Original Article

Assessment of Procurement, Distribution, Availability, and Utilization of Rabies Biologicals for Postexposure Prophylaxis in Seven States of India

Ashwath Narayana D. Hanumanthaiah[1], Ravish Shankaraiah Haradanhalli[2]

[1]Professor and Head, [2]Professor, Department of Community Medicine, Kempegowda Institute of Medical Sciences, Bengaluru, Karnataka, India

Abstract

Background: To achieve the elimination of dog-mediated human rabies by 2030, all bite victims shall have access to life-saving rabies biologicals across the country. The information on procurement, distribution, availability, and utilization of rabies biologicals for postexposure prophylaxis is insufficient. **Objectives:** The objective of the study is to assess the demand, procurement, distribution, availability, storage, and utilization of rabies biologicals and to appraise the monitoring and reporting of rabies biologicals at all the levels. **Methods:** A multicentric survey was conducted from July to December 2017 in seven regional representative states across the country. The survey team visited the offices in-charge for logistics of rabies biologicals at the survey states and districts; information was collected using structured pro formas and perusing relevant records. District vaccine stores and health institutions in urban and rural areas were visited to assess the availability and stock-outs of rabies biologicals. **Results:** Procurement, distribution, and availability of rabies biologicals grossly vary between states, since it is the state subject. In Gujarat, both vaccines and immunoglobulins were available even at the Primary Health Centre level; paradoxically, there was a scarcity of both at the district level in Manipur. Immunoglobulins were used only in nine of the surveyed 27 government health-care facilities (33.3%) and two of the eight private facilities (25%). The cold chain facility for storage of rabies biologicals was satisfactory; however, the monitoring and reporting of rabies biologicals were not complete. **Conclusion:** The procurement, distribution, availability, and utilization of rabies biologicals were not universal across the states. Frequent shortages of supply have to be improved to attain universal coverage.

Key words: Availability, distribution, procurement, rabies biologicals, utilization

Introduction

Rabies is a neglected zoonotic disease, which affects the poor people living in remote rural areas and urban slums of the developing world.[1] The World Health Organization (WHO) estimates that >59,000 human deaths occur globally every year. Over 95% of the global human rabies deaths occur in Asia and Africa.[2] Rabies continues to be a major public health problem throughout India; an estimated 20,000 human rabies deaths and 17.4 million animal bites occur annually.[3]

Rabies is a preventable disease and is most amenable to control, as the appropriate tools for prevention, i.e., postexposure prophylaxis (PEP) are available.[4] In rabies, endemic country like India, where every animal bite is potentially suspected as rabid exposure, the exposed individuals should seek early and proper health care; simultaneously, PEP should be started immediately at the health-care facility.[5] In this background, the Government of India has launched the National Rabies Control Programme (NRCP) with the objective to reduce human deaths due to rabies.[6] One of the important strategies is to provide proper and complete PEP. Therefore, the rabies biologicals should be available at all the levels in the country.[7]

India is the manufacturing hub for anti-rabies vaccine (ARV), and rabies immunoglobulin (RIG)/rabies monoclonal antibody (RMAb), and these products are even exported to other countries in Asia and Africa.[8] There are six vaccine

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Address for correspondence: Dr. Ravish Shankaraiah Haradanhalli, Department of Community Medicine, Kempegowda Institute of Medical Sciences, Banashankari 2nd Stage, Bengaluru - 560 070, Karnataka, India.
E-mail: drravishhs@rediffmail.com

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producers in India (1 in public sector and 5 in private sector) with installed capacity of 53.6 million doses (public sector 12.2 million [22.8%] and private sector 41.4 million [77.2%]). Currently, 10 brands of rabies vaccines are available: purified chick embryo cell rabies vaccine-2 and purified vero cell rabies vaccine-8. Likewise, there are 5 equine RIG (ERIG) producers in the country; 2 in public sector and 3 in private sector with an installed capacity of 4.3 million mL (public sector 0.14 million mL [3.2%] and private sector 4.2 million mL [96.8%]).[9] A Novel RMAb is produced indigenously in the private sector with an installed capacity of 4 million vials and being marketed in India.[10]

India is a vast country with population >1.2 billion spread over 30 states, 5 union territories, and 2 islands. Since health is a state subject, each state government has a different mechanism of procurement of rabies biologicals by their drug procurement agencies (State Drug Logistics Societies/State Medical Services Corporations).[11] Hence, the availability and accessibility of these life-saving ARV and RIG/RMAb vary in different states. However, the present status needs to be assessed also.

To achieve the elimination of dog-mediated human rabies by 2030, all cases should have access to life-saving rabies biologicals in the entire country.[12] However, there is little information on procurement, distribution, availability, and utilization of rabies biologicals with monitoring and reporting of its use. In this context, the present study was conducted to assess the demand, procurement, distribution, availability, storage, and utilization of rabies biologicals in the surveyed states and to appraise the monitoring and reporting of rabies biologicals at all the levels.

