the **past one year?**	YES.1 NO..0 →	YES.1 NO..0 →	YES.1 NO..0 →	YES.1 NO..0 →	YES.1 NO..0 →	i
		DK.98 →	DK.98 →	DK.98 →	DK.98 →	DK.98 →	j
13i	Why is the dog not vaccinated?						
13j	How is this dog confined?						

CODE FOR SL NO (a):NONE=01 FOOD=02 WATER=03SHELTER=04 VETERINARY CARE=05 OTHERS**(SPECIFY)**_____96
CODE FOR GENDER(c): MALE=01 FEMALE = 02
CODE FOR SL NO (i):TOO YOUNG=01 NO VACCINE AVAILABLE FROM VETERINARIANS=02 NO MONEY TO BUY VACCINE=03 NO VACCINE AVAILABLE FROM GOVERNMENT=04 NO NEED TO VACCINATE=05 NOT AWARE=06 OTHERS**(SPECIFY)**_____96
CODE FOR SL NO (j):
ALWAYS CONFINED AT HOME=01 SOMETIMES ALLOWED TO ROAM FREELY OUTSIDE=02 ALWAYS ALLOWED TO ROAM FREELY OUTSIDE=03 OTHERS (SPECIFY)_____96

14	In the past year, have you acquired any new dogs?	YES.....1 NO.....0 →	14f
14a	If yes, How many new dogs were acquired?	NUMBERS.....	
14b	Dogs acquired from within community?	NUMBERS:.....	
14c	Dogs acquired from outside community?	NUMBERS:.....	
14d	In the past did the dog give birth to puppies? (only for female dogs)	YES.....1 NO.....0 →	14f
14e	How many?	NUMBERS:.....	
14f	In the **past year**, has/have any dog(s) you owned died?	YES.....1 NO.....0 →	15
14g	How many?	NUMBERS:.....	

		DOG 1	DOG 2	DOG 3	DOG 4	DOG 5
14h	How did each dog die?					
14i	If response is Disease/Illness/ Don't know for Q 14h, did the dog show any of these signs shortly before dying?					

CODE FOR SL NO (14h):HIT BY VEHICLE=01 POISONED=02 DISEASE/ILLNESS=03 AGE-RELATED CAUSES=04 OTHERS (SPECIFY)_____96 DON'T KNOW=98
CODE FOR SL NO (14i):HYPERSALIVATION=1 AGGRESSION=2 BITING=3 DIFFICULTY IN WALKING=4 CHANGES IN DOGS BARK=5 OTHERS (SPECIFY)_____96 DON'T KNOW = 98

15	Does your family care for any dogs in the community that you do not own?	YES.....1 NO.....0 →	16
15a	How many?	NUMBERS:.....	

15b	What type of care does you/your family provide for these community dog(s)? **(MARK ALL THAT APPLY)**	NONE.....1 FOOD.....2 WATER.....3 SHELTER.....4 VETERINARY CARE.....5 OTHERS**(SPECIFY)**_____96	

16. Please provide some information on each bite event that has occurred among members of your " household (Repeat for all the bite victims mentioned in Q.8J) Check Q.8J & repeat							
	Details	**Victim 1**	**Victim 2**	**Victim 3**	**Victim 4**	**Victim 5**	
16 a	What is the type of animal that bit them [Name from Q.8a]?	☐☐	☐☐	☐☐	☐☐	☐☐	
16 b	Only If dog **(Else skip to Question 16f)**	PET....1 STRAY..2	PET....1 STRAY..2	PET....1 STRAY..2	PET....1 STRAY..2	PET..1 STRAY.2	
16 c	What was the vaccination status of the biting dog?	☐☐	☐☐	☐☐	☐☐	☐☐	
16 d	Was the dog available for 10 days observation?	YES....1 NO....0 →	YES....1 NO....0 →	YES....1 NO....0 →	YES....1 NO....0 →	YES...1 NO....0 →	.16 f
16 e	What was the status of the dog after 10 days?	ALIVE.01 DEAD..02 DON'T KNOW.98	ALIVE.01 DEAD..02 DON'T KNOW.98	ALIVE.01 DEAD..02 DON'T KNOW.98	ALIVE..1 DEAD...2 DON'T KNOW.98	ALIVE01 DEAD.02 DON'T KNOW.98	
16 f	Where were they when they were bitten?	☐	☐	☐	☐	☐	
16 g	Was it a provoked or unprovoked bite?	☐	☐	☐	☐	☐	
16 h	Total number of bite wounds	☐☐	☐☐	☐☐	☐☐	☐☐	
16 i	Where, on the body, was the person [NAME] bitten by the animal on this occasion?	☐☐	☐☐	☐☐	☐☐	☐☐	
16 j	What are the types of Wounds (Mark all that apply?	☐☐	☐☐	☐☐	☐☐	☐☐	
16 k	After the bite, on this occasion, what did the victim [NAME]do?	☐☐	☐☐	☐☐	☐☐	☐☐	

16 l	Were other people bitten by the same animal?	☐☐	☐☐	☐☐	☐☐	☐☐	
16 m	Did the victim [NAME]seek medical care at a health facility for this bite?	YES....1 NO.....0 →	YES....1 NO.....0 →	YES....1 NO.....0 →	YES....1 NO.....0 →	YES...1 NO....0 →	16w
16 n	What was the time gap between the bite and when medical care was sought?	H H D D	H H D D	H H D D	H H D D	H H D D	
16 o	Did they receive rabies vaccine for this bite?	YES....1 → NO.....0	YES....1 → NO.....0	YES....1 → NO.....0	YES....1 → NO.....0	YES...1 → NO....0	16 t
16 p	What was the site of vaccination?	☐☐	☐☐	☐☐	☐☐	☐☐	
16 q	How many doses of vaccine did they receive?	☐☐	☐☐	☐☐	☐☐	☐☐	
16 r	Type of health facility where rabies vaccine was received	☐☐	☐☐	☐☐	☐☐	☐☐	
16 s	Type of health facility where Rabies immunoglobulin(RIG) received	☐☐	☐☐	☐☐	☐☐	☐☐	
16 t	Did they receive rabies immunoglobulin (RIG) for this bite?	YES....1 NO.....0 →	YES....1 NO.....0 →	YES....1 NO.....0 →	YES....1 NO.....0 →	YES...1 NO....0 →	Q.16 x
16 u	Type of RIG received	☐☐	☐☐	☐☐	☐☐	☐☐	
16 v	Site of RIG administration	☐☐	☐☐	☐☐	☐☐	☐☐	
16 w	Why did they not seek medical care for this bite?	☐☐	☐☐	☐☐	☐☐	☐☐	
16 x	Did the person have wound infection?	YES....1 NO.....0	YES....1 NO.....0	YES....1 NO.....0	YES....1 NO.....0	YES...1 NO....0	
16 y	Do you know of anyone in your family who has died of Rabies after dog bite?	YES....1 NO.....0	YES....1 NO.....0	YES....1 NO.....0	YES....1 NO.....0	YES...1 NO....0	

CODE FOR SL NO (16a): DOG=01 CAT=02 LIVESTOCK=03 BAT=04 MONGOOSE=05 OTHERS**(SPECIFY)**_____96

CODE FOR SL NO (16c): UNVACCINATED=01PARTIALLY VACCINATED=02FULLY VACCINATED=03DON'T KNOW=98

CODE FOR SL NO (16f): AT HOME=0 OUTSIDE HOME=1

CODE FOR SL NO (16g):UNPROVOKED ATTACK=0 PROVOKED ATTACK=1

CODE FOR SL NO (16i): HEAD/FACE=01 TORSO/TRUNK=02 ARM/FOREARM/HANDS=03 LEG/FEET=04 OTHERS**(SPECIFY)**____96

CODE FOR SL NO (16j): ABRASION=01 LACERATION=02 PUNCTURE WOUND=03 AVULSION=04 OTHERS**(SPECIFY)**_____96

CODE FOR SL NO (16k): NOTHING=01 WASH WOUND WITH WATER=02 WASH WOUND WITH WATER AND SOAP=03 APPLIED ANTISEPTICS=04 CONSULTED A TRADITIONAL HEALER=05 CALL A MEDICAL DOCTOR=06 CALL A VETERINARIAN=07 APPLY IRRITANTS=08 OTHERS**(SPECIFY)**_____96

CODE FOR SL NO (16l):YES=01 NO=00 DON'T KNOW=98

CODE FOR SL NO (16p): DELTOID=01 ANTERO LATERAL THIGH=02 GLUTEAL=03 ANTERIOR ABDOMINAL WALL=04 INTO THE WOUND=05 OTHERS**(SPECIFY)**_____96

CODE FOR SL NO (16 r & s): GOVERNMENT HOSPITAL=01 PRIVATE HOSPITAL =02

CODE FOR SL NO (16 u): ERIG=01 HRIG=02 DON'T KNOW=98

CODE FOR SL NO (16 v): DELTOID=01 ANTERO LATERAL THIGH=02 GLUTEAL=03 ANTERIOR ABDOMINAL WALL=04 INTO THE WOUND=5 OTHERS**(SPECIFY)**_____96

CODE FOR SL NO (16w): NOT AWARE TO SEEK CARE=01 HOSPITAL TOO FAR=02 TOO EXPENSIVE=03 NO TRANSPORTATION=04 CAN'T MISS WORK=05 OTHERS_____96 DON'T KNOW=98

17.	**Cost analysis questioner at the end of the proforma**					
18	Do you know of anyone in your community who has ever died from an illness they got within 3 months of being bitten by an animal excluding reptiles or birds?		YES.....1 NO.....0 DON'T KNOW.....98			} 19
18a	How many?		NUMBERS..... ☐☐			
18b	Please provide some information for these persons					
	PERSONS **(NAME)**	AGE	SEX M F	PLACE OF DEATH	YEAR OF DEATH **CODE 98 IF UNKNOWN**	Bitting animal :code
	1 --	☐☐	1 2	HOME.....1 HOSPITAL.....2	☐☐☐☐	☐☐
	2 --	☐☐	1 2	HOME.....1 HOSPITAL.....2	☐☐☐☐	☐☐
	3 --	☐☐	1 2	HOME.....1 HOSPITAL.....2	☐☐☐☐	☐☐
	4 --	☐☐	1 2	HOME.....1 HOSPITAL.....2	☐☐☐☐	☐☐
	5 --	☐☐	1 2	HOME.....1 HOSPITAL.....2	☐☐☐☐	☐☐
	CODE FOR SL NO (18b): DOG=01 CAT=02 LIVESTOCK=03 BAT=04 MONGOOSE=05 OTHERS **(SPECIFY)**_____ 96					
19	Do you know anyone in your community who has ever died from a disease called 'rabies'?		YES.....01 NO.....00 DON'T KNOW.....98			} 20
19a	How many?		NUMBERS..... ☐☐			
19b	Please provide some information for these persons					
	PERSONS **(NAME)**	AGE	SEX M F	PLACE OF DEATH	YEAR OF DEATH **CODE 98 IF UNKNOWN**	Bitting animal :code
	1 --	☐☐	1 2	HOME.....1 HOSPITAL.....2	☐☐☐☐	☐☐
	2 --	☐☐	1 2	HOME.....1 HOSPITAL.....2	☐☐☐☐	☐☐
	3 --	☐☐	1 2	HOME.....1 HOSPITAL.....2	☐☐☐☐	☐☐
	4 --	☐☐	1 2	HOME.....1 HOSPITAL.....2	☐☐☐☐	☐☐
	5 --	☐☐	1 2	HOME.....1 HOSPITAL.....2	☐☐☐☐	☐☐
	CODE FOR SL NO (19b): DOG=01 CAT=02 LIVESTOCK=03 BAT=04 MONGOOSE=05 OTHERS **(SPECIFY)**_____ 96					

