Rolling Out a Vaccine in India

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Roadmap of vaccine Introduction in India

1978 EPI ⇨ 1985 UIP

1985
Vaccines against VPDs- Measles, DPT, TB, Polio

6 VPDs

2002
Hep. B pilot

2006
JE vaccine introduced

2010
Measles 2nd dose (2010-13)
Hep. B scaled up nationwide

2011
Pentavalent (2011-2015)

2013
JE 2nd dose
Open Vial Policy

2015
IPV introduction (2015-16)

IPV 3rd dose in Jan 2023

2016
Rotavirus vaccine
Switch from tOPV to bOPV

2017
MR
PCV
JE Adult

2018
Td replacing TT

2019
Rotavirus scale up Nationwide

2021
PCV scale up Nationwide

12 VPDs

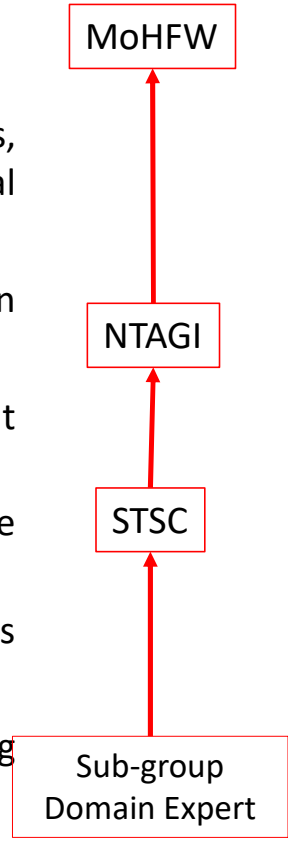
Vaccine introductions – in National Programme

- **New Vaccine introductions**
  - PCV (**P**neumococcal **C**onjugate **V**accine)
  - Rota virus vaccine
  - IPV (**I**nactivated **P**olio **V**accine)
  - Pentavalent vaccine (**D**iphtheria **P**ertussis **T**etanus + **Hep**atitis **B** + **H**emophilus **I**nfluenza type **b**)
- **Switch from one vaccine type to another**
  - tOPV to bOPV (**t**rivalent/**b**ivalent **O**ral **P**olio **V**accine)
  - DPT & HepB to Penta (DPT + HepB + Hib) for primary schedule
  - Measles to Measles & Rubella
  - **T**etanus **T**oxoid (TT) to **T**etanus **T**oxoid with adult Diphtheria dose (Td)
- **Change vaccination schedule**
  - Measles & JE (Japanese Encephalitis) from Single to two dose schedule
  - Fractional dose IPV from two to three dose schedule
- **Vaccine product interchangeability** – Different Rota, JE, PCV, MR products

