Template for a human rabies vaccine introduction plan

This template has been adapted to guide countries in developing a practical plan for introducing the human rabies vaccine. It is intended to provide suggestions for key areas to be considered; as such, some items relevant to a particular country may be missing or may not be relevant. Each country and vaccine introduction will have different characteristics and requirements, so each country’s introduction plan will need to be adjusted accordingly. The overall recommended length for this plan is 10–20 pages.

The introduction plan should build on plans, strategies and activities outlined in the country’s own broader strategic plans (e.g. National Immunization Plan, National Health Plan, Comprehensive Multi-Year Plan or national rabies control strategic plan). Countries should consider including any steps taken that incorporate a One Health multisectoral mechanism, such as those described in the [*Tripartite Zoonoses Guide (TZG)*](https://www.who.int/initiatives/tripartite-zoonosis-guide). Additionally, countries may wish to consider developing an introduction plan for lower administrative levels in the country that translates goals and activities articulated nationally into those that more relevant sub-nationally.

Section numbers in footnotes refer to sections of the main document: [*Principles and consideration for adding a vaccine to a national immunization programme*](https://iris.who.int/bitstream/handle/10665/111548/9789241506892_eng.pdf?sequence=1).

# Executive summary

Summarize key aspects of the introduction plan, such as:

* Justification, goals and objectives (short-, intermediate- and long-term) of the human rabies vaccine introduction, with reference to the National Health (or Immunization) Plan, the Comprehensive Multi-Year Plan or the national rabies control strategic plan, as well as expected impacts on the immunization programme and the health system.
* The vaccine and presentation to be introduced, the specific populations to be targeted, the phased or nationwide implementation of introduction and delivery strategies.
* Cross-sectoral coordination mechanisms and key partnerships (including all key stakeholders) for overseeing the introduction.
  + Identify and describe key stakeholders working on rabies and immunization in-country (e.g. government, civil societies, academia, nonprofit organizations).
  + How will the introduction of the Human Rabies Vaccine Programme be coordinated with the Expanded Programme on Immunization (EPI) and other immunization programmes?
  + How will the introduction of the Human Rabies Vaccine Programme be coordinated with other relevant programmes (e.g. One Health, Neglected Tropical Diseases)?
* Opportunities provided by the human rabies vaccine introduction to improve the immunization programme and health system (e.g. key issues and weaknesses to be addressed by the vaccine introduction).
* Major activities of the introduction (e.g. expanding health-worker capacity including for intradermal vaccination, reaching hard-to-reach populations with social mobilization, improving the cold chain and logistics system, updating standard operating procedures for management of potential rabies exposures).
  + Consider health-worker training needs for post-exposure prophylaxis and intradermal administration. Are knowledge and skills sufficient for human rabies vaccine introduction?
  + How will rabies education/awareness and vaccine accessibility be improved in-country, particularly for high-risk and vulnerable populations?
* Costs and financing of the short- and intermediate-term human rabies vaccine introduction activities and the associated operational costs with assurance that PEP will be provided free of charge to the patient.
* Sources of funding and the contribution of the Government

