

Increasing immunisation in Karachi, Pakistan: a feasibility and acceptability study of the vaccine indicator and reminder band community intervention

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About this formative study

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Executive summary

The global efforts to reach Universal Coverage for RI is near realization as we observe above 90% Baccille—Calmette—Guérin (BCG) vaccine coverage in many developing countries. However, there is notable dropout between BCG (88% global coverage) and 3rd dose DTP containing vaccine (86% global coverage) observed at the global level. It is important to reduce dropout rates but equally critical to ensure timely initiation and completion of the RI schedule to prevent death and disability and disease outbreaks in the most vulnerable, under-one year, age group.

The VIR band formative evaluation study was funded by the International Initiative for Impact Evaluation (3ie) to assess the feasibility of scaling the intervention and qualify for a higher-powered impact evaluation. A formative mixed method research design was selected to closely monitor activities undertaken during the design and pretesting of program to guide the rollout of the VIR band intervention at a larger scale. Formative evaluation also allows to detect and monitor any unanticipated events in program implementation and address them accordingly.

The VIR band intervention formative evaluation was carried out in two peri-urban settlements of Sachal Goth (village) and Pehalwan Goth of District East, in Karachi, Pakistan. Though the intervention site is a peri-urban community in a metropolis city, the vaccination timeliness and Penta-3 completion rates match that of rural Pakistan.

The study enrolled 497 infants when they first visited the vaccination center for their BCG vaccine, and each participant followed for 18 weeks till they completed their three doses of Penta-valent (1,2,3) vaccine. Every infant enrolled in the study received an activated VIR band, secured to their ankle and parents were informed to return to the vaccination center when the white "timestrip" membrane turned completely red. Each infant received three VIR bands, a Yellow VIR band on the first, a Purple VIR on the second and an Aqua VIR on the third visit. At the fourth visit the infants were provided with their EPI's paper homebased vaccination record and the VIR band study enrollment number. The enrollment number would allow parents to get a copy of their children's immunization records upon request to TVI. For every infant, an electronic immunization record was created in an online registry. The digital immunization registry was updated in real time at the vaccination center during each immunization visit.

Based on the problem statement and research objectives the primary research questions were 1) "What is the level of parental and community acceptance of the VIR band?", 2) "How is parental compliance with VIR band?", 3) "What is the accuracy of the VIR band/timestrip indicator" and 4) "Is VIR band an effective reminder to parents of the vaccine due date?". The primary questions of the process evaluation were 1) Difference between budgeted and actual implementation cost", 2) "number of planned activities completed on time", 3) "understanding the challenges faced by the program staff in the field" and 4) "identifying possible mechanisms for implementing the intervention".

The results of the study showed an almost 100% acceptance of the VIR band and more than 86% retention of the VIR band at each subsequent vaccination visit. Among the cohort, 61.9% of the infants completed the third dose of DTP containing vaccine (Penta-3). Among the enrolled infants, overall follow-up visits wise compliance to immunization schedule, for 1st

follow-up was 91.5%, for 2nd follow-up was 70.6% and for the 3rd follow-up was 61.9%. Among those who completed the RI schedule up-to Penta 3, the proportion of those returning late for immunization (i.e., beyond seven days of the date of the prescribed follow-up visit) was observed to be 28.6% for 1st follow-up, 56.4% for 2nd follow-up and 76.0% for the 3rd follow-up visits respectively.

The VIR band can be considered for a larger impact evaluation design with lessons learned from the formative evaluation. Conducting the VIR band impact evaluation study in a health demographic surveillance system (HDSS) setting would allow for ease of enrolling infants at birth. The VIR band intervention can reach a wider pool of infants if they are enrolled at home, instead of a vaccination center so children who would otherwise have delayed initiation would also benefit from it.

Non-SMS based reminder like VIR band might be feasible for improving routine immunization timelines and completion. Further studies are required to look into whether the VIR band can have a substantial impact in improving routine immunization in areas of low coverage and completion as observed in rural settings. Whether the VIR band alone alter parental attitudes and behavior needs to be evaluated by better-powered studies, comparing the different social behavior change communication strategies addressing all levels of the socio-ecological sphere. Parental knowledge of vaccine-preventable diseases, RI schedules and barriers to action for its timely completion need to be assessed in the context of low and middle-income countries.

Improving RI timeliness and completion needs a targeted approach coupling a robust social behavior change communication strategy harnessing all the available health producing resources and coupled with an active reminder like the VIR band to provide visual cues to action.

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Abbreviations and acronyms

BCG	Baccille—Calmette—Guérin
CHA	Child Health Ambassadors
DTP	Diphtheria—Tetanus toxoid—Pertussis
DHO	District Health Officer
EOC	Emergency Operating Cell
EPI	Expanded Program on Immunization
FCV	Female Community Volunteers
GoS	Government of Sindh
GCE	Grand Challenges Exploration
HDSS	Health and Demographic Surveillance System
3ie	International Initiative for Impact Evaluation
KP	Kaplan Meier Curve
LHW	Lady Health Worker Program For Family Planning and Primary Healthcare
LMIC	Low and Middle Income Countries
MICS	Multiple Indicator Cluster Survey
NGO	Non-Governmental Organization
PDHS	Pakistan Demographic and Health Survey
RCT	Randomized Control Trials
RMNCH	Reproductive, Maternal, Neonatal and Child Health
RI	Routine immunization
SBCC	Social Behavior Change Communication
SIA	Supplementary Immunization Activities
TBA	Traditional Birth Attendants
TVI	Trust for Vaccines and Immunization
UC	Universal Coverage
UTD	Up to Date
VIR	Vaccine Indicator and Reminder
WHO	World Health Organization

1. Introduction

Globally about 88% of infants initiate routine immunization (RI) and receive their first vaccine dose of Baccille—Calmette—Guérin (BCG) vaccine (WHO, 2018a), and 86% continue to receive their 3rd dose of Diphtheria—Tetanus toxoid—Pertussis (DTP) containing vaccine at the fourth visit (WHO, 2018b). The coverage for the BCG and DTP-3 vaccines has increased from 2000 (BCG: 80% & DTP3: 72%) but these figures have remained stagnant since 2010 (BCG: 90% & DTP3: 85%) and a persistent dropout rate between the first and fourth visit of RI schedule (Ryman, Diet & Cairns, 2008) (Centers for Disease Control and Prevention (CDC), 2011, VanderEnde et al., 2018).

According to the World Health Organization (WHO), the 2017 reported immunization coverage for Pakistan is at 85% for BCG and 72% for 3rd dose DTP containing vaccine (Penta-3) (WHO and UNICEF estimates of immunization coverage, 2018). These figures are at the national level, at the Provincial (sub-national) level there is a wider gap between the WHO recommendation and reported coverage (Khowaja et al., 2015, Mitchell et al., 2009). According to the Multiple Indicator Cluster Survey (MICS) 2014 in Sindh, the second most populous province of Pakistan, BCG coverage is at 76% and Penta-3 at 52% among children 12-23 months of age. Within this province, district Dadu has the lowest reported coverage at 56.5% for BCG and at 41.9%, 35.8% and 21.4% for Penta-1,2, 3 respectively (Bureau of Statistics Planning & Development Department Government of Sindh Pakistan, 2015).

The WHO and MICS figures for RI initiation and completion in Pakistan are reported for children 12-23 months of age. Analysis of the Pakistan Demographic and Health Survey 2006-07 data shows that among children up to 52 weeks of age less than half (45%) had received their Penta-3 vaccine (National Institute of Population Studies (NIPS), Macro International Inc, 2008). Zero immunization coverage is very much a health systems failure but initiating the RI schedule and not completing is mainly an issue of parental compliance (Rainey et al., 2011).

Timely initiation and completion of RI are as vital as its universal coverage in preventing death, disability and disease outbreaks. The delays in initiation and delays in receiving the RI vaccines at the recommended age are globally reported. The median of median delays for low and middle-income countries, calculated by Clark et.al. for all the vaccines in the RI schedule are at 2.3 weeks (IQR 1.4-4.6) for BCG and 6.2 weeks (3.5-8.5) for DTP3 (Clark, Sanderson, 2009). The delayed initiation, completion and high dropout rates also add to immunization program inefficiency due to waste of resources.

Routine Immunization programs globally and in developing countries have in place several supply-side interventions to ensure community access and quality services at the vaccination centers. To date various intervention are being tested to also increase the demand for uptake and improve parental compliance for RI in different parts of the world. SMS text messages to parents for vaccination due date reminders is the most widely tested intervention in many low- and middle-income countries (Hall, Cole-Lewis & Bernhardt, 2015). The SMS text reminders are usually coupled with other interventions like health behavior change communication, conditional-cash-transfers, and follow-up by community health workers (Kazi et al., 2012) (Wakadha et al., 2013). Several Randomized Control Trials (RCT) and Impact Evaluations studies have been completed and reported for SMS based reminders.

The RCT by Kazi et. al. assessing the effectiveness of the SMS-text based reminders for improving vaccination coverage and timeliness in Karachi, Pakistan is comparable to socio-cultural context of the VIR band formative evaluation study site. The RCT reports improved

coverage (76.0% vs. 71.3%, $P=.36$) only for Penta 1 vaccine (scheduled at 6 weeks of age) among children whose parents received SMS-test reminders for Penta 1-3. According to the study authors, there was no statistically significant difference in coverage between the intervention and control group for Penta-2 vaccine (58.7% vs. 52.7%, $P=.30$) and Penta-3 (31.3% vs. 26.0%, $P=.31$) scheduled at 10 and 14 weeks of age. The authors reported that after the 6 weeks visit there is reduced compliance among parents for prioritizing the vaccination of infants. The reasons, collected during the informal inquiry, include mother's increased workload, the child getting irritable after receiving the 6 weeks' vaccine dose, misplacing the paper-based immunization record card and difficulty reaching the vaccination center (Kazi et al., 2018).

The recent and most extensive (total $n=1600$) impact evaluation of SMS-Text based reminders for improving vaccination coverage and timeliness at 12 months in Kenya is reported by Gibson et.al. (Gibson et al., 2017). According to the study there was not a significant difference in the proportion of children with full immunization at 12 months of age for children in the control group (82%) and children whose caregivers received SMS reminders (86%) and SMS reminder and 72 KES incentive (86%). Only children whose parents received SMS-text reminders plus 200 KES group were significantly more likely to achieve full immunization at 12 months of age (relative risk 1.09, 95% CI 1.02–1.16, $p=0.014$) than children in the control group. In both of the Pakistan and Kenya RCT studies, enrollment was done pre-birth and at home of the infant. Both these studies were conducted in a Health Demographic Surveillance System (HDSS) settings, where the eligible population resides in an active surveillance area. Their findings are similar regarding the dropout rate between the first visit (BCG) and the fourth visit (Penta 3) among enrolled children. The above two studies have described their assumptions on expected and actual dropout rate, coverage rates, and effect size, as per standard practice in RCTs.

