




BMJ Open Partnerships in the introduction of new routine vaccines in Bangladesh: evidence from a prospective process evaluation

Sharmin Khan Luies ¹, Tahmina Sultana,² Ashwin Budden,³ Mohammad Asaduzzaman,⁴ Md. Billal Hossain,⁵ Matthew Kelly ⁶, Darren Gray,⁶ Md. Jasim Uddin,⁷ Haribondhu Sarma ⁶

To cite: Luies SK, Sultana T, Budden A, *et al.* Partnerships in the introduction of new routine vaccines in Bangladesh: evidence from a prospective process evaluation. *BMJ Open* 2022;**12**:e061742. doi:10.1136/bmjopen-2022-061742

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-061742>).

Received 07 February 2022
Accepted 28 August 2022

ABSTRACT

Objective To assess the contribution of partners in the introduction of two new vaccines concurrently: pneumococcal 10-valent conjugate vaccine (PCV-10) and inactivated polio vaccine (IPV) into the routine Expanded Programme on Immunization (EPI) in Bangladesh.

Design We conducted a prospective process evaluation that included the theory of change development, root cause analysis and in-depth investigation. As part of process tracking, we reviewed relevant documents, observed trainers' and vaccinators' training and key stakeholder meetings. We analysed the data thematically.

Setting We purposively selected eight *Upazila* (subdistrict) and one city corporation covering nine districts and seven administrative divisions of Bangladesh.

Participants Nineteen national key informants were interviewed and 16 frontline health workers were invited to the group discussions considering their involvement in the vaccine introduction process.

Results The EPI experienced several challenges during the joint introduction of PCV-10 and IPV, such as frequent changes in the vaccine introduction schedule, delays in budget allocation, vaccine supply shortage and higher wastage rates of IPV. EPI addressed these challenges in collaboration with its partners, that is, the World Health Organization (WHO) and United Nations Children's Fund (UNICEF), who provided technical assistance to develop a training curriculum and communication materials and enhanced demand generation at the community level. In addition, the WHO conducted a country readiness assessment for PCV-10, and UNICEF supported vaccine shipment. Other government ministries, City Corporations and municipalities also supported the EPI.

Conclusions The partnership among the EPI stakeholders effectively addressed various operational challenges during the joint introduction of PCV-10 and IPV helped strengthen Bangladesh's immunisation systems. These accomplishments are attributed to several factors that should be supported and strengthened for future vaccine introductions in Bangladesh and other low and-middle countries.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This prospective design of this evaluation is one of the strengths of this study, which helped us understand the entire process with continuous collection and analysis of data.
- ⇒ We had retrospectively assessed a few documents and stakeholder perspectives (ie, meetings and events held in 2013) considering the time taken in the initiation of our project in 2014.
- ⇒ Recall bias was a risk we aimed to mitigate through continuous triangulation of information.
- ⇒ We faced challenges in collecting relevant programme documents promptly, and, in some cases, found that documentation was lacking.
- ⇒ We could not access all vaccine introduction events because we did not obtain approval from authorities for some inhouse meetings.

INTRODUCTION

Since its establishment in 1974, Bangladesh's Expanded Programme on Immunization (EPI) has achieved high levels of immunisation coverage against vaccine-preventable diseases (VPDs),^{1 2} with the proportion of fully vaccinated children rising from 2% in 1984 to 84% in 2019.³ Over the last 40 years, the Government of Bangladesh (GOB) has adopted four vaccines in its immunisation schedule by committing to the Global Universal Child Immunization Initiative (UCI): Bacille Calmette-Guerin, pentavalent vaccine, oral polio vaccine (OPV) and measles-rubella (MR) vaccine.^{4 5} EPI has a robust infrastructure monitored by the Directorate General of Health Services (DGHS) under the Ministry of Health and Family Welfare (MoHFW). Under its health sector-wide approach, the EPI is integrated from top to bottom with other programmes within primary healthcare; such as maternal and neonatal healthcare, integrated management



© Author(s) (or their employer(s)) 2022. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

Correspondence to

Sharmin Khan Luies;
sharminkhan.luies@gmail.com



of childhood illness and health education and counselling.⁴ A total of 17 532 frontline health workers (ie, Health Inspectors, Assistant Health Inspectors and Health Assistants) are active at the community level for ensuring vaccination of children aged 0–11 months along with other assigned duties. District managers (Civil Surgeon) and subdistrict-level managers (Upazila Health & Family Planning Officer) supervise them.⁶

Gavi, the vaccine alliance (hereafter called Gavi) has supported Bangladesh's EPI since 2001, providing funding for introductions of new and underused vaccines, health and immunisation system strengthening and implementing a mass vaccination campaign for MR vaccine.⁷ Gavi's core immunisation partners globally are UNICEF and the WHO, and Gavi funds technical assistance on surveillance of adverse events following immunisation and effective vaccine management through these organisations. The UK's Department for International Development, Japan International Cooperation Agency and the Canadian International Development Agency also support Bangladesh in vaccine procurement, capacity building and monitoring of EPI activities.⁸ Through its Partners' Engagement Framework (PEF), Gavi promotes sustainable increases in coverage and equity of immunisation and improvements in planning, coordination and accountability of alliance partners at the country level to streamline vaccine access. PEF ensures that technical assistance provided by the partners is relevant, efficient, effective, and responsive to country needs.⁹

With support from Gavi and its partners, UNICEF and WHO, the GOB jointly introduced two vaccines in 2015: pneumococcal 10-valent conjugate vaccine (PCV-10) and inactivated polio vaccine (IPV).¹⁰ PCV-10 addresses childhood pneumonia, the single leading cause of mortality in children less than 5 years old in developing countries; the incidence in this age group is estimated to be 0.29 episodes per child-year. About 6 million cases occur each year in Bangladesh.¹¹ *Streptococcus pneumoniae* is one of the main pathogens associated with childhood pneumonia that causes an estimated 821 000 child deaths worldwide.^{11–13} Poliomyelitis (polio) is also a highly infectious disease caused by *poliovirus*, which has caused large outbreaks of paralysis and mainly affects young children.¹⁴ The introduction of IPV aligned with the goals set out by the Global Polio Eradication Initiative (GPEI) to maintain the status of many countries, including Bangladesh, as poliofree and to mitigate known risks of OPV use.⁹