# Background and country context

* Brief background information about the country (e.g. geography, population size, health status of children).
  + **Guidance reference:** [Template for National Strategic Plan to Control Rabies | United Against Rabies Forum.](https://www.unitedagainstrabies.org/uar-best-practice/template-for-national-strategic-plan-to-control-rabies/)
* Brief background on the national immunization programme, such as:
  + Goals, plans and human rabies post-exposure prophylaxis (PEP), including rabies immunoglobulin (RIG), in the current immunization programme.
    - Is the country using WHO prequalified human rabies vaccines?
    - How many vials of PEP (i.e. vaccine and RIG) are currently procured by the Government annually? How many of those vials are used?
    - Has the country developed a national rabies control strategic plan, which demonstrates complementary multi-sectoral rabies control initiatives? If so, please attach this strategy/plan with your introduction plan. This strategy should include plans for dog vaccination and social mobilization.
  + Programme performance and achievements (e.g. trends in PEP accessibility for human exposures, accelerated rabies control efforts) disaggregated by sex, geography and wealth quintile, to the extent possible.
    - Describe the current surveillance system. Is a risk-based approach used to assess patients presenting to health facilities with potential exposures? To what extent is integrated bite case management (IBCM) implemented?
    - Describe the current data reporting and sharing mechanisms for human rabies, human rabies exposures and rabies PEP. This resource may provide an aide: [UAR Minimum Data Elements](https://www.unitedagainstrabies.org/wp-content/uploads/2023/09/2023_MinimumDataElements_V4_Sep2023_EN.pdf).
  + Past experience with new vaccine introductions and lessons learnt, key findings from a recent EPI review, post-introduction evaluation, Effective Vaccine Management (EVM) assessment, or other analyses and how identified issues and recommendations are being addressed by the immunization programme.
  + Recent improvements made to the immunization programme and health systems that will facilitate introduction of the human rabies vaccine (e.g. increase in cold chain capacity)
* Burden of rabies in the country (e.g. summary of local data or regional or global estimates of disease burden, estimates of the economic burden of the disease), data on incidence of dog bites and data on dog vaccination where available.
  + Include real national and sub-national surveillance statistics for number of human exposures, human rabies cases, PEP including adherence to regimen and animal rabies cases.
  + Modelled data can also be included from publications including: [The potential effect of improved provision of rabies post-exposure prophylaxis in Gavi-eligible countries: a modelling study - The Lancet Infectious Diseases](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(18)30512-7/fulltext)
* Decision-making process regarding the human rabies vaccine introduction, such as the decision-making body involved (e.g. NITAG, special task force), types of evidence reviewed and rationale for the decision (e.g. contribution to national and/or global disease prevention and health goals; cost, affordability and cost–effectiveness of the vaccination vs other prevention and control measures), involvement of stakeholders and experts from different agencies and sectors of society, government review and approval process (e.g. Health and Social Care Committee (HSCC), Interagency coordinating committee (ICC), other health departments).
  + Is current National Policy for human rabies vaccine protocols in line with WHO’s position on PEP?
    - [WHO position on Rabies Vaccine (April 2018)](https://apps.who.int/iris/bitstream/handle/10665/272371/WER9316.pdf)
    - [WHO Expert Consultation on Rabies: WHO TRS N°1012 Third report](https://www.who.int/publications/i/item/WHO-TRS-1012)
    - A WHO rabies-specific guide can be found here: [Guide to introducing human rabies vaccine into national immunization programmes (who.int)](https://www.who.int/publications/i/item/9789240052499)

# Goals, objectives and expected impact and challenges of the vaccine introduction

* Goals, objectives and targets (e.g. short-, intermediate- and long-term), and alignment with regional and/or global timelines such as [Zero By 30](https://www.who.int/publications/i/item/9789241513838) : the global strategic plan to end human deaths from dog-mediated rabies by 2030.
* Expected impact of the vaccine (e.g. on rabies incidence and mortality, on equity related to gender, wealth and geography, among other factors, on the overall immunization programme and health system).
* Major challenges and risks of the human rabies vaccine introduction (e.g. programmatic, financial, cultural/societal) and the country’s ability to address them. An equity analysis (gender, wealth, geography) should be conducted that includes suggested actions to mitigate any equity-related barriers that are identified.

# Strategies and policies for introducing the human rabies vaccine into the national immunization programme

* Choice of vaccine product to be introduced and rationale (including availability and acceptance of alternative presentations or products, if relevant)1;
* Vaccine administration and regimen to be introduced (i.e. intradermal (ID) vs intramuscular (IM), Institut Pasteur du Cambodge (IPC) vs Essen vs Zagreb regimen);
* National advisory groups or National Immunization Technical Advisory Group (NITAG) that have reviewed or updated human rabies vaccine recommendations in the country;
* Updated immunization schedule(s) and administration routes including plans for the transition to and scale up of the updated regimen;
* Identify potentially exposed person, target high-risk ages and populations, and increase health-seeking behaviours and compliance with PEP;
* Delivery strategies to be used, including how to overcome barriers to reach new and hard-to-reach populations, the possible role of other sectors (e.g. animal health and education).4 Include current programme that build awareness on rabies, bite prevention and what to do when you are bitten by an animal;
* Opportunities for integrating activities related to delivery of the human rabies vaccine with other health interventions5;
* Phased or nationwide introduction and planned month of national introduction or timetable for a phased introduction6. Consider a phased approach with stepwise expansion across the country.

