INTRODUCTION OF ROTAVIRUS VACCINE (RVV) IN INDIA

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Deputy Commissioner (Immunization)
Ministry of Health and Family Welfare
Government of India
Rotavirus Burden in India

Preparation for RVV introduction at National Level

Trainings

State and District preparedness for RVV introduction

Achievements, Challenges and Future Plans
Rotavirus Diarrhea
Burden of rotavirus in India

Episodes:
11,373,098 (9,745,967 – 13,194,028)  
1 in every 2  (2 – 3) children*

Outpatient visits:
78,583  (76,019 – 81,206)  
1 in every 345  (334 – 356) children*

Hospitalizations:
872,315  (596,662 – 1,231,452)  
1 in every 31  (22 – 45) children*

Deaths:
3,271,187  (2,237,486 – 4,617,948)  
1 in every 8  (6 – 12) children*

* Estimates based on 2011 birth cohort of 27,098,000 children (UNICEF India Statistics)
Preparation for RVV introduction
Vaccine introduction in India

- Multi-level consultative process with key stakeholders

- A comprehensive review of
  - existing evidences,
  - programmatic challenges
  - and system preparedness

- Informed decision making
RVV introduction in India
The Decision Making

NTAGI
Recommended RVV introduction in Universal Immunization Program (UIP)
Introduction in phased manner

MSG
Highest policy making & steering institution under National Health Mission
Approved NTAGI’s recommendation

EXPERT GROUP
Identified four states for RVV initial introduction.
State selection

Criteria for 4 State selection for RVV introduction

- Diarrheal disease burden
- AEFI preparedness
- Routine immunization coverages and system preparedness
- State willingness to introduce RVV

~9 % of the total birth cohort of 27 million
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<table>
<thead>
<tr>
<th>S.No</th>
<th>States</th>
<th>No. of Districts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Andhra Pradesh</td>
<td>13</td>
</tr>
<tr>
<td>2</td>
<td>Odisha</td>
<td>30</td>
</tr>
<tr>
<td>3</td>
<td>Himachal Pradesh</td>
<td>11*</td>
</tr>
<tr>
<td>4</td>
<td>Haryana</td>
<td>21</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>75</strong></td>
</tr>
</tbody>
</table>

* Kangra district not included
Intimation for RVV introduction in 4 states

- Letter issued on 1st Dec. 2015 informing 4 states about national introduction of RVV.

- Followed by a letter on 11th Dec. 15 on training plans and partners support.

Dear [Name],

As you are well aware that diarrhoea is one of the leading causes of post-natal child death in India and rotavirus is a causative agent in nearly 30-40% of all cases. Vaccination against rotavirus if one of the most effective means available to reduce morbidity and mortality related to Rotavirus. Based on recommendation of National Technical Advisory Group on Immunization (NTAGI) and approval by the Mission Steering Group (MSG), Rotavirus vaccine will be introduced under Universal Immunization Programme (UIP) of India in a phased manner.

In this regard, your state has been selected for initial introduction. Govt. of India has initiated the process of vaccine procurement and it is anticipated that vaccines may be available to your state for introduction of Rotavirus vaccine in 1st quarter of 2016. Rotavirus vaccine is an oral vaccine and will be provided to children under routine immunization at 6th, 10th and 14th week in a 3 dose schedule along with Pentavalent vaccine and DTP.

You are requested to initiate the preparatory activities like training and capacity building, demand generation, updation of recording and reporting formats etc. for successful launch and integration of Rotavirus under UIP. Ministry of Health & Family Welfare will provide support to state Governments in ensuring that all preparatory activities are completed in time for a seamless and timely introduction.

