Project site experience on delivery of rabies biologicals and country wide scale up of access

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WHO meeting at Johannesburg, South Africa:
12-14, September 2018
WHO-APCRI Indian Rabies Survey 2017: Programmatic Experiences

- **9 months** (May, 2017 to January 2018)
- **Seven states & Two Islands**

**Activities:**

- **Community survey:** 1012 households
- **Health facility survey:** 21 ARCs
- **Veterinary survey**
- **Logistics of rabies biologicals in Government & Private sector**
- **Market mapping & Landscaping of rabies biologicals**
- **Developing background vaccine policy paper**
- **Operational feasibility of Rabies Monoclonal Antibody (RMAb)**
- **Reporting mechanism of surveillance of dog bites & human rabies in surveyed states.**
- **Initiating laboratory surveillance in two rabies free islands.**
Background: Scenario in India

- Estimated 20,000 human rabies deaths; 97% due to dogs; 17.4 million animal bites (WHO-APCRI National Multi-centric Rabies Survey, 2003).

- National Rabies Control Programme (NRCP) was started in 2012.

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- State Governments procure rabies biologicals from State Drug Logistics Societies/ State Medical Services Corporations.

- 06 vaccine producers in India (01 in Public sector & 05 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 vaccine available (PCECV- 2 and PVRV- 8).
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- 05 ERIG producers; 02 in Public sector and 03 in Private sector with installed capacity of 4.3 million mL (Public sector 0.14 million mL (3.2%) and Private sector 4.2 million mL (96.8%).

- Rabies Monoclonal Antibody (RMAb) is now indigenously produced in the private sector with an installed capacity of 4 million vials and being marketed in India from November, 2017.

- The cost (to the patient) of one vial of rabies vaccine is about USD 5 and that of ERIG is about USD 7.

- Government sector use vaccine by IM & ID route.

- Private sector predominantly use vaccine by IM route.
Logistics of Rabies biological supplies (including cold chain)

Government sector:

Manufacturer

Regional or District drug ware houses

The Rabies biologicals are kept along with other EPI vaccines in the walk-in coolers / cold rooms and the temperature log maintained.

Peripheral institutions

The Rabies biologicals are kept in cold boxes stored separately in a domestic refrigerator with other non-EPI vaccines and drugs. The EPI vaccines are stored separately in designated ice-lined refrigerators (ILRs)

The cold chain is robust and the rabies biologicals are well handled to safeguard their potency and sterility
Dr. M. K. Sudarshan, Project Lead assessing vaccine & RIG logistics at Surat, Gujarat and Kottayam, Kerala
Logistics of Rabies biological supplies (including cold chain)

Private/Trade sector:

**Manufacturer**

- **Air cargo / Refrigerated Van**

**Clearing and forwarding (C&F) agents at the state capital**

Rabies biologicals 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.

- **Courier/ Cargo services**

**Stockists / Distributors**

- **Omni vans / Goods Auto**

**Retailer/ Druggist and Chemist store**

Rabies biologicals are stored in domestic refrigerators with UPS

- **Patients / practitioners**

- 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.
Walk in cooler in a C&F agency with temperature log and siren hood
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- State Governments procure rabies biologicals annually based on the consumption levels of the current year (April to March) + An additional quantum of 10% as buffer.

- 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.

- The use of RIG in the government was 34% and in private sectors was only 20%.

- The stock outs of RIG was more frequent (43%) than that for vaccines (14%) in Government sector.

- There was minimal usage of ERIGs; HRIG, being expensive was used in smaller quantities in bigger cities/metros.

- Procurement & Delivery of rabies biologicals grossly vary between states.
  
  Gujarat: Both vaccines & RIGS are available, even at the PHC level.
  
  Manipur: Scarcity of both Vaccine & RIG, even at the District level.
Conclusions

- India has the infrastructure and capacity for producing modern cell culture vaccines, equine rabies immunoglobulin and rabies monoclonal antibodies.
- The logistics & cold chain is robust and the rabies biologicals are well handled to safeguard their potency and sterility, both in Government & private sector.
- The production levels of rabies biologicals in public sector is low.
- Government sector: There are frequent shortages of ARV and RIG for PEP. State governments often face resource crunch to procure rabies vaccines which are considered secondary vaccines.
- The level of awareness amongst medical professionals about the use of rabies biologicals particularly for RIG is far from satisfactory.
Recommendations to Scale up of access to Rabies biologicals country wide

- A reassessment & regulation of production, pricing, domestic distribution, export & usage of rabies vaccines, RIGs/ RMAbs in the country is required.
- The production of rabies biologicals in the public sector must be increased.
- The rabies vaccines and RIGs/ RMAbs must be obtained by central government and provided to state governments/Union Territories as grant-in-aid under the National Rabies Control Programme (NRCP).
- All government medical facilities shall provide PEP free of cost.
- ARV and RIG procurement, distribution and delivery mechanism has to be further improved by universal delivery mechanism similar to UIP vaccines by the central government.
- Regular professional training programmes on the correct usage of rabies biologicals needs to be conducted across the country.
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