This study of immunisation partnership is part of a prospective process and outcome evaluation conducted for the Gavi Full Country Evaluations (FCE) between 2013 and 2016.⁹ We defined immunisation partnership as the contribution and engagement of the key development partners in delivering the technical assistance as per the country's needs. The prospective process design was a novel approach to evaluating vaccine introductions. It was intended to provide holistic, real-time evidence to Gavi and immunisation programme stakeholders to support timely decisions and programme adaptations,

drawing on principles of developmental evaluation.¹⁵ The prospective process design also complements other types of vaccine and immunisation systems research and evaluations, including economic evaluation,¹⁶ cost-effectiveness analysis,^{17 18} social network analysis on the decision-making process,¹⁹ evaluation of safety of new vaccine introduction²⁰ and evaluation of serotypes causing pneumococcal disease. The main objectives of this study of the joint introduction of PCV-10 and IPV are to document how Gavi's resources, processes and partnership function in Bangladesh; and communicate lessons for strengthening vaccine introductions and routinisation in Bangladesh and elsewhere.

MATERIALS AND METHODS

Study design

For the process evaluation, we used qualitative methods. We collaboratively developed a theory of change (TOC) framework of new vaccine introduction related to PCV-10 and IPV within the FCE consortium, depicting programme implementation milestones and indicators. Considering the joint introduction of the two vaccines, we modified and merged the two different TOC frameworks (figure 1) used initially in the cited report.²¹ Under the 'process tracking' component, we collected and reviewed documents (ie, programme guidelines, reports, meeting minutes, peer-reviewed study and grey literature), conducted direct observations and conducted fact-checking interviews with key stakeholders directly involved in introducing PCV-10 and IPV. These collaborative process tracking components monitored programme implementation fidelity, efficiency and comprehensiveness and detected emergent, unanticipated results. We triangulated and synthesised process tracking information, prioritised issues requiring deeper investigation and used root cause analysis (RCA) to identify underlying causes of challenges and successes. We then conducted an in-depth investigation using key informant interviews (KII) and focus group discussions (FGD) with key stakeholders and service providers to validate and confirm assumptions and hypotheses from the RCA and develop recommendations for adaptive actions.

TOC framework of PCV-10 and IPV introduction

In the TOC framework (figure 1), we defined the successful introduction of PCV-10 and IPV based on three criteria: (1) timely implementation of launch events such as the launch ceremony occurring as planned; (2) achieving targets for the roll-out of the vaccine as planned without significant problems, such as out of stock vaccines and lack of demand for the vaccine and (3) implementing comprehensive postlaunch monitoring activities, such as postlaunch supervision and a postintroduction evaluation. Successful introduction of both vaccines required implementing various preparatory processes. The blue boxes in the figure below describe critical milestones for key processes. The orange boxes highlight the management

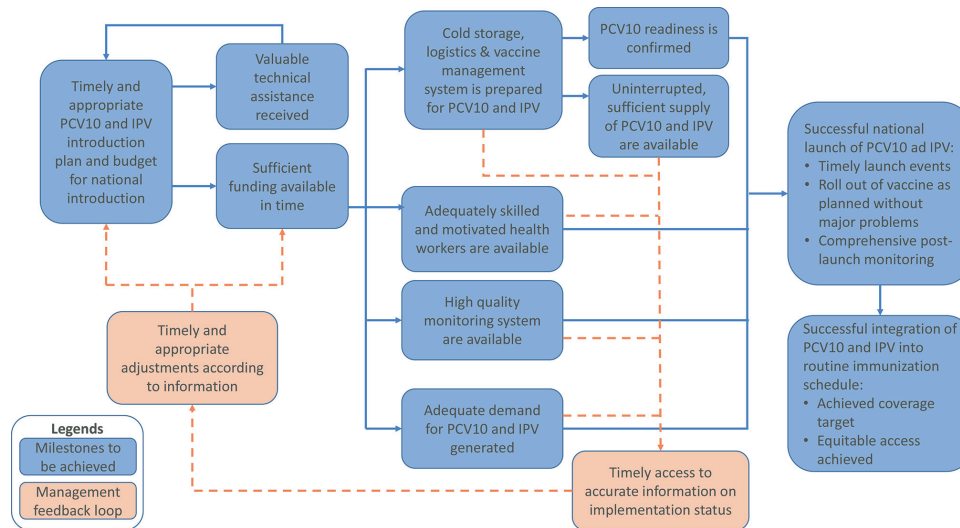


Figure 1 TOC evaluation framework for PCV-10 and IPV. IPV, inactivated polio vaccine; PCV-10, pneumococcal 10-valent conjugate vaccine; TOC, theory of change.

feedback loop that involves timely and accurate information on implementation status to ensure corrective adjustments with additional technical assistance by government stakeholders and partners.

Study area

We conducted the process evaluation at national, district and *Upazila* levels in urban and rural zones covering all administrative divisions of Bangladesh. We purposively selected eight *Upazila* and one city corporation covering nine districts and all seven administrative divisions.

Study team

The eight-person process evaluation team consisted of senior-level and junior-level evaluators, male and female researchers. The team had prior experience in conducting qualitative research.

Data collection

The prospective design entailed continuous data collection over time rather than a single point or episodic data collection. We initiated *process tracking* to gather real-time information on the implementation of PCV-10 and IPV introductions, including planned and unplanned activities, management and decision-making process, and outputs and milestones achieved or missed. Documents were collected through routine distribution channels such as from websites and personal communication and then reviewed. In total, we collected and reviewed a total of 48 documents.