Looking forward for your support,

Yours Sincerely,

[Signature]

(Dr. Rakesh Kumar)
Cascade model for RVV trainings

- National Level Program officers and partners
  - National TOT
    - State TOT
      - District Level Trainings
        - Block Level Trainings
      - District Level Trainings
        - Block Level Trainings
- State officials, DIOs, DIEC Officers, partners
- Block Medical Officers
- Health workers and Mobilisers
Training material for RVV introduction

- Training Material developed for all levels (i.e. program managers to mobilisers) to ensure uniformity
  - Operational Guidelines
  - FAQs for Medical officers
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Training material for RVV introduction

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  - Operational Guidelines
  - FAQs for Medical officers
  - FAQs for health workers (in regional languages i.e. Hindi, Odiya and Telugu)
  - Single pager pamphlets for mobilisers (in regional languages i.e. Hindi, Odiya and Telugu)
Capacity Building
National Trainers

- National Master Trainer’s workshop was conducted on 29th Dec. 2015 led by Immunization division of MoHFW.

- Attended by national representatives of key immunization partners like WHO, UNICEF, JSI, BMGF, ITSU, GHS, PATH etc.

Workshop ensured
- Standardization of
  - Training material
  - Power point slides and messages
  - Agenda for State TOTs
State Level ToT

- All four states conducted State level Training of Trainers (ToT) simultaneously between 4th to 6th January 2016

- More than 400 personals were trained as state master trainers.

- The District Immunization Officer, two Block Medical officers and District IEC officer attended workshop.
District and block level trainings

By 15th March 2016, 2849 Medical officers, 4223 Cold chain Handlers, 26544 ANMs, 90525 ASHAs, 112768 Anganwadi workers (AWW) were trained for RVV introduction
State, District and Block preparedness for RVV introduction
Regional AEFI workshops were conducted in Ahmedabad, Gujarat to ensure that the four states were trained on revised AEFI guidelines.

Similarly the state AEFI workshops for Himachal Pradesh and Odisha were preponed and completed in December 2015. This allowed states to prepare for the new vaccine introduction and update their state and district AEFI committees as well as conduct trainings at various levels in accordance to the revised AEFI guidelines, well before the schedule launch of RVV.
State and district level preparedness checklist

- A preparedness assessment checklist was developed to assess the district-wise status.

- All districts submitted their filled checklist to States and States to Ministry.

- Checklists were analyzed by SEPIOs with support from partners to identify gaps and level of preparedness through state and district level scoring system.

- Key gaps identified and action initiated to plug these at states and districts levels.
Mother and Child Protection Card

- MCP card updated to include Rotavirus vaccine column and made available to most of the districts before introduction.

- Simultaneously districts were advised to use existing MCP card in case new MCP card not received before introduction.
Immunization Records and Registers

All Immunization records and registers like, RCH registers, due list cum tally sheets, vaccine stock registers updated to include RVV
Cold Chain Assessment

- Electronic data base (NCCMIS data) of cold chain equipment reviewed for 3300 cold chain points (CCP) and points requiring strengthening were identified.

- Identified sites were assessed by field investigation to quantify shortage.

- Subsequently, CCP were strengthened before RVV introduction by
  - Repair of non-functional equipment
  - Re-location of cold chain equipment
  - Allocation of new cold chain equipment
  - Creating additional CCP as satellite points for vaccine storage in case of long distribution time in field
## Cold Chain Assessment

<table>
<thead>
<tr>
<th>States</th>
<th>DVS assessed</th>
<th>DVS reported shortage</th>
<th>Shortage in CCE in Feb 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andhra Pradesh</td>
<td>13</td>
<td>3</td>
<td>126</td>
</tr>
<tr>
<td>Odisha</td>
<td>30</td>
<td>2</td>
<td>167</td>
</tr>
<tr>
<td>Haryana</td>
<td>21</td>
<td>3</td>
<td>74</td>
</tr>
<tr>
<td>Himachal Pradesh</td>
<td>11*</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>75</td>
<td>10</td>
<td>382</td>
</tr>
</tbody>
</table>

* Kangra district not included

None of the State/Regional/District Vaccine stores and cold chain points have reported shortage of Cold chain space since RVV introduction.
Procurement of Rota Virus Vaccine

- Base on specifications for Rota Virus Vaccines approved by expert committee under Director General of Health Services (DGHS), the procurement division of the Ministry floated a tender for procurement of available licensed Rota Virus Vaccines.