Since early 2010, there has been technological progress to address issues with linking the immunization records of infants to auto generating SMS messages. In low and middle-income countries most cell phone accounts are pre-paid, and it is reported that parents on average for 3-4 months don't have sufficient funds to keep their accounts active (Wakadha et al., 2013). These periods of inactivity also occur during the RI schedule time period thus negatively affecting the effectiveness of SMS interventions. To counter periods of account inactivity parents are also provided airtime credit transfers while they are enrolled in a program to receive SMS reminders. However, using SMS based reminders by default introduces inequity in reaching out to infants whose parents are too poor that they cannot afford to maintain a mobile phone or mothers who cannot read. There is a reported 20% gender gap in mobile phone ownership among women, and no single mobile service has 100% of coverage or clients.

The Vaccine Indicator and Reminder (VIR) band innovation was conceived and developed as an alternative to the SMS based reminder that is not dependent on mobile phone technology and is more equitable. The VIR band received a GCE award in 2012 for proof of concept study¹. The VIR band is the only alternative to the SMS based intervention that gives active reminders to parents of the vaccine due dates of RI. There are two other wearable band-based interventions for vaccine due date reminder that are close in function to the VIR band. The

¹ <https://gcgh.grandchallenges.org/grant/time-dependent-color-changing-vaccine-reminder-ankle-bands>

interventions are tested by Alma Sana in Nigeria and by Interactive Research and Development (IRD) in Pakistan. Alma Sana also received the GCE award in the same round of funding as the VIR band². The Alma Sana and IRD bands are also made of silicon, and have symbols on the band for each visit to the vaccination center. The symbols are punched at each visit, and the mother of child/child wears the band. The Alma Sana proof of concept study was conducted in Peru around the same time as the VIR band proof of concept study was carried out in Karachi during 2012-2013. Currently, an RCT is underway testing the effectiveness of the Alma Sana Band in Nasarawa State in North Central Nigeria³. Direct Consulting and Logistics (DCL) Nigeria, the local implementing agency conducting the Alma Sana RCT is also the implementing partner of the VIR band study in Kebbi State, Nigeria; however, there is no geographical overlap between the two studies. The second wearable vaccine due date reminder bracelet RCT is being conducted by IRD in Landi Town, Karachi, Pakistan. The socio-cultural settings of the IRD study are identical to the VIR band study in Karachi. The results of IRD study are also awaited⁴. In 2017 two new researchers received GCE grant for proof of concept study for wearable vaccine due date reminders^{5 6}. Both these concepts were evaluated by VIR band team in 2013 and after feedback from end users were dropped off for further testing. These two studies are still in the conceptual stages after receiving their grants in fall 2017.

The RCT results of the "KhushiBaby" intervention, published in November 2018 is the only peer reviewed study reporting on a wearable immunization record. It is comparable to the VIR band as it is a wearable immunization record that serves as a visual cue of the vaccine due date. It is different from VIR band as the record, a necklace, holds a digital NFC (Near Field Communication) pendent, the intervention also sends voice call reminders to parent's cell phone if there is a delay in vaccination of registered children. The "Khushibaby" RCT is a recipient of a 3ie and UNICEF grants^{7 8}. The reported effectiveness of the NFC Sticker (n=62), NFC Pendent (n=61), and NFC Pendent +Voice Call (n=72) for DTP3 completion within two months from the time of registration was 27.4% (Control Arm), 37.7% (2nd Arm) and 38.7% (Nagar et al., 2018).

The SMS based reminder intervention has been tested in different socio-cultural and geographical locations since early 2000s. This intervention has been around for a while and large-scale impact evaluation studies have being carried out to assess its effectiveness.

Sending text messages and giving cash incentives have improved vaccination coverage rates still there is a need to invest in vaccine reminders and cues to action that are equitable and do not have to rely on parental access to a cell phone.

The VIR band proof of concept study was completed in June 2015, and the formative evaluation study was started in January 2016. The primary objective of the VIR band formative evaluation study was to assess the feasibility of implementing this intervention in a healthcare setting of a low and middle-income country and assess community acceptance and parental

² <http://www.almasanaproject.org>

³ <https://dclnigeria.com/index.php/2018/02/22/vaccine-reminder-bracelet-to-help-improve-timeliness-and-completion-in-nigeria/>

⁴ <http://ird.global.program/maternal-and-child/projects/immunization-reminder-bracelets/#detail>

⁵ <https://gcgh.grandchallenges.org/grant/wristband-immunization-alert-wia>

⁶ <https://gcgh.grandchallenges.org/grant/using-bracelets-improve-timeliness-immunizations>

⁷ <http://unicefstories.org/2015/11/12/medical-record-necklace-khushi-baby-wins-unicefs-wearables-for-good-challenge/>

⁸ <http://www.3ieimpact.org/en/evidence/impact-evaluations/details/3408/>

compliance. The secondary objective of the VIR band formative evaluation was to identify the structures and process that need to be in place for rolling out the intervention at scale and conduct an RCT to generate evidence and assess the impact of VIR band for improving vaccination timely initiation and completion rates in low-income settings like Pakistan.

This report provides a detailed description of the VIR band formative evaluation study which was implemented in two communities in Karachi, Pakistan from January 2016-January 2018. The formative evaluation study was designed for implementation in four phases, in the first phase from January-December 2016 the team completed the baseline qualitative study, social mapping exercise and quantitative household survey. During this phase, the team also developed the tools and process for rolling out the VIR band enrollment study. Simultaneously the close testing of the VIR band form and function was carried out. In the second phase from January till April 2017 the team carried various community engagement and VIR band awareness-raising activities, mainly through engaging community health workers, birthing assistants and healthcare providers in the community. These activities were carried out to facilitate the acceptance of the VIR band in the community as well as facilitate the timely initiation of the RI schedule.

The third phase of the study was carried out from May 2017 till January 2018, in this phase the team enrolled 497 infants in the VIR band enrollment study and every participant was followed for 18 weeks. During this phase, the feasibility of rolling out the VIR band intervention at scale, parental acceptance and compliance with the VIR band and the performance of the VIR band were assessed. This phase was the most crucial component of the study as it was to identify the key challenges and their possible solutions for the successful implementation of the VIR band intervention at scale.

In the fourth phase, completed in January 2018, the team conducted the end-line study completion/exit interviews with the parents of the infants enrolled in the VIR band study, and carried out a rapid social mapping exercise. The study team tried its best to reach parents for exit interview up until March 2018.

This report is structured to provide details of the geographical and sociocultural context in which the VIR band study was conducted, Theory of Change (ToC) framework used to guide the intervention design, intervention monitoring plan, description of the intervention components in each phase, primary and secondary research objectives and research methods employed for exploring the research questions. The key findings of the mixed method research, implications of findings, implications for future research and the major challenges and lessons learned during the VIR band formative evaluation study are also presented.

2. Context

2.1 Vaccine delivery structure

In Pakistan the Expanded Program on Immunization (EPI), a vertical program, is the public sector sole provider of routine immunization⁹ for children under five years of age. EPI mandate is to achieve universal immunization coverage, and all vaccines are provided free of cost through its fixed site and outreach vaccination facilities. The EPI vaccination centers are nested in the government health department and non-profit/religion-based health service delivery centers, but the vaccinators, transport, and storage logistics of vaccines and

⁹ EPI Routine Immunization in Pakistan covers 9 vaccine preventable diseases,

immunization record keeping is all under the jurisdiction of the provincial EPI office. The EPI is also mandated to conduct supplementary immunization activities (SIA) conducting mass immunization campaigns for diseases of major public health concern namely Polio and Measles.

Pakistan, Afghanistan, and Nigeria are the last three countries in the world where Polio has not been eradicated. The Pakistan Emergency Operating Cell (EOC) of the Polio Eradication Program, funded by multilateral donor agencies and supported by the provincial ministry of health, conduct campaigns administering Oral Polio Vaccines (OPV) every month to about 15.5 million children in highest risk districts. A large proportion of human resource from the primary health care system is engaged during each Polio campaign, disrupting their routine services including routine immunization. To alleviate workload of the EPI staff at fixed sites, the EOC has hired 16,000 new Female Community Volunteers (FCV)¹⁰ for SIA who visit door to door for identification of children under five years of age and administration of OPV during every round.

2.2 Study site selection criteria

Since 2008 the cosmopolitan city of Karachi has received in-migration from different regions of Pakistan, mainly from; the flood-affected regions of the Sindh and Balochistan Province and Taliban War-torn areas of Khyber Pakhtunkwa Province and Federally Administrated Tribal Areas (FATA). This massive influx of communities from rural and underdeveloped parts of the country to Karachi, Sindh has resulted in its rapid population growth, estimated to have grown from 16 to 27.5 million in ten years. The in-migration has not only compromised the availability of public services like water, sanitation, and housing but also resulted in the constant arrival of under-vaccinated and never-vaccinated children in the city. The disease surveillance agencies identify this constant movement of unvaccinated children into and out of the city as one of the reasons for continuously emerging cases of Polio in Karachi. According to the WHO, End Polio: Pakistan, April 2017 report, in Karachi, the two areas of “Gadab” and “Baldia” are ranked as high risk, “Site” area as medium and “Gulshan Iqbal” as low-risk areas for polio transmission. The two VIR band intervention communities are in “Gulshan Iqbal” which is a low-risk area, but nevertheless is at risk of polio transmission. Trust for Vaccines and Immunization (TVI), the implementing agency for the VIR band intervention, completed the first phase of the Polio Demonstration Project in 2014 which reached fifty-eight thousand children under five years old age in selected UCs of Karachi and Kashmor District and Bajur Agency (FATA) in one year. TVI had previously collected primary data on immunization and the socio-demographics characteristics in Gulshan Iqbal. Based on the TVI census data the VIR band intervention communities of Sachal Goth and Pehalwan Goth were selected because their low immunization timeliness and completion rates.

Sachal Goth is located in Union Council 29 and Pehalwan Goth in Union Council 27 of District East, Karachi. Though the intervention site is a peri-urban community of a major metropolis city, the vaccination timeliness and Penta-3 completion rates match that of rural areas. During the proposal development phase in September 2015, “Gadab” town was selected for the VIR band intervention but on the recommendation of the Provincial EPI directorate, the site was changed to Gulshan Iqbal. The EPI was concerned about the safety of vaccination staff in Gadab after several Polio workers were gunned down in those communities. The VIR band intervention had to be implemented in a community with optimal coverage of immunization

¹⁰ 7-10 FCVs are hired for each Union Council (UC), 1 FCV supervisor per UC and 1 Coordinator at the district level

services and where vaccination centers were easily accessible for parents/caregivers. The above factors were considered during in the final selection of two intervention sites.