We observed a total of 44 planning and technical meetings and implementation events and conducted three in-person and phone-based fact-checking interviews to clarify and validate observations. Meetings, training and orientations were observed at the respective venue of national (ie, EPI headquarters), subnational (ie, district hospitals) and *Upazila*-level health facilities (ie, *Upazila* Health Complex) and City Corporation's Office.

As part of an in-depth investigation, we developed and finalised the topic guides and checklist for KII and FGD for different administrative levels. We used a purposeful sample of potential key informants who we identified from our reviewed documents, and who were directly involved in the planning, designing and implementation phase of introducing the vaccines then expanded the sample through snowballing. The informants included national-level officials from the DGHS, EPI Head Quarter and partner organisations (WHO, UNICEF). At the subnational (district) level, we selected the managers, first-line supervisors and medical technicians to understand the implementation plans, challenges and successes. We further used key informant responses to identify how they mitigate emerging challenges in real time, to the extent possible. We conducted 19 country-level KIIs from national to *Upazila* levels by directly visiting their workplaces.

For FGDs, we randomly selected two *Upazila* and purposively selected the service providers from all unions of the selected *Upazila*. With the approval of the respected authority, we conducted two FGDs at the *Upazila*-level health facilities with 16 frontline health workers who are directly involved in the field-level implementation of PCV-10 and IPV. For both KII and FGDs, we recorded the discussions with their permission, took notes and maintained the confidentiality of the data as per organisational policy. Table 1 describes data collection and respondents' characteristics.

Data analysis

We summarised and presented the data from process tracking in a tabular format. This systematic analysis helped to understand and identify the key issues for in-depth investigations. We conducted RCA²² to identify the underlying causes of the challenges and facilitators of the key findings. Both the KII and FGD were transcribed,

Table 1 Data collection and respondents' characteristics

Method	Details	Total number of documents collected/ participants attended in the interviews or discussions
Process tracking	Collected and reviewed documents from EPI HQ and other administrative areas of the health system of the country including <ul style="list-style-type: none"> ▶ Relative GOB issued letters, ▶ meeting minutes of interagency coordination committee (ICC), ▶ Technical subcommittee (TSC) ▶ Other GOB documents, for example, health bulletins, and Comprehensive Multi-Year Plan (cMYP) ▶ Gavi applications for new vaccine support (NVS) ▶ Gavi approved decision letters for the NVS ▶ Expression of Interest 	48
	Conducted fact-checking interviews (FCIs), as brief interviews at the national and sub-national levels to confirm any factual information.	3
	Observed several meetings including ICC meeting: <ul style="list-style-type: none"> ▶ Advocacy meetings for introducing PCV-10 and IPV, ▶ Launching ceremony for introducing PCV-10 and IPV, ▶ Trainings for PCV-10, and ▶ Orientations on IPV at all administrative level (national, divisional, district and <i>Upazila</i>). 	44
Key Informant Interviews (KIIs)	<ul style="list-style-type: none"> ▶ KIIs were conducted with 14 GOB personnel and five development partner representatives from national to <i>Upazila</i> levels. ▶ High officials from DGHS, EPI Head Quarter and partner organisations (the WHO, UNICEF) at the national level were interviewed. ▶ Managers, first-line supervisors and medical technicians were interviewed at sub-national (district) level. 	19
Focus Group Discussions (FGDs)	Two FGDs were conducted at <i>Upazila</i> level with the community-level Health Assistants, who are directly involved with the implementation of new vaccines at the EPI sessions.	16

DGHS, Directorate General of Health Services; EPI, Expanded Programme on Immunization; GOB, Government of Bangladesh.

coded and arranged using thematic analysis with the support of *Atlas.ti* (V.6.2) software. Two authors coded and categorised codes into broad themes that reflect the TOC's milestones, summarised results and presented those in a data display matrix. The data display matrix allowed authors to triangulate the findings generated across different data collection techniques (ie, KII, FGD and documents review). In this analysis phase, two authors interpreted the findings, critically reviewed and discussed them with the other coauthors, to reach a consensus. It also helps us to identify the data saturation point. We augmented the presentation of findings by citing respondents' quotations.

Patient and public involvement

No patient involved.

RESULTS

The introduction of the new vaccine experienced various challenges; however, implementation partners helped to adapt and accelerate the process along with EPI stakeholders. The timely response of the EPI partners like the

WHO and UNICEF, drawing on their respective multi-country experiences, helped mitigate the challenges without generating additional risk to the programme.

Partners support Gavi's Vaccine Introduction Grant applications

Well-targeted budgets and timely disbursement of funds for vaccine introductions indicated efficient management capacity of the EPI, traditional partners and MoHFW. EPI Head Quarter led the development of separate applications for Gavi's Vaccine Introduction Grants, with the collaboration from the WHO and UNICEF, and submitted applications to the Gavi Secretariat. In the application process, the WHO assisted EPI with its technical assistance by providing the VPDs surveillance data. With the Surveillance Medical Officer (SMO) network, a standard surveillance system for VPDs is functional at all levels, which makes disease burden data available on a regular basis. UNICEF estimated the amount of vaccine, the number of doses, vaccine type according to disease pattern or demand. All stakeholders of EPI, the WHO and UNICEF, reviewed the initial drafts and shared

them with Inter-agency Coordination Committee (ICC). After getting approval from the ICC, GOB applied Gavi. Gavi's Secretariat sent a decision letter to the GOB after getting consent from its Independent Review Committee, with information of the funding period, the volume of vaccines and percentage or level of the country's co-financing contribution for the PCV-10 and IPV.