SECTION IV: RABIES KAP

20	How much do you know about a disease called rabies? **{INTERVIEWER MUST EVALUATE BASED ON RESPONDENTS ANSWER}** a) I HAVE NEVER HEARD OF RABIES.....1 b) LITTLE KNOWLEDGE **(I.E., HAVE HEARD OF RABIES/DOG DISEASE,BUT CAN'T IDENTIFY TRANSMISSION ROUTES OR SEVERITY OF DISEASE)**.....2 c) BASIC UNDERSTANDING **(KNOWLEDGE THAT RABIES IS BOTH A HIGHLY FATAL DISEASE AND IS TRANSMITTED BY ANIMAL BITE)**.....3 ~~d)~~ EXTENSIVE KNOWLEDGE **(BASIC UNDERSTANDING PLUS KNOWLEDGE OF NON-BITE ROUTES OF EXPOSURE AND WILDLIFE RESERVOIRS BESIDES DOGS WITHOUT PROMPTING)**.....4		
21	Have you ever heard about a disease called 'Rabies'?	YES.....01 NO.....00→	25
22	How severe do you think is this disease called rabies?	MILD.....01 RECOVERABLE.....02 FATAL.....03 DON'T KNOW.....98	
23	Do you know how humans get rabies from an infected animal? **(MARK ALL THAT APPLY)**	BITE.....01 SCRATCH.....02 OBSERVING THE ANIMAL.....03 TOUCHING THE ANIMAL.....04 CONTACT WITH BLOOD.....05 CONTACT WITH SALIVA.....06 CONTACT WITH URINE/FECES....07 OTHERS **(SPECIFY)**_____96 DON'T KNOW.....98	
24	On a scale of 1-5, with 1 being little to no risk of rabies from that animal and 5 being very high risk of rabies from that animal, list the rabies risk of each animal.		
	a) DOGS 1 2 3 4 5 b) CATS 1 2 3 4 5 c) LIVESTOCK (CATTLE, SHEEP, GOATS, ETC.) 1 2 3 4 5 d) MONGOOSE 1 2 3 4 5 e) MONKEYS OR OTHER PRIMATE 1 2 3 4 5 f) WILD BIRDS 1 2 3 4 5 g) BATS 1 2 3 4 5 h) RODENTS 1 2 3 4 5 i) SNAKES 1 2 3 4 5		
25	What would you do, if you were bitten by a dog that **<u>you recognize or own?</u>** **(MARK ALL THAT APPLY)**	NOTHING.....01 WASH WOUND WITH WATER.....02 WASH WOUND WITH WATER AND SOAP.....03 APPLY IRRITANTS.....04 CONSULT TRADITIONAL HEALER..05 CALL A MEDICAL DOCTOR.....06 CALL A VETERINARIAN.....07 ACTIVELY SEEK CARE AT MEDICAL FACILITY.....08 SEEK RABIES POST-EXPOSURE PROPHYLAXIS.....09 DON'T KNOW.....98 OTHERS **(SPECIFY)**_____96	

25a	What would you do to the dog?	NOTHING.....01 ISOLATE THE DOG FOR OBSERVATION.....02 SUBMIT DOG FOR DISEASE TESTING.....03 KILL THE DOG.....04 OTHERS(SPECIFY)_____96	
26	What would you do if you were bitten by a dog that you **do not** recognize or own? (**MARK ALL THAT APPLY)**	NOTHING.....01 WASH WOUND WITH WATER.....02 WASH WOUND WITH WATER AND SOAP.....03 APPLY IRRITANTS.....04 CONSULT A TRADITIONAL HEALER05 CALL A MEDICAL DOCTOR.....06 CALL A VETERINARIAN.....07 ACTIVELY SEEK CARE AT MEDICAL FACILITY.....08 SEEK RABIES POST-EXPOSURE PROPHYLAXIS.....09 DON'T KNOW.....98 OTHERS(SPECIFY)_____96	
27	What would you do to the dog?	NOTHING.....01 ISOLATE THE DOG FOR OBSERVATION.....02 SUBMIT DOG FOR DISEASE TESTING.....03 KILL THE DOG.....04 OTHERS(SPECIFY)_____96	
27a	If you saw a dog in your village that looked sick, what would you do? **(MARK ALL THAT APPLY)**	NOTHING.....01 CALL POLICE.....02 CALL LOCAL HEALTH WORKER....03 CALL A FRIEND.....04 CALL LOCAL VETERINARIAN /LIVSTOCK INSPECTOR.....05 AVOID THE ANIMAL.....06 SCARE (SHOO) ANIMAL AWAY....07 KILL THE ANIMAL.....08 KILL AND SUBMIT THE ANIMAL FOR TESTING.....09 OTHERS(SPECIFY)_____96	

SECTION V: HEALTH CARE ACCESSIBILITY

No.	QUESTIONS AND FILTERS	*CODING CATEGORIES*	SKIP
28	How far do you travel for routine medical care**?(One way)**	KM ☐☐☐ I DON'T KNOW.....98	
29	How far do you have to travel to a facility where you can receive rabies vaccination? **(One way)**	☐☐☐ KM I DON'T KNOW.....98	
30	What is the primary mode of transportation you would use to visit a health facility?	WALK.....01 BIKE.....02 CAR.....03 BUS.....04 OTHERS**(SPECIFY)**_____96	
31	What are the primary obstacle for getting rabies prophylaxis in your community? **(MARK ALL THAT APPLY)**	LACK OF FACILITIES TO PROVIDE TREATMENT.....01 LACK OF TRAINED PERSONNEL AT FACILITIES.....02 LACK OF MEDICINES AT FACILITIES.....03 NO MEANS OF TRANSPORTATION..04 NO MONEY TO PAY FOR TREATMENT.....05 CAN'T MISS WORK.....06 DON'T KNOW.....98 OTHERS**(SPECIFY)**_____96	
32	**Awareness of Pre exposure prophylaxis** -Can one take Rabies vaccine as pre-bite prophylaxis	YES.....01 NO.....00 DON'T KNOW.....98	
32a	If Yes, How many doses	☐	
33	Have You taken preventive vaccination**(Before exposure to an animal bite)** against rabies?	YES.....1 NO.....0	
34	If Yes, How many doses?	☐	
34a	Where did you take?	GOVERNMENT HOSPITAL.....1 PRIVATE HOSPITAL.....2	

EPIDEMIOLOGIC EVALUATION OF ANIMAL BITES AND RABIES EXPOSURES IN THE COMMUNITY

Cost analysis of post exposure prophylaxis (PEP)

(From bite victim only)

Study ID/Household no.(Obtain from app): Date of survey:

Name of the State: Name of District: Name of taluk:

Cluster Name:

Name of the field investigator: Mobile no.:

Name of the subject: Mobile no.: Date of bite:

	PEP items	**COST(in Rupees)**						**TOTAL**
1.	**RIG (Brand)**	**Detail**	**D-0**	**D-3**	**D-7**	**D-14**	**D-28**	
1a	HRIG (If Don't know:98)					x	x	
1b	ERIG (If Don't know:98)					x	x	
1c	Place of administration. Govt.=1/Private = 2					x	x	
1d	Other medicines, etc.							
1e	Consultation cost					x	x	
1f	Administration cost					x	x	
1g	Hospitalization cost					x	x	
1h	Travel /Transport cost					x	x	
1i	Loss of pay, if any							
1j	Others (Specify)							
	Sub-total							
2.	**VACCINE(Brand)**							
2a	**ID (If Don't know:98)**							
2b	**IM (If Don't know:98)**							
2c	Place of vaccination Govt. =1/ Private=2							
2d	Other medicines, etc							
2e	Consultation cost							
2f	Administration cost							
2g	Hospitalization cost							
2h	Travel /Transport cost							
2i	Loss of pay, if any							
2j	Others(Specify)							
	Sub – total							
	GRAND TOTAL							

Annexure-6.3 Health Facility Survey- Proforma

Health care facility survey Proforma

SECTION I: INFORMATION OF HEALTH FACILITY (To be filled by co-investigator)

State:_____ ☐☐

District:_____ ☐☐☐

Taluka/ Block/ Tehsil:_____ ☐☐☐☐☐

Locale: Rural.....1 Urban.....2

Health Facility Code: ..... ☐

Name & address of health facility:_____

Name of the medical officer:_____

Land Phone:☐☐☐☐☐☐☐☐☐☐ Mobile 1: ☐☐☐☐☐☐☐☐☐☐

Email : _____ Mobile 2: ☐☐☐☐☐☐☐☐☐☐

GPS Coordinate of health facility :N:_____ E: _____

Facility type	Hospital.....1 Health centre.....2 Speciality anti rabies clinic.....3
Organization type	Government.....1 Private.....2
Services provided **MARK ALL THAT APPLY**	Maternal care..... 01 Mental health.....02 Preventive care.....03 Paediatric care.....04 Emergency.....05 Others(specify) _____ 96

FORM HF1: HEALTH FACILITY (ANTI RABIES CLINIC) INFORMATION

To be filled by Medical officer

Please provide the number of dog bite cases and total number of patients attending health facility weekly:

Week 1 beginning: Date ☐☐ Month ☐☐ Year ☐☐☐☐

WEEK	Number of DOG BITE CASES	TOTAL NO.OF PATIENTS
1	☐☐	☐☐☐☐
2	☐☐	☐☐☐☐
3	☐☐	☐☐☐☐
4	☐☐	☐☐☐☐
5	☐☐	☐☐☐☐

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ADULT CONSENT FORM (AGE 18 or OVER)

SECTION 1: INTERVIEW INFORMATION	
Patient ID	
Interviewer Name & code:	
Date of interview: DAY	**MONTH** **YEAR**

Why is this study being done?
The WHO-APCRI are researching diseases that are transmitted by animals to people. We are asking you to participate in a survey.

What will happen in this study?
We will ask you questions about your experiences with dogs and other domestic and wild animals and your knowledge about diseases that you can get from animals. If you choose to be in this study. We will ask you questions for about 30 min.

What are the risks?
There are NO risk for being in the study. We are only asking for information about your experiences and knowledge. Your participation is completely voluntary.

Will anything good happen to me?
You may not get any direct benefit from being in this study, but you will help us know more about animal bite injuries and diseases in your community. Information obtained from this study may help the Ministry of Health to prevent and treat illnesses caused by animals, particularly in your community.

What about privacy?
The information we collect in this study is confidential. To protect your privacy, and all the information collected in this project will be kept in locked computer files. Only authorized persons involved in the survey can view your responses.

What happens if you don't take part or want to stop?
You are free to join the study or not to join. You may leave the study or refuse to answer a particular question, at any time, for any reason. Nothing will happen to you if you decide not to join or to drop out.