# Resources, costs, financing and sustainability

* Overall trend of country immunization financing, including government funding, private sector and donor funding, as applicable;
* Identification of key immunization programme and health system needs for human rabies vaccine introduction such as human resources (e.g. addressing number, distribution, turnover and skills of vaccinators, nurses, logisticians, supervisors, delivery truck drivers, equipment, systems).
* Estimated cost of adding the human rabies vaccine to the immunization programme, including non-vaccine operational costs; plans for financing the additional costs of the new vaccine being introduced
* Overview of the comprehensive multi-year plan (cMYP), highlighting any funding shortfalls and plans to address these, and potential impact on the human rabies vaccine introduction

1 See Sections 2.3.1 and 3.3 of the main document.

2 See Sections 3.2.3 and 3.2.4.

3 See Section 3.2.3.

4 See Section 3.2.5.

5 See Section 3.2.6.

6 See Section 3.2.1.

# Strategies and activities for the vaccine introduction, including opportunities to improve the immunization programme and overall health system during the introduction

This is the core of the Introduction Plan. It should include all activities that need to take place to prepare for a smooth vaccine introduction. It should incorporate activities that address the issues, challenges and weaknesses of the existing immunization programme that were identified during the last EPI review, post-introduction evaluation, EVM assessment or a situational assessment. It should also include discussion of the existing rabies programme in the country. Suggested areas to describe and address include:

* 1. **Coordinating and monitoring the preparation and implementation of the vaccine introduction7**
     + Groups that will coordinate and oversee the introduction (e.g. steering committee or ICC, technical sub-committees to plan and monitor different aspects of the introduction, and persons to be included on these committees);
     + How the various committees will function (e.g. frequency of meetings, chairpersons, and secretariat, to whom they report);
     + Partnerships for the introduction, including sectors and types of organizations to be involved (e.g. education, civil society, medical associations, animal health services) and how they will participate in the planning and implementation of the vaccine introduction.
  2. **Planning for procurement and distribution of vaccine8**
     + National licensure status of the selected vaccine or process and timeframe for licensure;
     + Forecasted vaccine needs, including estimated size of the target population by year and estimated number of doses and injection supplies required per year (taking into account any catch-up vaccinations in the first year of introduction, or in subsequent years);
     + Procurement procedures such as likely source(s) of vaccine and procurement process;
     + Shipping and distribution, including customs regulations and requirements that may affect timing of vaccine deliveries, and planned frequency of vaccine deliveries to regions, districts, and health facilities.
  3. **Expanding or upgrading cold chain, logistics, and vaccine management9, 10**
     + Current cold chain capacity at different levels of the system and source of these data; additional requirements at various levels for cold storage, transportation and equipment to accommodate the new vaccine; how any gaps will be filled;
     + Current status of vaccine stock management system, including recent assessments, key issues (e.g. freeze monitoring) and any planned improvements;

7 See Section 3.1.2.

8 See Sections 3.4 and 3.5.

9 See Section 3.5.

10 See Section 3.5

* + - Plans to increase supervision for vaccine management as part of the vaccine introduction.
  1. **Planning for increased waste management and injection safety needs to accommodate the new vaccine11**
     + Current waste management capacity and practices and injection safety practices and their adequacy; changes needed to accommodate additional volume of wastage due to new vaccine, and plans for upgrading the waste management system.
  2. **Revising health and immunization management information/data collection forms and systems12**
     + Revisions to add the new vaccine and any additional or innovative improvements to be made to the forms or information systems, including Child Health or Vaccination Cards/Booklets, to improve data quality and to take advantage of the new vaccine introduction; coordination with the persons or departments responsible for revising, printing and distributing the various forms or for improving the information system, and the estimated timeline.
  3. **Planning for the monitoring and evaluation of the new vaccine introduction**
     + Monitoring the vaccine introduction and programme performance (e.g. plans for monitoring short-, intermediate-, and long-term targets and objectives); also for monitoring the new vaccine coverage13;
     + Planning and implementing pre- and post-introduction evaluations using available tools, (e.g. Annex 4 to this document – “New Vaccine Introduction Checklist”, and WHO’s “New Vaccine Post-Introduction Evaluation (PIE) Tool”);
     + Updating or enhancing surveillance and reporting of adverse events following immunization (AEFI; e.g. current national AEFI monitoring policy and practices and planned improvements)14;
     + Supportive supervision and pre- and post-introduction monitoring, including plans for supervision activities before, during and after the introduction of the new vaccine (e.g. pre-introduction visits to assess readiness for introduction; immediate post-introduction monitoring visits; post-introduction evaluation or EPI review)15;
     + Measuring the impact of the new vaccine (e.g. description of any current disease surveillance plans for monitoring vaccine impact and timeframe)16.
  4. **Training of health workers (or other professionals involved in vaccination)17**
     + Types and numbers of personnel who provide or assist with vaccination and need to be trained, results of any recent assessments of health worker skills and knowledge;