Challenges and difficulties encountered in the process of introducing the vaccines

Country stakeholders encountered several challenges from the planning to the implementation phase of both vaccines. One of the critical challenges was a global supply shortage of PCV-10, which causes the launch to be postponed in Bangladesh from 2013 to 2014; when Gavi only approved launches in countries with a smaller targeted population. A similar supply challenge was observed for IPV as well when Gavi failed to approve a preferred 5-dose vial presentation for Bangladesh and instead sent a decision letter with a 10-dose vial in June 2014. This causes EPI stakeholders and partners to miss the opportunity for integrating PCV-10 and IPV training and advocacy meetings. However, partners could prevent this delay by providing pre-emptive assistance and advance communication with Gavi. Political unrest and movement restriction were the contextual challenges that EPI stakeholders encountered during the readiness assessment of PCV-10. This readiness assessment was a key to the nationwide introduction of PCV-10. Many cross-cutting events cause repeated schedule changes for the implementation of both the vaccines, which was also challenging for the key stakeholders; however, EPI adjusted their decisions to overcome this challenge considering the country's situation.

Need-based and timely response from EPI partners mitigated various challenges throughout the planning and implementation process

PCV-10 introduction was a priority for Bangladesh because of the country's pneumonia burden, but they faced many contingent challenges throughout the planning and implementation process. In contrast, EPI opted to introduce IPV because of strong global advocacy from the GPEI, despite the country having been certified as polio free since 2006. For PCV, GOB initiated the planning process in 2011, intending to introduce PCV-10 in 2013.

However, the global supply shortage deferred the plan, and GOB had to wait until 2014 to receive the first decision letter from Gavi. Consequently, planned activities such as the preparation of training materials were initially prolonged due to the inadequate workforce at EPI Head Quarters. Later, with technical assistance from UNICEF and the WHO, EPI prepared joint training materials with all details of PCV-10 and IPV. The initial deferment in preparing the training material resulted in a domino effect on delaying the PCV-10 training, readiness assessment and vaccine shipment. The PCV-10 introduction plan was then deferred to December 2014. On the other hand, it was challenging to begin the joint preparatory activities (eg, training, advocacy programmes) of PCV-10 and IPV without an IPV decision letter.

Figure 2 illustrates an underlying chain of factors and drivers of the challenges of the joint introduction as assessed through RCA. For instance, PCV-10 training and readiness assessment were completed by 10 January 2015 at all administrative levels. Gavi required all countries introducing PCV-10 to undertake a readiness assessment before introduction to confirm adequate human

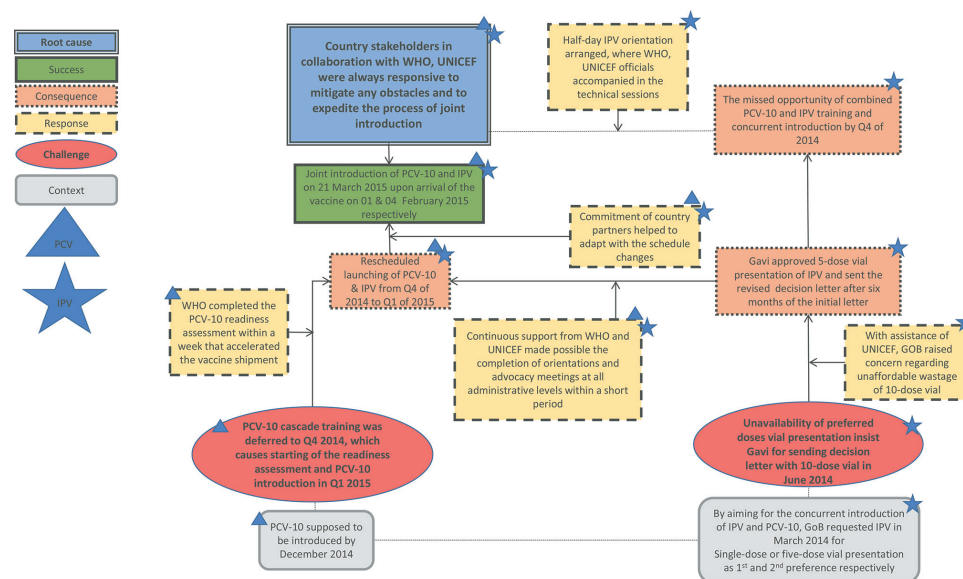


Figure 2 Timely and expeditious response of the stakeholders help to speed up the process of joint introduction of new vaccines. GOB, Government of Bangladesh; IPV, inactivated polio vaccine; PCV-10, pneumococcal 10-valent conjugate vaccine.

resources, cold chain management knowledge and infrastructure for using the preservative-free PCV-10 vaccine. Despite the countrywide political unrest, the WHO conducted the assessment at the district, and *Upazila* level, and submitted the report to Gavi on time.

Figure 2 shows that timely and expeditious response of the stakeholders helps to speed up the process of joint introduction of new vaccines. With the support of the core EPI partners, that is, WHO and UNICEF, country stakeholders mitigated all the challenges encountered during the introductions of two new vaccines; for example, deferment in training, supply challenges of IPV, etc. For capacity building of the health workers, EPI arranged cascade training for PCV-10 and later half-day orientation for IPV when getting approval of the expected five-dose vial of IPV. EPI also arranged joint advocacy at all administrative levels for demand generation and completed PCV-10 readiness assessments within a week, which accelerated the vaccine shipment. The figure shows from planning to execution, the partners supported EPI in all the crisis moments and how they were responsive to any challenges and their consequences to expedite the implementation.

The effort of EPI and the WHO accelerated the process of PCV-10 readiness assessment, so that UNICEF could proceed with the vaccine shipment without further delays. Gavi also sent a reminder and guidance for PCV readiness assessment 6 months prior to the initially planned PCV-10 roll-out date.

With IPV, the decision process was prolonged because of a discrepancy in the dosage preparation approved by Gavi. GOB had requested a five-dose vial preparation in its application, but Gavi approved a 10-dose vial preparation because of a global shortage. Concerned about cost and vaccine wastage, GOB refused the decision. Here, we found a communication gap with Gavi and country partners that could potentially be minimised. However, 6 months later, Gavi offered a decision with five-dose vial preparation. Bangladesh's ICC subsequently approved the joint launch of PCV-10 and IPV on 21 March 2015.

