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REVIEW ARTICLE

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Adoption of BOT Model to Introduce Vaccines: Tablet Approach

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Abstract

Objective: The introduction of the rotavirus vaccine (RVV) in India is one of the major achievements of the immunization program of India. Faced with various challenges, including different product specifications and competing for other program priorities, the introduction of the rotavirus vaccine in the universal immunization program was a monumental task. Considering the successful introduction of RVV, there is a need for a knowledge transfer tool that can enable policymakers and other countries to adopt it to formulate informed strategies and introduce new vaccines.

Methods: The review was conducted in two phases. In the first stage, a literature review was conducted to identify and analyze all the published literature on Build-Operate-Transfer (BOT) model and RVV introduction in India. In the second phase, an analysis of the shortlisted literature was conducted utilizing the framework method.

Results: Following the analysis, several similarities were observed between the approach to rotavirus vaccine introduction, and BOT model. Hence, based on the above analogy new public health project implementation framework, TaBLET (Technical Advice, Build capacity, Leverage partnerships, Engineer innovations, Transfer assets) approach, was proposed.

Conclusion: This article has proposed a new TaBLET approach adapted from the BOT model. The RVV introduction has shown that a project implementation framework like TaBLET can be successfully employed for efficiently utilizing existing resources, increased outreach with existing human resources, and complete transfer of tangible and intangible assets, which can be imbibed in the existing health system. This article highlights the genesis and the multifactorial benefits of the TaBLET approach in introducing new vaccines as well as in other allied health care programs.

Keywords: Rotavirus vaccine; routine immunization; Universal immunization program; Build-operate-transfer; Capacity building

Introduction

Inclusion and nationwide roll-out of the rotavirus vaccine (RVV) despite several challenges in the national immunization program is one of the major commitments and achievements of India's fight against vaccine-preventable diseases (VPDs) [1]. The new vaccine introduction in the Universal Immunization Program (UIP) is broadly categorized under three main time frames, namely, from the start of UIP till the national launch of polio eradication activities such as national immunization days (NIDs) as part of the Global Polio Eradication Initiative (GPEI) (1985-1995), from the initiation of the polio eradication activities till the certification of polio-free status (1995-2014) and, from the polio-free certification till present day (2014-2021) [2].

On March 26, 2016, India became the first nation in World Health Organization's (WHO's) Southeast Asian region to introduce RVV in its UIP through a phased roll-out. Initially, four states introduced the vaccine in phase one (2016), with five in phase two (2017), and then two additional states in phase three (2018) [3]. In the first three phases covering 11 states, an estimated 56% of the country's birth cohort was covered in around 30 months [4]. In June 2019, the Ministry of Health and Family Welfare, Government of India decided to cover the entire country under the rotavirus vaccination campaign under the "100 days" agenda. The ministry devised a large-scale plan of the activities to be completed within 100 days of the new government taking charge. Hence, in the final phase, the immunization of the remaining 44% of the birth cohort across 26 states and union territories was completed in a record time of around three months. In September 2019, India achieved a nationwide roll-out of the RVV in all its 37 states and union territories [5].

The introduction of RVV was faced with dual challenges related to product specifications and competing programme priorities. Currently, two types of RVV products are used in the UIP: a frozen liquid RVV and a lyophilized RVV. Both the products have the same administration schedule, but the dose differs-five drops for the frozen liquid RVV (administered using a dropper; frozen liquid vaccine is transported to the vaccination at a temperature of -15°C