Agreement
This study has been explained to me. I have had a chance to ask questions. Any questions I had, were answered. I can choose to be in this study. I can drop out of the study at any time. I am 18 years of age or older and I agree to join the study,

Name/ Signature :_____

Date: _____

(If participant is illiterate, take thumbprint and signature of witness* below)

*Witness_____ Date: _____

FORM HF2: DAY 0 - ANIMAL BITE ENROLLMENT FORM
(NEEDS TO BE LINKED TO THE PERTINENT HEALTH FACILITY)

Enumerator Name & mobile number: WILL BE PART OF THE USERNAME INFORMATION

FACILITY CODE:NEEDS TO BE AUTO POPULATED UTILISING INFORMATION FROM SECTION I OF HF1	Date D D M M Y Y Y Y	Patient ID:

No.	QUESTIONS AND FILTERS	CODING CATEGORIES	SKIP
01	What is your age? Date of birth D D M M Y Y Y Y	Age in completed years..... Don't know 98	
02	What is your sex?	Male .....1 Female 2	
03	What is your education?	Illiterate.....1 Less than primary complete.....2 Primary complete/middle incomplete....3 Middle complete/secondary incomplete..4 High school/secondary complete/Pre-university incomplete .....5 Pre-University complete/ Degree incomplete .....6 Degree complete.....7 Post Graduation.....8	
04	**Address** Name :_____ House number:_____ Street Name:_____ Landmark :_____ Village/Town:_____Taluka:_____ District:_____ State:_____ Land Phone: Mobile1: 2: Email : _____		
05	Occupation	Cultivator.....1 Agricultural labourer.....2 Non-agricultural labourer.....3 Business.....4 Salaried employment.....5 Housework.....6 Student.....7 Not working/unemployed.....8 Other**(specify)** _____96	
06	What is your current marital status?	Married.....1 Married, not living with spouse.....2 Widowed.....3 Divorced.....4	

		Separated.....5 Deserted.....6 Never married.....7	
07	Date of animal bite	Day ☐☐ Month ☐☐ Year ☐☐☐☐ Don't know 98	
08	Biting animal	Dog.....01 Cat.....02 → 09 Livestock.....03 Mongoose.....04 Monkey.....05 Rodent .....06 Others(specify)_____96	10
08 a	If the biting animal is a dog?	Pet .....01 Stray .....02 Community.....03	
09	If animal was a dog or cat, was it vaccinated against rabies in the past year?	Yes.....01 No.....00 Don't know.....98	
10	Type of animal Exposure **MARK ALL THAT APPLY**	Bite (skin broken and bleeding).....01 Scratch (no bleeding).....02 Lick on(open wound).....03 Lick on(skin intact).....04 Saliva contact with mucous membrane..05 Other (specify)_____96	
11	Where, on the body, you had the exposure/ bite? **MARK ALL THAT APPLY**	Head/Face/Neck.....01 Trunk.....02 Arm/Hand(s) .....03 Leg/Feet.....04 Others(specify)_____96	
12	Where were you, when bitten by the animal?	Home .....1 Outside of home 2	
13	Was it a provoked or unprovoked bite?	Provoked.....01 Unprovoked .....02 Don't know.....98	
14	At the time you were bitten, was the animal displaying any of these signs? **MARK ALL THAT APPLY**	Hypersalivation.....01 Aggression.....02 Biting other animals.....03 Difficultly in walking.....04 Changes in dogs bark.....05 None.....00 Don't know.....98	
15	Did you apply anything to the bite wound? **MARK ALL THAT APPLY**	Turmeric/ coffee/ chilli powder.....01 Cow dung/ mud.....02 Plant sap/ coin .....03 Others (SPECIFY) _____96	
16	Did you wash the wound immediately after the bite?	Yes….....01 No.....00 → Don't know / Not sure .....98 →	16b
16 a	What did you use to wash the wound?	Water.....01 Water & soap.....02 Others(specify)_____96	
16 b	Did you apply antiseptic to the wound(s)?	Yes.....01 No.....00 Don't know.....98	

17	What else did you do, before coming to this health facility? **MARK ALL THAT APPLY**	Nothing.....01 Visited another health facility…....02 Visited a traditional healer.....03 Consulted veterinarian.....04 Other **(specify)**_____96	
18	What happened to the animal that you were exposed to?	Nothing .....00 Isolated (dog/cat) for observation...01 Submitted for laboratory testing.....02 **Name of Lab:** _____ Killed the dog.....03 Escaped.....04 Don't know.....98 Other **(specify)**_____96	
19	Have you ever been vaccinated against rabies in the past?	Yes.....01 No.....00 Don't know.....98	} 20
19a	If yes, When did you get vaccinated? **MARK ALL THAT APPLY**	Before the bite .....01 After the bite 02	
19b	How many doses did you receive?	☐☐	
20	Excluding this bite, have you ever been bitten by any animal in the past?	Yes.....1 No.....0 →	21
20 a	If yes, How many times have you been bitten by an animal in the **last 1 year?**	☐☐	
20 b	What was the biting animal and what treatment did you seek for these previous animal bites? **(CHECK ALL THAT APPLY)**		

	20c BITING ANIMAL	**20d TREATMENT SOUGHT**	**20e TYPE OF VACCINE**	**20f NO.OF DOSES**	
	☐	☐☐	☐☐	☐	
	☐	☐☐	☐☐	☐	
	☐	☐☐	☐☐	☐	
	☐	☐☐	☐☐	☐	
	☐	☐☐	☐☐	☐	
	☐	☐☐	☐☐	☐	

BITING ANIMAL: DOG=1; CAT=2; LIVESTOCK (CATTLE, SHEEP, GOAT etc..)=3; MONGOOSE=4; MONKEYS=5; RODENTS=6

TREATMENT SOUGHT:RABIES POST EXPOSURE PROPHYLAXIS=01; ANTIBIOTICS=02; TETANUS TOXOID=03; TRADITIONAL MEDICINE=04; OTHER**(SPECIFY)**_____96

TYPE OF VACCINE: NERVE TISSUE VACCINE=1; MODERN CELL CULTURE VACCINE=2; DON'T KNOW=98

KNOWLEDGE, ATTITUDE & PRACTICE(KAP)			
21	Have you ever heard about a disease called 'Rabies'?	Yes.....1 No.....2 →	30
22	How severe is the disease called rabies?	Non-fatal (Recoverable).....1 Fatal(death).....2 Don't know.....3	
23	On a scale of 1-5, with 1 being little to no risk of rabies from that animal and 5 being very high risk of rabies from that animal, list the rabies risk of each animal.	No Risk → High risk	
	a. DOG	1 2 3 4 5	
	b. CAT	1 2 3 4 5	
	c. LIVESTOCK (CATTLE, SHEEP, GOATS, ETC.)	1 2 3 4 5	
	d. MONGOOSE	1 2 3 4 5	
	e. MONKEYS	1 2 3 4 5	
	f. BATS	1 2 3 4 5	
	g. RODENTS	1 2 3 4 5	
24	How do humans get rabies from an infected animal? **MARK ALL THAT APPLY.**	Bite with bleeding..... 01 Scratch without bleeding.....02 Observing the animal.....03 Touching the animal.....04 Contact with blood of infected.....05 Contact with saliva of infected.....06 Contact with urine/feces of infected.07 Don't know.....98 Other (Specify)_____96	
25	What would you do if you were bitten by a dog? **(MARK ALL THAT APPLY)**	Nothing.....01 Wash wound with water.....02 Wash wound with water and soap.....03 Apply irritants.....04 (turmeric/coffee/ chilli powder) Consult a traditional healer.....05 Consult a medical doctor.....06 Consult a veterinarian.....07 Seek care at medical facility.....08 Seek post-exposure prophylaxis.....09 Don't know.....98	
26	How many doses of anti-rabies vaccine have to be taken if you are bitten by a dog?	☐☐	
27	Do you know about any injection which needs to be given to all bite wounds with bleeding to prevent rabies?	Yes.....1 No.....0	
28	When do you think the vaccine against Rabies can be taken? **MARK ALL THAT APPLY**	Anytime before the bite or exposure...1 Anytime after the bite or exposure ...2 Don't know .....98 Others (SPECIFY) _____96	30

29	How many doses of vaccine do you think one needs to take before the bite or exposure for protection against rabies?	☐☐	

Details of POST EXPOSURE PROPHYLAXIS
(TO BE FILLED BY THE MEDICAL OFFICER)

30	Post Exposure Prophylaxis Recommended:	Yes.....1 No.....0	
31	Patient weight:	In Kilograms ☐☐☐	
32	WHO Exposure Category	I.....1 II.....2 III.....3	
33	Rabies Immunoglobulin administered?	Yes.....1 No.....0	→ 34
33 a	Type of Rabies Immunoglobulin administered?	Human Rabies Immunoglobulin (Brand Name):_____ Equine Rabies Immunoglobulin (Brand Name):_____ Total dosage given(in ml): ☐☐	
33 b	Site(s) administered	Only wound infiltration.....01 Only systemic administration.....02 (Gluteal/ Thigh/ Deltoid) Both wound infiltration & systemic...03 Others(specify)_____96	
34	Rabies vaccine administered?	Yes.....1 No.....0	→ 35
34 a	If Yes,	Brand name of the vaccine: _____ Lot #: _____ Manf. Date:_____ Exp.date:_____ Vaccinator (Name): _____ Route administered : IM ☐ ID ☐ Remaining number of doses: _____ Date patient should complete vaccination ☐☐ ☐☐ ☐☐☐☐	
35	What other treatments were provided **MARK ALL THAT APP**	Wound irrigation.....01 Wound dressing.....02 Wound drain.....03 Suture.....04 Antibiotics.....05 Pain medication.....06 Tetanus toxoid.....07 Radiography, suspect fracture.....08 Admit to hospital.....09 Other **(Specify)**_____96	

Details of serum sample for rabies virus neutralizing antibodies (RVNA)

This study has been explained to me. I have had a chance to ask questions. Any questions I had, were answered. I can choose to be in this study. I can drop out of the study at any time. I am 18 years of age or older and I agree to join the study and I will give my full consent to draw the blood for RVNA analysis.

Name and Signature :_____ Date: _____ **(If participant is illiterate, you will need thumbprint and signature of witness* below)** ***Witness:** _____ Date: _____			
36	Blood sample drawn for RVNA analysis, if feasible (AFTER TAKING SIGNED CONSENT)	Yes.....1 No.....0 [PROVIDE SIGNED CONSENT FORM]	37
36 a	If yes	Day ☐☐ Month ☐☐ Year ☐☐☐☐	
36 b	Date of transportation to NIMHANS, Bangalore	Day ☐☐ Month ☐☐ Year ☐☐☐☐	
36 c	RFFIT results **(Will be filled at APCRI head quarters & feedback given)**	☐☐ IU/ ML	

Details of Cost incurred

Sl. No.	Details	Cost(in INR)
37	**Anti Rabies Vaccine**: Brand:_____ Route of administration: IM/ID	
38	**Rabies Immunoglobulin**: HRIG/ ERIG; Brand: _____	
39	Other Medicines (Inj. T.T, anti-septic, anti-inflammatory & antibiotics, etc)	
40	Hospital charges	
41	Cost of travel for patient and attendants	
42	Cost of food for patient and attendants	
43	Loss of wages(If any)for the patient and attendants	
44	Cost of PEP availed at other centers	
45	Others (Specify)_____	
46	**TOTAL COST**	

FORM HF 3: DAY 3 FOLLOW-UP VACCINATION VISIT

Enumerator Name & mobile number: WILL BE PART OF THE USERNAME INFORMATION

FACILITY CODE:NEEDS TO BE AUTO POPULATED UTILISING INFORMATION FROM SECTION I OF HF1	Date ☐☐ ☐☐ ☐☐☐☐	Patient ID: ☐☐☐☐☐☐

No.	QUESTIONS AND FILTERS	CODING CATEGORIES	SKIP
1	Did you experience any kind of adverse reactions after you received the vaccine last time?	Yes.....1 No.....0 → 4	
1a	What kind of reactions did you experience at the site of vaccination? **MARK ALL THAT APPLY**	Yes / No Swelling.....01 / 00 Redness.....01 / 00 Soreness.....01 / 00 Pain.....01 / 00 Numbness.....01 / 00 Others (SPECIFY)_____96 / 00	
2	Did you seek any medical care for this?	Yes.....1 No.....0	
3	Did you use any over the counter medications?	Yes.....1 No.....0 → 4	
3a	Please list	_____ _____ _____	