The orientation of vaccinators for IPV was organised separately, about 2 months following the completion of PCV-10 training. Key stakeholders from UNICEF and WHO conducted training sessions, orientations and advocacy meetings at all administrative levels, alongside the EPI stakeholders. A key informant involved with the training manual development and training procedure at national level mentioned that

Though the training manual integrated both information on PCV-10 and IPV, we did not highlight the IPV part during PCV-10 training. However, some of the health workers were curious and they indeed had gone through all details of IPV at that time. We conducted formal orientation on IPV again.

EPI stakeholders and partners missed the opportunity for integrating PCV-10 and IPV preparatory activities, which, could have been a more effective arrangement if the country partners communicated efficiently. However, they organised joint advocacy meetings, including in urban municipalities and city corporations within a short

period, before the launching of vaccine. The advocacy meetings were conducted for mass social mobilisation. All health and family planning officials and workers participated in these sessions, including NGO representatives, Journalists, respected personnel from *Upazila* administration, officer in-charge of police stations, municipality mayors and religious leaders. The joint advocacy was possible because of strong commitment and timely support from UNICEF, the WHO and other government ministries, particularly the Ministry of Local Government and Rural Development.

The increased capacity of the EPI workers through cascade training helped to cope with challenges associated with the accumulation of more vaccines in the routine immunisation system, despite the increase in their workload. After the success of the largest MR vaccination campaign in 2014 (also supported by the EPI partners), the frontline health workers gained confidence in managing the joint launches of PCV-10 and IPV. One sub-national level health worker stated in this regard:

Let any new vaccine arrive, let Rotavirus come along with PCV-10 and IPV, we can handle them all and create no problems. This is because we conducted the MR campaign, a model for the world. Has any other country provided as many vaccines? It was successful, so what can we not achieve?

Table 2 summarises the critical successes and challenges and narrates how partnership contributed to the specific success or addressed the challenge based on the TOC milestones.

DISCUSSION

Overall, rolling out two new vaccines nationally is a very challenging task. Our study revealed many global-level shortcomings that created contingent challenges for the national planning process, such as global supply shortage of vaccines, communication problems with manufacturers and misalignment of requested vaccines. Previous experiences introducing new vaccines have demonstrated strong partnerships around the EPI programme.^{23–25} Here, we identified five key characteristics for a successful partnership, based on our evaluation of PCV-10 and IPV introductions in Bangladesh; that is, motivation for improvement, long-term commitment, financial and technical support, partners mandate to support the government and coordination. In Bangladesh, motivation for achieving success in the EPI programme is one of the key characteristics on which country stakeholders, field workers and policymakers rely and this also builds a foundation of a strong partnership. In Bangladesh, the WHO and UNICEF are the long-term partners of EPI and have, over the years, built commitment and trust. All partners were on board and actively involved in discussions, decision-making and policy changes under the chair of Secretary, MoHFW regarding any new vaccine introductions.^{24–26} Timely support from the partners helped

Table 2 Partners contribution on key successes and to address challenges*

Milestone heading	Key success/challenges and response	Timeline
Timely and appropriate PCV-10 and IPV introduction plan and budget for national introduction	<ul style="list-style-type: none"> ▶ EPI, WHO and UNICEF start intensive planning to develop both Vaccine Introduction Grant applications. ▶ Intending to introduce PCV-10 in 2013, the GoB applied for PCV in May 2011, with a detailed implementation plan and budget, which was approved in April 2012 by the Gavi Secretariat. 	Q2 2011–Q2 2012
	<ul style="list-style-type: none"> ▶ GoB applied for IPV on 30 March 2014 and received the decision on 30 June 2014. 	Q1 to Q2 2014
	<ul style="list-style-type: none"> ▶ EPI received technical assistance from the WHO and UNICEF to support immunisation activities; for example, provide updated information in developing the proposal, training/orientation curriculum etc. ▶ Surveillance data are critical to the design and planning of any vaccine rollout. In Bangladesh, the WHO had identified the pneumococcal disease burden through its established surveillance network through the Surveillance Medical Officers, which informed the decision to introduce PCV-10. ▶ UNICEF supported regular effective vaccine management assessments (EVMA). They initiated the EVMA and the information helped EPI in the PCV-10 application process. 	Q2 2011–Q4 2014
	<ul style="list-style-type: none"> ▶ PCV-10 launch was postponed in Bangladesh from 2013 to 2014 due to a shortage of global supply; Gavi only approved launches in countries with a smaller targeted population. 	Postponed until Q4 2014
Cold storage, logistics and vaccine management system is prepared for PCV-10 and IPV	<ul style="list-style-type: none"> ▶ Vaccine and other logistics systems (reporting forms, Child EPI cards) were updated, and PCV-10 fridge stickers (for ILR & vaccine carrier that described the criteria for maintaining the cold chain of PCV-10.) were printed timely with the support of UNICEF. 	Q4 2014
	<ul style="list-style-type: none"> ▶ EPI trained the cold chain staff to ensure proper cold chain maintenance. 	Q4 2014
Adequately skilled and motivated health workers are available	<ul style="list-style-type: none"> ▶ WHO and UNICEF supported EPI in taking the training sessions at different administrative levels. 	Q4 2014 for PCV-10
	<ul style="list-style-type: none"> ▶ EPI HQ organised 2 days training programme for each administrative level (national, district, <i>Upazila</i>) for PCV-10, and later organised a half-day orientation for IPV. 	Q1 2015 for IPV
	<ul style="list-style-type: none"> ▶ EPI stakeholders and partners missed the opportunity for integrating PCV-10 and IPV training and advocacy meetings. 	Q4 2014
PCV-10 readiness is confirmed	<ul style="list-style-type: none"> ▶ GOB confirmed the readiness assessment with the support of WHO's Surveillance Medical Officer, who has adequate knowledge in the immunisation programme. 	Q1 2015
	<ul style="list-style-type: none"> ▶ Despite political unrest and movement restrictions, WHO conducted the readiness assessment adopting a strategic manner 	Q1 2015
Uninterrupted, sufficient supply of PCV-10 and IPV is available	<ul style="list-style-type: none"> ▶ IPV was available in the country from February 1 2015, and PCV-10 vaccines arrived in the country on February 4 2015. 	Q1 2015
	<ul style="list-style-type: none"> ▶ EPI HQ distributed the vaccine to the sub-national/district level prior to introduction. 	Q1 2015
Adequately skilled and motivated health workers are available	<ul style="list-style-type: none"> ▶ Post Introduction Evaluation (PIE) for both PCV-10 and IPV was conducted that demonstrated skilled and motivated health workers are available at different administrative levels. 	Q2 2015
	<ul style="list-style-type: none"> ▶ No separate training assessment was conducted for PCV-10 considering the successful outcome of the programmatic assessment report. 	
Adequate demand for PCV-10 and IPV generated	<ul style="list-style-type: none"> ▶ IEC materials (sticker, poster, billboard, folder, brochure, TV spot) were developed for demand generation activities; UNICEF helped GoB to print out some IEC materials. 	Q4 2014
	<ul style="list-style-type: none"> ▶ GoB arranged National Advocacy Programme to ensure full participation of all stakeholders, and to promote these new vaccines among the targeted population. 	Q1 2015
	<ul style="list-style-type: none"> ▶ Advocacy meetings held at all administrative levels. 	
	<ul style="list-style-type: none"> ▶ Joint launching Ceremony of PCV and IPV occurred on 21 March 2015 with the presence of Hon'ble Minister of Health and Family Welfare along with other guests. 	Q1 2015

