

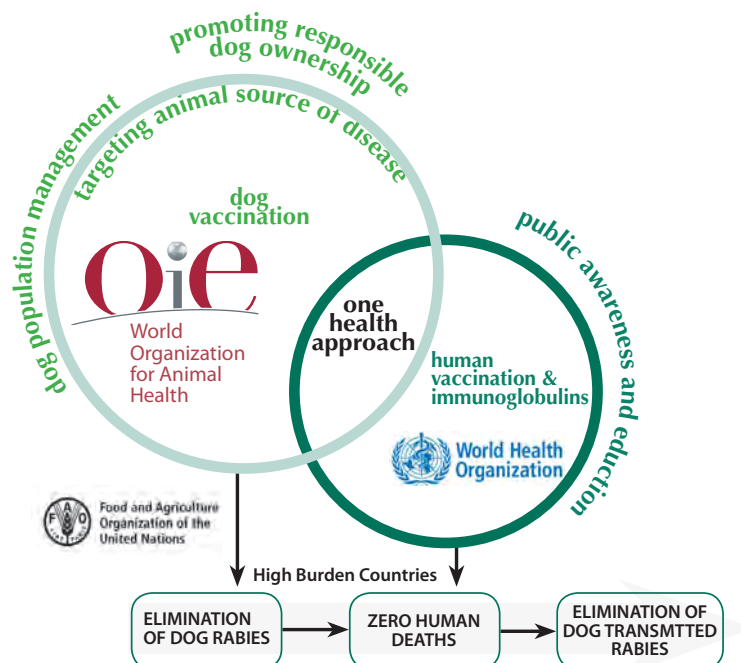
Human and dog rabies vaccines and immunoglobulins

REPORT OF A MEETING

Geneva, 12–13 October 2015



RABIES – the 100% preventable zoonotic Neglected Tropical Disease (NTD)
optimized supply & coordination = expedited achievement of ZERO deaths



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Executive summary

The World Health Organization (WHO) in collaboration with the World Organization for Animal Health (OIE) convened a meeting of country representatives, manufacturers and other stakeholders at WHO headquarters in Geneva, Switzerland on 12-13 October 2015, to discuss and develop ideas for improving the current system of procurement of quality-assured, safe and affordable dog and human rabies vaccines and rabies immunoglobulins (RIGs).

The objectives of the meeting were:

- to assemble forecasts of human and dog rabies vaccines and RIGs from specific countries;
- to understand the manufacturing capacity for rabies vaccines and RIGs, shortfalls and logistical needs;
- to obtain a shared understanding of global supply of vaccines and RIG needs or forecasts; and
- to explore bulk purchasing options for countries through WHO/UNICEF (human vaccine and RIG) and OIE/WHO (animal vaccine) mechanisms.

The current situation was presented by WHO and OIE experts, country representatives (from Bangladesh, Mexico, the Philippines, South Africa, Sri Lanka, Uganda and the United Republic of Tanzania), manufacturers of vaccines and RIGs, and the Strategic and Technical Advisory Group for Neglected and Tropical Diseases. The WHO-UNICEF mechanisms for vaccine procurement were presented using the example of a meningitis vaccine stockpile, and insights gained into the Pan American

Health Organization (PAHO) revolving fund, the WHO prequalification process and OIE dog rabies vaccine banks.

Key messages

The participants identified and discussed four major issues: forecasting; quality of vaccines and RIGs; funding strategies; and procurement. The discussions confirmed the need for provision of a procurement mechanism and coordination for both dog and human vaccines and RIGs, with joint leadership from WHO and OIE. The importance of creating political will to raise awareness of rabies as a public health priority was emphasized.



Forecasting vaccine needs

Human vaccine:

- Proactive use of vaccine will progressively improve the accuracy of forecasts which will generate higher quality data over time. Consistent country forecasts will stabilize demand, production and availability of vaccine.
- Improved data will feed into national policies.
- Cost-benefit and value analyses (public health, healthy workforce, improved economy) will be key.

- Manufacturers of human vaccine need to include intradermal routes of administration on product label.

Dog vaccine:

- Identifying dog vaccine requirements is fundamentally linked to country-level plans.
- There is a wide range of readiness, good work is being done and opportunities exist to share lessons learned and success stories, such as the use of a regional coordinating platform.
- Although 70% of dog population would ideally forecast vaccine needs, in the absence of population estimates identifying a corridor or source area and starting to vaccinate will start the process of building accurate dog estimates. Current estimates are available for 192 countries, but their quality varies.
- Vaccine manufacturers consider 18 months to 5 years a useful timespan for vaccine forecasts. However, donor funded programmes rarely extend beyond 3 years. Consolidated regional estimates will improve timing of requirements, including seasonal campaigns, leading to assured production and sales.

Quality of vaccines and RIGs

Quality assurance differs for dog vaccine, human vaccine and RIGs:

- For dog vaccine, the OIE has established and maintains intergovernmental standards for manufacturers; there is no OIE prequalification procedure for vaccine suppliers.