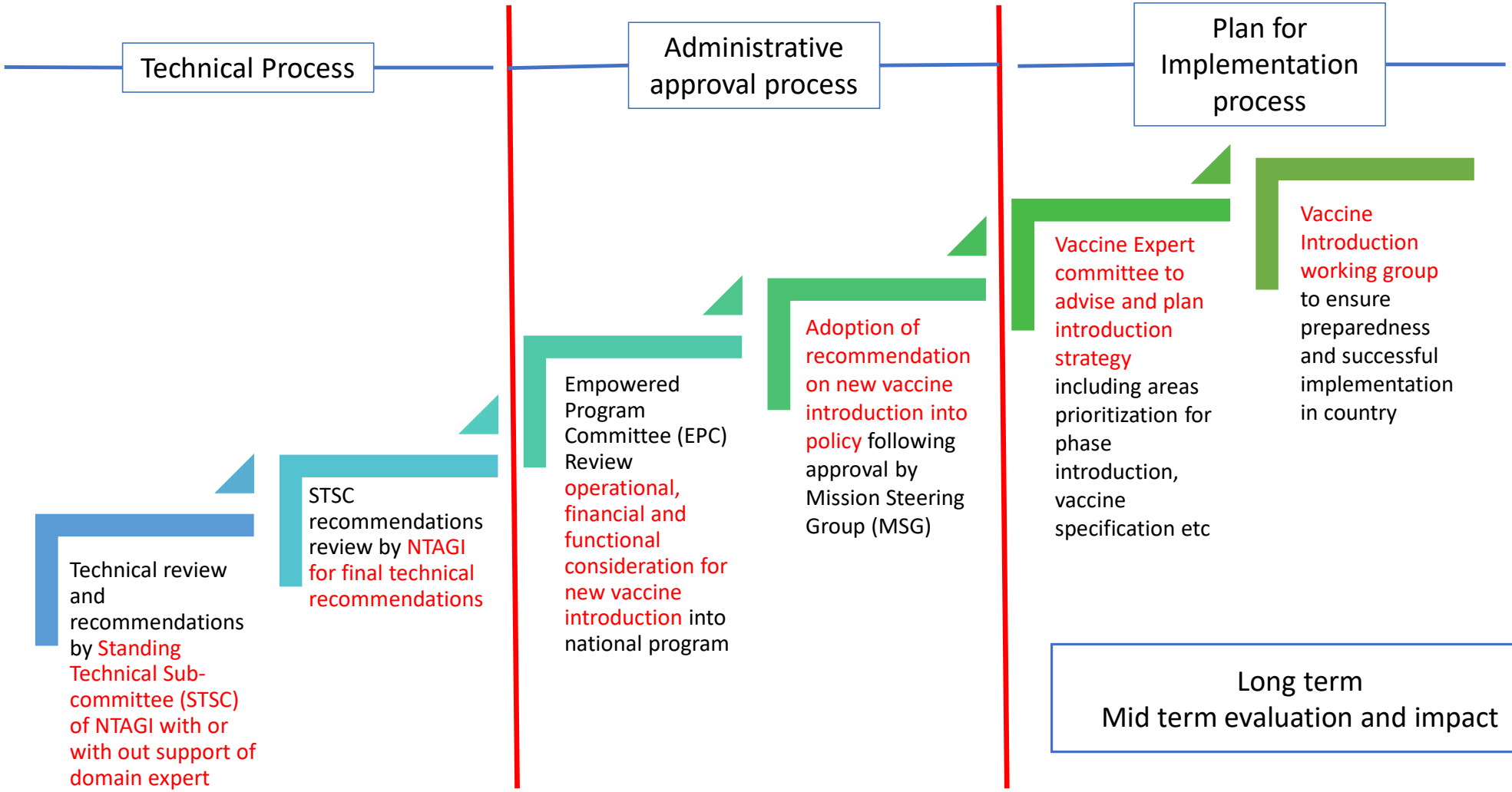
NTAGI – Key features

National Technical Advisory Group on Immunization (NTAGI) constituted in 2002 and amended thereafter from time to time.

- An apex advisory body to the MoHFW that makes technical recommendations related to immunization, including introduction and expansion of new and underutilized vaccines.
- Group of experts from vaccination and immunization related fields in India
  - ✓ from areas of Public health, Pediatrics, Epidemiology, Infectious Disease (ID), Clinicians, Immunologists, Medical Microbiologists, Cold chain experts/ logisticians, Statistic modelers, Social scientists, and Drug regulators
  - ✓ also includes experts in ethics, health economics, nursing/pharmacy (from field), immunization program managers, and representatives of the civil society etc.
  - ✓ ex-officio members from the Ministry of Health and Family Welfare, state government representatives.
- National papers and International guidelines from World Health Organization, WHO-SAGE etc. are assessed as per the country specific 'situational analysis' to introduce a new vaccine.
- The NTAGI is supported by STSC which is further supported by subgroups for specific areas such as vaccine security, vaccine ethics, equity, economic benefit, and improvements in health system etc.
- It is mandatory for the members to declare conflicts of interest to ensure unbiased decision making process



New Vaccine Introduction process in India



Criteria considered for selection for New Vaccine Introduction

NTAGI Tech Body

- Disease burden (incidence/prevalence, absolute number of morbidity/mortality, epidemic/pandemic potential);
- Safety and efficacy of the vaccine under consideration;
- Cost effectiveness of the vaccination program and also of the alternatives other than vaccination
- Vaccination schedule, interchangeability

EPC/MSG Admn Body

- Availability of a domestic or external vaccine production capacity;
- Affordability and financial sustainability of the vaccination program, even if the initial introduction is supported by the external funding agency;
- Program capacity to introduce a new antigen, including cold chain capacity;

Other operational aspects & preparations of Technical Specifications

- Once the inclusion is approved by EPC and MSG, a technical expert committee is constituted to guide on the operational aspects such as phasing, route and dose of vaccine, delivery strategies, states readiness etc.

- Technical Specifications committee is established to formulate technical specifications of the proposed new vaccine that is to be introduced. Key members include: officials from DGHS, ICMR, Immunization Division, public health experts, immunization partners, DCGI etc.