2.3 Socio-economic setup of the intervention communities

There are no government/official updated maps, household, facilities or population lists available for the two intervention communities of Sachal Goth and Pehalwan Goth. The district government and even the local union council office had no accurate information about the socio-demographic situation of the two communities. An extensive social mapping exercise was conducted to gain an in-depth understanding of the intervention sites. Detailed maps were developed and verified, and complete line listing of all the households in the communities were made.

There were a total of 1367 and 1098 household and 434 and 414 children under two years of age in Pehalwan and Sachal Goths respectively. Both the communities had several birthing centers, primary healthcare clinics and secondary healthcare facilities conducting cesarean sections. There was a total of 9 healthcare facilities that provided RI services. A social mapping report was developed containing a comprehensive list of all the health and education resources available to the two communities.

A baseline household survey (HHS) was conducted to identify the population characteristics and their knowledge—attitudes—practice regarding vaccination in the intervention community. Majority of the community members belonged to two major ethnicities of Pushto and Sindhi and identified as Muslims. Majority of the mothers had some formal education, and the majority of the fathers were small business owners. A significant finding of the survey was that only 32% of the respondents correctly stated that children are vaccinated/visit the vaccination center four times by four months of age. Vaccination timeliness was observed in only a quarter of the sampled population, and only 11 children had completed the RI schedule at the recommended ages.

The characteristics of the study population are comparable to most peri-urban settings in Pakistan. The BCG coverage in the intervention area at 82% is comparable to the 85% national average and better than the provincial average of 76%. The Penta 3 coverage of 58.7% is much lower than the national average of 72% and comparable to the provincial average of 52.7%. Our HHS results are for children up to 30 months of age whereas the provincial MICS reports coverage among children 12-23 months, still, Penta-3 coverage in Sachal and Pehalwan Goth are better than the provincial averages. Compared to the Sindh province (52.3%), maternal literacy is much higher in the intervention area at 85%.

The findings of the social mapping and household survey justified the site selection and the VIR band intervention design. A detailed description of the two intervention communities at baseline was reported in the Social Mapping and Household Survey Reports.

3. Intervention description, intervention logic, monitoring plan and the theory of change

3.1 VIR Band form and function

The VIR band is a silicon anklet consisting of three main parts; 1) silicon band, 2) encased “Timestrip” indicator and 3) onetime locking button.

The silicone band is FDA approved and safe for close contact with infant’s skin. Each silicon band has an embossed unique identification number that is used to connect the child to his/her digital records stored in a computer and cloud database. Digital records allow for adding

repeated information on the child's health and immunization (vaccine dosage and type, adverse events,) stored for at least five years.

The Timestrip indicator consists of a patented white membrane and a blister that contains red ink. The Timestrip is activated by pressing (firmly between finger and thumb) the blister, it breaks an internal seal and brings the ink in contact with the white membrane. The ink migrates along the length of the membrane by capillary action at a time-controlled rate to reach the end. As the ink moves along the white membrane it colors it red showing the time lapse since the Timestrip was activated. The red ink is made of natural dye in vegetable oil. The plant-based ink is fully safe for contact with human skin so leakage or ingestion should it occur, is not a health concern. The progression of the ink on the membrane is accurately calibrated to reach the end-point in 6 or 4 weeks. The rate of progression of the ink is dependent on its viscosity hence is affected by heat. The progression of the ink in the Timestrip indicator used in the VIR band has been calibrated according to the external body temperature of infants. During the design phase, the high and low temperatures (50 – 0 degrees Centigrade) were taken into consideration. However, since the VIR band is kept in close proximity of the infants it is not expected that the VIR band would be exposed to extreme temperatures.

The silicon band length was determined after taking the median ankle circumference of 100 newborn infants (50 boys and 50 girls) delivered at Children Hospital in Karachi, Pakistan. The lower end of the VIR band has several punched holes to allow for accommodating the variance in ankle circumference of newborns. The VIR band is secured on the ankle of the infant after placing a rounded wooden peg (3 cm diameter) between the ankle of the infant and VIR band, and the one-time button lock is pressed, securing both ends, for a snug fit and at the same time ensuring the band is not too tight.

The infants receive their first Yellow VIR band when they get their first vaccine dose of BCG, usually soon after birth. The activated VIR band is secured on the ankle of the child, and the parents are explained that when the red dye fills the entire window/white membrane, they must return for the child to receive the next set of vaccine doses. The Yellow VIR band Timestrip is completely filled in 6 weeks. The second Purple VIR band (activated) is secured to the ankle of the infant on the second visit when they receive their Penta-valent I vaccine dose. The third Aqua VIR band is provided to infants when they receive their Penta-valent II vaccine. The purple and aqua VIR band Timestrip are calibrated to be filled in exactly 4 weeks. When the child visits the vaccination center for the Penta-valent III vaccine their Aqua VIR band is collected back and the parents are informed that they can collect the immunization record of their child up till Penta-valent III vaccine from TVI upon request by providing the name, date of birth, parent's name and address.

The challenge of extending the VIR band reminder for Measles and later vaccine are two folds: 1) the indicator ink progresses to its end in weeks, therefore, it cannot be used to indicate the time for Measles vaccines which are scheduled at 9 and 15 months of age. As infants grow in size and ankle circumference over a period of nine months, the VIR band issued at 14-18 weeks cannot be continued till the Measles vaccine are scheduled at nine and fifteen months. 2) As with any home-based health record, it's a challenge to ensure that families value immunization and health documentation and will keep the VIR band on the ankle until nine months of age. Parents are educated when to return for the Measles vaccine according to the age of the child. The VIR band is made of durable material and can be kept as a record for reference of the doses of vaccines administered to a child. Abbreviations of the vaccines administered during each of the first 3 visits of the RI schedule are also embossed on the VIR band.

3.2 VIR band design ideation study

The VIR band design ideation study was conducted from January 2013 to June 2014 in Karachi, Pakistan. During this phase, a human-centered approach was used to develop a product that was safe and comfortable for infants and of value to parents. During the design the daily bathing, oiling and clothing practices of infants in rural and urban communities was taken into consideration. Several rounds of interviews were carried out with mothers, grandparents, fathers and vaccination staff. During each interview, various design ideations were shown made of materials like beads, chains, and thread for the use of the reminder band. The interviewees were asked about their preference for material, texture, shape, and color for a vaccine reminder band. The interviewees were asked who did they think should wear the reminder device, the father and vaccinators suggested that mothers should wear the device, but the mothers insisted that the baby should wear the device. The feedback from end users was used to design the prototype of the VIR band. The 1st generation prototypes were tested among 346 infants in Karachi between July 2014-June 2015 for safety, comfort, and feasibility. The feedback from parents and functioning of the initial prototype were used to refine the form and function and develop the 2nd generation VIR band prototypes used during the formative evaluation study.

3.3 Key Intervention Components

The VIR band formative evaluation study had four main components, conducted in four phases in two years. The first phase was to gain a comprehensive understanding of the socio-cultural dynamics of the intervention sites. The baseline data was also used for designing the intervention. During this phase, the tools were developed for monitoring and evaluation of the study.

The second component conducted in the next phase was community engagement and communication activities, leading to the third phase and the main component, the VIR band enrollment study. The complete detail of the community engagement and communication activities is provided in table 1.

The VIR band enrollment study consisted of screening and enrolling 497 infants, up to two weeks of age, when they visited the vaccination center for their first vaccine dose. The vaccination history of all enrolled infants was entered in a digital database and each was followed for 18 weeks. The last component of the study carried out in the fourth phase consisted of completing the VIR band enrollment study completion/exit interviews assessing parental experience and feedback regarding the VIR band. During the last phase, a quick assessment was carried out in the intervention community to list any changes in the health, education and social services in the intervention community.

Further details of activities conducted during the VIR band intervention are given in annexure C.