to -25°C, and at the vaccination centre it is stored at a temperature of 2°C to 8°C, before adminsitration) and 2.5 mL for the lyophilized RVV (administered using an oral syringe; lyophilized vaccines are developed by a process in which water is removed from a product after it is frozen and placed under vacuum). Also, the introduction of RVV coincided with several other ongoing major initiatives like sustaining polio elimination status, vaccination campaigns for measles elimination, the introduction of other new vaccines in the UIP, and the Mission Indradhanush-a massive catch-up campaign. Thus, there was a need to develop a strategic plan to introduce RVV with well-defined objectives, clear and appropriate allocation of resources and deadlines to stakeholders, and catalytic support provided by leading organizations in a public-private partnership (PPP) model [6]. As we know that the Build-Operate-Transfer (BOT) model has been typically used in infrastructure projects developed through public private partnerships, with shared knowledge and resources, low risks, and complete knowledge transfer at the end of the project. New vaccine introduction like rotavirus vaccine are also largely dependent on public private partnerships. Keeping this as the basis of the analysis and comparing RVV introduction with BOT model, the authors aimed to draw an analogy between the two.

This article conducts a review of the introduction and nationwide roll-out of RVV in the UIP to serve as a knowledge transfer tool that can enable countries, policymakers to devise evidence-based strategies and introduce new vaccines. The authors have documented strategies, innovations, and practices adopted for the introduction and rapid scale-up of the rotavirus vaccine in India and examine this collective learning in the light of the BOT model to propose a new public health project implementation framework known as TaBLET approach.

Methods

In this article, the 'retrospective process analysis' method is outlined to uncover detailed insights into the operational implementation of RVV introduction and phased roll-out in the national UIP. The study used a qualitative research plan and was conducted in two phases: i) literature search, and ii) analysis.

The retrospective process analysis has been most helpful in this study and intends to transfer practical knowledge which can enable policy makers and practitioners to plan and implement their community health initiative to a large success [7]. The analysis included review of academic and other literature, supported by input from key actors [8].

Review research question

Within the existing and available literature pertinent to RVV introduction, how can the public private partnerships be leveraged to successfully introduce new vaccines?

What is the analogy between BOT model and RVV introduction, and how can the BOT model be used to build upon a new framework applicable to new vaccine introductions and other community-based health programs?

The various steps included in the analysis were:

Step 1: Identify existing literature

The authors systematically searched PubMed, Scopus, Google Scholar, and the Cochrane Library for article published between January 2014 to January 2022. Only the articles in English language were included in the search. The goal of the authors was to identify and analyse all the published literature, including retrospective research, reviews, and grey literature comprising of guidelines on new vaccine introduction and RVV, meeting notes, partner documents, administrative and monitoring data, preparedness assessment reports, programme implementation review reports, newsletter, and other published literature on RVV introduction in India. The search was also conducted to identify the relevant literature on the Build-operate-transfer (BOT) model.

Step 2: Evidence search

In this stage the literature search was conducted in three broad categories: identification of literature on RVV introduction in India, BOT model, and role of public private partnerships in new vaccine introductions. This search includes citation search of key policy guidelines, policy documents, research and surveillance reports, studies, reviews, and editorials on the subject. The following search strategy was used: (Rotavirus vaccine) AND (UIP), (Built Operate transfer Model), (New Vaccine Introduction) AND (Public private partnership).

Step 3: Document selection

Documents included from screening of titles and abstracts were considered for selection into the review. The full texts of documents initially screened were further sorted and selection for inclusion primarily based on two criteria: 1) relevance in terms of how public-private partnerships were effectively used in RVV introduction, 2) the aspects of BOT model that are relevant to and can be adapted in devising an outline for a new framework on new vaccine introduction based on the BOT model. Major contributions include documents including reports and guidelines on RVV introduction, research articles on RVV introduction, and other articles on BOT model and PPP in new vaccine introductions.

Step 4: Data extraction

Data extraction was done in two stages. Initially, the selected documents with relevant details were extracted in a table that gave an insight in the descriptive account of the RVV introduction, BOT model, and role of PPP in new vaccine introductions.

Step 5: Data synthesis

Inferences have been made on the basis of the extracted data and qualitative discussion within the program team based on a retroductive approach. Various themes emerged following the data analysis which were documented in the review. Towards the end of the detailing process, the review team revisited various sections of the review that may require reassessment. The process continued till there was no new information provided by the evidence or stakeholder involvement, essentially reaching theoretical saturation.