- Technical specifications of the vaccine to initiate the procurement process.

- Once the vaccine specifications are finalized then procurement process is initiated by raising indent which is based on phasing plan of introduction.

- The decision for NVI is then communicated to selected states as per phase plan introduction, operational guidelines and IEC are developed, trainings are planned and vaccine supplies are ensured.

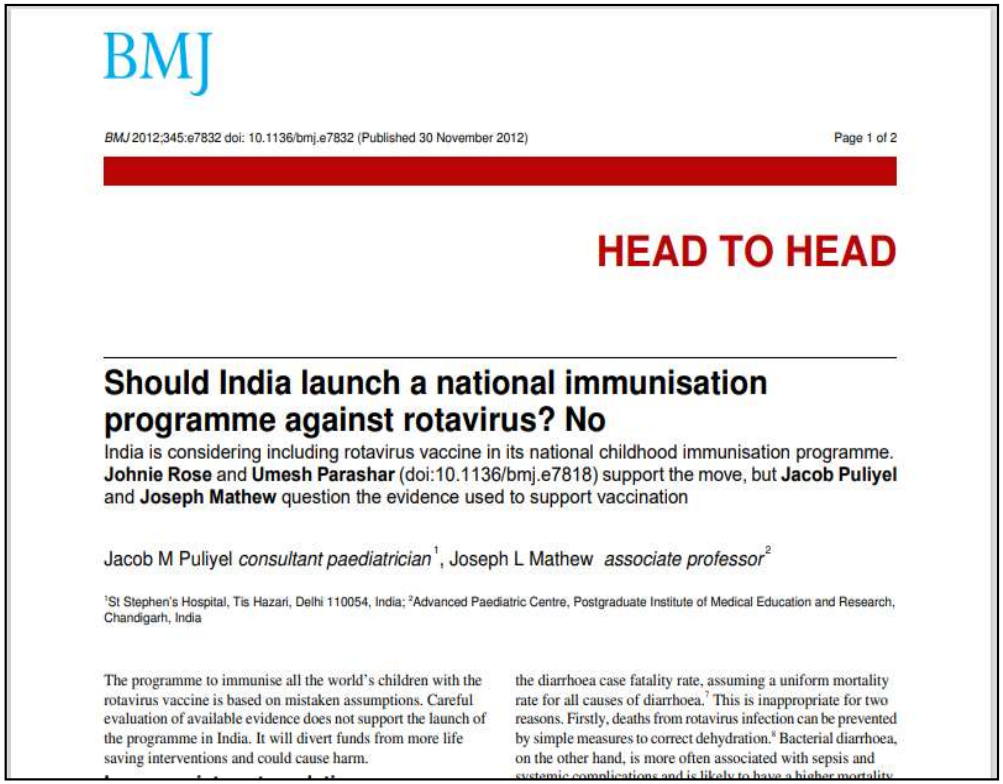
Various Strategies for New Vaccine introduction

1. **Campaign** followed by routine. Require large volume of vaccines, HR mobilization at other program cost therefore not preferred choice until there are technical or Public Health Reasons, Example MR, JE

2. **Routine introduction** with cutoff date on introduction strategies. Example Rota, PCV, IPV which is tag to existing vaccine already under programme like Penta 1st dose as eligible criteria for introduction to avoid campaign of 1 year old existing cohort.

3. **Clear plan for replacement** of existing vaccine with new vaccine
   - tOPV to bOPV (tOPV campaign till last dose utilized followed by switch)
   - Measles to MR (exhausting measles dose before switch to MR)
   - TT to Td (exhausting TT dose before switch to Td)

Challenges prior to RVV introduction



BMJ

BMJ 2012;345:e7832 doi: 10.1136/bmj.e7832 (Published 30 November 2012)