Figure 1: Intervention Logic for the VIR band study in Karachi, Pakistan

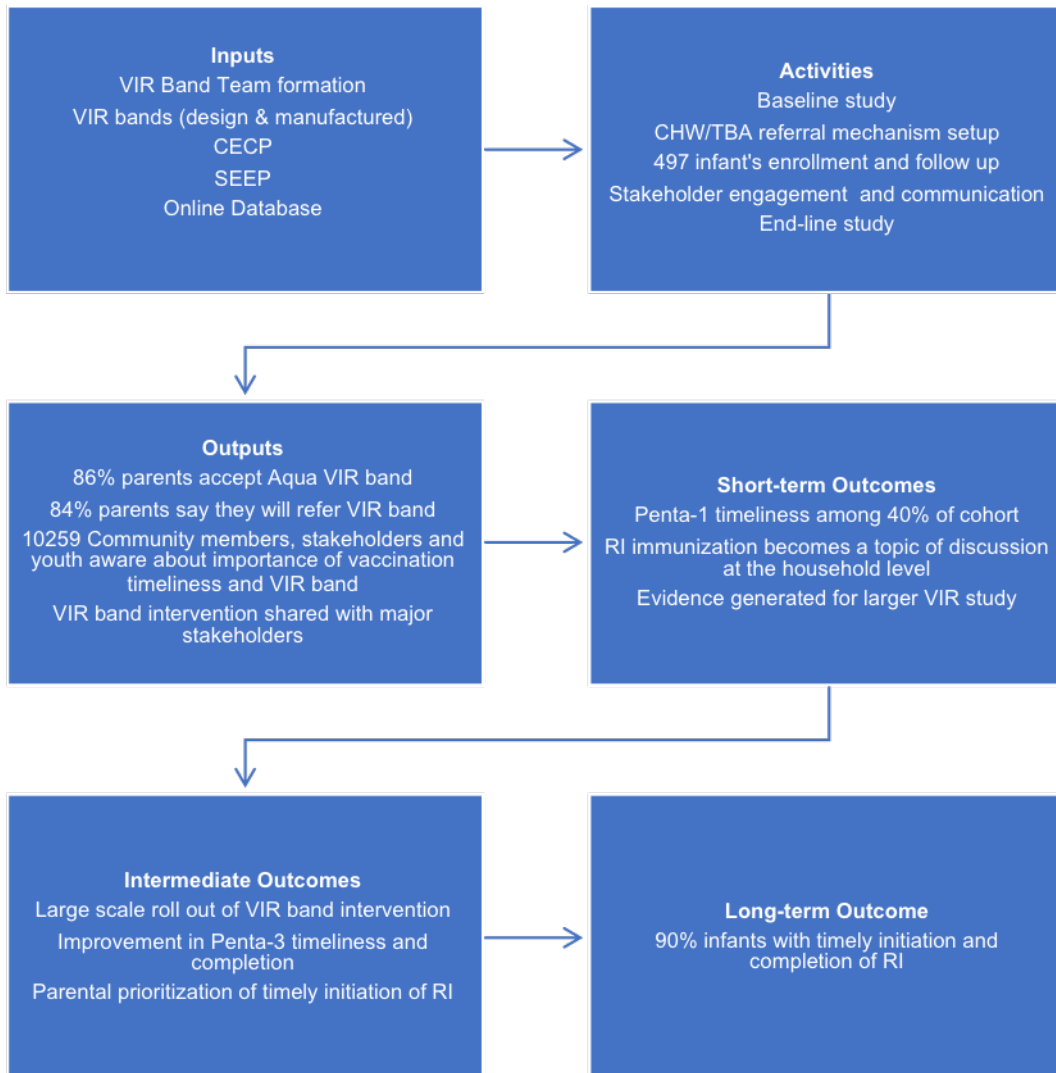


Table 1: Community Engagement and Communication Activities, May-December 2017

Activity	Beneficiaries
Counseling Session in the Healthcare and EPI Vaccination Centers	7820 Parents/Grandparents/Caregivers
Vaccine Preventable Diseases Awareness Sessions in School	1515 students enrolled in Primary, Middle and Higher Secondary
VIR Band and Vaccine Preventable Diseases Awareness Sessions	554 community members in Roadside Cafes, Churches, Mosques, Imam Bargah, Hindu Community Centers and Sports Clubs
VIR Band and Vaccine Preventable Diseases Awareness Sessions	147 Lady Health Workers/ Female Community Volunteers/ Community Health Workers
Counseling to promote RI timely initiation and VIR band introduction	75 Doctors practicing in the intervention community
One on one meetings with community gatekeepers for promoting timely initiation and introducing the VIR band	124 Religious/Political/Traditional Leaders, Educations institution Principals/ CSO Representatives
Recognition of Families for Timely Completing RI schedule	20 Household heads give certificate and shields embossed "Health Champion" placed on their front doors
Leadership and communication training to promote timely initiation	24 male/female youth volunteers from the intervention community
VIR Band Brochure and BCG vaccination days/locations distributed and content explained to recipient	10700 community members at large

3.4 Logical framework and monitoring plan to track implementation

The main focus of the logical framework was the VIR band enrollment study, that depended on parental acceptance of the VIR band and their compliance to keep it secured on their infant's ankle for 14 weeks. The digital database was key in tracking implementation and monitoring the results. The digital database allowed the team to see on a daily basis the number of infants screened, enrolled and returning for follow-up. The key monitoring indicators were 1) acceptance of the Yellow, Purple and Aqua VIR bands, 2) cohort completing the study, 3) parents reporting what other said about the band (Yellow, Purple and Aqua) and 4) parents

gaining knowledge about correct age of Penta-valent vaccine 1, 2, & 3 and 5) parents reporting they would recommend the VIR band to family and friends.

The main monitoring indicator for the process evaluation was assessing the difference between the budgeted and actual cost of implementation and challenges in implementing the intervention.

The baseline data collection during social mapping and qualitative study were carried out close together and due to delays in initiating the VIR band enrollment study the HHS was conducted almost 7 months after the qualitative study. The final intervention design and the Community Engagement and Communication Plan (CECP) were developed by data triangulation of qualitative and quantitative studies. The baseline data collected during the social mapping, qualitative study and HHS were utilized to refine the design of the intervention, develop communication material and identify stakeholders. Separate reports on social mapping & qualitative study and baseline HHS were submitted to 3ie. The key findings of the HHS and qualitative study are reported briefly in this report. The VIR band enrollment study, exit interview results and end-line social mapping are reported in detail in this final report. The logical framework with details of the implementation plan and indicators for monitoring are reported in the Logical Framework table in the annexure C.

3.5 Theory of change

Since first introduced in 1950s the Health Belief Model's (HBM) six constructs namely perceived 1) susceptibility, 2) severity, 3) benefits, 4) barriers to action, along with 5) self-efficacy and 6) cue to action/reminder have been extensively evaluated for predicting preventive health behaviors by individuals (Janz, Becker, 1984). Though the construct "cue to action" is not the strongest predictor of positive health behavior uptake (Carpenter, 2010) it forms the basis of most reminders (SMS, public announcements, reminder letters etc.) for behavior change. With the advent of cellular phone technology, SMS messages as a cue to action have been widely used and tested for effectiveness in various health interventions like text messages for smoking cessation and better medication compliance (Tseng et al., 2017), vaccinating adolescent girls with second dose of HPV vaccine (Kharbanda et al., 2011) and diabetes self-management (Dobson et al., 2018) to name a few. The HBM served as a guide for the VIR band intervention Theory of Change (ToC) with the key premise that the VIR band will serve as an external visual cue to action for parents for timely completion of the Penta-valent 1-3 vaccines. The key assumption was that the gradual change in color of the "timestrip" card will provide active reminder to parents to plan their trip to the vaccination center and ensure timely completion of the vaccination schedule. The VIR band is designed to remain secured on the ankle of the infant, so immediate family members like grandparents, father, sibling and neighbors would be aware of upcoming vaccination visit as indicated by the ink progression on the "timestrip" and will facilitate the visit. The 2nd premise was that parents will complete the RI schedule in a timely manner if they are informed of its importance. The underlying assumption was that vaccination services are accessible and acceptable to the community. The 3rd premise was that VIR band community engagement and communication activities would help reach infants close at birth and serve as stimuli for discussion around child health and vaccinations at the household and community level.

The VIR band intervention ToC framework was developed by the team drawing on literature, with input from implementing partners and 3ie during the proposal finalization. The team revisited the ToC framework and assumptions were verified (assumption met/not met) after the baseline data collection, during implementation and again at study end-line.

The ToC framework and assumptions are presented in annexure C-2 and a simplified diagram is presented in annexure C-3.

3.6 Roles and responsibilities

The VIR band intervention components were carried out by staff hired for the project as it was a formative evaluation study. Engaging the EPI/governmental machinery to deliver the VIR band was not feasible during the formative evaluation stage, as during this phase the research team had to tackle the implementation challenges and bottlenecks. The EPI Pakistan policy makers and program managers are usually reluctant to adopt any new protocol or have their staff conduct an additional task if the intervention effectiveness is not supported by evidence of large-scale impact evaluation study to improve vaccination coverage.

During the VIR band formative study the role of EPI and government was mainly via their support to allow testing of the intervention. The EPI vaccinator's role was to direct and encourage the parents to meet the VIR team after vaccinating their child. EPI support was vital as it endorsed the VIR band among parents and community members. The provincial health department personnel also conducted monitoring visits to ensure that the VIR intervention team was following the protocols defined in the letter of understanding.

The role and responsibilities of the various government and non-government personnel in the delivery of the intervention are provided in the table in Annexure A. The reporting hierarchy within the health care system and of the VIR band team are provided in the figure in annexures B and C.

3.7 Technologies used

During the VIR band intervention, an online digital database was developed for record keeping of all children enrolled in the study. The project staff created and updated the immunization record of all children enrolled in the study at the enrollment center. The VIR band data manager checked the database on a daily basis and provided technical and troubleshooting support to the VIR band field staff.

3.8 Incentives for community health workers and volunteers

Three cadres of community health workers namely the i) The Lady Health Workers (LHW) employed by the Government of Sindh (GoS), ii) Female Community Volunteers (FCVs) hired by the EOC (UNICEF) and traditional birth attendants (TBAs) were engaged and provided incentives for counseling and referring parents for timely initiation of RI. They were not directly involved in distributing VIR band or vaccines to infants but were given a Pak Rupees (PRs.) 300.00 (3 US\$)¹¹ as an incentive for every child they referred. This incentive was given only once, for the newborn they referred and who was brought to the vaccination center within 15 days of age and his/her parents agreed to enroll in the VIR band study. This incentive was to cover their travel and communication expenses to revisit or call parents of newborn infants. During the FGD/qualitative study the LHWs were asked what would be an acceptable incentive for them to refer infants to the VIR band study and if it was monetary what would be the minimum acceptable amount. With feedback from the LHWs and their program managers the amount was agreed upon for a successful referral.

The average pay of the LHWs is 20,000 PRs (200 US\$), and they are often engaged by various other vertical programs for health, nutrition (identifying severely/moderately acute malnourished children) and SIA (Polio and Measles). In addition to their base salary, LHW

¹¹ Note: Exchange rate 1US\$ = 100 PRs

also receives payments from different vertical programs that engage them at various times. The FCVs are paid 15,000 PRs (150 US\$) salary, and are not engaged by any other vertical program. The VIR team engaged the LHWs and FCVs after securing formal written permission from their respective Program Directors (PD) and local supervisors. EPI vaccination staff and the healthcare providers at the immunization centers did not receive any incentives. Since every infant visiting the EPI vaccination centers was screened and enrolled if eligible, even if they came without referral by CHWs, so the introduction of referral cards or incentive by the VIR band intervention did not result in any selection bias into the study.

3.9 Monitoring Plan

The input, output and outcome indicators to measure and monitor the intervention are presented in the Logframe table in Annexure C. The source and mode of data collection for each of the relevant indicators are also included in the Logframe. The VIR band study team developed a detailed work-plan which was revisited monthly and revised quarterly. The study team compiled monthly work and reporting plans, quarterly evaluation progress and learning reports and quarterly Stakeholder Engagement and Evidence uptake Plan (SEEP) reports. The principal investigator (PI), grant manager, field coordinator (FC) and the VIR team conducted a project review meeting at the beginning of every month, and research supervisor shared the meeting minutes with the team. During the monthly meeting progress of each activity was checked against the work plan. If the activity was completed according to plan, its status was confirmed, but if there were any delays the reasons for the delay was noted. The team identified the challenges faced in completing the activity and discussed possible solutions by mutual agreement. The details of the problems faced and solutions proposed were documented in the quarterly evaluation progress and learning reports. The minutes for monthly team meetings were also reported in the quarterly reports shared with 3ie.

The progress of the field activities was monitored on a fortnightly basis. The field team (research assistants, research associates, community mobilization officers) submitted to the field coordinator their biweekly and monthly field activity report and challenges and problems faced report. The FC, in turn, shared the field activity reports with research supervisor who compiled the evaluation progress and learning reports. The SEEP activities conducted with policymakers were listed in the SEEP report. The research supervisor developed the quarterly progress and learning reports and SEEP reports which were reviewed and edited by the principal investigator and shared with grant manager who reviewed and approved the reports.

The team developed monitoring tools for each activity like the baseline social mapping, HHS and the enrollment study. For the HHS daily tally sheets were made for the number of households visited, the number of mothers interviewed, the number of immunization records of children collected. The VIR band enrollment study was monitored on a daily basis for the number of children screened, number of ineligible children (segregated by ineligibility due to age and/or place of residence), the number of refusals and the total number of children enrolled and the number of children returned for each of the three follow-up visits. The enrollment and follow-up database was monitored daily by the data manager and monthly by the PI to ensure for consistency, completeness, and accuracy of the data entry. The enrollment form design and database technology-related challenges faced by the research assistants was addressed on a daily basis and reports generated monthly. Biweekly summary reports were generated from the database and field team records by the data manager and shared with PI and grant manager.