- For human vaccine, WHO prequalification procedures ensure that vaccines meet quality standards and are safe and efficacious.
- For RIGs, no international quality standards are available and minimum standards must be established to improve the quality of RIGs.
- Poor delivery systems can impact a vaccine's quality.
- The next-generation human vaccine (single or two-dose vaccine) should provide improvements, such as longer shelf-life and thermostability at ambient temperatures.
- Better and purer antigens will improve safety and efficacy and lead to greater quality overall.

Funding strategies

- Funding strategies for human and dog vaccines may need to consider support beyond the cost of the vaccines (for delivery, training, logistics, equipment, etc.).
- National joint human/dog programmes, as support by WHO, OIE, the Food and Agriculture Organization of the United Nations (FAO) and the Global Alliance for Rabies Control (GARC), lead to more effective programmes and better use of resources.
- There is no one solution for all countries: a variety of strategies is needed (national/regional/local).
- Donor funds should be considered "kick-starter injections" and not long-term solutions.
- Pooled funding and transparent tendering processes improve cost efficiency and drive competition.
- Political will is needed to raise awareness of rabies as a public health priority. Cost/benefit/value analysis is a key factor in creating that political will.

Procurement

- The ideal procurement system is one that benefits both manufacturers and recipients, with information on quantities and timing generated by reliable, accurate data from forecasting mechanisms.
- For human vaccine, an integrated “pull” and “push” system is envisioned: the pull part providing negotiation on behalf of countries (as for PAHO), with a focus on middle-income countries; the push part being donor funded (as for the system for funding oral cholera vaccine), with a focus on low-income countries.
- For RIGs, a pull system is preferred, with supply being made available to middle-income countries already engaged in control programmes. Another system would be needed for countries without programmes, with a focus on African countries.
- For dog vaccine, the current procurement mechanism used by OIE and WHO for vaccine banks works well. Expanding to a sustainable, long-term programme to cover African and other endemic countries requiring support was suggested. The PAHO procurement system has proven particularly effective in Latin America and could be used as a model.

Next steps

WHO and OIE are committed to working together to advance the rabies vaccine agenda, in collaboration with relevant partners and with the continued support and engagement of the participants at the meeting. Outcomes of the meeting and next steps will be presented at the conference on “Global Elimination of Dog-mediated Human Rabies – The Time is Now” (Geneva, 10-11 December 2015). An action plan specifying activities, responsibilities and timelines will follow.

1 Background and objectives of the meeting

Rabies is preventable through vaccination, yet dog-mediated rabies kills tens of thousands of people every year worldwide. In the past few years, proof-of-concept programmes using mass dog vaccination and post-exposure prophylaxis (PEP) have proven highly effective in controlling or eliminating dog-mediated human rabies in several endemic countries in Asia and Africa. This report addresses human rabies transmitted by dogs and not rabies transmitted by wildlife.

Currently, many countries with ongoing rabies elimination programmes do not have effective procurement systems for human and dog vaccines and rabies immunoglobulins (RIGs). Consequently, the price of the PEP remains high, its availability is erratic and the quality of the vaccines varies, leading to avoidable deaths and rabies outbreaks. To achieve the goal of global elimination of rabies as a health problem, quality-assured, safe human and dog vaccines and RIGs are needed. To ensure successful programme planning and expansion in the next 5 years and beyond, the current system of procurement must be improved.

The World Health Organization (WHO) in collaboration with the World Organization for Animal Health (OIE) convened a meeting of country representatives, manufacturers and other stakeholders at WHO headquarters in Geneva, Switzerland on 12-13 October 2015. The list of participants is annexed to this report.

The objectives of the meeting were:

1. **to assemble forecasts of human and dog rabies vaccines and RIGs from specific countries;**
2. **to review the manufacturing capacity for rabies vaccines and RIGs, shortfalls and logistical needs;**
3. **to obtain a shared understanding of the global supply of vaccines as well as RIG needs and forecasts; and**
4. **to explore bulk purchasing options for countries through WHO/UNICEF (human vaccine and RIG) and OIE/WHO (animal vaccine) mechanisms.**



2 Context

The meeting served to broker a common understanding of the current situation through presentations from WHO and OIE experts, country representatives (Bangladesh, Mexico, the Philippines, South Africa, Sri Lanka, Uganda and the United Republic of Tanzania), manufacturers of vaccines and RIGs (on current capacity, shortfalls and logistical needs) and on behalf of the Strategic and Technical Advisory Group for Neglected Tropical Diseases. The WHO–UNICEF mechanisms for vaccine procurement were presented using the example of a meningitis vaccine stockpile, and insights gained into the Pan American Health Organization (PAHO) revolving fund, the WHO prequalification process and the OIE dog rabies vaccine banks. Participants explored options for making products more easily available and developing partnerships among involved parties

3 Key issues

Participants identified key issues, their scope and implications, and potential solutions.

Discussion of the following issues focused on ensuring reliable access to safe, efficacious vaccines and RIGs at optimal prices:



3.1 Forecasting

Improved data collection will lead to more accurate, reliable forecasting and eventually to more stable, timely and consistent product availability.

3.1.1 Human vaccine needs and demand

Accurately predicting the requirements for human vaccine is a significant challenge that calls for improved collection of high-quality data, analysis and projection. Data on bites, number of vaccines, compliance, lives saved, wastage, and intramuscular (IM) versus intradermal (ID) administration can inform regional/global projections.

Policies to increase awareness of rabies are

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