HEAD TO HEAD

Should India launch a national immunisation programme against rotavirus? No

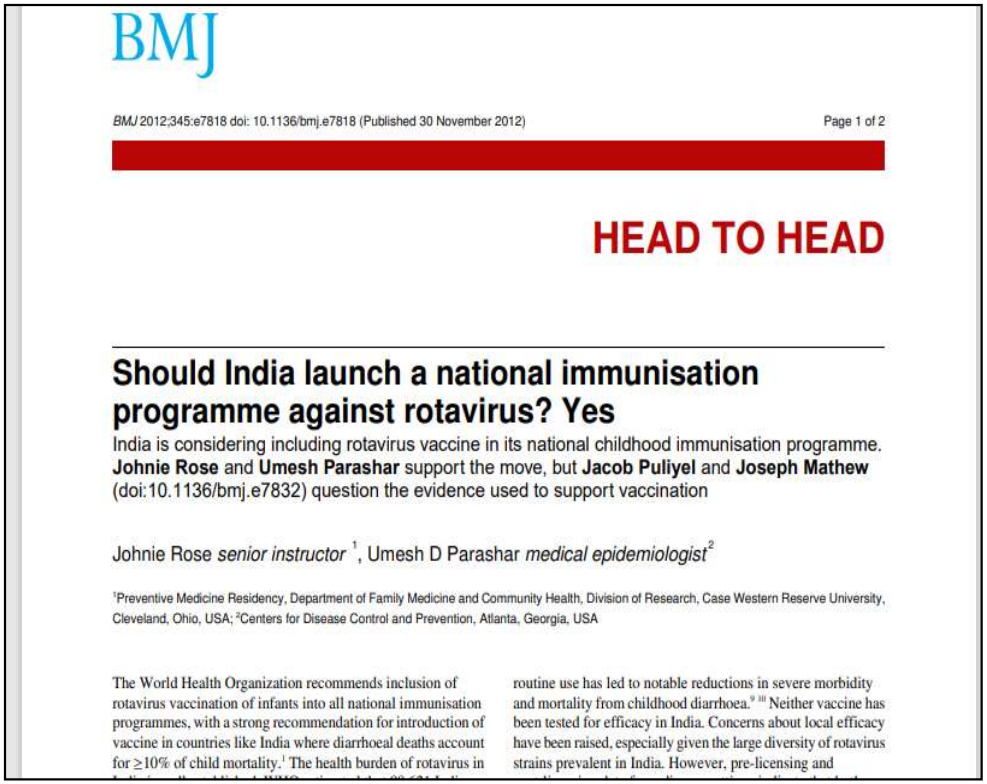
India is considering including rotavirus vaccine in its national childhood immunisation programme. **Johnie Rose** and **Umesh Parashar** (doi:10.1136/bmj.e7818) support the move, but **Jacob Puliyel** and **Joseph Mathew** question the evidence used to support vaccination

Jacob M Puliyel *consultant paediatrician*[1], Joseph L Mathew *associate professor*[2]

[1]St Stephen's Hospital, Tis Hazari, Delhi 110054, India; [2]Advanced Paediatric Centre, Postgraduate Institute of Medical Education and Research, Chandigarh, India

The programme to immunise all the world's children with the rotavirus vaccine is based on mistaken assumptions. Careful evaluation of available evidence does not support the launch of the programme in India. It will divert funds from more life saving interventions and could cause harm.

the diarrhoea case fatality rate, assuming a uniform mortality rate for all causes of diarrhoea.[7] This is inappropriate for two reasons. Firstly, deaths from rotavirus infection can be prevented by simple measures to correct dehydration.[8] Bacterial diarrhoea, on the other hand, is more often associated with sepsis and



BMJ

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Should India launch a national immunisation programme against rotavirus? Yes

India is considering including rotavirus vaccine in its national childhood immunisation programme. **Johnie Rose** and **Umesh Parashar** support the move, but **Jacob Puliyel** and **Joseph Mathew** (doi:10.1136/bmj.e7832) question the evidence used to support vaccination

Johnie Rose *senior instructor*[1], Umesh D Parashar *medical epidemiologist*[2]

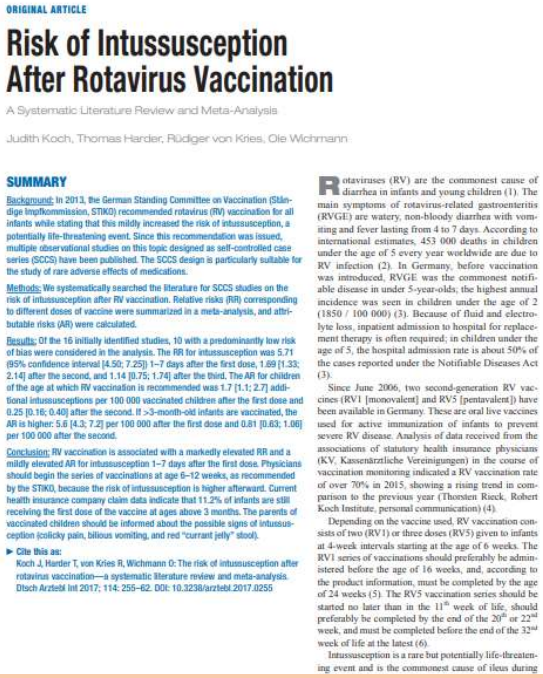
[1]Preventive Medicine Residency, Department of Family Medicine and Community Health, Division of Research, Case Western Reserve University, Cleveland, Ohio, USA; [2]Centers for Disease Control and Prevention, Atlanta, Georgia, USA