Materials and Methods

The study was conducted as a part of national survey on programmatic experiences of rabies prevention and control by the Association for Prevention and Control of Rabies in India (APCRI), supported by the WHO.

A descriptive study was conducted from July to December 2017 in seven states namely Himachal Pradesh, Bihar, West Bengal, Manipur, Kerala, Madhya Pradesh, and Gujarat having geoscatter representative sample from different regions of the country, namely North, East, West, South, Central, and North-East. In each state, a simple random sampling technique was used to select one district within the state. Random numbers were generated using the "Randbetween" function of Microsoft Excel software in choosing the districts.[13] The survey teams comprising trained public health experts visited all the logistically feasible agency/organization/office responsible for the logistics of rabies biologicals at the state and district levels of all the selected seven states. Pretested, structured pro forma/checklist was used to collect the information from the concerned officials/personnel through an interview and perusing the relevant records on procurement, distribution, storage including cold chain, availability and utilization of rabies biologicals with monitoring and reporting of stocks and adverse drug events.

District vaccine stores/other related places in the selected districts were also visited to assess the mechanism of demand, procurement, and distribution of rabies biologicals by interviewing the persons in-charge and reviewing the relevant records and also interviewed regarding monitoring and reporting of rabies biologicals. In each district, at the peripheral level, the health-care facilities in both the urban and rural areas were visited randomly, and the concerned medical officers/pharmacists were interviewed to ascertain the availability of the logistics of the rabies biologicals; specifically about stock outs and monitoring and reporting of rabies biologicals.

The data collected from all the settings/centers across the country were compiled and analyzed using the principles of descriptive statistics.

Results

The various components of logistics with regards to rabies biologicals for PEP are described below:

Demand and procurement of rabies biologicals

Government sector

The annual requirement/demand of rabies vaccines was usually based on the consumption levels of the previous year, namely April–March plus an additional quantum of about 10% as buffer was added. This was usually worked out by the institutions, and the consolidated report was submitted by the district health/medical officer to the state drug logistics society/medical services corporation. Subsequently, the consolidated annual quantum was purchased through a public E-tender notification issued on the website of the society/corporation. These government-owned drug procurement agencies purchased rabies vaccines approved by the Drug Controller General of India, Central Drug Standards and Control Organization, Government of India; and incidentally, these vaccines were WHO prequalified, which means the standards of manufacturing and distribution was approved by the WHO and could be purchased and used by any of the WHO member countries. Both ARV and ERIG had been brought under the drug price control by the Indian government. The MRP of one vial of rabies vaccine was around INR 340.00, and that of ERIG was around INR 485.00. However, the rates at which the individual state governments procured ARV or RIG through competitive bidding varied from state to state [Table 1].

The quantum of purchase may be from a single company or divided among 2–3 pharma companies to avoid monopolization and ensure good competition. The successful bidder(s) supplied the approved quantity directly to the regional/district drug warehouses. This resulted in different brands of vaccines getting supplied to the hospitals; and sometimes, when one company failed, the other company was asked to supply to avoid stock-outs. If stock-outs occurred, which was common; the institutions/district level officer was authorized to buy

Table 1: Details of procurement of rabies biologicals by the government sector in seven states of India

States	Special agencies for procurement	E-tender	Technical committee	Supply by producer (time lag)*
Himachal Pradesh	HP state civil supplies corporation under ministry of finance	Yes	Yes	90 days
Bihar	BMSICL	Yes	Yes	90 days
West Bengal	No special procurement agencies. Directorate of health services	Yes	Yes	90 days
Manipur	No special procurement agencies. Directorate of health services	No	Yes	Variable
Kerala	KMSCL	Yes	Yes	60 days
Madhya Pradesh	MPPHSCL	Yes	Yes	90 days
Gujarat	GMSCL	Yes	Yes	90 days

States of Bihar and Manipur do not procure RIG; local purchases made occasionally. *Time lag: Interval between the placement of order and the supply from the agencies. BMSICL: Bihar Medical Services And Infrastructure Corporation Limited, KMSCL: Kerala Medical Services Corporation Limited, MPPHSCL: MP Public Health Services Corporation Limited, GMSCL: Gujarat Medical Services Corporation Limited

the vaccines from the open market at the pre-approved rates/rate contract list to avoid public outcry. ERIG was procured and mostly used in states of Gujarat, Kerala, and Himachal Pradesh; however, scarce/sparingly used in other survey states. Likewise, the human RIG (HRIG) was procured only in the states of Gujarat (predominant use) and Kerala (occasional use).