4	Did you experience any of the following symptoms after your last dose of rabies vaccine? If yes, Indicate how severe.	NO ↓ SKIP to next symptom	YES → PROCEED to severity	MILD	MODERATE	SEVERE	
	a) Headache	0	1	1	2	3	
	b) Malaise	0	1	1	2	3	
	c) Body aches	0	1	1	2	3	
	d) Itching	0	1	1	2	3	
	e) Nausea	0	1	1	2	3	
	f) Vomiting	0	1	1	2	3	
	g) Rash	0	1	1	2	3	
	h) Fever	0	1	1	2	3	
	i) Painful Joints	0	1	1	2	3	
	j) Sweating	0	1	1	2	3	
	k) Chills	0	1	1	2	3	
	l) Numbness (fingers/toes)	0	1	1	2	3	
	m) Tingling (fingers/toes)	0	1	1	2	3	
	n) Hives (Redness + itching + swelling)	0	1	1	2	3	
	o) Shortness of breath	0	1	1	2	3	
	p) Other **(SPECIFY)**_____	0	96	1	2	3	

4a	Did you seek any medical care for this?	Yes.....1 No.....0	
4b	Did you use any over the counter medications for this?	Yes.....1 No.....0 → 5	

4c	Please list	_____ _____ _____	
Post Exposure Prophylaxis Provided			
5	What type of Rabies Immunoglobulin was administered? (If not administered on Day 0)	Not administered .....0 Human Rabies Immunoglobulin (Brand Name):_____ Equine Rabies Immunoglobulin (Brand Name):_____ Total dosage given (in ml): ☐☐	
5a	Site(s) administered	Only wound infiltration…….....01 Only systemic administration…….....02 (Gluteal/ Thigh/ Deltoid) Both wound infiltration & systemic…..03 Others(specify)_____96	
6	Rabies vaccine administered?	Yes.....1 No.....0 →	7
6a	If Yes,	Brand name of the vaccine: _____ Lot #: _____ Manf. Date:_____ Exp.date:_____ Vaccinator (Name): _____ Route administered : IM ☐ ID ☐ Remaining number of doses: _____ Date patient should complete vaccination by: D D M M Y Y Y Y	
7	What other treatments were provided? **MARK ALL THAT APPLY**	Wound irrigation.....01 Wound dressing.....02 Wound drain.....03 Suture.....04 Antibiotics.....05 Pain medication.....06 Tetanus toxoid.....07 Radiography, suspect fracture.....08 Admit to hospital.....09 Other **(Specify)**_____96	

Details of Cost incurred

Sl. No.	Details	Cost (in INR)
8	**Anti-Rabies Vaccine:** Brand:_____ Route of administration: IM/ID	
9	**Rabies Immunoglobulin:** HRIG/ ERIG; Brand: _____	
10	Other Medicines (Inj. T.T, local antiseptic, Anti-inflammatory and antibiotics, etc)	
11	Hospital charges	
12	Cost of travel for patient and attendants	
13	Cost of food for patient and attendants	
14	Loss of wages (If any)for the patient and attendants	
15	Cost of PEP availed at other centers	
16	Others (Specify)_____	
17	**TOTAL COST**	

FORM HF 4: DAY 7 FOLLOW-UP VACCINATION VISIT

Enumerator Name & mobile number: WILL BE PART OF THE USERNAME INFORMATION

FACILITY CODE:NEEDS TO BE AUTO POPULATED UTILISING INFORMATION FROM SECTION I OF HF1

Date ☐☐ ☐☐ ☐☐☐☐

Patient ID: ☐☐☐☐☐☐

No.	QUESTIONS AND FILTERS	CODING CATEGORIES	SKIP
1	Did you experience any kind of adverse reactions after you received the vaccine last time?	Yes.....1 No.....0 →	4
1a	What kind of reactions did you experience? **MARK ALL THAT APPLY**	Yes / No Swelling.....01 / 00 Redness.....01 / 00 Soreness.....01 / 00 Pain.....01 / 00 Numbness.....01 / 00 Others (SPECIFY)_____96 / 00	
2	Did you seek any medical care for this?	Yes.....1 No.....0	
3	Did you use any over the counter medications?	Yes.....1 No.....0 →	4
3a	Please list	_____	

4	Did you experience any of the following symptoms after your last dose of rabies vaccine? Indicate how severe if yes.	NO ↓ SKIP to next symptom	YES → PROCEED to severity	MILD	MODERATE	SEVERE
	a) Headache	0	1	1	2	3
	b) Malaise	0	1	1	2	3
	c) Body aches	0	1	1	2	3
	d) Itching	0	1	1	2	3
	e) Nausea	0	1	1	2	3
	f) Vomiting	0	1	1	2	3
	g) Rash	0	1	1	2	3
	h) Fever	0	1	1	2	3
	i) Painful Joints	0	1	1	2	3
	j) Sweating	0	1	1	2	3
	k) Chills	0	1	1	2	3
	l) Numbness (fingers/toes)	0	1	1	2	3
	m) Tingling (fingers/toes)	0	1	1	2	3
	n) Hives (Redness + itching + swelling)	0	1	1	2	3
	o) Shortness of breath	0	1	1	2	3
	p) Other **(SPECIFY)**_____	0	96	1	2	3

4a	Did you seek any medical care for this?	Yes.....1 No.....0	
4b	Did you use any over the counter medications?	Yes.....1 No.....0 →	5
4c	Please list	_____	

Post Exposure Prophylaxis Provided			
5	What type of Rabies Immunoglobulin was administered? (If not administered on Day 0& Day 3)	Not administered .....0 Human Rabies Immunoglobulin (Brand Name):_____ Equine Rabies Immunoglobulin (Brand Name):_____ Total dosage given (in ml): ☐☐	
5a	SITE(S) ADMINISTERED	Only wound infiltration….....01 Only systemic administration….....02 (Gluteal/ Thigh/ Deltoid) Both wound infiltration & systemic...03 Others(specify)_____96	
6	Rabies vaccine administered?	Yes.....1 No.....0 →	7
6a	If Yes,	Brand name of the vaccine: _____ Lot #: _____ Manf. Date:_____ Exp.date:_____ Vaccinator (Name): _____ Route administered : IM ☐ ID ☐ Remaining number of doses: _____ Date patient should complete vaccination by: ☐☐☐☐☐☐☐☐ (D D M M Y Y Y Y)	
7	What other treatments were provided? **MARK ALL THAT APPLY**	Wound irrigation.....01 Wound dressing.....02 Wound drain.....03 Suture.....04 Antibiotics.....05 Pain medication.....06 Tetanus toxoid.....07 Radiography, suspect fracture.....08 Admit to hospital.....09 Other **(Specify)**_____96	

Details of Cost incurred

Sl. No.	Details	Cost (in INR)
8	**Anti Rabies Vaccine**: Brand:_____ Route of administration: IM/ID	
9	**Rabies Immunoglobulin**: HRIG/ ERIG; Brand: _____	
10	Other Medicines (Inj. T.T, local antiseptic, Anti-inflammatory and antibiotics, etc)	
11	Hospital charges	
12	Cost of travel for patient and attendants	
13	Cost of food for patient and attendants	
14	Loss of wages(If any)for the patient and attendants	
15	Cost of PEP availed at other centers	
16	Others (Specify)_____	
17	TOTAL COST	

FORM HF 5: DAY 14 FOLLOW UP

Enumerator Name & mobile number: WILL BE PART OF THE USERNAME INFORMATION

FACILITY CODE:NEEDS TO BE AUTO POPULATED UTILISING INFORMATION FROM SECTION I OF HF1	Date D D M D Y Y Y Y	Patient ID:

No.	**QUESTIONS AND FILTERS**	**CODING CATEGORIES**	**SKIP**
1	Did you experience any kind of adverse reactions after you received the vaccine last time?	Yes.....1 No.....0 → 4	
1a	What kind of reactions did you experience? **MARK ALL THAT APPLY**	Yes / No Swelling.....01 00 Redness.....01 00 Soreness.....01 00 Pain.....01 00 Numbness.....01 00 Others (SPECIFY)_____96 00	
2	Did you seek any medical care for this?	Yes.....1 No.....0	
3	Did you use any over the counter medications?	Yes.....1 No.....0 → 4	
3a	Please list	_____ _____	

4	Did you experience any of the following symptoms after your last dose of rabies vaccine? Indicate how severe if yes.	NO ↓ SKIP to next symptom	YES → PROCEED to severity	MILD	MODERATE	SEVERE	
	a) Headache	0	1	1	2	3	
	b) Malaise	0	1	1	2	3	
	c) Body aches	0	1	1	2	3	
	d) Itching	0	1	1	2	3	
	e) Nausea	0	1	1	2	3	
	f) Vomiting	0	1	1	2	3	
	g) Rash	0	1	1	2	3	
	h) Fever	0	1	1	2	3	
	i) Painful Joints	0	1	1	2	3	
	j) Sweating	0	1	1	2	3	
	k) Chills	0	1	1	2	3	
	l) Numbness (fingers/toes)	0	1	1	2	3	
	m) Tingling (fingers/toes)	0	1	1	2	3	
	n) Hives (Redness + itching + swelling)	0	1	1	2	3	
	o) Shortness of breath	0	1	1	2	3	
	p) Other **(SPECIFY)**_____	0	96	1	2	3	

4a	Did you seek any medical care for this?	Yes.....1 No.....0	

4b	Did you use any over the counter medications?	Yes.....1 No.....0 →	5
4c	Please list	_____ _____ _____ _____	
5	Do you know what happened to the animal after it bit you?	Quarantined .....01 Place_____ Not Quarantined .....02 Don't know 98	
6	At any time after the animal bit you did it display any of the following signs?	Nothing.....00 Hyper salivation.....01 Aggression.....02 Biting.....03 Difficultly walking.....04 Changes in dogs bark.....05 Others (Specify) 96	
7	Has the animal bitten anyone else in the last 14 days?	Yes.....01 No.....00 Don't know.....98	8
7a	How many	Numbers..... ☐☐	
	Name of person bitten:_____ Telephone number for contact:_____ Name of person bitten:_____ Telephone number for contact:_____ Name of person bitten:_____ Telephone number for contact:_____		
8	What is the current status of the animal?	Alive and healthy.....1 Died.....2 Not available for observation .....3 Date became ill:_____ Date died:_____ Submitted for rabies testing: Place_____	11
9	If the biting animal was captured by veterinary team & released in the community, have you seen the animal in the past 14 days?	It was killed .....01 Yes, looked healthy.....02 Yes, looked sick.....03 It died.....04 No.....00 Don't know.....98	11
10	If killed, was the animal submitted for rabies testing?	Yes.....01 No.....00 Don't know.....98	
Post Exposure Prophylaxis Provided			
11	Rabies vaccine administered?	Yes.....1 No.....0 →	12
11a	If Yes,	Brand name of the vaccine: _____ Lot #: _____ Manf. Date:_____ Exp.date:_____ Vaccinator (Name): _____ Route administered : IM ☐ ID ☐ Remaining number of doses: _____ Date patient should complete vaccination by: D D M M Y Y Y Y	

12	What other treatments were provided? **MARK ALL THAT APPLY**	Wound irrigation.....01 Wound dressing.....02 Wound drain.....03 Suture.....04 Antibiotics.....05 Pain medication.....06 Tetanus toxoid.....07 Radiography, suspect fracture.....08 Admit to hospital.....09 Nothing.....00 Other **(Specify)**_____96	

Details of serum sample for rabies virus neutralizing antibodies (RVNA)

This study has been explained to me. I have had a chance to ask questions. Any questions I had, were answered. I can choose to be in this study. I can drop out of the study at any time. I am 18 years of age or older and I agree to join the study and I will give my full consent to draw the blood for RVNA analysis.

