REACHING “ZERO BY 30”:
THE GLOBAL STRATEGIC PLAN

Unleashing the Power of Rabies Vaccines
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Rabies is a lethal zoonotic disease

Every 15 minutes one death

40% of deaths in children

80% of deaths in rural areas

99% from dog bites
It burdens vulnerable populations

- 54% Productivity losses due to premature death
- 0.01% Rabies surveillance (data)
- 2% Dog vaccination & population control
- 6% Livestock losses
- 15% Lost income seeking treatment
- 20% Direct costs
- 2% Travel costs

8.6 billion US$ per year

Source: World Health Organization
Endemicity of dog transmitted rabies
Rabies is preventable

Needs safe, efficacious and optimally priced biologicals

Awareness

Timely care

Dog vaccination
# New WHO position on rabies immunization: Safety - programmatic savings - feasibility

<table>
<thead>
<tr>
<th>Topic</th>
<th>2010</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEP regimen duration</td>
<td>3-4 weeks 4-5 visits</td>
<td>1-2 weeks 3-4 visits</td>
</tr>
<tr>
<td>Vaccine savings PEP</td>
<td>ID: 0.8 ml IM: 5 ml</td>
<td>ID: -20% (0.6 ml) IM: -20% (4 ml)</td>
</tr>
<tr>
<td>RIG infiltration</td>
<td>Wound + distant IM</td>
<td>Wound only -40% RIG vials -80% RIG volume/person</td>
</tr>
<tr>
<td>RIG allocation</td>
<td>All category III exposures</td>
<td>When scarce: High risk cat. III exposures</td>
</tr>
</tbody>
</table>
Updated Report

Some highlights include:

- Practical approaches to improve surveillance in animals and humans
- Updates on laboratory techniques
- Guidelines for palliative care of rabies patients
- Safe and feasible human and animal immunization policies
- Potential of new rabies biologics to improve delivery to (rural) communities
- Role of oral vaccination in dog campaigns
- Processes for countries to validate 0 human rabies deaths, verify breaking of dog-mediated rabies transmission and rabies freedom
- Research agenda

http://www.who.int/rabies/resources/who_trs_1012/en/
A mission driven coalition to eliminate dog-mediated human rabies by 2030 “Zero by 30”
Puts countries at the centre

**ZERO by 30**

By maximising resources and impact, countries move towards their SDG targets which collectively contributes to improved global outcomes.

- Bring private & public development partners together
- Avoid duplication of effort

**PARTNERS**

maximizing resources & impact

**UNIFIED AGAINST RABIES**

coordinating, catalytic & country-centric

Supporting efforts through:
- Rabies awareness & prevention
- Establishing global norms & standards
- Coordinating global elimination effort
- Monitoring progress and results

**COUNTRIES**

leading elimination efforts

- Increases preparedness and surveillance
- Mobilises domestic resources
- Promotes one-health approach through cross-ministry collaboration

- Country initiatives are the foundation of the global strategy to reach “Zero by 30”
- Countries taking control enables ownership and accountability
Theory of change to reach ‘Zero by 30’
Rabies Biologic Manufacturer’s Survey

Objectives

Survey

Map global rabies biologic market

Inform global strategy to end human rabies deaths

42 companies contacted

Data collected anonymously

Production capabilities

Product characteristics

Can market support country demand?

Inform stockpile & bank development?
Summary statistics of respondents

- 54.8% response rate (23 of 42 manufacturers)
- Human vaccines n=13
- RIG and mAbs, n=7
- Animal vaccines, n=10
Rabies Biologic Manufacturer’s Survey

Global manufacturing locations & capacity

Regional manufacturing

<table>
<thead>
<tr>
<th>Region</th>
<th>No. manufacturing sites per region</th>
</tr>
</thead>
<tbody>
<tr>
<td>WPRO</td>
<td></td>
</tr>
<tr>
<td>EMRO</td>
<td></td>
</tr>
<tr>
<td>EURO</td>
<td></td>
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<tr>
<td>SEARO</td>
<td></td>
</tr>
<tr>
<td>AMRO</td>
<td></td>
</tr>
<tr>
<td>AFRO</td>
<td></td>
</tr>
</tbody>
</table>