Continued

Table 2 Continued

Milestone heading	Key success/challenges and response	Timeline
Timely access to accurate information on the implementation status	▶ Collaborative efforts of partners available in the decision-making process and implementation activities	Q2 2011 to Q1 2015
	▶ EPI through frequent meetings and discussions with the development partners made decisions.	
	▶ EPI adjusted the challenge of repeated schedule changes and made decisions by considering the country's situation	2013–2015
Timely and appropriate adjustments according to information	▶ GOB accessed information on Gavi funding windows through Gavi's website and emails and responded as needed.	2011, 2014
The successful national launch of PCV-10 ad IPV	▶ GOB's Interagency Coordination Committee approves joint vaccine introduction based on vaccine availability;	Q1 2015
	▶ PCV-10 and IPV are launched at scale on 21 March 2015	Q1 2015

*Blue rows indicate findings related to successes and orange rows indicate challenges and responses. The QYEAR referred as calendar year, Q means quarter of a year (eg, Q1=January–March, Q2=April–June, etc) GOB, Government of Bangladesh; IEC, Information Education Communication; IPV, inactivated polio vaccine; PCV-10, pneumococcal 10-valent conjugate vaccine.

EPI address initial implementation challenges and overcome all major obstacles in implementing joint vaccine introduction. Partners intend to provide financing and technical support for routine immunisation in lower and lower middle-income countries.^{27 28} In our case, the Government was helped with the financial and technical support from both the partners and the long-term involvement with these partners contributed to this successful support due to in-depth knowledge the country's health system. In addition, the mandate of the partners was also aligned with the government's priority and actions. Partners have played vital roles during country readiness (ensuring the funding from Gavi with appropriate applications, increasing worker capacity through training, timely programmatic readiness assessment by the WHO, timely procurement and shipment of vaccine by UNICEF) and successful launch of the vaccine, which is revealed from other studies as well.^{24 25}

Coordination is another key characteristic of strong partnership, which was also observed throughout the process of the vaccine's introduction. WHO and UNICEF are partners with each other and they both are well coordinated. Both the partners maintain strong coordination with the relevant ministries and local government bodies and other departments, which helps them to better communicate any specific situation and need-based adjustments.²⁸ Gavi also reminded BGD about the importance of preparing for and implementing the PCV-10 readiness assessment, drawing on FCE reports about readiness assessment gaps in other countries that had just introduced PCV.^{27 29} While other countries, that is, Mozambique, Uganda and Zambia introduced PCV-10 in 2013, experienced challenges with the readiness assessment component and compromised to translate global-level guidance into action,³⁰ Bangladesh successfully completed this with WHO's support through the SMOs.

The WHO provided greater support with the technical expertise of SMO network on disease surveillance for new vaccine introduction. Over the years, the SMOs are supporting strengthening routine immunisation, the introduction of new vaccines, VPD surveillance, measles elimination, polio eradication, data analysis, capacity-building, microplanning and conducting national immunisation days.³¹ With the support of the WHO, Bangladesh has developed a strong VPD surveillance system that makes disease burden data available on a regular basis. This has helped support Bangladesh's success story in immunisation, compared with other neighbouring countries.^{5 32} For example, India has identified barriers to strengthening their immunisation programme, such as poor VPD surveillance system; lack of data on disease burden and shortage of a trained workforce to manage the Universal Immunization Program at the Center, and State levels.³³ The contribution of partners together with an enthusiastic and skilled workforce also enhanced the success of any mass vaccination campaign,²³ disease eradication programmes in Bangladesh.^{23 34}

A study from Israel demonstrated that a vaccination programme could be successfully implemented by systematically identifying the root causes of the challenges and engaging all relevant stakeholders.³⁵ Our findings are constructive in identifying challenges commencing from the planning phase to the implementation phase of the vaccine introduction, determining the appropriate response or risk mitigation strategies and overall timely implication of that initiative.

The role of EPI, partnering with WHO and UNICEF in the new vaccine introduction process helped generate practical evidence for future steps and contributions of partners by exploring country expectations and attainments in this regard. If we consider a different context where partners' contribution is limited, willingness from

the country stakeholders is the key to adapting to the introduction and implementation of new vaccines. We found that Bangladesh EPI stakeholders are optimistic and flexible to handle all hurdles and work pressure about the joint introduction of vaccines, which was new for the country. And to build this, strong advocacy is required at all administrative levels as evident in this case, besides strengthening the workforce's capacity. The joint vaccine introduction also came with an increased implementation burden on the partners and the health workforce, and it has revealed that both the partners and the health workforce went above what would normally be expected for their roles and the confidence they experienced from the largest vaccination campaigns.