The analysis discovered themes that helped to construct a model for future new vaccine introduction, which can also be adapted for new interventions in non-immunization health domains.

Results

The analysis included key characteristics and innovative elements of the RVV introduction processes across the core program domains. The key focus was on the rapid expansion of the RVV footprint in 2019 following an initial staggered launch initiated in 2016. When these processes were compared vis-à -vis BOT model, it was observed that the processes involved in the introduction of rotavirus vaccine ran parallelly to the BOT model. Based on this analogy, a new approach for the introduction of new vaccines, TaBLET (Technical Advice, Build capacity, Leverage partnerships, Engineer innovations, Transfer assets) approach was proposed.

Discussion

Role of PPP in new vaccine introduction

The PPP displays a significant involvement of non-state actors from non-governmental organizations and private-sector organizations. Several global PPPs have emerged in recent years with the aim to develop drugs and vaccines against communicable diseases, provide health education, improve health services, and distribute medicines and vaccines [9].

Different technical partners have traditionally supported the new vaccine introduction in the UIP- the engagement model being different for each new vaccine introduction. In the initial days of UIP, WHO and UNICEF were the key immunization partners who supported the national and state governments in strengthening the routine immunization programme, including NVI. These agencies provided support primarily through the resources available at their country offices. However, the support was mostly sporadic.

The introduction of new vaccines was used to strengthen immunization systems by training/re-training health personnel, assessing and correcting existing cold chain problems, improving program monitoring and supervision, and enhancing reporting of adverse events following immunization (AEFI). These were supported by WHO-NPSP, UNICEF, ITSU, NCCVMRC, UNDP, GHS, JSI. In addition, the extensive network of development partners (DPs) was used for system preparedness, capacity building, monitoring the roll-out, and program review, with the lead partners coordinating the entire activity. Table 1 depicts the characteristics of partner support for various new vaccines introduced in India.

The need for innovative models in new vaccine introduction

The new vaccine introduction has a positive impact on reductions in disease burden and improvement in disease and vaccine safety surveillance, training, cold chain and logistics capacity, and safe injection practices. However, opportunities for strengthening the wider health system are often not a priority during NVIs. An important concern is a weak plan for meeting human and financial resource needs [10].

A variety of factors may contribute to lower than desirable levels of an NVI in the low- and middle-income countries (LMICs). The decision-making processes, economic and financial aspects of NVIs are critical ones and have been extensively described [11-22]. Besides these attributes, implementation, and amalgamation of new vaccines bring additional logistical complexity to the delivery of existing immunization programs in LMICs. The storage and transport facility needs to be changed based on the increased quantities and products with different temperature sensitivity profiles [23].

Given the above challenges, NVI requires technical guidance, tools, and adequate financing [10]. To avoid and bridge the gaps in planning for NVI that may compromise existing immunization and health systems, the need arises for PPP with innovative strategies to provide adequate and timely support to facilitate country planning for NVI. Such strategies can also be imbibed in the existing health systems to strengthen and prepare them for future NVIs.

Build-Operate-Transfer Model

The Build-Operate-transfer (BOT) approach is described as a project delivery method, usually for large-scale infrastructure ventures. A private unit receives a concession from the public sector to invest, plan, construct, own, and operate a facility stated in the concession contract. This enables the project promoter to salvage its investment, operating, and maintenance cost in the project. BOT is generally a model used in public-private partnerships [23].

BOT approach is primarily used as an innovative approach for direct private sector investment in large-scale infrastructure projects such as rail, port, telecommunications, toll road, highway, etc., in many developed and developing countries [24,25]. BOT is a well-established solution used in the engineering and construction industries where offshore suppliers can deliver the local and traditional information required to establish a secondary proprietorship on behalf of the client business. The BOT model allows the client business to focus on their essential capabilities. At the same time, the offshore partner provides all of the operational planning and infrastructure required to establish the offshore development center. After a designated period and the handover of the project, the company can incorporate the processes into its methods and appreciate the advantages of a skilled, qualified team ready to proceed [13,26].