Private sector

The market demand was usually assessed by the manufacturer through their network of marketing personnel; accordingly, the clearing and forwarding (C and F) agencies were supplied with vaccines. In exceptional situation, due to limited supplies, there was a rotation of brands of vaccines at stockist levels and was invariably accepted. ERIG was scarce/sparingly used in the private sector, and HRIG was used in bigger cities for higher-income group.

Distribution and storage of rabies biologicals

Government sector

The manufacturer supplied the rabies biologicals in a refrigerated van by surface transport to the designated places in the states, i.e., usually, the drug warehouses at the regional/district levels. The vaccines were stored in the walk-in coolers (WIC), and the temperature log was maintained. From the regional/district warehouses, the rabies biologicals were supplied in cold boxes to the peripheral institutions using jeeps/vans with the travel time of 1–6 h. At the health center level, the rabies biologicals were stored separately in a domestic refrigerator at 2–8°C with other non-Universal Immunization Programme vaccines and drugs. At the health centers, the vaccines/RIGs were kept in the vaccine carrier/ice pack during the time of vaccination [Table 2].

There were adequate cold chain equipment and temperature log systems in place. The health staffs were well trained in cold chain management and vaccine/RIG handling mainly from their work experience in UIP and Polio eradication program.

Private sector/trade

The vaccines/RIGs were transported from the manufacturer to the C and F agents by air cargo/refrigerated van, depending on the distance at the state capital. At the C and F, vaccines/RIGs were stored in the WIC with temperature log maintained by

Table 2: Storage place and delivery system of rabies biologicals in seven states of India

States	Storage	Delivery to peripheral institutions
Himachal Pradesh	District drug store	Vehicle from CMO office
Bihar	District drug store	Vehicle from CMO office
West Bengal	District reserve store	Vehicle from CMO office
Manipur	State directorate	DHS vehicles
Kerala	District ware houses	District ware house vehicles
Madhya Pradesh	Drug distribution center	CMHO vehicle
Gujarat	6 RDDCS	Supplier vehicles

Rabies biologicals are stored separately from UIP vaccines.
RDDCS: Regional drug distribution centers

cobalt device, in case of any cold chain failure, it sent text/voice message to the mobile phone of the C and F agent/sound alarm for corrective action. However, as the WICs were provided with UPS, instances of cold chain failure were rare. The C and Fs were periodically supervised by the manufacturer and also by regulatory authorities, namely State Drugs Controller. From C and F, the ARV/RIGs were transported to stockists/distributors in the thermocol boxes or vaccine carrier for short distances using vans/other vehicles. For longer distances, it was sent through special transport logistics/courier/cargo services by road under the cold chain. All related communications were made by E-mail and using telephones/mobile phones.

At the stockist/distributor level, the vaccines/RIGs were stored in the WICs depending on the volume and geo-area coverage. From stockist to the retailers/chemists, druggist shops, hospital/nursing home/doctor; they were transported in 2–4 h using vaccine carriers. The retailer/druggist and chemist stored the vaccines/RIGs in domestic refrigerators with UPS and mostly dispensed to the patients/practitioners directly.

Availability of rabies biologicals

Rabies vaccines

In government sector, different types and brands of ARV were available. There were frequent stock-outs of rabies vaccine due to high animal bite caseload vis-a-vis supply. This was particularly more frequent in states of Bihar,

Manipur, and Madhya Pradesh as rabies vaccine was used by intramuscular (IM) route, instead of cost-effective intradermal (ID) use.

In the private sector, when a particular brand of ARV was not available in the market, it was substituted by other available brands of ARV, thus ensuring continuous and uninterrupted supply. The stock-out of vaccine was occasional/sometimes in the government sector (14%) and never in the private sector as some brand of rabies vaccine was always available.

Rabies immunoglobulin

ERIG was available and mostly used in the states of Gujarat, Kerala, and Himachal Pradesh; but, scarce/sparingly available/used in other four survey states. Likewise, the HRIGs were available only in the states of Gujarat (predominant use) and Kerala (occasional use). Otherwise, its use is limited to mostly private sector, in bigger cities and for higher-income group. Among the surveyed 27 government health-care facilities, RIG was used only in the 9 (33.3%) of them; likewise, in private sectors among the 8 health-care facilities, RIG was administered only in 2 (25%) of them. The stock-out of RIG was more frequent in government sector as compared to private sector [Table 3].

Utilization of rabies biologicals in both government and private sectors

In government sector, ARV was provided both by IM and ID route and in private sector, it was predominantly by IM route. ERIG was provided in majority of government hospitals when compared to HRIG in private hospitals [Table 3].

In majority of government hospitals across the states surveyed, ARV and RIG were provided free of cost for all animal bite cases below the poverty line but nominally charged in autonomous government institutions. However, in private hospitals, these biologicals were prescribed to be brought from private pharmacies @ INR 340 per dose of vaccine and INR 485 per 5 mL ERIG; INR 5500/2 mL of HRIG.