The World Health Organization recommends inclusion of rotavirus vaccination of infants into all national immunisation programmes, with a strong recommendation for introduction of vaccine in countries like India where diarrhoeal deaths account for ≥10% of child mortality.[1] The health burden of rotavirus in

routine use has led to notable reductions in severe morbidity and mortality from childhood diarrhoea.[9 10] Neither vaccine has been tested for efficacy in India. Concerns about local efficacy have been raised, especially given the large diversity of rotavirus strains prevalent in India. However, pre-licensing and

Challenges prior to RVV introduction

Known but rare adverse event



ORIGINAL ARTICLE

Risk of Intussusception After Rotavirus Vaccination

A Systematic Literature Review and Meta-Analysis

Judith Koch, Thomas Harder, Rüdiger von Kries, Ole Wichmann

SUMMARY

Background: In 2013, the German Standing Committee on Vaccination (Ständige Impfkommission, STIKO) recommended rotavirus (RV) vaccination for all infants while stating that this mildly increased the risk of intussusception, a potentially life-threatening event. Since this recommendation was issued, multiple observational studies on this topic designed as self-controlled case series (SCCS) have been published. The SCCS design is particularly suitable for the study of rare adverse effects of medications.

Methods: We systematically searched the literature for SCCS studies on the risk of intussusception after RV vaccination. Relative risks (RR) corresponding to different doses of vaccine were summarized in a meta-analysis, and attributable risks (AR) were calculated.

Results: Of the 16 initially identified studies, 10 with a predominantly low risk of bias were considered in the analysis. The RR for intussusception was 5.71 (95% confidence interval [4.50; 7.25]) 1–7 days after the first dose, 1.69 [1.33; 2.14] after the second, and 1.14 [0.75; 1.74] after the third. The AR for children of the age at which RV vaccination is recommended was 1.7 [1.1; 2.7] additional intussusceptions per 100 000 vaccinated children after the first dose and 0.25 [0.16; 0.40] after the second. If >3-month-old infants are vaccinated, the AR is higher: 5.6 [4.3; 7.2] per 100 000 after the first dose and 0.81 [0.63; 1.06] per 100 000 after the second.

Conclusion: RV vaccination is associated with a markedly elevated RR and a mildly elevated AR for intussusception 1–7 days after the first dose. Physicians should begin the series of vaccinations at age 6–12 weeks, as recommended by the STIKO, because the risk of intussusception is higher afterward. Current health insurance company claim data indicate that 11.2% of infants are still receiving the first dose of the vaccine at ages above 3 months. The parents of vaccinated children should be informed about the possible signs of intussusception (colicky pain, bilious vomiting, and red "currant jelly" stool).

► Cite this as:
Koch J, Harder T, von Kries R, Wichmann O: The risk of intussusception after rotavirus vaccination—a systematic literature review and meta-analysis. Dtsch Arztebl Int 2017; 114: 255–62. DOI: 10.3238/arztebl.2017.0255

Rotaviruses (RV) are the commonest cause of diarrhea in infants and young children (1). The main symptoms of rotavirus-related gastroenteritis (RVGE) are watery, non-bloody diarrhea with vomiting and fever lasting from 4 to 7 days. According to international estimates, 453 000 deaths in children under the age of 5 every year worldwide are due to RV infection (2). In Germany, before vaccination was introduced, RVGE was the commonest notifiable disease in under 5-year-olds; the highest annual incidence was seen in children under the age of 2 (1850 / 100 000) (3). Because of fluid and electrolyte loss, inpatient admission to hospital for replacement therapy is often required; in children under the age of 5, the hospital admission rate is about 50% of the cases reported under the Notifiable Diseases Act (3).