- For the current phase of the program, the 116E Rota Virus Vaccine, manufactured by Bharat Biotech was selected based on availability and affordability.
Vaccine product challenge

- Concerns raised on the number of times the vaccine can withstand freeze thaw cycle without loosing potency and Manufacturer demonstrated 9 such cycle.
- RVV storage and transportation at various levels follows the same principles of storage temperature as that of oral polio vaccine which is based on above observation.
- The VVM2 is used in RVV same as OPV. Since there no open vial policy for RVV, hence position of VVM is on cap.
- RVV vaccine to be used within expiry date or VVM reaching end point which ever is earlier.
Rotavirus vaccine: Packaging

Govt. of India is supplying Rotavac® vaccine manufactured by Bharat Biotech to be used under UIP

- Each vaccine vial contains 10 doses in liquid form
- The carton pack contains 30 vials of 10 dose vial i.e. 300 doses.
- Does not require reconstitution
- Colour of the vaccine is generally pink: it may sometimes be orange or yellow. The colour of vaccine does not impact its quality.
- All RVV vials are supplied with a VVM
- Vaccine to be stored at (-)20deg C at State, Region and district stores and (+)2 to (+)8 deg C at sub-district stores and last cold chain points
Vaccine Distribution Plans

- States received first supply of vaccines by second week of Feb’16
- More than 1,600,000 doses were supplied in the first month
- Vaccine distribution monitored to ensure that every session has at least 1 vial of RVV
COMMUNICATION

- IEC materials on Rotavirus vaccine introduction developed and pretested in field between 2nd and 3rd weeks of January 16

- States and districts developed communication plan and printed communication material before vaccine launch
Media Workshops conducted before launch to ensure positive media advocacy and enhanced coverage for RVV
India became the first Asian country to launch RVV in RI on 26th March 2016.
Extensive media coverage of the launch
AND MANY MORE
Achievements, challenges and future plans
# Immunization Schedule

<table>
<thead>
<tr>
<th>Age</th>
<th>Schedule (after introduction of Rotavirus vaccine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>At birth</td>
<td>BCG, OPV-0, Hep B birth dose</td>
</tr>
<tr>
<td>6 weeks</td>
<td>OPV-1, <strong>RVV-1</strong>, fIPV, Pentavalent-1</td>
</tr>
<tr>
<td>10 weeks</td>
<td>OPV-2, <strong>RVV-2</strong>, Pentavalent-2</td>
</tr>
<tr>
<td>14 weeks</td>
<td>OPV-3, <strong>RVV-3</strong>, IPV or fIPV, Pentavalent-3</td>
</tr>
<tr>
<td>9 months</td>
<td>MCV-1, Vit A*, JE-1#</td>
</tr>
<tr>
<td>16-24 months</td>
<td>DPT-B1, OPV-B, MCV -2, JE-2#, Vit A*,</td>
</tr>
<tr>
<td>5-6 Years</td>
<td>DPT-B2</td>
</tr>
<tr>
<td>10 years</td>
<td>TT</td>
</tr>
<tr>
<td>16 years</td>
<td>TT</td>
</tr>
<tr>
<td>Pregnant Mother</td>
<td>TT-1 &amp; TT2</td>
</tr>
</tbody>
</table>

*Vitamin A to be given every 6 months till five years of age.
#JE vaccine given in selected endemic districts.

BCG: Bacillus Calmette-Guerin; DPT: Diphtheria-Pertussis-Tetanus; HepB: Hepatitis B; Pentavalent vaccine: DPT+HepB+ Hib (Haemophilus influenzae type b); JE: Japanese Encephalitis; MCV: Measles Containing Vaccine; OPV: Oral Polio Vaccine; TT: Tetanus Toxoid; IPV: Inactivated Poliovirus Vaccine. RVV- Rotavirus vaccine
The dose of Rotavirus vaccine currently being supplied under UIP is **5 drops given orally**.