Name and Signature :_____

Date: _____ ☐

(If participant is illiterate, you will need thumbprint and signature of witness* below)

***Witness:** _____ Date: _____

13	Blood sample drawn for RFFIT analysis,if feasible (after signed consent) :	Yes.....1 No.....0 →	14
13a	If yes	Day ☐☐ Month ☐☐ Year ☐☐☐☐	
13b	Date of transportation to NIMHANS, Bangalore	Day ☐☐ Month ☐☐ Year ☐☐☐☐	
13c	RFFIT results	IU ☐☐	

Details of Cost incurred

Sl. No.	Details	Cost (in INR)
14	**Anti-Rabies Vaccine**: Brand:_____ Route of administration: IM/ID	
15	Other Medicines (Inj. T.T, local anti septic, Anti inflammatory and antibiotics, etc)	
16	Hospital charges	
17	Cost of travel for patient and attendants	
18	Cost of food for patient and attendants	
19	Loss of wages(If any)for the patient and attendants	
20	Cost of PEP availed at other centers	
21	Others (Specify)_____	
22	**TOTAL COST**	

FORM HF 6: DAY 28 FOLLOWUP

Enumerator Name & mobile number: WILL BE PART OF THE USERNAME INFORMATION

FACILITY CODE:NEEDS TO BE AUTO POPULATED UTILISING INFORMATION FROM SECTION I OF HF1	Date D D M D Y Y Y Y	Patient ID:

No.	QUESTIONS AND FILTERS	CODING CATEGORIES	SKIP
1	Did you experience any kind of adverse reactions after you received the vaccine last time?	Yes.....1 No.....0 → 4	
1a	What kind of reactions did you experience? MARK ALL THAT APPLY	Yes / No Swelling.....1 / 0 Redness.....1 / 0 Soreness.....1 / 0 Pain.....1 / 0 Numbness.....1 / 0 Others (SPECIFY)_____96 / 0	
2	Did you seek any medical care for this?	Yes.....1 No.....0	
3	Did you use any over the counter medications?	Yes.....1 No.....0 → 4	
3a	Please list	_____ _____ _____	

4	Did you experience any of the following symptoms after your last dose of rabies vaccine?	NO ↓ SKIP to next symptom	YES → PROCEED to severity	MILD	MODERATE	SEVERE	
	a) Headache	0	1	1	2	3	
	b) Malaise	0	1	1	2	3	
	c) Body aches	0	1	1	2	3	
	d) Itching	0	1	1	2	3	
	e) Nausea	0	1	1	2	3	
	f) Vomiting	0	1	1	2	3	
	g) Rash	0	1	1	2	3	
	h) Fever	0	1	1	2	3	
	i) Painful Joints	0	1	1	2	3	
	j) Sweating	0	1	1	2	3	
	k) Chills	0	1	1	2	3	
	l) Numbness (fingers/toes)	0	1	1	2	3	
	m) Tingling (fingers/toes)	0	1	1	2	3	
	n) Hives (Redness + itching + swelling)	0	1	1	2	3	
	o) Shortness of breath	0	1	1	2	3	
	p) Other **(SPECIFY)**_____	0	96	1	2	3	
4a	Did you seek any medical care for this?	Yes.....1 No.....0					

4b	Did you use any over the counter medications?	Yes.....1 No.....0 →	5
4c	Please list	_____ _____ _____	
5	Rabies vaccine administered?	Yes.....1 No.....0 →	6
5a	If Yes,	Brand name of the vaccine: _____ Lot #: _____ Manf. Date:_____ Exp.date:_____ Vaccinator (Name): _____ Route administered : IM ☐ ID ☐ Remaining number of doses: _____ Date patient should complete vaccination by: D D M M Y Y Y Y	
6	What other treatments were administered? **MARK ALL THAT APPLY**	Wound irrigation.....01 Wound dressing.....02 Wound drain.....03 Suture.....04 Antibiotics.....05 Pain medication.....06 Tetanus toxoid.....07 Radiography, suspect fracture.....08 Admit to hospital.....09 Others **(Specify)**_____96	

Details of Cost incurred

Sl. No.	Details	Cost(in INR)
7	**Anti Rabies Vaccine**: Brand:_____ • Route of administration: IM/ID	
8	Other Medicines (Inj. T.T, local anti septic, Anti inflammatory and antibiotics, etc)	
9	Hospital charges	
10	Cost of travel for patient and attendants	
11	Cost of food for patient and attendants	
12	Loss of wages(If any)for the patient and attendants	
13	Cost of PEP availed at other centers	
14	Others (Specify)_____	
15	**TOTAL COST**	

Compliance to anti rabies vaccination										
No	**Name**	**Phone No.**	**Biting animal**	**Fate of the Animal**	**Category of wound**	**D0**	**D3**	**D7**	**D14**	**D28**
						Reasons for drop-out(Single/ Multiple)				
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
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28										
29										
30										

Reasons for dropout with codes:

Out of station=1; High cost incurred=2; Forgotten dates=3; Long distance=4; Loss of wages=5; Interferes with school timing=6; Negligence=7; Not properly advised=8; Others (specify)_____ _____= 96.

FORM HF7: DAY 90 PATIENT FOLLOW-UP

Enumerator Name & mobile number: WILL BE PART OF THE USERNAME INFORMATION

FACILITY CODE:NEEDS TO BE AUTO POPULATED UTILISING INFORMATION FROM SECTION I OF HF1	Date D D M D Y Y Y Y	Patient ID:

No.	QUESTIONS AND FILTERS	CODING CATEGORIES	SKIP
1	Since your last visit for rabies vaccination did you experience any serious illness?	Yes.....1 No.....0	
2	If Yes, When did illness begin(approximately how long ago)	Days ☐☐ Months ☐☐ Year ☐☐☐☐	
3	Did you seek medical care?	Yes.....1 No.....0 →	5
4a	Date	Day ☐☐ Month ☐☐ Year ☐☐☐☐	
4b	Were you admitted to a hospital?	Yes.....1 No.....0 →	5
4c	Name of facility & place	_____	

5	**List characteristics of your illness**	Yes	No	Onset date DD/MM/YYYY
	a. Experience headache?	1	2	
	b. Experience nausea or vomiting?	1	2	
	c. Have fever (hot body)?	1	2	
	d. Experience fatigue?	1	2	
	e. Experience sudden, involuntary contraction of a muscle?	1	2	
	f. Experience localized weakness, numbness or pain(legs,arm,neck,etc.)?	1	2	
	g. Display paralysis?	1	2	
	h. Experience loss of control of bodily movements?	1	2	
	i. Difficulty in swallowing?	1	2	
	j. Excessive salivation?	1	2	
	k. Display any sudden behavioral change (eg. irritability, nervousness etc)?	1	2	
	l. Display aggressive behaviour towards others	1	2	
	m. Show signs of anxiety?	1	2	
	n. Show signs of confusion/ hallucination?	1	2	
	o. Have a fear of water?	1	2	
	p. Have a fear or sensitivity to air?	1	2	
	q. Have a fear/sensitivity to light?	1	2	
	r. Experience a loss of appetite?	1	2	
	s. Experience difficulty sleeping/staying asleep?	1	2	
	t. Experience seizures?	1	2	

6	Was any laboratory diagnosis performed?	Yes.....1 No.....0 →	8

7	List relevant laboratory diagnostics performed for any illness?				
	DISEASE	**Test performed**	**Date tested**	**Result**	**Comment**
	Encephalitis				

	Rabies					
	Mosquito-borne encephalitis					
	Herpes Simplex Virus					
	Zoster encephalitis					
	Enterovirus					
	Measles virus					
	Bacterial Meningitis					
	Malaria					
	Toxoplasmosis					
If the patient has died, Informant to Answer →						
8	Informant name/ /Mobile number(s)					
8a	Relationship to the patient	PARENT.....1 PARENT-IN-LAW.....2 SPOUSE.....3 FRIEND/NEIGHBOUR.....4 SIBLING.....5 COMMUNITY LEADER.....6 SON/DAUGHTER.....7 HEALTHCARE WORKER.....8 OTHER **(SPECIFY)**_____96				
9	Did the patient die from the illness?	Yes.....1 No.....0 Don't know.....98				
9a	Date	Day ☐☐ Month ☐☐ Year ☐☐☐☐ Don't know 98				
9b	Where did the patient die?	Home.....1 Hospital (Name facility):_____2 Other **(specify)**_____ 96				
9c	Is a post-mortem or death certificate available?	Yes.....1 No.....0 Don't know.....98				
9d	If yes, cause of death	Rabies.....1 Non rabies.....2 don't know.....98				

Annexure-6.4 Veterinary Survey- Proforma

Biting dog investigation form: <u>Veterinary form- 1 (preliminary)</u>

State:	☐☐
District:	☐☐
Taluka:	☐☐
Locale: Rural…….....1 Urban…….....2	
Organization type: Government…….. 1 Private…….....2 NGO ..…….....3	
Name of the Veterinary Investigator: Organization: Phone: Date of Investigation:	D☐☐ M☐☐ Y☐☐☐☐
Name of the Health facility: GPS coordinates: _____ _____ (Download '**Smart compass app.'** from your android phone)	
Name of the Medical Officer: Phone Number:	
Name of the dog bite victim: _____ Patient ID #: _____ Age: Gender: Date of bite: Place of bite: Address with Phone Number:	

TO BE FILLED BY THE VETERINARY INVESTIGATOR IN THE FIELD ONLY IF THE BITING ANIMAL IS DOG (to be filled up on the first day of catching the dog)

NO.	QUESTIONS & FILTERS	CODING CATEGORIES	SKIP
1	Was the biting dog?	Owned.....1 Stray/ unowned.....2 Abandoned .....3 Don't know.....98	
2	Location of dog bite	Residence _____ Ward/Village _____ Street_____ Unknown	
3	How many people were bitten by this dog?	☐☐	

4a	What is the average age of the exposed people	☐☐	
4b	How long ago were the people bitten (in days) (average)	☐☐	
4c	How many bitten people received rabies vaccine?	☐☐	
4d	How long after the bite did they receive the vaccine (in Days)(average)?	☐☐	
5	What other animals were bitten by this dog (multiple response)	Dog.....1 Cat .....2 Livestock .....3 Wildlife.....4 Other (Specify) .....96 _____	
6a	How many other animals were bitten by this dog (write numbers)?	Dog ☐☐ Cat ☐☐ Livestock ☐☐ Wildlife ☐☐ Other (specify)_____	
6b	Whether bitten animal received First aid / post exposure vaccination	Yes.....1 No 0	
7a	Whether the biting dog is traced?	Yes.....1 No 0	
7b	If yes	Alive….....1 Escaped.....2 Killed by owner.....3 Killed by public…….....4 Hit by a vehicle…….....5 Died naturally.....6 Unknown whether it had died.....7	
7c	Where the dog was traced?	Residence_____ Ward/Village _____ Street_____ Nearby Forest_____	
8a	Dog collar Id (State/District/HCF/No.)		
8b	GPS Coordinate with photo (Download **Smart compass app** from your android phone)		
8c	Breed and Colour of the dog		
8d	What is the dog's age? (Years)	Puppy.....1 Adult.....2 Don't know.....98	

8e	What is the gender of the dog?	Male…….....1 Female…….....2 Don't know.....98	
9	If Stray, then place of quarantine		
10	If pet, address of quarantine		
11	Microchip No. if any		
12	Feed provided to the dog	Type: Who fed:	
13	Whether the dog was neutered?	Yes.....1 No .....0 Don't know.....98	
14a	Whether the dog has been vaccinated for rabies?	Yes.....1 No .....0 ➡ Don't know.....98	13
14b	If yes, year of 1st vaccination	☐☐☐☐	
14c	Details of any further vaccination for rabies if done and available	Yes.....1 No .....0 Don't know.....98	
14d	Year of last vaccination	☐☐☐☐	
15a	Whether the dog is de wormed?	Yes……1 No……..2 Don't know……..98	
15b	If yes, what is the brand?		