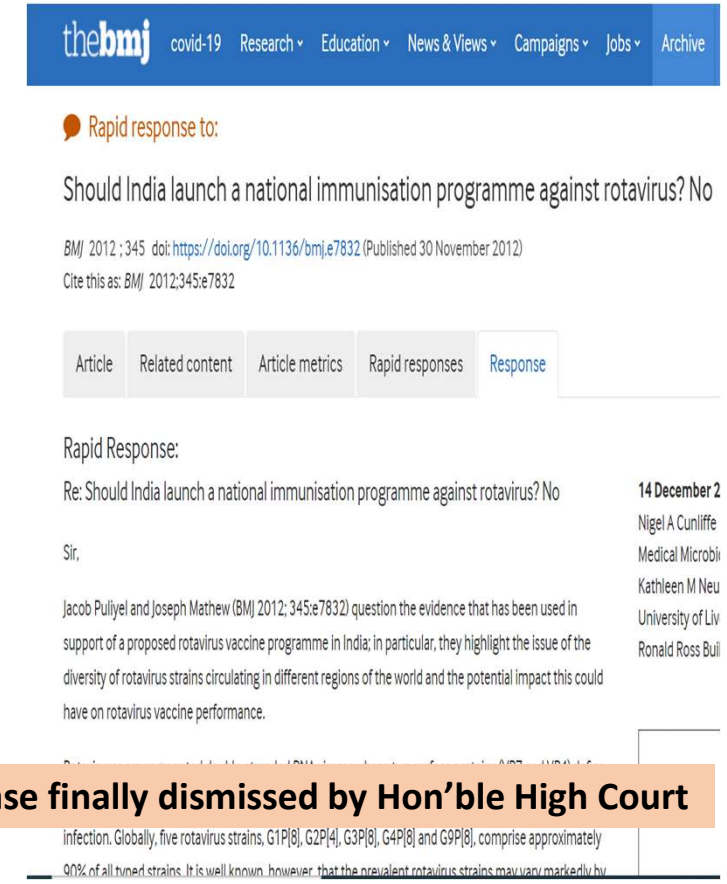
Since June 2006, two second-generation RV vaccines (RV1 [monovalent] and RV5 [pentavalent]) have been available in Germany. These are oral live vaccines used for active immunization of infants to prevent severe RV disease. Analysis of data received from the associations of statutory health insurance physicians (KV, Kassenärztliche Vereinigungen) in the course of vaccination monitoring indicated a RV vaccination rate of over 70% in 2015, showing a rising trend in comparison to the previous year (Thorsten Rieck, Robert Koch Institute, personal communication) (4).

Depending on the vaccine used, RV vaccination consists of two (RV1) or three doses (RV5) given to infants at 4-week intervals starting at the age of 6 weeks. The RV1 series of vaccinations should preferably be administered before the age of 16 weeks, and, according to the product information, must be completed by the age of 24 weeks (5). The RV5 vaccination series should be started no later than in the 11th week of life, should preferably be completed by the end of the 20th or 22nd week, and must be completed before the end of the 32nd week of life at the latest (6).

Intussusception is a rare but potentially life-threatening event and is the commonest cause of ileus during

Petitions and polls against the launch of the vaccine

A WRIT PETITION IN PUBLIC INTEREST UNDER ARTICLE 226 OF THE CONSTITUTION OF INDIA SEEKING A WRIT DIRECTING THE RESPONDENTS TO PROVIDE COMPLETE DATA OF THE RESULTS OF A MULTICENTRE CLINICAL TRIAL OF ROTAVIRUS VACCINE DONE ON INFANTS



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Rapid response to:

Should India launch a national immunisation programme against rotavirus? No

BMJ 2012 ; 345 doi: https://doi.org/10.1136/bmj.e7832 (Published 30 November 2012)
Cite this as: *BMJ* 2012;345:e7832

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Rapid Response:

Re: Should India launch a national immunisation programme against rotavirus? No

14 December 2

Nigel A Cunliffe
Medical Microbi
Kathleen M Neu
University of Liv
Ronald Ross Bull