11 See Section 3.6.

12 See Sections 3.9 and 4.1.

13 See Sections 3.1 and 4.1.

14 See Section 4.3.

15 See Sections 3.7.2 and 4.4.

16 See Section 4.2.

* + - Training plan with strategy (e.g. cascade training), numbers and types of people to be trained at national and district levels, duration and content of training at each level, materials to be developed, monitoring and evaluation of training, and timeline;
    - Updating or creation of training modules to be used to train the trainers and health workers. A reference to assist training is here: [Rabies & One Health: From basics to cross-sectoral action to stop (openwho.org)](https://openwho.org/courses/NTDs-Rabies-and-one-health).
  1. **Planning and conducting social mobilization, communications and advocacy activities18**
     + Considerations for handling and obtaining informed consent for vaccination, if required;
     + Description of any community assessments of Knowledge, Attitude, Practice and Behaviour (KAPB), focus group discussions or formative research for the disease or vaccine that have or will take place and how the findings will inform the messages and strategies for information, education, communication, and training;
     + Advocacy plans to sensitize opinion leaders and the media at national, regional and district levels regarding the introduction and benefits of the new vaccine, and to obtain their active support;
     + Development of a communication strategy and a crisis communication plan;
     + Securing high coverage of PEP, leaving no patient behind. Planning of securing universal **availability** and **accessibility** also in remote locations. Securing that vaccine is free of charge to the patient, hence completely **affordable**. Adapting PEP provision to be **adequate** and **acceptable** to communities in their respective socio-cultural contexts. PEP provision should be as much targeted as possible to reach high risk populations. **Providers** should **comply** with technical and social aspects of PEP provision to foster **patient adherence.** (Reference Obrist B, Iteba N, Lengeler C, Makemba A, Mshana C, et al. Access to healthcare in contexts of livelihood insecurity: a framework for analysis and action. PLoS Med. 2007;4: 1584–1588).

# Suggested annexes:

1. New Vaccine Introduction Checklist and New Vaccine Introduction Activity List and Timeline (see Annex 4)
2. Budget (see example of following budget and resource table)

**Sample budget and resource table for vaccine introduction activities**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **Nongovernment support** | | **Total support secured** | **Shortfall in support** | **Comment** |
| **Activity** | **Total Cost** | **Government Support** | **Name** | **Amount** |  |  |  |
| Programme management and coordination |  |  |  |  |  |  |  |
| Planning and preparation |  |  |  |  |  |  |  |
| Social mobilization, IEC and advocacy |  |  |  |  |  |  |  |
| Training and meetings |  |  |  |  |  |  |  |
| Materials production and data management |  |  |  |  |  |  |  |
| Human resources and incentives |  |  |  |  |  |  |  |
| Cold chain equipment |  |  |  |  |  |  |  |
| Transport for implementation and supervision |  |  |  |  |  |  |  |
| Immunization session supplies |  |  |  |  |  |  |  |
| Waste management |  |  |  |  |  |  |  |
| Surveillance and monitoring |  |  |  |  |  |  |  |
| Post-introduction evaluation |  |  |  |  |  |  |  |
| Technical assistance |  |  |  |  |  |  |  |
| Other (specify) |  |  |  |  |  |  |  |
| Total |  |  |  |  |  |  |  |