Veterinary Form -2 (To be filled up on 14 days of observation of quarantine dog)

16a	Whether the dog was showing signs of rabies	Yes.....1 No .....0 ➡ 14 Don't know.....98	
16b	If yes (signs of rabies)	Aggression…….....1 Biting…….....2 Excessive salivation…….....3 Paralysis…….....4 Lethargy.....5 Hyperesthesia..... ……...6 Don't know.....98	
16c	Since how many days these symptoms been noticed?	☐☐	
17a	Assessment of rabid status of dog	Healthy .....1 Sick.....2 Not rabies.....3 Rabies.....4	
17b	How was the assessment decision made	Clinical Symptoms……..1 Lab diagnosis……...2 Other (Specify) .....96 _____	
18	Quarantine results	Healthy after 14 days .....1 Died.....2	
19	If the dog is healthy, after 14 days, then any treatment given during the quarantine	Yes----- No------ If yes, please provide details	
20	Whether there was history of previous animal bite to the dog	Yes.....1 No 2	
21	Any injury or bite marks on the body at the time of the reporting?	Yes……..1 No…….0	
22	Whether the dog had any other systemic infection earlier?	Yes……1 No…….0	
23	What symptomatic treatment was provided to the dog during quarantine?	Specify _____	
24a	Whether RFFIT / FAVN report of dog/animal available?	Yes……1 ➡ 21a No…….0	
24b	If Yes	Protective……..1 Non-Protective……..…2	

25	Whether the dog released after observation?	Yes……1 No…….0	
26a	If the dog died, date of death of dog	☐☐ ☐☐ ☐☐☐☐	
26b	Cause of death	Euthanize .....1 Natural causes .....3 Other (Specify)…….. .....96 _____	
27a	Whether the dog brain sample submitted for testing rabies?	Yes.....1 No .....0 ➡	16b
27b	If yes, date of submission of specimen to lab	☐☐ ☐☐ ☐☐☐☐ ➡	17
27c	If not, why?	Dog not found .....1 Body discarded .....2 Decomposed/Burned.....3 Unwillingness of Owner…….4 Other (Specify) .....96 _____	
27d	Laboratory test results Sellars /DFA/ LFA/ PCR (Encircle the test /s)	Positive.....1 Negative…….....2 Inconclusive…….....98	
27e	How the carcass was disposed	Burried:--------- Burnt: ----------	
28a	Whether the status of dog reported to the health facility	Yes.....1 No 0	
28b	If yes, date of reporting	☐☐ ☐☐ ☐☐☐☐	

Annexure 6.5: Details of the clusters for the community survey

1. Himachal Pradesh

Community Survey clusters						
District selected	**Block selected**	**Rural: Urban proportion**	**Cluster**	**Name**	**Total households**	**Total Population**
Shimla	Theog	5:1	Rural	Bundu	10	55
				Sanai	10	65
				Roni Matiana	66	271
				Majholi	41	230
				Chamhech	30	162
				Sanai		
			Urban	Theog	159	634

2. Bihar

Community Survey clusters						
District selected	**Block selected**	**Rural : Urban proportion**	**Cluster**	**Name**	**Total households**	**Total Population**
Darbhanga	Biraul	5:1	Rural	Kataya	735	3844
				Gayri	303	1510
				Murwara	835	4483
				Sonpur	959	4562
				Awan	744	3919
	Darbhanga		Urban	Darbhanga	1050	5658

3. West Bengal

Community Survey clusters						
District selected	**Block selected**	**Rural: Urban proportion**	**Cluster**	**Name**	**Total households**	**Total Population**
North 24 Paraganas	Rajarhat	4:2	Rural	Khamar	220	827
				Nawabad	505	2277
				Thakdari	1053	4247
				Baligari	824	4193
			Urban	Raigachhi	1644	8245
				Ghuni	5671	24249

4. Manipur

Community Survey clusters						
District selected	**Block selected**	**Rural: Urban proportion**	**Cluster**	**Name**	**Total households**	**Total Population**
Senapati	Mao Maram	4:2	Rural	Kamalong	128	777
				Makulongdi	214	1167
				Willong Khullen	628	4276
				New Magaimai	80	571
	Sadar Hills west		Urban	Kangpokpi	1437	7476
				Kangpokpi	1437	7476

5. Kerala

Community survey clusters						
District selected	**Block selected**	**Rural: Urban proportion**	**Cluster**	**Name**	**Total households**	**Total Population**
Kottayam	Kanjirappally	3:3	Rural	Cheruvally	1645	6447
				Chirakkadavu	7386	29717
				Elamgulam	3420	14080
	Meenachil		Urban	Palai(M)	229	1122
				Palai(M)	202	885
				Palai(M)	262	1166

6. Madhya Pradesh

Community survey clusters						
District selected	**Block selected**	**Rural: Urban proportion**	**Cluster**	**Name**	**Total household**	**Total Population**
Khandwa (East Nimar)	Punasa	4:2	Rural	Gurada	360	1640
				Phiphari Mal	218	1104
				Bawadiya	182	795
				KelwaKhurd	422	1905
			Urban	Omkareshwar	97	378
				Omkareshwar	173	803

7. Gujarat

Community Survey clusters						
District selected	**Block selected**	**Rural: Urban proportion**	**Cluster**	**Name**	**Total households**	**Total Population**
Tapi	Valod	3:3	Rural	Butwada	323	1333
				Ambach	627	2672
				Bedkuva	795	3416
	Songadh		Urban	Songadh	730	3449
				Ukai	1665	7453
				Songadh	682	3423

Annexure-6.6: Proforma for logistics of rabies biologicals (human)

Characteristic	HP	Bihar	W Bengal	Manipur	Kerala	MP	Gujarat
1. Special agency							
2. Part of DHS/ Separate							
3. Procurement							
a. E-Tender							
b. Technical Committee (Yes)							
c. Time lag (producer)							
d. Cost (from MRP)							
4. Storage							
a. District/Regional							
b. EPI/Separate							
b. Equipment							
5. Stock-outs (yes) Frequent / sometimes/occasional							
6. Delivery to Health Institutions							
a. Vehicles							
b. Persons							
c. Cold chain							
7. Demand (Frequency)							
8. AEFI reporting (Yes/No)							
9. Remarks							

Note – A similar one for RIG was used

Annexure-6.7: Assessment of Rabies Post-Exposure Prophylaxis (PEP) Provision, Distribution & Delivery in India *(Provided to the states)*

Name of the State: _____ **Date: _____**
Name of the interviewer: _____ **Name of the key informant: _____**

Designation & Organization: _____

Sl. No	Questions	Response
1.	**Program delivery**	
1a	Please describe how persons needing PEP get access to it, and what the process is for getting access to **vaccine** and **RIG**	
	➢ Where (at what level) is vaccine/RIG available	
	a) Please describe any differences in urban vs rural access	
	b) Public vs private sector	
	➢ When is RIG given?	
	➢ Are there bite referral/treatment centers?	
1b	Have you seen a change in the number of people seeking PEP treatment over the last 1-5 years? (Increase # of PEP vials procured? Logistics e.g. refrigerators)	
	• What are the factors that have contributed to the change (e.g. number of facilities offering PEP, increase supply of vaccine within country, etc.)?	
1c	What type of administration is used (intramuscular or intradermal)?	
1d	Which dosage schedule for PEP is used?	
1e	Cost to the patient (public and private)	
	➢ What is the cost of the vaccine/dose?	
	➢ What is the cost of RIG?	
	➢ What is the cost of the consultation, gloves, syringes, etc.?	
2	**Vaccine procurement and requests**	
2a	How is rabies vaccine procured?	
	➢ Is there a focal person responsible for procurement?	
	➢ What vaccines do you procure (Verorab, Rabipur,etc.)?	
	• How/why do you choose that particular type of vaccine?	
	➢ How long does it take for vaccine to arrive in-country or in state (from the time the order is placed)?	
	➢ What is the cost per dose of vaccine to the government? If cost varies depending on which vaccine is procured, please specify range.	
2b	How is RIG procured?	
2c	What are the main sources of human vaccine and RIG? Please specify (e.g. donations, procurement, research purposes, other)	
2d	Are there any standardized forms used for procurement and is any information required in order to procure more e.g. # of people vaccinated, # of vials used?	
2e	How are rabies vaccine and RIG requests made at each level (who is responsible? who are requests made to? how often?)?	
3	**Vaccine distribution and cold chain**	
3a	How is rabies vaccine and RIG distributed from the central level to health facilities once the request has been processed?	
	➢ Who is responsible for distributing it?	
	➢ Does distribution occur through the same system as routine vaccine distribution?	
3b	What type of cold chain and vaccine storage do you have for PEP at each level?	
	➢ Do rabies vaccines use the same cold chain/storage as routine vaccines?	
	➢ Is there continuous temperature monitoring and log books at the central level?	
	➢ Is there dedicated PEP storage space at each level?	
4	**Vaccine and RIG forecasting**	
4a	How is rabies vaccine and RIG need forecasted? (bite-burden, previous month's consumption, budget)	
5	**Vaccine monitoring, utilization, and reporting**	
5a	Patients	
	➢ What information is collected on patients? Where and how is this recorded (bite register?)	
	➢ Are there any standardized tools/forms at health facilities to track completion rates of rabies vaccine?	
	➢ Is there a follow up system for patients who have not completed a full course?	
	➢ How are returning patients tracked (patients with repeat bites)?	
5b	Vaccine	
	➢ How is rabies vaccine and/or RIG stock/use currently monitored (stock monitoring books, registers, logs etc.)?	
	➢ Who is responsible for monitoring rabies vaccine and/or RIG stock/utilization?	
	➢ How often do rabies vaccine stock outs occur and what are the most common reasons for stock-outs?	