Three doses of rotavirus vaccine is administered to all infants at 6, 10 and 14 weeks along with other vaccines in routine immunization schedule.

No booster dose of Rotavirus vaccine is recommended.

RVV has to be used within 4 hrs of opening. There is no open vial policy for RVV.
## Phase 1 of Rotavirus vaccine rollout

<table>
<thead>
<tr>
<th>State</th>
<th>Target infant population (millions)</th>
<th>Field roll out of RVV (first session)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andhra Pradesh</td>
<td>0.85</td>
<td>22nd April 2016</td>
</tr>
<tr>
<td>Haryana</td>
<td>0.55</td>
<td>13th April 2016</td>
</tr>
<tr>
<td>Himachal Pradesh</td>
<td>0.11</td>
<td>15th March 2016</td>
</tr>
<tr>
<td>Odisha</td>
<td>0.81</td>
<td>6th April 2016</td>
</tr>
</tbody>
</table>
## State wise cumulative coverage since introduction in Mar 16

All figure in thousand

<table>
<thead>
<tr>
<th>State</th>
<th>Annual target</th>
<th>Cumulative coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>RVV1</td>
</tr>
<tr>
<td>Andhra Pradesh</td>
<td>858</td>
<td>165.9</td>
</tr>
<tr>
<td>Haryana</td>
<td>549</td>
<td>112.2</td>
</tr>
<tr>
<td>Himachal Pradesh</td>
<td>114</td>
<td>24.9</td>
</tr>
<tr>
<td>Odisha</td>
<td>811</td>
<td>194.1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2,332</strong></td>
<td><strong>497.1</strong></td>
</tr>
</tbody>
</table>
State wise cumulative coverage Arp-Jul’16 (in percentage)
RVV monthly cumulative coverage in thousand doses

- Total RVV: 81, 273, 504, 997, 1494
- RVV1: 81, 204, 313, 497, 681
- RVV2: 0, 68, 155, 321, 487
- RVV3: 0, 0, 36, 181, 326
- ~ 500,000 infants have been reached to receive RV vaccine
- ~ 180,000 infants have been immunized with 3 doses of RV vaccine
- ~ 997,000 doses of RV vaccine have been given by July 16
- No or Low dropout from 1 to 2 & 2 to 3 dose
General Challenges

- Continuous supply of RVV through supply chain management as one state reported delay receipt of RVV from supplier.
- Challenge of RVV dropper mix-up with OPV dropper.
- The vaccine wastage of approximately 35-40% by third month. Expected to reduce further.
- None of the cold chain has reported shortage in storage space
- The AEFIs reported are being investigated as per new guidelines
- Challenge of partial introduction nationally.
- Subsequent impact demonstration of RVV introduction
- Program review before further expansion plan to cover more states in current year.

RVV introduction in India is an example of how new vaccine introduction can be an opportunity to strengthen the routine immunization system
Unique Challenges

- **Training Content:** The operational guidelines and training material could not be finalized till the type of RVV was finalized by procurement as all three vaccines have different requirement, doses, schedule etc.

- **Cold Chain:** The three available types of RVV had different temperature requirement and therefore storage modality and space requirement could not be finalized
  - Training content will all three types of vaccine and cold chain capacity assessment with different combination was performed in advance and then tailor made for the chosen product

- **Interchangeability of Vaccine:** All three type of RVV are available in private sector and there is no data on interchangeability for a child receiving one dose of one type from private sector and then coming to public sector for next dose

- **Partial introduction:** As the introduction was limited to four states, the problem of handling children coming from neighboring states in border districts

- **Expiated Introduction:** RVV introduction is of the fastest introduction of a new vaccine under UIP. Synchronizing all steps of preparation, capacity building, procurement and monitoring etc.
India successfully introduced Rotavirus vaccine under its immunization programme.

Three major reasons for success of RVV introduction are:
- efficient planning,
- synchronized implementation and
- continuous monitoring.

RVV introduction is also an exemplary example of government leadership and unified partners support towards a common goal.
Thank You