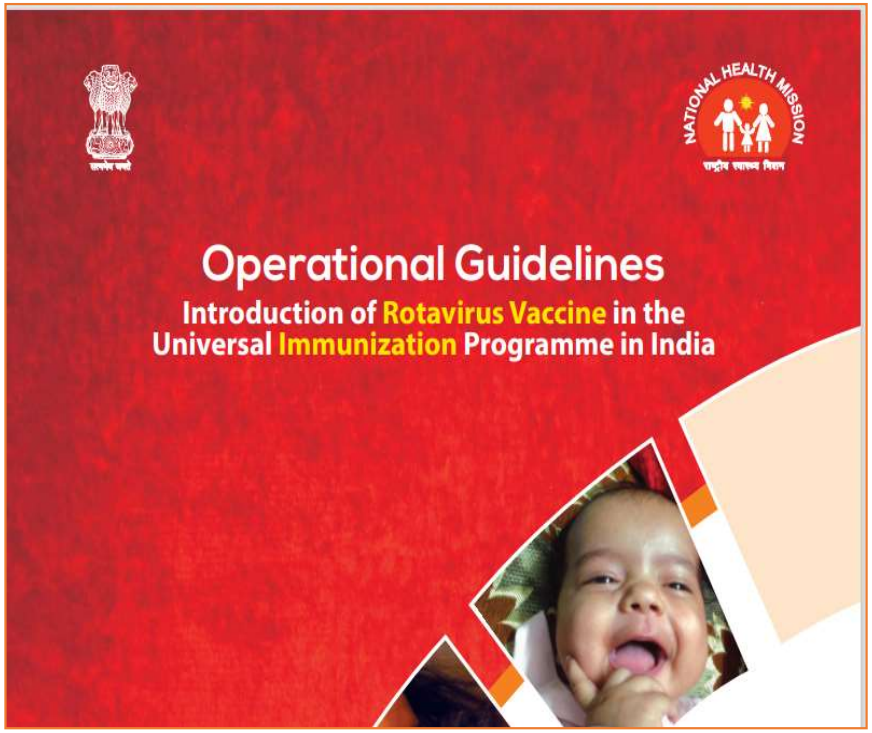
Sir,

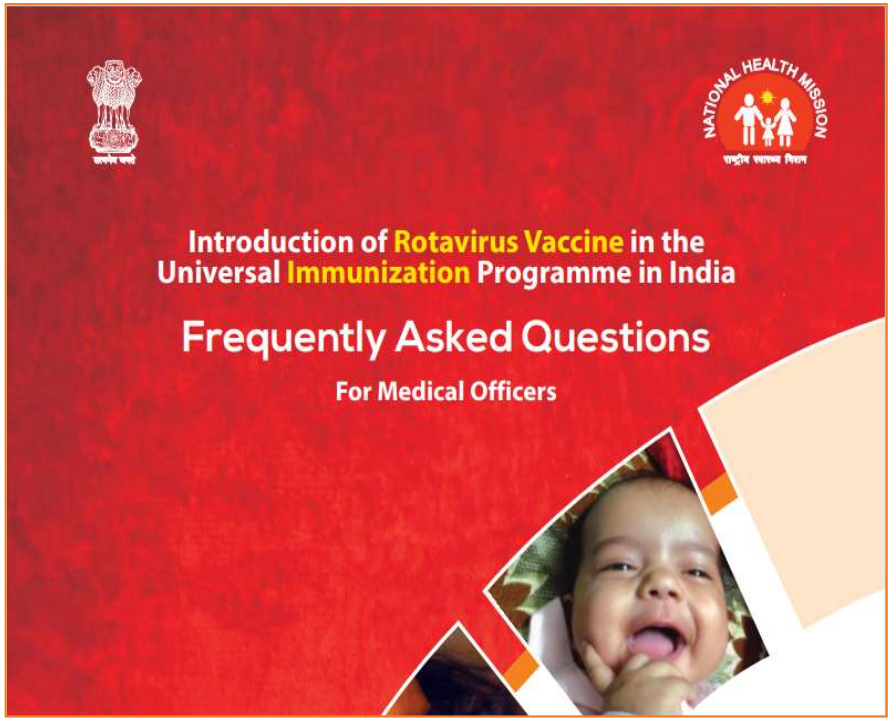
Jacob Puliyel and Joseph Mathew (BMJ 2012; 345:e7832) question the evidence that has been used in support of a proposed rotavirus vaccine programme in India; in particular, they highlight the issue of the diversity of rotavirus strains circulating in different regions of the world and the potential impact this could have on rotavirus vaccine performance.

infection. Globally, five rotavirus strains, G1P[8], G2P[4], G3P[8], G4P[8] and G9P[8], comprise approximately 90% of all typed strains. It is well known, however, that the prevalent rotavirus strains may vary markedly by