	➢ How long do stock-outs typically last?	
	➢ Is any information on wastage collected?	
5c	Reporting	
	➢ Is information on PEP utilization reported (who reports, to whom, how often, what is reported)?	
5d	Adverse Events	
	➢ Is there a system for monitoring and reporting adverse events following rabies PEP?	
	• What information on adverse events is collected and how often is it collected?	
	• How do adverse events get reported and to whom are they reported?	
6	**Vaccine demand (human use only)**	
6a	# of rabies vaccine doses procured/year in the last 2-5 years	
6b	# of people receiving rabies vaccine/year in the last 2-5 years	
6c	# of people receiving RIG /year in the last 2-5 years	
6d	# of rabies vaccine doses requested/year	
6e	# of rabies vaccine doses distributed/ year	
7.	**General comments / Remarks**	

Annexure-6.8: Assessment of Rabies Post-Exposure Prophylaxis (PEP) Provision, Distribution & Delivery in India (Provided to Pharmaceutical companies)

Date: _____

Names & Designations of the informants:

1._____2. _____

3._____4._____

Name of the Product: (*Kindly use separate forms for each product)*

1.	**Name and address of the producer and Head (Designation & Email)**		
2.	**Type of the company & year of ESTD.**		
3.	**Production[in 100,000 vials per year]**		
	1. Installed (year & capacity)		
	2. Demand (2012-2016) (5 years)		
	3. Production (2012-2016) (5 years)		
	4. Domestic use (2012-2016) (5 years)		
	5. Export volume (2012-2016 (5 years)		
4.	**Domestic supplies :** [100,000 vials] [in 2016]	**Public sector**	**Private sector**
	1. Quantity [in vials]		
	2. Time lag between order and supply from to the customer [in days]		
	3. Place of storage at mfg. site		
	4. Type of storage at mfg. site		
	5. Stored with other vaccines or separate?		
	6. If separate, dedicated space available?		
	7. Duration of stock outs [or none]		
	8. If yes, How managed?		
	9. Wastage- frequency/ Quantum		
	10. Mode of delivery		
	11. Frequency of deliveries		
	12. Delivery vehicles		
	Delivery to states / districts / zones		
	1. Delivery persons		
	2. Cold Chain equipment's used		
	3. Temperature log		
	4. Mode of communications		
	5. Records maintenance		
	6. Cost per vial		
	7. Any Forecasting done?		
5.	**a. Is the demand (in last 5 years) increasing /decreasing /same?**		
	b. REASON for the same		
6	**How is the demand calculated? Annually /Quarterly/SOS**		
7.	**Adverse Events**		
	i. Frequency of monitoring & Reporting of AEFI		
	ii. What action is taken after AEFI is reported?		
8.	**General Comments /Remarks**		

Annexure-6.9:To document rabies biologicals procurement, distribution, delivery mechanism and cost in selected states of India and in rural & urban settings

Date:_____

State/District:_____ City/Town:_____

Name of the facility [address, mobile number and email ID]:_____

Type of Facility:_____

Key informant/s. (Name, Designation& Mobile Number)

1_____

2._____

Description	**OBSERVATION / REMARKS [Record Problems / Suggested remedies] [With permission some photos may be taken]**	
	VACCINE	**RIG**
Forecasting		
Procurement		
Storage[[incl. Cold chain]		
Distribution		
Logistics Management Information System (LMIS)		
Capacity building		
COST/Budget [relevant]		
Remarks /Conclusion:	**1.....** **2.....** **3. .....**	

Annexure-6.10: Proforma for appraisal of anti-rabies clinics						
Name of the Anti-Rabies centre						
1	**Type**					
	Urban/ Rural					
	Govt./ Private					
2	**Location**					
	Inside/ Outside/ Independent (of Hospital)					
	Easy accessibility (Y/ N)					
3	**Staff**					
	Medical Officer (No.)					
	Paramedics (Type & No. Specify)					
4	**Facilities**					
	Continuous power supply/ UPS (Y/ N)					
	Running tap water (Y/ N)					
	AC (Y/ N)					
	Wound wash facility (Y/ N)					
	Antiseptics used (Y/ N)					
5	**Cold chain equipment (Functional)**					
	Domestic refrigerator (Y/N)					
	ILR (Y/ N)					
	Deep freezer (Y/ N)					
	Temperature log (Y/ N)					
6	**Vaccines available (Y/ N)**					
	Brand (s) used					
	Stock out (Freq./Sometimes/Occasionally)					
	Cost/ dose or vial (Specify)					
7	**New Cases of animal bite [number / per day]**					
8	**Route of administration**					
	Predominantly IM/ Predominantly ID/ both					
9	**RIG available (Y/ N)**					
	ERIG [Write brand (s) used]					
	Use/ Stock out(NS/NU/Freq./ST/Occ.)					
	Cost/ dose or vial (Specify)					
	HRIG [Write brand (s) used]					
	Use/ Stock out(NS/NU/Freq./ST/Occ.)					
	Cost/ dose or vial (Specify)					
	Local infiltration (Y/ N)					
	Systemic injection (Y/ N)					
10	**Follow up method (s)**					
11	**Records maintained**					
	OP register (Y/ N)					
	ART register (Y/ N)					
	ART case form (Y/ N)					
	Stock register (Y/ N)					
12	**Others (Specify)**					

Annexure-6.11: Proforma for Market mapping and landscape		
		Date: _____
1. Company & Address:_____		
2. Key informant/s with designations:_____		
1.	**Rabies vaccine**	**Product:**
1.1	Rabies epidemiology / Disease burden (as per company perspective)	
1.2	Current market distribution (incl. Competitive brands) (%)	
1.2.1	Government / Private	
1.2.2	Urban / Rural	
1.2.3	Region wise in India –North –East – Northeast –South – Central – West	
1.2.4	Among Private: GPs/Specialists/ Paediatricians / others (%)	
1.2.5	Private hospitals /corporate hospitals / ARCs /others	
1.2.6	Domestic / Export /Import (wherever applicable)	
1.3	List & elaborate demand drivers in the Indian market	
1.4	Installed capacity – Demand – Production (in lakh vials per year) (last 5 years from 2012-16)	
1.5	Projections/plans for the future (5 years i.e. 2017 -21)	
2.	**Rabies immunoglobulins**	**Product:** *Kindly use separate form for each product*
2.1	Rabies epidemiology / Disease burden (As per company perspective)	
2.2	Current market distribution (incl. Competitive brands) (%)	
2.2.1	Government / Private	
2.2.2	Urban / Rural	
2.2.3	Region wise in India –North –East – Northeast –South – Central – West	
2.2.4	Among private: GPs/Specialists/ Paediatricians / others (%)	
2.2.5	Private hospitals /corporate hospitals / ARCs /others	
2.2.6	Domestic / Export /Import (wherever applicable)	
2.3	List & elaborate demand drivers in the Indian market	
2.4	Installed capacity – Demand – Production (in lakh vials per year) (last 5 years from 2012-16)	
2.5	Projections/plans for the future (5 years i.e. 2017 -21)	

Annexure-6.12: SWOT analysis – Rabies pharmaceutical companies (Rabies biologicals)			
SWOT	**My company**	**Competitator-1** **.....**	**Competitor-2** **.....**
(Confidential & Write Legibly)			
I. STRENGTHS			
1. What are your business advantages?			
2. What are your core competencies?			
3. Where are you making the most money?			
4. What are you doing well?			
II.WEAKNESSES			
5. What areas are you avoiding?			
6. Where do you lack resources?			
7. What are you doing poorly?			
8. Where are you loosing money?			
9. What needs improvement?			
III.OPPORTUNITIES			
10. Any beneficial trends?			
11. Niches the competitors are missing?			
12. New technologies?			
13. New needs of customers?			
IV. THREATS			
14. Obstacles to overcome?			
15. Aggressive competitors?			
16. Successful competitors?			
17. Negative economic conditions?			
18. Government regulations?			
Date: _____		**Initials: _____**	

Annexure- 6.13: Health Services Scenario in Rabies free Islands	
Details	**Nos.**
Health Institutions { Total }	
Medical College	
Tertiary hospital	
Community Health Centers (CHCs)	
Primary Health Centers (PHCs)	
Sub Centers (SCs)	
Urban Health Centers	
Homeopathy Dispensary	
Ayurvedic Dispensary	
Others (specify) ……..	
Health Manpower	
Doctors	
Nurses	
Other Para medicals	
Other information	
Hospital Beds	
Bed Population Ratio	
Doctor Population Ratio	
Nurse Population Ratio	
Literacy Rate (2011)	
Infant Mortality Rate	
Birth Rate	
Death Rate	
Maternal mortality rate	
Date : …… **Name and Signature ……**	

Annexure- 6.14: Animals cases treated in Rabies free Islands during 2007-17				
Year	**Hospital- 1 Name:**	**Hospital- 2 Name:**	**Hospital- 3 Name:**	**Total**
2007				
2008				
2009				
2010				
2011				
2012				
2013				
2014				
2015				
2016				
2017				
Total				
Remarks	1…… 2. …… 3……			
Date : ……		**Name and Signature ……**		

Annexure-6.15: Human rabies cases in the last 10 years in the Rabies free islands (2007 to 2017)

Year	Hospital- 1 Name:	Hospital- 2 Name:	Hospital- 3 Name:	Total
2007				
2008				
2009				
2010				
2011				
2012				
2013				
2014				
2015				
2016				
2017-May				
Total				
Remarks	1…… 2. …… 3……			

Date : …… Name and Signature ……

Annexure- 6.16: Status of veterinary facilities in the Rabies free Islands			
Type	**Andaman**	**Nicobar**	**Total**
1. Veterinary Hospital			
2. Veterinary Dispensary			
3. Veterinary Sub Dispensary			
4.			
5.			
6.			
7.			
Total			
Veterinary Manpower			
1. Senior Veterinary Officer			
2. Veterinary Assistant Surgeon			
3. Livestock Supervisor			
4. Senior Veterinary Compounder			
5. Veterinary Stockman			
6. Veterinary Compounder			
7. Veterinary Dresser			
Date : ……	**Name :……..**		

Annexure-6.17: District wise animal census in Rabies free Islands {include all known rabies vectors of the Island & write nil if absent}

Animal Census	Year			Year			
	Island 1	Island 2	Sub Total	Island 1	Island 2	Sub Total	Total
Dogs							
Cats							
Cattle							
Buffalo							
Goats							
Pigs							
Horses/Donkey							
Rabbits							
Foxes							
Jackals							
Mongoose							
Total							

Date : ..... **Name and Signature .....**

Annexure- 6.18: Details of Dogs & Cats treated in the Rabies free Islands from 2007-2017			
YEAR	**DOG**	**CAT**	**TOTAL**
2007-08			
2008-09			
2009-10			
2010-11			
2011-12			
2012-13			
2013-14			
2014-15			
2015-16			
2016-17			
2017-18			
Date :		**Name and Signature .....**	

Annexure- 6.19: Incidence of rabies among animals during 2007-2017 in Rabies free islands

Animal	Clinical grounds		Laboratory Methods		Comments (if any)
	No. of cases examined	No. of cases suspect	No. of cases suspect	No. of cases confirmed+ (Positive)	
1. Canine					
2. Feline					
3. Bovine					
4. Equine					
5. Caprine					
6. Wolf					
7. Fox					
8. Porcaine					
9. Bear					
10._____					
Source:					
+Method used: _____ _____					

Annexure-6.20: Animal Birth Control (ABC) programme in ____Islands

Name of the NGO(s) with address: _____

Phone no:_____ E-mail ID: _____

Year	Number of dogs sterilized	No. of dogs vaccinated against rabies
2007		
2008		
2009		
2010		
2011		
2012		
2013		
2014		
2015		
2016		
2017		

Date :……. Name & Designation ……

Annexure-6.21: Information on animal rabies from Veterinary personnel in Rabies free Islands (Give number /details of the animal rabies cases seen on the islands)

Sl No	Name	Qualification	Designation	Working since (yrs)	Rabies cases seen (Y/N)	Mobile No.	E-Mail ID
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

Name :..... Signature .....

Annexure -6.22: Information on human rabies from Medical personnel in Rabies free Islands (Give number /details of the human rabies cases seen on the islands)

Sl No	Name	Qualif.	Designation	Working since (yrs)	Rabies cases Seen (Y/N)	Mobile	E-Mail ID
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

Name :..... Signature .....