Total manufacturing capacity

- China and Indian manufacturers are likely highly represented in SEARO
- The production of RIG doses was lower than vaccines; reflects lower demand compared to vaccines.
- For 2017, one manufacturer indicated a production capacity 2 million vials of mAbs
Rabies Biologic Manufacturer’s Survey

Characteristics of market

- Market expansion
  - RIG & mAbs: 85.7% (n=6)
  - Human vaccines: 61.5% (n=8)
  - Animal vaccines: 90% (n=9)

- Storage capabilities
  - Volume (10^x):
    - n=6
    - n=9

- Manufacturing lead times
  - Days:
    - n=6
    - n=10
    - n=9

* Percentage of total respondents who could expand production

- Many manufacturers could expand production
- Many could store biologics; important consideration for rabies biologic banks
- Vaccine and RIG lead times ranged were 0-420 days, and 30-420 days, respectively
## Biological characteristics / formulation of vaccines & immunoglobulins

<table>
<thead>
<tr>
<th></th>
<th>human vaccines</th>
<th>RIG &amp; mAbs</th>
<th>animal vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Biological source</strong></td>
<td>Cell derived, n=13</td>
<td>Cell line, n=2 eRIG, n=2 hRIG=3</td>
<td>Cell derived, n=9</td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td>Lyophilized 92% 0.67 ± 0.07</td>
<td>Liquid 86% 3.13 ± 1.13</td>
<td>Liquid 100% 1.02 ± 0.09</td>
</tr>
<tr>
<td>vial size (mean ± SEM)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Storage 2-8°C (No. responses)</strong></td>
<td>13 69% 8</td>
<td>7 57% 1</td>
<td>7 29% 2</td>
</tr>
<tr>
<td>Thermotolerance (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vial monitors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Administration Route</strong></td>
<td>IM only, n=4 IM:ID, n=9</td>
<td>IM only, n=4 IM:ID, n=3</td>
<td>IM and/or SC, n=8 Oral, n=1</td>
</tr>
<tr>
<td>(% of responses)</td>
<td></td>
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</tbody>
</table>

3 vaccines were WHO pre-qualified
Conclusions: Rabies biologics for human PEP

Annual post-bite vaccination rate is 15 million people\(^1\)

Only 2% of patients who need it, receive RIG\(^2\)

Ensuring access to Rabies biologics saves lives

In 2017, 22.5 million complete PEP vaccination courses produced (assuming 4 visits, 0.5 or 1ml dose, IM regimen)

+ possible market expansion of \(~14.6\) million PEP courses (assuming 65% market expansion within 5 years)

Total RIG capacity < than vaccines

3 WHO-Prequalified vaccines


\(^2\)WHO. Background paper: Proposed revision of the policy on rabies vaccines and rabies immunoglobulins. 2017; Available from: [http://www.who.int/immunization/sage/meetings/2017/october/1_Background_paper_WG_RABIES_final.pdf](http://www.who.int/immunization/sage/meetings/2017/october/1_Background_paper_WG_RABIES_final.pdf)
Conclusions: Animal vaccines for dog vaccination

70% dog vaccination coverage to breaks transmission
≈ 375 million dogs

In endemic regions ~ 20% of dogs are vaccinated

In 2015, only 150 million doses were used.

Mass dog vaccination reduces human rabies risk

181 million doses produced in 2017

up to 304 million dogs could be vaccinated
(using 2017 survey data + 68% market expansion)

Rabies Biologic Manufacturer’s Survey

**Countries**
- Develop National plans in line with global strategy & WHO guidelines
- Forecast & finance supply chain needs to improve access

**Manufacturers**
- mAbs will improve immuno-globulin supply long term
- Encouraged to seek WHO-PQ for purchase by procurement agencies
- Should adopt new WHO guidelines

**Global Partners**
- Rabies stockpiles & banks can shape market
- Procedures for the registration of high quality rabies mAbs & RIG needed

Lack of demand limiting market

Manufacturers can likely meet future supply needs for rabies elimination programmes

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Thank you!

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http://www.who.int/rabies/en/