Although the prospective design of this evaluation helped us understand the entire process with continuous collection and analysis of the findings, it has certain limitations. The findings are mostly subjective, time-consuming and difficult to interpret. Also, we retrospectively assessed a few documents and stakeholder perspectives, which were potentially wrapped in recall bias. But we tried mitigating the risk through data triangulation. We assessed the contribution of partners in the introduction of two new vaccines in this paper, which was totally based on the technical assistance of the partners. We assessed whether these technical assistants were timely provided, or whether they have any effects on vaccine introduction. We also assessed how these technical assistants adjusted to implementation demands or not. However, further exploration would be helpful about the extent to which Gavi-funded technical assistance is building sustainable, in-house capacity at EPI, such that EPI is relying less on WHO and UNICEF.

CONCLUSION

The partnership among the EPI stakeholders played an essential role in the joint introduction of PCV-10 and IPV, besides strengthening the immunisation systems in Bangladesh. Despite some challenges in implementation, the vaccine roll-out proceeds according to the TOC milestones. Development partners act rapidly with their technical assistance throughout and they expedite the implementation process by developing the training and communication materials. The partners also supported the government with logistics to ensure implementation without delay caused by a lengthy procurement process in government's system. With all these essential activities and supports, Bangladesh has been able to successfully introduce two new vaccines at the first time. These accomplishments are attributed to various factors that should be supported in the upcoming Gavi-supported introductions of new vaccines in Bangladesh. The lessons learnt can be used in other countries, aiming to introduce new vaccines into their routine EPI. We expect this partnership to ensure the programmatic and financial sustainability of EPI programme in the future and lessons generated for other countries introducing new vaccines.

Author affiliations

¹Infectious Diseases Division, icddr,b, 68 Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka 1212, Bangladesh

²Research Program, Bangladesh Institute of Governance and Management, Dhaka, Bangladesh

³D'EVA Consulting, Washington, District of Columbia, USA

⁴SanMarkS at iDE (International Development Enterprises), iDE Bangladesh, Dhaka, Bangladesh

⁵Department of Sociology, Shahjalal University of Science and Technology, Sylhet, Bangladesh

⁶National Centre for Epidemiology and Population Health, The Australian National University, Canberra, Australian Capital Territory, Australia

⁷Health Systems and Population Studies Division, icddr,b, 68 Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka 1212, Bangladesh

Acknowledgements The authors thank all study participants and all the research team members for their time and contribution. This research study was funded by Gavi, The Vaccine Alliance. icddr,b acknowledges with gratitude the commitment of Gavi, The Vaccine Alliance to its research efforts. icddr,b is also grateful to the GOB, Canada, Sweden and the UK for providing core/unrestricted support.

Contributors HS, MA and AB designed the qualitative part of the study, and HS was the principal investigator and responsible for the overall content as the guarantor. TS, SKL and MBH conducted key informant interviews, moderated focus group discussions, analysed the qualitative transcripts. HS and AB also conducted a few high-level, in-depth interviews. HS, AB supported the implementation of the study and the analysis and interpretation of findings. SKL drafted the paper, along with AB and HS. MK, DG and JU reviewed and helped revise various drafts of the manuscript and supported finalising the paper for submission. JU served as PI for the FCE and was responsible for the design and oversight. All authors reviewed and approved the final version of this article.

Funding This study was funded by Gavi, the Vaccine Alliance. Award/grant number (N/A).

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Please see the methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study was approved by the Institutional Review Board (IRB) of icddr,b, which comprises two committees: the Research Review Committee and Ethical Review Committee. Ethics Approval ID: PR-14075. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data supporting findings are not publicly available due to participants' confidentiality. For further information regarding access, please contact Haribondhu Sarma (haribondhu.sarma@anu.edu.au).

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iDs

Sharmin Khan Luies <http://orcid.org/0000-0001-6005-1692>

Matthew Kelly <http://orcid.org/0000-0001-7963-2139>

Haribondhu Sarma <http://orcid.org/0000-0003-1553-8498>

REFERENCES

- 1 Sheikh N, Sultana M, Ali N, *et al*. Coverage, Timelines, and determinants of incomplete immunization in Bangladesh. *Trop Med Infect Dis* 2018;3:72.
- 2 Luby SP, Brooks WA, Zaman K, *et al*. Infectious diseases and vaccine sciences: strategic directions. *J Health Popul Nutr* 2008;26:295–310.
- 3 EPI. DGHS. *Bangladesh EPI coverage evaluation survey (CEs) 2019, 2020*.