Annexure-6.23: Assessment of Rabies free _____ Islands

Check List- Veterinary

I. Information (Statistics) collected:

1. Import of animals (Procedure, Rules, etc): Yes ( ) No ( ) _____
2. Quarantine of animals (Procedure, Rules, etc): Yes ( ) No ( ) _____
3. Licensing of Pets (Procedure, Rules, etc): Yes ( ) No ( ) _____
4. Licensing of animal breeders (Procedure, Rules, etc): Yes ( ) No ( ) _____
5. Control of stray animals (Procedure, Rules, etc): Yes ( ) No ( ) _____
6. Rabies notification/ reporting Yes ( ) No ( ) _____
7. Anti-Rabies Vaccines (Procurement/storage/usage) Yes ( ) No ( ) _____
8. Rabies statistics (2007-17) Yes ( ) No ( ) _____
9. Veterinary infrastructure (Diagnostic facilities) etc. Yes ( ) No ( ) _____
10. Others (Specify)_____

II. Sources (Write Nos.)

1. A H Directorate _____
2. H Q Hospital_____
3. Veterinary Centers_____
4. Private Centers_____
5. Others (Specify) _____
6. _____
7. _____
8. _____

III. Informants (Write Nos.)

1. Airport HO _____
2. Sea Port H O _____
3. H. O _____
4. AHD _____
5. V O _____
6. V I _____
7. Private Vet's _____
8. Others (Specify) _____
9. _____
10. _____

IV. Methods (Write Nos.)

1. Interviews _____
2. Records _____
3. Others (Specify):_____
4. _____
5. _____
6. _____
7. _____
8. _____

Annexure-6.24: Assessment of Rabies free _____ Islands

Check List- Medical

I. Information (Statistics) collected:

1. Disease notification/reporting: Yes ( ) No ( ) _____
2. Animal bite statistics (2007-2017): Yes ( ) No ( ) _____
3. ARV and ARS (Procurement/storage/usage) Yes ( ) No ( ) _____
4. Human Rabies (2007-2017) statistics Yes ( ) No ( ) _____
5. Health infrastructure and Services Yes ( ) No ( ) _____
6. Others (Specify)

II. Sources (Write Nos.)

1. D H S _____
2. H Q Hospital _____
3. District Hospital _____
4. UHC _____
5. CHC _____
6. PHC _____
7. SC _____
8. Private hospitals/clinics _____
9. Others (Specify) _____
10. _____
11. _____
12. _____

III. Informants (Write Nos.)

1. HO _____
2. DHS _____
3. MoH _____
4. Specialists _____
5. GDMO _____
6. Health staff _____
7. Formal leaders _____
8. Informal Leaders _____
9. Community Informants (Postal/schools etc.) _____
10. PMPs _____
11. Others (Specify)

IV. Methods (Write Nos.)

1. Interviews _____
2. Records _____
3. Others (Specify): _____
4. _____
5. _____
6. _____

V. Enclosures (Specify and Nos)

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

VI. Dates and Days (Nos.) of survey:

Annexure-6.25: Assessment of Rabies free _____ Islands

Data Collection/ Survey instrument.

Day and Date:___

II. Institution/Source (Name, Address):_____

Phone/Fax/E mail: _____

III. Informants (Name and Designation) (Stay duration with dates)

1. _____ 4. _____
2. _____ 5. _____
3. _____ 6. _____

IV. Data/Information Provided: Medical ( ) Veterinary ( ) Both ( )

Items of Information	Medical	Veterinary
1.	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____

V. Information

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

VI. Records/ Reports per used

1. _____ 4. _____
2. _____ 5. _____
3. _____ 6. _____

VII. Records/Reports Enclosed (Xerox) (Please specify)

1. _____ 4. _____
2. _____ 5. _____
3. _____ 6. _____

VIII. Comments (If any)

1. _____ 4. _____
2. _____ 5. _____
3. _____ 6. _____

X. Enclosures (Total No. of Pages): _____

Name of Investigators	Signature
1. _____	_____
2. _____	_____
3. _____	_____

Annexure 6.26: Assessment of rabies free_____ Islands, India

Sample collection & reporting format

Date: _____

1.	Animal /Species	
2.	Stray/Owned (Name & Address if owned)	
3.	Reference No. (if any)	
4.	Species	
5.	Gender	Male ☐ Female ☐
6.	Breed	
7.	Age	
8.	Color	
9.	Vaccination details	
10.	Contact details of owner	E-mail: Phone No: Mobile No:
11.	Number of persons exposed	
12.	Date of sample collection (Post-mortem)	
13.	Sample type	
14.	Date of sample submitted to laboratory	
15.	Person submitting sample	
16.	Person receiving sample at the laboratory (with signature)	

Note: Brain samples should be sent in cold chain or 50% glycerol saline.

Signature of Clinician

……

Reporting Form

Date: _____

1.	Sample	
2.	Animal/Species	
3.	Sample received from (Name & Address of sender)	
4.	Date received	
5.	Lab No	
6.	Test Performed	
7.	Test Result	
Interpretation		

Signature of Technologist **Signature of reporting officer**

Annexure-6.27: Proforma for appraisal of human rabies cases						
Characteristic	**2012**	**2013**	**2014**	**2015**	**2016**	**Total**
Total cases						
1. Area						
Urban						
Rural						
2. Sex						
Male						
Female						
3. Age						
Adult						
Child(≤14yrs)						
4. Animal						
Dog						
Cat						
Wild Animal						
Others						
5. IP(days)						
Unknown						
Not Rec.						
6. Bite site						
Head						
Trunk						
UL						
LL						
Groin						
UK						
NR						
7.ARV						
Received						
Not Received						
NR						
NK						
8.RIG						
Received						
Not Received						
NR						
NK						
9. Outcome						
Died						
NR						
NK						
10.Survival(D)						
NR						
NK						
11. Others						

Annexure-6.28: Assessment of logistics of rabies vaccines for post exposure prophylaxis in the survey states

Sl.No	Characteristic	Himachal Pradesh	Bihar	West Bengal	Manipur	Kerala	Madhya Pradesh	Gujarat
1.	**Special agency**	HP state civil supplies corporation under ministry of finance	Bihar medical services & infrastructure corporation limited (BMSICL)	No	No	Kerala Medical Services Corporation Limited (KMSCL)	MP Public Health Services Corporation Limited (MPPHSCL) under ministry of Public health	Gujarat Medical Services Corporation Limited (GMSCL)
2.	**Part of DHS/ Separate**	Now through drug procurement cell under DHS	Separate	DHS – central medical store	DHS	Separate	Separate	Separate
3.	**Procurement**							
a.	E - Tender	Yes once in 2 years	Yes	Yes. SMIS software used	No	Yes	Yes	Yes
b.	Technical Committee (Yes)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
c.	Time lag(producer)	90 days	90 days	90 days	Variable	60 days	90 days	90 days
d.	Type of vaccine	Abhayrab 0.5 / 1 ml	Abhayrab 0.5 / 1 ml	Abhayrab/ Rabipur	Rabipur &Vac rabies	Abhayrab 0.5 / 1 ml	Abhayrab 0.5 / 1 ml	Abhayrab 0.5ml/ Rabipur 1ml
e.	Cost (from MRP)	Rs. 141.07/- 44% of MRP	Rs. 119.89/- 37% of MRP	Rs. 121.13	---	Rs. 135.45	Rs.122.35	--
4.	**Storage**							
a.	District/Regional	District drug store	District drug store	District reserve store	State directorate	District Ware Houses	Drug distribution centre	6 Regional Drug distribution centres (RDDCS)
b.	EPI/Separate	Separate	Separate	Separate	Separate	Separate	Separate	Separate
c.	Equipment	Nil	Yes	Yes	Yes	Yes Walk in cold rooms	Yes	Yes
5.	**Stock-outs- Frequent/ sometimes/ 0casional**	Occasional	Occasional	Occasional	Frequent	No	Occasional	No
6.	**Delivery to Health Institutions**							
a.	Vehicles	CMO vehicle	CMO vehicle	CMO vehicle	DHS vehicles	District ware house vehicles	CMHO vehicle	Supplier vehicles
b.	Persons	CMO / block PHC	CMO / block PHC	CMO / block PHC	DHS	District ware house persons	CMHO / block PHC	District store
c.	Cold chain	Yes	Yes	Yes	Yes	Yes	Yes	Yes
7.	**Demand (Frequency)**	Once a year – not online	Once a year – online	Once a year	Once a year	Once a year	Once in 2 years	Drug Demanding & Demand raising officer
8.	**AEFI reporting (Yes/No)**	No	No	No	No	Yes – To DMOH	No	Yes – THO
9.	**Remarks**	Purchase by CMO's through NHM budget & general budget	---	Registration of all ARCs using code system. Utilization certificate used.	RIGs not procured	---	MP Aushadi software	--

Annexure-6.29: Assessment of logistics of rabies Immunoglobulins (RIGs) for post exposure prophylaxis in the survey states

Sl. no	Characteristic	Himachal Pradesh	Bihar	West Bengal	Manipur	Kerala	Madhya Pradesh	Gujarat
1.	**Special agency**	HP state civil supplies corporation under ministry of finance	Local purchase	No	No	Kerala Medical Services Corporation Limited (KMSCL)	MP Public Health Services Corporation Limited (MPPHSCL) under ministry of Public health	Gujarat Medical Services Corporation Limited (GMSCL)
2.	**Part of DHS/ Separate**	Now through drug procurement cell under DHS	Separate	DHS – central medical store	DHS	Separate	Separate	Separate
3.	**Procurement**							
a.	E - Tender	Yes, once in 2 years	Local Purchase /Separate	DHS – central medical store	No	Yes	Yes	Yes
b.	Technical Committee (Yes)	Yes	Yes	No	Yes	Yes	Yes	Yes
c.	Time lag(producer)	90 days	90 days	DHS – central medical store	Variable	60 days	90 days	90 days
d.	Type of RIG	ERIG from CRIK &Premirab	Not procured	ERIG from VINS.	Not procured	ERIG from VINS.	ERIG from VINS. HRIG from Berirab-P	No ERIG procurement HRIG – Plasma Rab
e.	Cost (MRP)	NA	NA	Rs. 364.35/- VINRIG Rs. 3749/- HRIG	NA	Rs. 294.52/- VINRIG	Rs. 280/- VINRIG Rs. 3650/- HRIG	NA
4.	**Storage**							
a.	District/Regional	District drug store	District drug store	Separate	District drug store	District Ware Houses	Drug distribution centre	6 Regional Drug distribution centres (RDDCS)
b.	EPI/Separate	Separate	Separate	Separate	Separate	Separate	Separate	Separate
c.	Equipment	Nil				Yes Walk in cold rooms	Yes	Yes
5.	**Stock-out**-Frequent/ sometimes/ occasional	Occasional	Not procured	Not procured last year & this year	Not procured	No	Occasional	No
6.	**Delivery to Health Institutions**							
a.	Vehicles	CMO vehicle	CMHO vehicle	CMHO / block PHC	CMHO / block PHC	District ware house vehicles	CMHO vehicle	Supplier vehicles
b.	Persons	CMO / block PHC	CMHO / block PHC	CMHO / block PHC	CMHO / block PHC	District ware house persons	CMHO / block PHC	District store
c.	Cold chain	Cold box	Yes	Yes	Yes	Yes	Yes	Yes
7.	**Demand (Frequency)**	Once a year – not online	Once a year/SOS	Once a year	Once a year	Once a year	Once in 2 years	Drug Demanding & Demand raising officer
8.	**AEFI reporting (Yes/No)**	No	No	No	No	Yes – To DMOH	No	Yes – THO
9.	**Remarks**	Purchase by CMO's through NHM budget & general budget	Not procured	Irregular Procurement -	Not procured	Karunya community pharmacy services (Wing of KMSCL) subsidised HRIG at 50 outlets (Rs. 3142/- Berirab –P)	MP Aushadi software	No procurement of ERIG

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About APCRI

APCRI was founded in the year 1998 with a vision to make **India Rabies Free by 2020. S**ince 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.