BOT approach has been found to be feasible in many countries for the health sector, especially for the development of new hospitals. The model was used to meet the public regional and long-term health needs of the country [27]. An other adaptation of the BOT approach, initiate-build-operate-transfer (IBOT), has been used in developing countries to establish and develop telemedicine programs and e-health educational services. The IBOT model has enabled the assessment of healthcare needs of the country, the development of the course and training programs, the establishment of a nationwide telemedicine network, and the integration of telemedicine into the core healthcare infrastructure. In the end, the sustainable telehealth program was transferred and imbibed into the country's existing healthcare resources [28]. Our analysis has revealed that the entire process of introduction and rapid scale-up of the RVV has various similarities with the BOT approach followed for various PPP projects in different sectors.

TaBLET approach

The genesis of a new approach for partner engagement in NVI: An innovative, catalytic engagement model, with an unburdened exit plan after providing time-bound focused support, is named **TaBLET** (**T**echnical advice, **B**uild capacity, **L**everage partnerships, **E**ngineer innovations, **T**ransfer assets), based on its core pillars of support and involvement.

The TaBLET approach is adapted from the BOT model used in large PPP projects for a complex, adaptive system (CAS) of health service delivery. A PPP in the healthcare sector is an attempt to focus on public health (and social development) problems through the joint efforts of public, private, and development groups. Each partner contributes to its core strength, bringing proficiency levels that may not otherwise be accessible to development projects. The partners in a PPP work towards a common trigger while simultaneously targeting their individualized goals. By appropriately applying PPP processes, public sector organizations, including the Health or Education Ministries-may accomplish their goals at an enhanced pace and with smaller inputs of finance, resources, and human resources. Development organizations are also able to fulfill their strategic objectives and vision *via* collaborations, utilizing the new resources available to them in the public health space, and becoming familiar with a viable and sustainable design to promote public health [29].

RVV and TaBLET

The prerequisites of the system for implementing the TaBLET

Table 1: Partner engagement in new vaccine introduction in different vaccine.

Vaccine	Lead partner	Nature of partner engagement	HR Structure	Scale	Sustainability	Exit plan
BCG, DPT, OPV	WHO, UNICEF	Sporadic support from DPs, mostly at the national level	Existing HR leveraged for the technical support	Mostly support at the national level	Need based support continued	No such exit plan as there was no dedicated DP support
Measles (1st dose)						
Measles (2nd dose)	WHO-NPSP; UNICEF	Lead partner coordinated activities for system preparedness, capacity building, monitoring the roll out and program review.	Polio network of WHO and also the resources of UNICEF	Support at the national, state and sub-state level	Need based sporadic support continued	The resources of WHO and UNICEF who supported continued to work on their core mandates
Hepatitis B Vaccine	WHO-NPSP; UNICEF	Sporadic support from the two big DPs	Mostly Polio network of WHO and field staff of UNICEF. Few dedicated HR for NVI	Support mostly at the national and state level	Support continued as part of larger support for strengthening routine immunization program	
Japanese encephalitis (JE) vaccine	PATH. Supported by WHO- NPSP, UNICEF	Support in developing technical guidelines and in trainings mostly by the lead partner	Dedicated HR from PATH for this NVI. Polio network of WHO and field staff of UNICEF used sporadically	Support at national and state level. Focused support for the endemic districts	Except Bihar, dedicated partner support has been withdrawn. State specific partners continue to support the districts and state on a need-based approach	PATH continues to receive grant for supporting JE vaccination campaigns in endemic districts.
Adult JE vaccine						
Pentavalent vaccine	WHO-NPSP and UNICEF. Supported by ITSU, NCCVMRC, UNDP, GHS, JSI	Extensive use of network of DPs for system preparedness, capacity building, monitoring the roll out and program review. The partner activities coordinated by the lead partners	Polio network of WHO and UNICEF. National level HR from ITSU, NCCVMRC, GHS and JSI. eVIN network of UNDP	Extensive support at the national, state and sub-state level	Pentavalent and IPV vaccine is now managed by the UIP managers. MR campaigns continues to be supported by the DPs, mostly WHO-NPSP. PCV is yet to be rolled out across India	There were no dedicated resources only for these NVI. The resources of these agencies who are engaged in overall support to immunization strengthening were involved and these continues on a need-based approach
IPV (full dose)						
fIPV (fractional dose)						
PCV						
MR						
RVV	JSI. Supported by WHO-NPSP, UNICEF, ITSU, NCCVMRC, UNDP & GHS	Time bound HR support for states by JSI. Leverage partner network for planning & preparedness, capacity building, communication activities, monitoring & review	Polio network of WHO and UNICEF. National level HR from ITSU, NCCVMRC, GHS. eVIN network of UNDP	At national and regional. In few high priority geographies, at state and sub state levels	Now managed primarily by the UIP managers	All regional, state and sub state level dedicate HR from JSI withdrawn. Remote monitoring and review support at national level continues for 1 year.
Td	ITSU, WHO-NPSP, UNICEF. Supported by NCCVMRC, UNDP, GHS, JSI	Support in developing technical guidelines, capacity building and immunization supply chain	Polio network of WHO and UNICEF National level HR from ITSU, NCCVMRC, GHS and JSI. eVIN network of UNDP	Mostly national level teams involved	No sub-national support as such and so continues to be managed by the UIP managers	No such exit plan as there was no dedicated DP support for field implementation