During the enrollment study, many "timestrip" indicators stopped functioning, this was an unanticipated event. As soon as faulty timestrips were reported the team to measures to keep records of all VIR bands that were returned and were defective. The defect for each band was individually assessed, images captured and date the "timestrip" indicator returned/stopped working were noted. All this data was shared on a regular basis with the "timestrip" Company and silicon band manufacturer, PDC.

The PI worked closely with the study field coordinator to review all the activities that were planned for the month and followed up on the completed activities on a monthly basis. The TVI grant manager also reviewed the monthly activities to ensure that timelines were followed. The FC worked with the field staff and received feedback from them on a daily basis and collected written reports on a fortnightly basis.

The steps for data quality assurance of the HHS survey and qualitative study are provided in this report under the respective sections.

Due to violent attacks on polio workers, additional security measures were taken; all the field staff was covered by an Injury and Loss of Life insurance plan procured by TVI. All the team members arrived and left the field site in chartered vehicles, the female staff visited the community in pairs and always accompanied by one male research associate and TVI driver. The research team regularly meet with community gatekeepers and informed them of their planned activities and whenever possible local residents accompanied the field staff. The team members observed the community's norms and always informed the field coordinator about their whereabouts.

4. Formative study evaluation questions and primary outcome

4.1 Primary objective

The VIR Band Community Engagement formative evaluation study was done to assess the VIR band performance and finalize the implementation design before rolling the VIR Band intervention at scale and qualify for a summative evaluation study. The value-adding component of this proactive study was to understand project development better and increase the likelihood of achieving a successful large-scale integration of the VIR Band in the EPI for RI. The theory of change for the VIR band intervention was also evaluated and redefined during this formative evaluation study. During the formative evaluation the study team also closely monitored the project activities and assessed the implementation efficiency and effectiveness.

4.2 Rationale for formative evaluation study

A mixed method research design was selected to answer the primary research questions to allow close monitoring of activities undertaken during the design and pretesting. The findings of the formative evaluation can be used to guide the design process of an intervention with larger sample size. The VIR band intervention has not been carried out in Pakistan or anywhere else globally till date. The VIR band study in Kebbi State Nigeria, though being carried out simultaneously, and completed in June 2018 mainly assessed the feasibility of distributing the VIR band through Traditional Birth Attendants (TBA) and parental compliance with the VIR band.

The formative evaluation allowed us to elucidate and understand the internal dynamics and operations of the program, identify its strengths and weaknesses (Patton, 1987) and detect and monitor any unanticipated events and adjust them where appropriate.

4.3 Primary research question

What is the level of parental and community acceptance of VIR band?

1. What proportion of parents of eligible infants attending the EPI centers accept to enroll in the VIR band study and receive the Yellow band?
2. Among children enrolled in the VIR band study and received a Yellow band what proportion agree to continue and get a Purple band?
3. Among children enrolled in the VIR band study and received a Purple band what proportion agree to continue and get an Aqua band?
4. What proportion of parents responded at the study exit interview that they will recommend the VIR band to a family and friend?
5. What is the feedback from the community, healthcare providers and health policymakers about the utility of the VIR band at baseline and end-line community engagement and SEEP activities?

Parental compliance with the VIR band

1. Among children enrolled at BCG vaccine and given a Yellow VIR band what proportion of infants return to the study center with the VIR band?
2. Among children enrolled at Penta-1 vaccine and given a Purple VIR band what proportion of infants return to the study center with the VIR band?
3. Among children enrolled at Penta-2 vaccine and given an Aqua VIR band what proportion of infants return to the study center with the VIR band?

What is the accuracy of the VIR band/timestrip indicator?

1. What proportion of Yellow VIR bands filled on time (six weeks)?
2. What proportion of Purple VIR bands filled on time (four weeks)?
3. What proportion of Aqua VIR bands filled on time (four weeks)?

Is the VIR band an effective reminder to parents of the vaccine due date?

1. What proportion of parents reported that the (Yellow, Purple, Aqua) VIR band reminded them for vaccination due date?
2. What proportion of parents reported that the (Yellow, Purple, Aqua) VIR band is an effective reminder as it changes color?

4.3.1 Process evaluation questions

1. Difference between actual and budgeted implementation cost, for each component of the intervention
2. Number (proportion) of planned activities completed on time
3. Facilitators and barriers of the intervention/program at the household, community, community health workers and health system level.
4. Understanding of the field staff of the program, problems faced by the field staff in implementing the program, challenges faced by the program staff in implementing each step of the program

5. Tools needed, developed and implemented during the intervention namely: i) IEC material, ii) Community Engagement and Communication Plan (CECP), iii) Stakeholder Engagement and Evidence Uptake Plan (SEEP), iv) online database, v) monetary incentive and reimbursement mechanism.

4.4 Secondary research question

4.4.1 Vaccination timeliness for Penta 1-3 vaccines

1. The proportion of children with functional VIR band returning to the vaccination center within one week and two weeks of Penta-1 vaccine due date
2. The proportion of children with functional VIR band returning to the vaccination center within one week and two weeks of Penta-2 vaccine due date
3. The proportion of children with functional VIR band returning to the vaccination center within one week and two weeks of Penta-3 vaccine due date

4.4.2 Vaccination completion for Penta-3 vaccine

1. The proportion of children enrolled in the VIR band study who returned for Penta-3 vaccine

5. Formative evaluation study design and methods

During the formative evaluation, qualitative and quantitative data were collected at different points and analyzed to develop various tools, validate findings and explain a given result. The study and intervention design were all informed by prior work experience in the field of mixed methods research and with technical input from the 3ie staff and expert reviewers. The formative evaluation was designed and implemented with a focus to develop an intervention that was of value to the communities and which would promote timely initiation and completion of childhood vaccination schedule among infants in all segments of the society and ultimately to fill the gaps in achieving Universal Coverage (UC) of Up to Date (UTD) for RI.

5.1 Qualitative study

At baseline qualitative data was collected through in-depth interviews and focus group discussions to assess 1) knowledge—attitudes—practices (KAP) regarding vaccines, 2) the need and acceptability of VIR band intervention and 3) to develop design features of the VIR band intervention.

The specific objectives of the qualitative study were to identify:

- Ongoing activity/program affecting the health behavior of the recipient community
- Supply-side factors of vaccine uptake like the quality of services at EPI centers, programs, and NGOs for child health
- Demand-side factors like availability and cost of transportation to vaccination centers, fears/negative view regarding immunization, religious leaders supportive of immunization, negative press/opponents of vaccination in the community on child health-seeking behaviors.

In-depth Interviews (IDIs) (a total of 28) were conducted in Pehalwan Goth and Sachal Goth with Religious Leaders, Political Leaders, NGOs Representatives, UC Chairman, Vaccinators, Healthcare Providers and Community Health Workers (CHW). A total of 6 Focus Group Discussions (FGD) were also conducted with mothers, fathers, and CHWs. During each FGD it was ensured that there were 6-8 individuals per group and that they were at same social stature to ensure everyone got a chance to share their views. FGDs were conducted

separately for mothers/caregiver, fathers/grandfathers and CHWs in both the catchment areas and findings have been reported by sex and age-segregated of the participants.

The respondents for these IDIs and FGDs were residents of the target communities. IDI's participants were identified during social mapping exercise in the intervention area, and respondents for FGDs were identified and gathered using a snowball sampling technique. All the tools and interview guides were pre-tested with separate groups of community members before the final qualitative study. The main points of discussion with the mother and father groups were to assess their knowledge regarding the appropriate age of vaccination, how many times a child needs to be vaccinated by 4 months of age and their willingness to participate in an intervention like the VIR band. The parents were also asked about their experience at the EPI centers and its staff and any access issues. The KAP data gathered during the qualitative study was also used to develop the baseline household survey questions and response choices. Later the household survey results were analyzed to confirm the qualitative study findings.

The main points of discussion with community health workers during the FGD was to assess their KAP regarding vaccination, their willingness to be part of the study and inquire about the incentives that would be acceptable to them for promoting early initiation of RI. The team also inquired from them about who should distribute the VIR bands to the infants, and the LHWs suggested that the study team should do the distribution, as they did not want to upset mothers whose infants did not meet the enrollment criteria to receive the VIR band. FGD were only conducted with LHW as in the initial phase the team planned on engaging only LHWs and female community midwives. The feedbacks from the LHWs were incorporated accordingly into the program design.

Qualitative data on parental compliance and VIR band affecting the daily routine of infants was also collected during the VIR band form and function close testing. and the feedback from parents was documented. Their feedback (through open-ended and close-ended questions) and experience with the VIR band was incorporated in the VIR band design. The color of the First VIR band was changed from Green to Yellow as one parent complained that "Green" is a sacred color, (Al-Hadith, a Sunni Muslim sect, wear green turbans to honor the green dome of the Mausoleum of the Holy Prophet of Islam) thus should not be worn on the ankle of a child. The locking mechanism, placement of vaccine names on the band and size of the VIR band were also modified after feedback from parents.

During the VIR band enrollment and follow-up study parents'/caregivers of infants were asked questions with built in response options as well as open-ended questions.

These questions and the built-in responses were derived from the experience gained during close testing of the VIR band.

The end-line study completion/exit interview was conducted with parents of all enrolled infants regardless of the Penta-3 completion. The questions in the exit interview also had options for opened ended response in addition to close-ended single and multiple responses options. Open-ended response option was allowed to capture as many responses as possible about parents' experience and feedback on VIR band.

5.2 Social Mapping

The primary objective of the social mapping exercise was to gain an understanding of the community to facilitate the intervention design and its smooth roll out. Detailed maps of the community were developed and validated to understand the placement of the healthcare

facilities available in the community especially vaccination centers and birthing centers and the community's access to these. Also, the study team collected data on all social resources in the community especially education centers, the religious centers and community centers which could be used as platforms to disseminate the VIR band intervention messages. During the social mapping, the team identified names and contact details of all the stakeholders, healthcare providers, and community health workers providing services to women and children in the two catchment areas.

Complete lists were made of all institutions, their head/in-charge, and type of services provided. These lists were referred to throughout the 2 years of the VIR band study in the community and for various components of the VIR intervention.

At the end of the study, the social mapping exercise was revised to identify any changes in the community. Mainly the health facilities were checked for any increase in vaccination days, new health facilities providing vaccination services and any health campaigns related to vaccinations. Community resources were also charted to locate any change in the religious and political institution, stakeholders and any negative views towards vaccination in the community. The end-line social mapping exercise showed that in the two years' period there were no significant changes in the resources available to the community and only one vaccine-related intervention had been introduced; a supply-side intervention providing palm held devices to vaccinators for immunization record data entry.