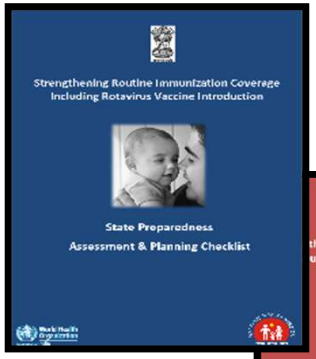
Court case to stop introduction of RVV due to increase of intussusception. The case finally dismissed by Hon'ble High Court

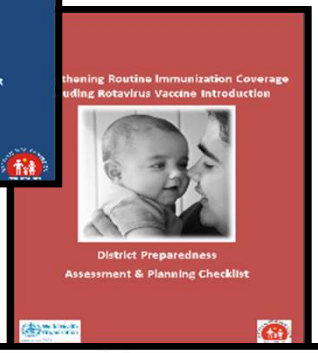
TECHNICAL DOCUMENTS/GUIDELINES DEVELOPED…..1

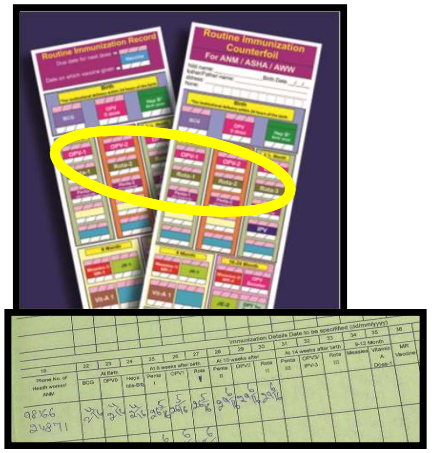


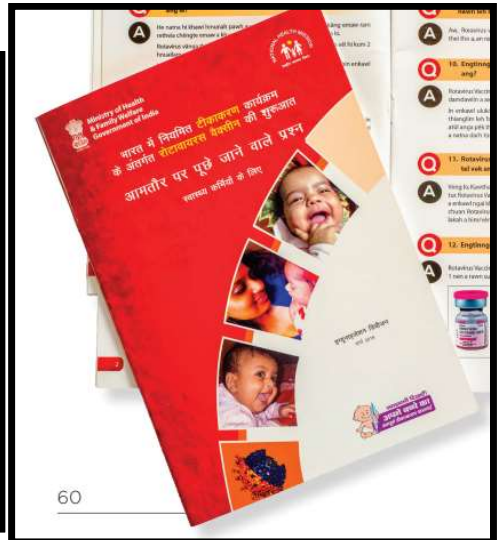


TECHNICAL DOCUMENTS/GUIDELINES DEVELOPED……2









National Immunization Schedule

Age	Vaccines given
Birth	BCG, OPV-0, Hepatitis B Birth dose
6 Weeks	OPV-1, Pentavalent-1, fIPV-1, Rota-1 & PCV-1
10 weeks	OPV-2, Pentavalent-2 & Rota-2
14 weeks	OPV-3, Pentavalent-3, fIPV-2, Rota-3 & PCV-2
9-12 months	MR1, JE-1*, PCV B-1, fIPV-3
16-24 months	MR2, JE-2*, DPT B-1, OPV B-1
5-6 years	DPT B-2
10 years	Td
16 years	Td
Pregnant Woman	**Td-1, 2 or Td Booster****

**in select states and districts*

*** one dose if previously vaccinated within 3 years*

Campaigns conducted as per the recommendations of technical expert groups:

1. **Pulse Polio rounds**
   - National and Sub- National
2. **Measles Rubella Campaign** at the time of introduction
   - Already carried out in 34 states/UTs (Delhi & West Bengal ongoing)
3. **JE campaign**
   - Campaign for children aged 1-15 years at the time of introduction
   - For adults: one time campaign in identified areas
4. **SIA to strengthen RI**
   - Mission Indradhanush

Reaching the unreached with all available vaccines

Conclusion

- **NTAGI recommended for new vaccine introduction and product interchangeability if any**
- **Introduction to be supported by scientific evidence on efficacy, safety and programme preparedness.**
- **Maternal immunization share common platform of child immunization hence any strengthening of RI also strengthen maternal immunization.**
- **Vaccination schedule should match with existing vaccination schedule ie Td vaccination and RSV can be co-administered in one session**
- **Sustainability after introduction**
- **Post Introductory Evaluation**
- **Impact of vaccine introduction.**

THANK YOU!

Do you have any questions?