BCG: Bacillus Calmette Guerin; DPT: Diphtheria, Pertussis, Tetanus; IPV: Inactivated polio Vaccine; PCV: Pneumococcal Conjugate Vaccine; MR: Measles Rubella; RVV: Rotavirus Vaccine; Td: Tetanus Diphtheria; WHO: World Health Organization; UNICEF: United Nations Children's Fund; WHO-NPSP-World Health Organization-national polio surveillance program; ITSU: immunization Technical Support Unit; UNDP: United Nation's Development Program; NCCVMRC: National Cold Chain & Vaccine Management Resource Centre; GHS: Global Health Strategies; JSI: John Snow Inc.; PATH: Program for Appropriate Technology in Health; eVIN: electronic Vaccine Intelligence Network; UIP: Universal Immunization Program; DP: Development Partners; HR: Human Resources

approach: The TaBLET approach for the introduction of a new vaccine in the routine immunization program of a country can be adopted if the health care delivery system has attained some level of maturity in terms of NVI. Besides the operational and other prerequisites, one of the key requirements is strong leadership, primarily at the national/federal government level and at the sub-national/state level. Along with good governance, there should be some level of system readiness like availability of frontline workers (FLWs), cold chain space, supportive supervision mechanism, recording and reporting system, communication, and advocacy platforms. The availability of immunization partner resources at national and sub-national levels is required to implement this approach.

The TaBLET approach: During the introduction of RVV in the UIP of India, the different activities under the various program domains can be grouped in the TaBLET themes. Table 2 describes the different components, exemplars, and impacts achieved by adopting the TaBLET approach in the RVV introduction.

Unique features of the TaBLET approach for partner engagement: Similar to BOT, the TaBLET is also a form of project delivery approach, primarily for the execution of projects in public health. While the BOT is a technology-driven, revenue-generating, and mechanistic business model, the TaBLET follows a deeper human-centric design with social diffusion and system sustainability.

Table 2: Components of the TaBLET approach, its key exemplars and impact.