The VIR team also took the end-line social mapping exercise as an opportunity to visit all their contacts in the community and inform them of completion of the formative evaluation study and how they can reach the team if needed.

5.3 Household Survey (HHS)

The HH survey was conducted to collect quantitative data on I) immunization history of children up to 30 months of age in the intervention community and II) parental/caregiver knowledge and attitude regarding vaccination timeliness and completion.

5.3.1 HHS Rationale

Maternal/caregiver knowledge and attitudes regarding vaccination timeliness and completion were collected to identify the context-specific issues that needed to be addressed during the intervention and design of the community engagement and communication plan. The immunization history of the children was also collected to get a rationale for conducting the VIR band intervention in the selected community and to later compare the findings of the baseline with the VIR band enrolled cohort.

5.3.2 Survey Population

In the two intervention communities, households with children less than 30 months of age were selected and mother/caregiver of the youngest child (termed as "Index Child") in household was selected for the detailed interview about their socio-economic status, knowledge—attitude—practices regarding vaccination and the infants' birth and vaccination history. Data was also collected about the vaccination status of all children, up to 30 months of age, in the household and effort was made to get this information from the mother of the child.

5.3.3 Sample Size Calculation

According to the Pakistan Demographic and Health Survey 2012-13, the BCG coverage rate among children 12-23 months of age is 89%, and the target is to reach 95% and above to achieve universal coverage. For two-sample comparison of proportions, the Stata (version

15) was used setting proportion 1 (p_1) as .89 and proportion 2 (p_2) as .95, setting alpha at 0.05 and 90% power a sample size of 376 was calculated. To account for a 10% non-response, rate the sample size was inflated to 413. To account for households closed/family moved out between line listing and actual survey the sample was inflating again by 10%, the sample of 454 was rounded off to the final sample of 500 households with children under 30 months of age.

5.3.4 Sampling Design

During the line-listing exercise data was collected on the number of children in the household and their age, this was to facilitate the random selection of only households with at least one child less than 30 months of age for the survey. From the line-listing exercise, a total of 734 households were identified which had at least one child up to 30 months of age and eligible for selection in the HHS.

A random cluster sampling design was employed; this design is especially useful for rapid assessment and sufficient for community-level surveys. According to this design 20 clusters are selected, since the total number of clusters in the two intervention sites was 20, 13 in Pehalwan Goth and 7 in Sachal Goth, all the clusters were included in the household survey. In each cluster, 25 households were randomly selected from the list of households prepared during line-listing. In case in a given cluster the number of households eligible for the selection was less than 25, the households from the adjacent succeeding cluster were selected to complete 25 surveyed forms.

The HHS data collection was completed in 1 month from 19 December 2016 to 18 January 2017. The household survey was done using a Computer Assisted Personal Interview (CAPI) device. The study team carried hard copies of the survey questionnaire, as a backup if for any reason their devices stopped working in the field. The data from hard copies was entered using statistical software Epidata, the data from the CAPI app was imported into MS Excel. All the final analysis for HHS was done with Stata 14.

5.3.5 Data quality management

The CAPI app was designed with built-in features to prevent punching and systematic errors, the checks ensured data quality for completeness, selection criteria for age of the child, and skip patterns. The data set was also cross-checked for quality and completion in Epidata. Data from the hard copies of the form were cross-checked by reentering 20% of the forms. Cross-tabulation was also run to check for any errors and corrected after rechecking the hard copies. A logical errors/constraints plan was developed for the HH survey data entry in Epidata.

The final data set contained information of knowledge—attitude—practice regarding vaccination from 500 respondents and the vaccination records of 562 children up to 30 months of age.

5.4 VIR Band Enrollment Study

The VIR band enrollment study was planned to be completed in 6 months (May-November 2017). During the social mapping exercise data on the number of infants initiating RI each month at the four EPI centers in the study-site was collected to estimate the time duration needed to enroll a sample of 500 infants in the study. The VIR band enrollment study aim was to enroll 500 infants less than up to 15 days of age from 4 select EPI designated vaccination centers. Infants were enrolled when they received their BCG vaccine dose (vaccination initiation) and followed for three subsequent visits scheduled for 6, 10 and 14 weeks of age to

receive their Penta 1-3 vaccine dose (vaccination completion). It was planned that each infant would be followed for 18 weeks from enrollment date. The primary and secondary objectives of the VIR band enrollment study were:

5.4.1 Primary objectives

- Identify the structures and develop the processes for rolling out the VIR band intervention at a larger scale
- Assess parental acceptance and compliance with the VIR band
- Measure VIR band “timestrip” card performance for accuracy
- Evaluate VIR band as an effective visual cue for the timely reminder of vaccination due time

5.4.2 Secondary objectives

- Penta 1 timeliness among enrolled children/received Yellow VIR band (measured at the second visit to EPI center)
- Penta 2 timeliness among enrolled children who received a Purple VIR band (measured at the third visit to EPI center)
- Penta 3 timeliness among enrolled children who received Aqua VIR band (measured at the fourth visit to EPI center)

5.4.3 Sample size calculation for VIR band enrollment study

Based on calculations 371 was the minimum sample size needed for analysis to detect a statistically significant difference in Penta 3 coverage after the intervention. This sample size, for two-sample comparison of independent proportions, was calculated with the following assumption: i) coverage for Penta 3 vaccine national average of 72%, ii) effect size of 10%, iii) power at 90% and iv) setting Alpha at 5%. After inflating the sample size for 30% loss to follow-up (10% at each of the three visits) the sample size of 482 was rounded to 500 as the team had 500 Yellow Bands. At the time of sample size calculation, the failure rate of the VIR bands was not anticipated at any stage and thus not accounted for. The assumption was that starting with a cohort of 500 even with the loss to follow up at each point at second, third and fourth visits there would still be a large number of infants in the cohort to have a statistically significant sample size to make inferences.

5.4.4 Selection criteria

Infants up to 15 days of age and residing in the community/not planning to move out in the next 18 weeks and whose parents consenting to enroll the child in the study.

5.4.5 Exclusion criteria

Children who did not meet the age and residence criteria and not fit to be vaccinated according to the EPI criteria to receive RI.

Children whose parents refuse to enroll their children in the study

5.4.6 Informed Consent

A written informed consent (one copy provided to parents) was secured for each enrolled child, and parent/caregivers were informed that they have the right to leave the study at any point in time without any explanation or consequences. The parents were also informed that there were no monetary benefits attached to enrolling their child in the study.

The EPI staff provides the parents/caregivers a home-based paper immunization record card after administering the vaccines to an infant. The VIR band team retained this card, and the parents were informed that they would receive the updated card at the completion of the RI

schedule or at any time upon request. The EPI paper vaccination card has the date the vaccine was administered and the return date for the next vaccine. This card was retained by the research team to assess the VIR band effectiveness in giving due date reminders and preventing parents from referring to the card of vaccination due date. The parent/caregiver of every enrolled infant was provided a VIR band brochure, explaining how the VIR band worked and the importance of timely and complete immunization. The parents were also informed that they could access the vaccination records of their infants from TVI upon request at any time since all the data is secured in a digital online database.

5.4.7 Screening for enrollment

Every child visiting the selected EPI centers for routine immunization was screened, and their information was also noted in the database. This was done to calculate the median age for vaccination initiation in the community and the reasons for the delay.

5.4.8 Online digital database

A digital electronic record was generated for each child enrolled in the study and updated at each of the subsequent visits. Through the digital record, the team tracked vaccination timeliness for Penta 1-3, reasons for delay if any and performance of the VIR band. At each visit, the parental and infant's experience with the VIR band was also noted and entered into the database.

5.4.9 Setting up the enrollment sites

The four enrollment sites were identified during the social mapping exercise and selected for the high volume of infants visiting the centers for BCG vaccination.

Field site office was rented and established to facilitate the study team travel to and from the enrollment centers and the research team to be close to the study sites to address any issues.

The research associates were recruited and trained in a phase-wise manner, the research associates who were hired for qualitative study and social mapping were retained as data collectors for the household survey and VIR band close testing. New team members were added as the workload increased and the previous staff was retained to ensure team members built up their complete understanding of the VIR band intervention.

5.4.10 VIR band close testing

The VIR band performance accuracy of 99% was based on the results of the three rounds of closed testing carried out between June-December 2016. In the third round, the "timestrip" indicators were tested for accuracy and 99% of these filled on time. Upon confirmation of the timestrip indicator accuracy, the team approved the final design of the VIR band and manufacturing of 3000 bands, 1500 for each study site in Karachi, Pakistan and Kebbi State, Nigeria. A set of Yellow, Purple and Aqua bands for each enrolled child.

5.4.11 Engagement and Training of Community Health Workers

Prior to the start of the enrollment, the study team met with district health officials, field coordinators for LHWs and FCVs and EPI district and provincial managers to inform of enrollment activities and secure reconfirmation of the terms that were signed by the respective programs in their Letter of Understanding (LoU) with VIR band team.

One week before the start of the enrollment study the CHWs (29 FCVs, 8 LHWs, 2 Lady Health Supervisors and 2 Vaccinators) were trained in a one-day workshop (April 29, 2017) on the enrollment criteria, referrals process and logistics of the reimbursement mechanism. They were explicitly informed that they would be reimbursed only for every successful referral, i.e.,

the child meets the enrollment criteria and is enrolled in the study. The training also covered details of the VIR band form and function and intervention components. They also received a refresher on vaccine-preventable diseases covered by the RI schedule and age for each vaccine.

5.4.12 Data management and quality control

VIR Band's online enrolment system has Login panel with 2 access modes i) Admin and ii) User/Operator. ID and passwords were given to all users by which they could log in to the system. Only the Admin had the rights to View, Add, Edit or Delete records and create other users.

Validation was implemented on all forms as per criteria of possible answers. Furthermore, no subsequent form could be filled without completing prior form (e.g. form E could not be filled/accessed without completing D form, and form D could not be submitted until form C had been filled/submitted during the previous visit). However, form F could be submitted at any stage after enrolment if parent/caregiver refused to continue in the study.

Routine Backups (of Data and Database) were made on a bi-weekly basis. Backup of Data was secured in CSV format, and backup of the whole database was done in .sql extension.

5.4.13 Monitoring of evaluation activities

The primary evaluation activities were 1) among children enrolled in the VIR band study, how many returned in time for their Penta 1, 2 and 3 vaccines and 2) study exit interviews completed.

The number of children returning on time, children who were delayed or failed to return was evaluated every fortnight by the data manager, PI, and the field team.