- 4 Government of People's Republic of Bangladesh. Comprehensive Multi-Year Plan of the National Immunization Program of Bangladesh 2011-2016. Government of People's Republic of Bangladesh, 2011. Available: <https://www.gavi.org/sites/default/files/document/comprehensive-multi-year-plan-for-2011-2016pdf.pdf>
- 5 National Institute of Population Research and Training (NIPORT), and ICF. *Bangladesh demographic and health survey 2017-18*. Dhaka, Bangladesh, and Rockville, Maryland, USA: NIPORT and ICF, 2020. <https://dhsprogram.com/pubs/pdf/PR104/PR104.pdf>
- 6 Government of the People's Republic of Bangladesh. Health Bulletin 2015. Ministry of health and family welfare. Available: <https://www.aidsdatahub.org/sites/default/files/resource/bangladesh-health-bulletin-2015.pdf>
- 7 Gavi, The Vaccine Alliance. Overview of Gavi full country evaluations findings. Bangladesh 2013-16. Available: https://path.azureedge.net/media/documents/DHS_gavi_bangladesh_br.pdf
- 8 Cambridge Economic Policy Associates (CEPA) LLP. Gavi Second Evaluation report, 2010. Available: https://www.gavi.org/sites/default/files/document/evaluations/GAVI_Second_Evaluation_Report_2010.pdf
- 9 Gavi Full Country Evaluations Team. *Gavi full country evaluations: 2016 dissemination report – Bangladesh*. Seattle, WA: IHME, 2017. https://www.healthdata.org/sites/default/files/files/policy_report/2017/Gavi-FCE_Bangladesh-Country-Report_2017.pdf
- 10 Gavi. Children in Bangladesh to benefit from dual vaccines introduction. Gavi the vaccine alliance, 2015. Available: <http://www.gavi.org/Library/News/Press-releases/2015/Children-in-Bangladesh-to-benefit-from-dual-vaccine-introduction/> [Accessed 18 Jun 2022].
- 11 O'Brien KL, Wolfson LJ, Watt JP, *et al.* Burden of disease caused by *Streptococcus pneumoniae* in children younger than 5 years: global estimates. *The Lancet* 2009;374:893–902.
- 12 Webster J, Theodoratou E, Nair H, *et al.* An evaluation of emerging vaccines for childhood pneumococcal pneumonia. *BMC Public Health* 2011;11 Suppl 3:S26.
- 13 Solomon T, Lewthwaite P, Perera D, *et al.* Virology, epidemiology, pathogenesis, and control of enterovirus 71. *Lancet Infect Dis* 2010;10:778–90.
- 14 Rudan I, Boschi-Pinto C, Biloglav Z, *et al.* Epidemiology and etiology of childhood pneumonia. *Bull World Health Organ* 2008;86:408–16.
- 15 Patton MQ. *Developmental evaluation. applying complexity concepts to enhance innovation and use*. New York: Guilford Press, 2010.
- 16 Kim S-Y, Lee G, Goldie SJ. Economic evaluation of pneumococcal conjugate vaccination in the Gambia. *BMC Infect Dis* 2010;10:260.
- 17 Melegaro A, Edmunds WJ. Cost-Effectiveness analysis of pneumococcal conjugate vaccination in England and Wales. *Vaccine* 2004;22:4203–14.
- 18 Sinha A, Levine O, Knoll MD, *et al.* Cost-Effectiveness of pneumococcal conjugate vaccination in the prevention of child mortality: an international economic analysis. *Lancet* 2007;369:389–96.
- 19 Wonodi CB, Privor-Dumm L, Aina M, *et al.* Using social network analysis to examine the decision-making process on new vaccine introduction in Nigeria. *Health Policy Plan* 2012;27:ii27–38.
- 20 Ellenberg SS, Foulkes MA, Midthun K, *et al.* Evaluating the safety of new vaccines: summary of a workshop. *Am J Public Health* 2005;95:800–7.
- 21 GAVI. GAVI full country evaluation: annual dissemination report 2014. Gavi the vaccine alliance, 2015. Available: <http://www.gavi.org/Library/GAVI-documents/Evaluations/Gavi-Full-Country-Evaluation-2014-Annual-Dissemination-Report/>
- 22 Rooney JJ, Heuvel LV. Root cause analysis for beginners. quality basics quality progress, 2004. Available: <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.618.8544&rep=rep1&type=pdf>
- 23 Koehlmoos TP, Uddin J, Sarma H. Impact of measles eradication activities on routine immunization services and health systems in Bangladesh. *J Infect Dis* 2011;204 Suppl 1:S90–7.
- 24 Uddin J, Sarma H, Bari TI, *et al.* Introduction of new vaccines: decision-making process in Bangladesh. *J Health Popul Nutr* 2013;31:211–7.
- 25 Burchett HED, Mounier-Jack S, Griffiths UK, *et al.* New vaccine adoption: qualitative study of national decision-making processes in seven low- and middle-income countries. *Health Policy Plan* 2012;27 Suppl 2:ii5–16.
- 26 Shen AK, Fields R, McQuestion M. The future of routine immunization in the developing world: challenges and opportunities. *Glob Health Sci Pract* 2014;2:381–94.
- 27 Blankenhorn A-L, Cernuschi T, Zaffran MJ. Exceptional financial support for introduction of inactivated polio vaccine in middle-income countries. *J Infect Dis* 2017;216:S52–6.
- 28 Sarma H, Budden A, Luies SK, *et al.* Implementation of the world's largest measles-rubella mass vaccination campaign in Bangladesh: a process evaluation. *BMC Public Health* 2019;19:925.
- 29 GAVI. GAVI full country evaluation: annual dissemination report 2015. Gavi the vaccine alliance, 2015. Available: <http://www.gavi.org/Library/GAVI-documents/Evaluations/Gavi-Full-Country-Evaluation-2015-Annual-Dissemination-Report/>
- 30 GAVI. GAVI full country evaluation 2013: process evaluation of pneumococcal vaccine introduction in Mozambique, Uganda, and Zambia. Gavi the vaccine alliance, 2014. Available: http://www.healthdata.org/sites/default/files/files/Projects/GAVI/GAVI_Full_Country_Evaluation_PCV_Findings_2014.pdf
- 31 Government of the People's Republic of Bangladesh. Polio transition plan Bangladesh. Available: <https://polioeradication.org/wp-content/uploads/2018/11/Bangladesh-national-polio-transition-plan-may-2018-180909.pdf>
- 32 Sarkar PK, Sarker NK, Doulah S, *et al.* Expanded programme on immunization in Bangladesh: a success story. *Bangladesh J Child Health* 2015;39:93–8.
- 33 Government of India. National vaccine policy. Ministry of health and family welfare, government of India, 2011. Available: <https://main.mohfw.gov.in/sites/default/files/108481119000.pdf>
- 34 Hanvoravongchai P, Mounier-Jack S, Oliveira Cruz V, *et al.* Impact of measles elimination activities on immunization services and health systems: findings from six countries. *J Infect Dis* 2011;204 Suppl 1:S82–9.
- 35 Levine H, Balicer RD, Laor D, *et al.* Challenges and opportunities in the Israeli 2009 pandemic influenza vaccination program. *Hum Vaccin* 2011;7:1077–82.