Sr No	TaBLET component	Key Exemplars
1	**T**echnical **a**dvice	Product (Rotasiil) handling, Cold chain space optimization, Use of WhatsApp for dissemination of key guidelines, customized rapid monitoring tools for the two types of vaccine products
2	**B**uild capacity	Develop training videos, telephonic assessment of training quality, training materials for multi-product handling, customized media information kit, national program review of RVV implementation
3	**L**everage partnerships	Partner support in preparedness assessment, Use of data from NCCMIS and eVIN portals, media sensitization workshops, multi-pronged field monitoring of roll out
4	**E**ngineer innovations	Small group intensive interaction during training workshops-'the station approach', online administration of pre and post-test in the trainings, job aids for FLWs, Bimonthly newsletter-RotaTalk, unique colour branding of the training package for the two RVV products, mid-term program implementation review for guiding further scale up, online geo-mapped mobile application for field monitoring
5	**T**ransfer assets	Training packages, tools for assessment of knowledge enhancement and retention, tools for rapid monitoring of NVI, applications for knowledge management

RVV: Rotavirus Vaccine; ANM: Auxiliary Nurse Midwife; ASHA: Accredited Social Health Activist; AWW: Anganwadi Worker; NCCMIS: National Cold Chain Management Information System; eVIN: electronic Vaccine Intelligence Network; ILR: Ice-lined Refrigerator; FLW: Frontline Workers; NVI: New Vaccine Introduction; MoHFW: Ministry of Health and Family Welfare.

Effective and complete utilization of partner resources and existing health care: The TaBLET approach has been used for the introduction of the new vaccine introduction (rotavirus vaccine) in India. It has been used to implement the new vaccine introduction by the national and state governments with the support of a lead technical partner. The unique feature of this approach is observed to be the availability of partner resources, especially the polio network resources, which were extensively and effectively utilized during the preparedness assessment, training, launch, and post-launch monitoring.

The phased introduction of the RVV enabled the strengthening of systems in a few geographies, handing over the assets and then moving on to different terrains for the RVV introduction. The learnings in one phase were utilized to do mid-course corrections. Also, there was sharing of experiences and learning between states which was helpful for the newer introductions.

Enhance outreach through existing human resources: The project was executed through donor support to the technical partner. The national and state governments provided stewardship throughout the project. The lead technical partner coordinated with all agencies-both government and non-government to execute the project. After providing technical support for a defined period-usually one year, the HR was withdrawn, and the resources were passed on to the state government.

Complete transfer of assets: It is an innovative approach for development partner support through a time and budget limited engagement, an HR light nimble approach, and a clear exit plan culminating in transferring all soft assets back to the government agencies and other stakeholders.

Future recommendations

The utilization of the BOT model in other health care services has shown that it has been effective in creating sustainability and integrated health care services or programs and may serve as a valuable prototype for instituting such programs in different countries. Furthermore, considering the success of the TaBLET approach in the introduction of the rotavirus vaccine, it can also be employed in the introduction of other new vaccines in the UIP. Besides, the multifactorial benefits seen in the adaptation of the TaBLET approach in NVI have implied that it can be used in other health system-driven services and allied healthcare industries.

Conclusions

Any program can be deemed effective and successful only when it can be specific and reproduced across different platforms. A module-oriented approach ensures a systematic assessment of "program" efficiency. The first question to be answered is the attainment of the reliable outcomes intended to achieve as part of the program objective in the first place. The program efficiency can only be proven through the sustained, reproducible model and reliant and measurable outcomes. As seen in the TaBLET approach, it was successfully employed in RVV introduction through the utilization of existing resources, enhanced outreach with existing HR, complete transfer of assets, which can be imbibed in the existing health system. However, further evaluation of the effectiveness based on outcomes linked to specific interventions will help better understand the replicability of the approach in other geographies and other sectors.

Ethics Approval

Written consent was taken from all the stakeholders interviewed during the qualitative discussion. The full purpose of the interview was explained to them, and their identification was kept anonymous. No generalizable interpretations were drawn from individual opinions.

Data

All data underlying the results are available as part of the article and no additional source data are required.

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Conflict of Interest

There are no potential conflicts of interest.

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