The study exit interviews were conducted in person with parents when they returned to the vaccination center or on the telephone if they failed to return to the EPI center (in this case these were labeled as "dropout"). In the case of telephone interviews, a record was maintained for the number of calls made to each parent and the status of each call. It was agreed in the protocol that if the parents did not pick the phone call after three separate attempts (each call made on a different day and time), they were labeled as a loss to follow. The research assistants and research associates noted the number of phone calls made, exit interviews completed and participants labeled as a loss to follow on a weekly basis and shared the report with FC and data manager.

5.5 Ethical Considerations

Ethical compliance was ensured at each phase; the National Bioethics Committee, Pakistan approved the entire intervention. During the household survey, qualitative study and VIR band enrollment study the respondents were asked to read and sign a consent form before taking part. The study team members read and filled the consent form for respondents who were unable to read and write. The contents of the consent form were explained to each respondent, especially the purpose of the study and its benefits. A copy of the informed consent was provided to each study participant and a copy kept by study team for internal records. All recordings of the IDIs and FGDs were also made with the informed consent of the participants.

All participant information is kept confidential. Personal identifiers (names and address) of all participants of the household survey and enrollment study are masked and will not be shared with unauthorized persons. The HHS and enrollment databases are secured and password protected, and only the research team has access to this information. All the hard copies of

the qualitative study, HHS and enrollment form are locked at TVI head office with limited access by authorized personnel only.

6. Formative study timeline

The formative study activities were formally started from January 2016 and recruitment of key staff (study coordinator, research supervisor) was completed in the first quarter. During the first quarter desk activities like working on protocols, tools and study guides were carried out. Field activities of pre-testing study tools and social mapping were started in the second quarter.

The first unanticipated delay was in the development of the HHS android based CAPI tool; thus, the HHS was moved forward by six months.

The VIR band enrollment study phase was moved forward by 8 months from September 2016 to May 2017, as there were unanticipated delays in testing and manufacturing of the VIR bands. The recruitment of new participants was extended for two more months (August and September 2017) months due to low turnover of infants to vaccination centers in the summer season and during religious festivities. The follow-up period was also extended for an additional one month (till January 31, 2018) since the team was stationed in the field site till that time and could follow-up on infants for study exit interviews.

At the end of the academic year for summer vacations (June-September) families visit their ancestral villages and three religious social events are enthusiastically observed in the intervention communities i) Ramadan (May 26 to June 24) and Eid ul Fitar during June 24-29, ii) ten days of Hajj and Eid ul Adha (Muslims observing the pilgrimage to Macca) during August 30 to September 4, 2017, and iii) fifteen days of Muharram rituals (commemorating the martyrdom of grandson of the Holy Prophet of Islam) from September 21 till October 19 2017. The healthcare center closures and reduced hours of operation of all public and private business during the three religious holidays was accounted for in the original work plan, and the team planned to start enrollment in September 2016 but due to delays in VIR bands manufacturing and arrival to Karachi the enrollment phase was conducted during the summer of 2017.

The original grant period was from December 2015 to March 2017 but due to delay the first No-Cost Extension (NCE) was requested and approved by 3ie for April 2017 to September 2017 and second NCE for October 1st 2017 to April 30th 2018.

7. Analysis and findings from the formative evaluation

7.1 Key findings of the qualitative and quantitative studies

The findings of the IDIs and FGD were similar, and there were no conflicting findings from the two data collection methods. A vast majority of community members were knowledgeable about the importance of vaccination in preventing disease and disability and were in favor of childhood routine immunization. They knew that the first doses of vaccines are given soon after birth and agreed on the importance of timely completion. Most of the infants do get the first vaccine within two weeks of age while others initiate one month after birth. The respondents were aware of the places where free vaccines are provided and did not have any access issues. It is common in the community to complete the immunization schedule, but some children miss the second dose of Measles vaccine. Apart from CHWs, none of the respondents were able to name the nine vaccine-preventable diseases. This was a crucial

finding as it identified the areas that needed attention during the communication and engagement activities.

Majority of community members use the home-based paper immunization record card to remember the dates of the scheduled doses but respondents from Sachal Goth who had experience with the VIR band phase one study identified the VIR and as a better option. Community members and community health workers stated that providing health information and reminders about vaccination due time is the best option for reminding parents about vaccination of their children. Both the parent groups and CHWs identified CHWs as the best means of promoting health messages in the community.

The respondents approved the VIR band intervention, and community members were open to new and innovative methods of vaccine due date reminders. Parents suggested they preferred getting the VIR from the health facilities or the CHWs while some also stated they preferred getting it from the VIR band team. Mothers in Sachal Goth site stated they needed their husband's permission to accept the VIR band for their baby while at Pehalwan Goth site they said they did not need permission from their husband to accept the VIR band.

The CHWs participating in the FGD were all trained about the importance and RI schedule; they were able to name the vaccine-preventable diseases and the prescribed ages to receive the vaccine doses. They all showed a willingness to participate in disseminating messages for timely vaccination and encouraging/referring parents for timely initiation. The CHWs in Pehalwan Goth stated that it is better for the study team to distribute the VIR band. The CHW (LHWs) stated that a sum of Pak Rupees 100-300 would be acceptable as an incentive for them to reach out to parents of newborn infants and refer them for timely initiation within 15 days of birth.

All the stakeholders during the IDI gave responses similar to the FGD participants; all were in favor of routine immunization, agreed to facilitate the uptake of VIR band in the community, were supportive of the VIR band intervention design and agreed to promote the message of vaccination timeliness and completion.

7.2 Key findings of quantitative study

In both study sites, vaccination centers were easily accessible to the community, most of the respondents in the household survey stated they walked to the center and for those who used motorized transport the cost was acceptable. The intervention sites have a large number of private healthcare providers, dentists, and trained birth attendants. There were several religious institutions and political parties active in the area and provide social services to the community members.

During the household survey, 97% of the respondents were in favor of vaccination and agreed that newborns should be vaccinated. Respondents were knowledgeable about vaccination timeliness, 70% of respondents reported that vaccination should be started soon after birth and 12% stated 1 week after birth as an appropriate age for initiation. However, respondents were not knowledgeable about complete RI schedule, as only 31% responded that a child has to visit the vaccination center four times/receive four doses of vaccine by four months of age. About 22% responded that they did not know the number of times a child receives vaccine by four months of age. Vaccination coverage is universal in the community as 93% of the children (analyzed for the youngest child in the household) in the household were vaccinated. However, the vaccination timeliness for Penta1-3 is a concern as less than a quarter of

youngest child in the household received the vaccine doses at the prescribed age. This finding supported our selection of the intervention site and design.

Community engagement and communication plan

The community engagement and communication activities were implemented during the second phase of the formative evaluation study. The 3ie technical reviewers encouraged the VIR study team to engage the community and stakeholders right from the beginning, for the design and later effective uptake of the intervention. The district health authorities allowed the VIR band team to enroll infants only up to two weeks of age, so to enroll a cohort of 500 infants it was also a logistic requirement to engage the community and CHWs to reach infants close at birth for timely initiation of the RI schedule. The conceptual framework of the socio-ecological model was used to develop community engagement and Social Behavior Change Communication (SBCC) activities to promote timely initiation of routine immunization of infants, as seen in Figure 2.

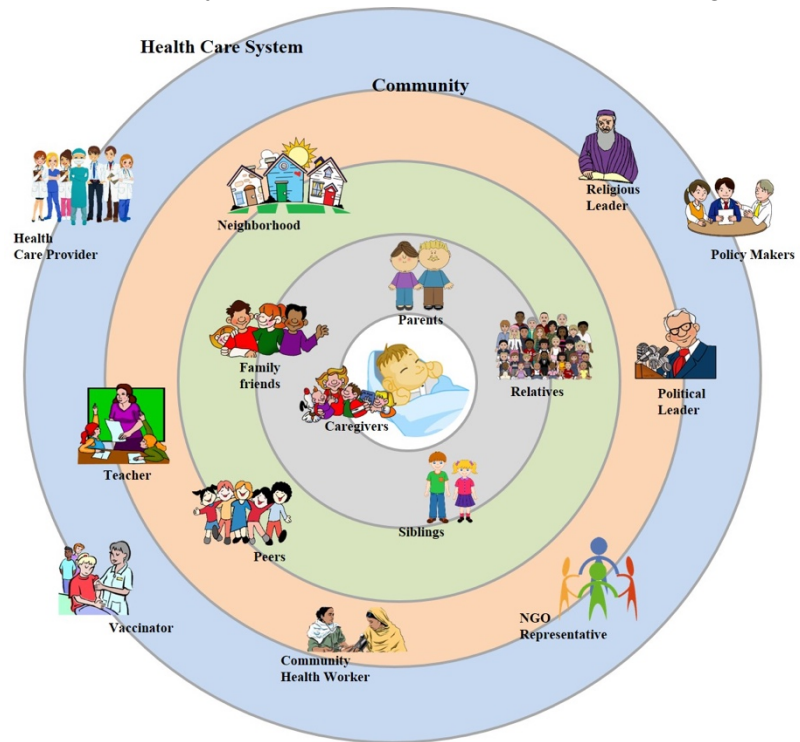


Figure 2: SBCC framework used in VIR Bank Study in Karachi, Pakistan

The behaviors of an individual are influenced not only by their personal perceived threats and benefits but is also affected and facilitated by the collective behavior of others in their surroundings (Salihi et al., 2015). Therefore, to reach an infant for timely routine immunization initiation, according to the socio-ecological framework, influencers at every level were identified. At the first level were (1) the parents/caregivers, siblings, family friends and immediate relatives of the infant. At the second level (2) were the neighborhood/neighbors, peers of siblings and parents and at the third level (3) were the community health workers and community influencers (religious, political and social leaders), NGO representatives working in the community and school teachers. Finally, at the fourth level (4) were the healthcare providers, vaccinators and immunization program planners, and managers who through service provision also influenced the vaccination status of the infant. Communication and engagement activities were planned around the four levels of the socio-ecological model to generate discussion about health and immunization at the household level so to bring about a social behavior change.

The community engagement and communication plan consisted of 7 different socio-behavior change activities:

1. Identification of Health Champions: The study team recognized households which had timely RI completion of their children (identified through the HHS) as a role model in

the community. They were provided with plaques placed on their home front door (with their permission) to motivate other people to follow their practice for timely and complete vaccination.

2. Selection, training, and engagement of child health ambassadors (CHA): Motivated and educated young community volunteers who meet the selection criteria were recognized as CHA. They were engaged by the study team to increase community participation and ownership of the VIR band intervention.
3. Individual meetings were conducted with various community influencers and union council members, district health officer (Karachi, East), and Directorate Health Services, Karachi Municipal Corporation
4. Group awareness session with community health workers, healthcare providers and parents/caregivers of infants in various cultural settings (religious centers, roadside cafes, community centers)
5. VIR band awareness session in schools in the community
6. One on one counseling of parents and caregivers at community health centers and in the community to promote timely initiation and completion of the RI schedule.