Monitoring and reporting

Most of the government health facilities maintained ARV and RIG inventory stock ledger showing daily, weekly, monthly, and yearly balance. They also maintained outpatient ARV register with details of name, age, sex, biting animal, category of bite vaccine dose, and RIG given. In some states, the data from anti-rabies clinics were compiled and reported to state nodal officer in charge of integrated diseases surveillance program and NRCP. Very few centers in the surveyed states had a system of animal bite cases follow-up (defaulters/dropouts) receiving PEP and informing them about need to complete the course of vaccination.

There was no formal system of monitoring and reporting of adverse events following rabies vaccination and RIG administration. However, in Kerala, any adverse events were reported to the District Medical Officer of Health office, and in Gujarat, it was reported to Taluka Health Officer. However, in the private sector, monitoring and reporting of animal bite cases or adverse drug reactions did not exist.

Discussion

In India, majority of animal bites are from stray dogs, affecting the poor and children, which often results in public hue and

Table 3: The usage of rabies vaccines and immunoglobulins in the seven states of India

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

RIGs: Rabies immunoglobulins, ERIGs: Equine Rabies Immunoglobulin, HRIG: Human rabies immunoglobulins, IM: Intramuscular, ID: Intradermal, SST: Skin sensitivity test

cry; nonavailability of rabies vaccines in public hospitals has become the subject of legislative debates both at the state level and national level.[14] There are frequent shortages of ARVs and RIG for PEP in government sector as state governments often face resource crunch; and as such, production levels of rabies biologicals in public sector are very low.[15] The cost of availing PEP in private sector is substantial and therefore, not affordable to many of the bite victims. Therefore, as per NRCP guidelines, every state should procure and use the rabies biologicals for all animal bite cases.

The present study showed that each state in India had a different mechanism of procurement of rabies biologicals by their state-owned drug procurement agencies, and hence, there was an interstate variation on the availability of rabies biologicals. Similarly, a study from four countries in Asia, namely Bangladesh, Bhutan, Cambodia, and Sri Lanka, conducted between March 2017 and May 2018 at various levels in public sector on procurement, distribution, monitoring, and reporting of rabies PEP have shown that, each country had a unique system of PEP procurement, distribution, monitoring, and reporting. PEP access was available in select health facilities in Bangladesh, Bhutan, and Sri Lanka; whereas, in Cambodia, PEP was provided only in the urban health centers. The availability of RIG in all four countries was limited. All countries had a monitoring system in place, but there was limited reporting of data, particularly to the central level.[16]

Likewise, a study from Tanzania showed that the rural-poor bite victims are less likely to receive PEP compared to their urban counterpart. Travel from remote rural areas to obtain PEP incurs travel cost and additional person accompanying will almost double the cost. Repeated visits to far off hospital deterred the animal bite cases from obtaining a complete course of PEP, and this has resulted in many rabies deaths. The study recommended that government has to make rabies PEP available and affordable to poor rural animal bite victims at all levels.[17]

During the past decade, some of the Asian countries have reduced human rabies by extending PEP services to animal bite cases through rural health center staff, usually nurses.[18,19] Likewise, one of the leading rabies biological manufacturers in India has eliminated intermediaries in the distribution process by directly supplying vaccine and RIG (10%–30% cheaper than other brands) through franchises, thereby reducing the cost, better supply management, and good cold chain.[20]

Now, it is time that, Government of India and the responsible agencies should ensure that all animal bite cases have timely access to adequate PEP through implementing cost-effective IDRV and making availability of rabies biologicals throughout the year at all levels of health care.[21,22] Investing in PEP would be an extremely cost-effective intervention that could substantially reduce disease burden and eliminate dog-mediated rabies.[23] Likewise, there is a need for reassessment and regulation of the production, pricing, domestic distribution, export and usage of rabies vaccines, RIGs/RMAbs, and increase in production of rabies biologicals in the public sector.

Significant progress has occurred during the 21st century regarding the provision of PEP; remaining barriers include an inter-related set of political, economic, cultural, social, educational, ecological, and technological factors to eliminate rabies by the year 2030.[24]

Conclusion

The procurement, distribution, availability, and utilization of rabies biologicals for PEP in India are not universal across the states; with frequent shortages of ARV and RIG in the Government sector due to resource crunch. Hence, there is needed to scale up the availability and accessibility of rabies biologicals countrywide under NRCP; so that, it is uniformly distributed and used in all the states for animal bite exposures. The rabies vaccines and RIGs/RMAbs must be obtained by the central government and provided to state governments/Union Territories as grant-in-aid to all government medical facilities and shall provide PEP free of cost in line with universal health coverage.[25]

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Conflicts of interest

There are no conflicts of interest.

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