The CECP activities were monitored on a biweekly basis and reported on a quarterly basis in the CECP reports generated by the study team. A complete list and number of beneficiaries of the CECP activities are given in table 1. The CECP activity reporting was stratified by gender.

7.3 VIR band Enrollment Study - Results

The enrollment study was extended for three more months and was completed between May 2017 to January 31, 2018. Parents who refused to engage with the VIR band team, due to any reason, and the number of parents who refused to enroll their child in the VIR band study is not reflected in the database, but this information was noted by the research associates separately. The refusal rate was very low as only 4 parents refused to enroll their child in the VIR band study. A total of 787 infants visiting 4 selected EPI vaccination centers were screened for enrollment eligibility.

Table 2: showing the VIR Band enrolment by month for each visit in the VIR band study in Pakistan									
	Month of enrolment								Total
	2017								
	May	Jun	Jul	Aug	Sep	Oct	Nov	Jan	
A Forms / Yellow Bands	97	74	155	142	29	0	0	0	497
C Forms / Purple Bands	0	12	68	75	88	73	2	0	318
D Forms / Aqua Bands	0	0	10	56	54	70	58	0	248
E Forms	0	0	0	5	34	49	83	56	171
F Forms	0	3	6	15	48	62	92	142	226

7.3.1 Enrollment process

The study team enrolled 497 infants as they only had 497 intact Yellow VIR bands. Three of the Yellow (3/500) bands were damaged/tempered by customs/courier personnel. New participants were enrolled in the study from May 7 to September 9, 2017, and the last Aqua band was distributed on December 31, 2017. The last enrolled child was followed for four weeks till January 31, 2018.

The low turnover for enrollment during May and June can be explained by two socio-environmental factors: the high summer temperatures in Karachi, reaching to 45-50 degrees Centigrade (May-June) and the one-month fasting observed during Ramadan (Muslim month of fasting from May 26 to June 24, 2017). In July the highest number of children were screened and enrolled as well as excluded due to overage. A large number of exclusions due to missing the age cutoff can be explained by the same factors that resulted in the low turnover at the vaccination centers during May and June. During July and August, two months into the VIR band enrollment study, the total number of referrals and enrollment reached to the maximum, and this can be credited to the efforts of the research team and the referrals by CHWs.

The breakdown of the enrollment data for age in days for children who were coming to the vaccination center and the reasons for delay highlight the factors preventing timely initiation of the RI schedule. During the study data was collected on all children who were excluded due to overage and the two significant factors were the 1) parental belief that child is too weak for RI initiation and 2) there was no one to take the infant to the vaccination center. The first is a parental attitude about the vulnerability of infants but the second reason is a matter of gender disparity in accessing healthcare services since 54% of the infants visiting vaccination center for RI immunization initiation were accompanied by the mother (34%) or aunt (19%).

7.3.2 Overall follow-up compliance and loss to follow-up

The VIR band study after enrollment had three visits across the 18 weeks of every child's follow-up (Figure 3: **Schematic depiction of enrollment and immunization compliance according to visit and type of VIR Band**). The schematic process of the enrollment and follow-up reflects that among the cohort 61.9% of the infants completed the third dose of DTP containing vaccine (Penta-3). In relation to the originally enrolled children, overall follow-up visits wise compliance to immunization schedule, for 1st follow-up was 91.5%, for 2nd follow-up was 70.6% and for the 3rd follow-up was 61.9%. Among those who completed the schedule

up-to Penta 3, the proportion of those returning late for immunization (i.e., beyond 7 days of the date of the prescribed follow-up visit) was observed to be 28.6% for 1st follow-up, 56.4% for 2nd follow-up and 76.0% for the 3rd follow-up visits respectively.

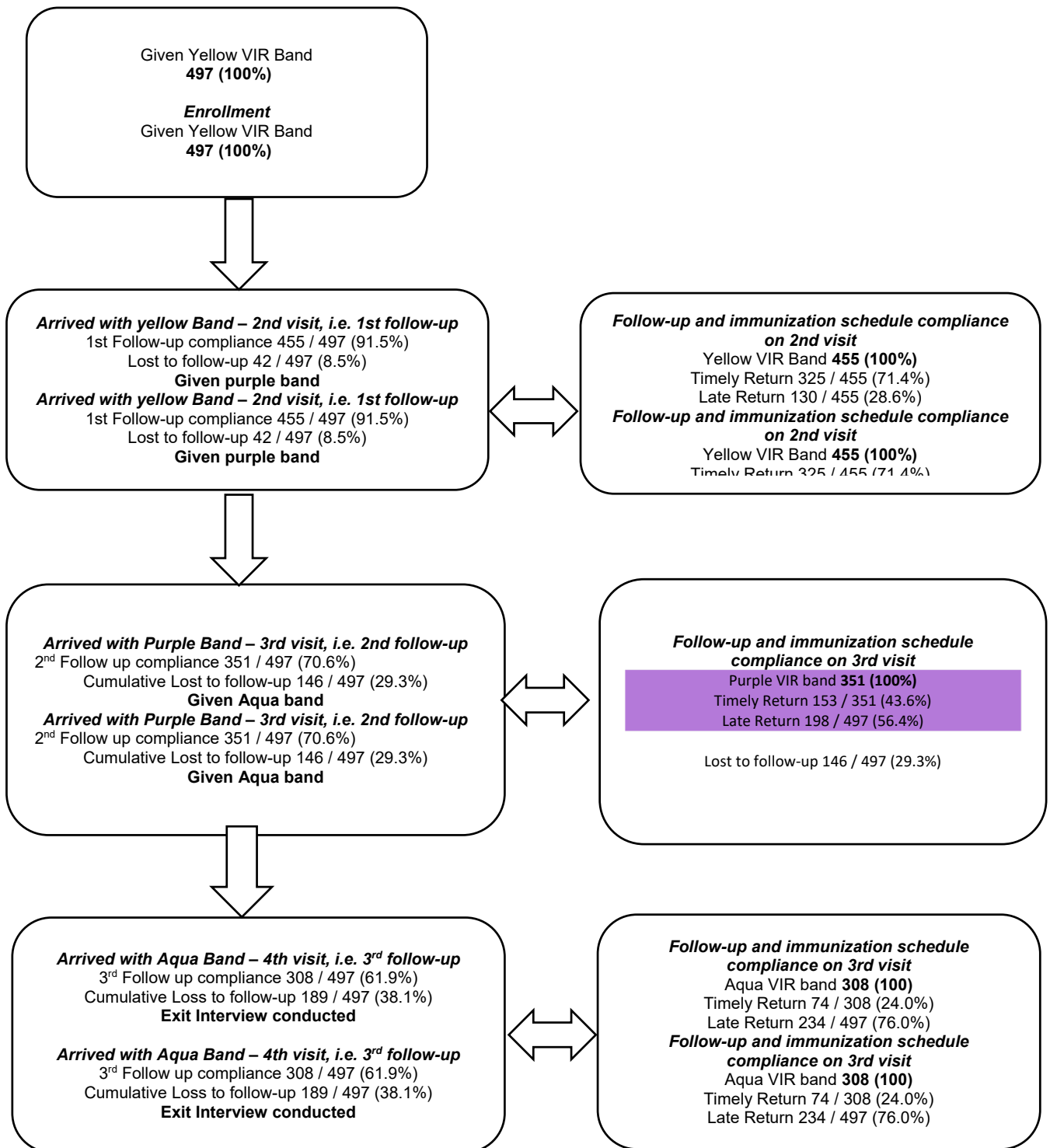


Figure 3: Schematic depiction of enrollment and immunization compliance according to visit and type of VIR Band

The loss to follow-up for the VIR band study reflected that overall there was nearly one-third of the originally enrolled children (38%) who were cumulatively lost to follow-up across the

	Enroll ment	Return for follow-up				P Value	
	#	%	#	%	#	%	
Yellow	497	100	455	91.5	42	8.5	
Purple	361	72.6	351	70.6	104	22.8	<0.001
Aqua	313	62.9	308	61.9	43	12.2	<0.055

visits. This conversely reflects as overall compliance of 61.9% (Table 3). The first follow-up had attrition of 8.5%, the second follow-up with 29.4% and the final and third follow-up reflecting 38.1%. The loss to follow-up was statistically significant for the 2nd follow-up (p-value < 0.001), while it was marginally significant for the last follow-up (<0.055).

	On time vaccination		Late Vaccination		Cumulative Loss to follow-up		Total	
	#	%	#	%	#	%	#	%
Yellow	325	65.4	130	26.2	42	8.5	497	100.0
Purple	153	30.8	198	39.8	146	29.4	497	100.0
Aqua	74	14.9	234	47.1	189	38.0	497	100.0

Among those visiting for follow-up visits, the timing for follow-up (within 7 days and beyond 7 days) was sub-categorized as on-time vaccination and late vaccination respectively (Table 4). It was observed that the proportion of late vaccination for the first follow-up was nearly one-quarter of the initially enrolled children (26.2%), more than one third in second follow-up (39.8%) and nearly half of them (47.1%) for the 3rd follow-up visit. Given that these latter proportions were non-cumulative, it is understood that with each subsequent follow-up visit, the rate of late follow-up increased. However, conversely it is also to be interpreted through the flow diagram and Table 4 findings, that the majority of parents/guardians had the PENTA 1-3 vaccines inoculated to their children, and these finding augurs well for the VIR reminder band innovation to improve EPI schedule compliance in resource-constrained settings of a developing country like Pakistan.

	#	%	N=497
Penta 1			
After prescribed date	130	28.6	26.2
Within prescribed date	325	71.4	65.4
Total	455	100.0	91.5
Penta 2			
After prescribed date	198	56.4	39.8
Within prescribed date	153	43.6	30.8
Total	351	100.0	70.6

Penta 3			
After prescribed date	234	76.0	47.1
Within prescribed date	74	24.0	14.9
Total	308	100.0	62.0

Further bisecting the timeliness of follow-up and compliance (Table 5) according to the Penta vaccine dose, it was derived that within each follow-up there was an increasing trend of those who were coming late for the Penta vaccines (with each subsequent dose), with Penta 2 visit having nearly half of the guardians/parents (56.4%) coming beyond 7 days of the prescribed vaccine date, and nearly three quarters (76%) for Penta 3. However, given the overall adherence of the majority i.e. nearly two thirds of the parents/guardians (61.9%) completing the Penta 3 vaccine, minor tweaking of reminder approaches for the VIR band may markedly increase the EPI schedule adherence rates, and consequently improve the vaccination completion and compliance rates in low and middle-income country settings.

Table 6: Follow-up visits for children who visited EPI center with or without referral card (RC) (RC was given by CHWs only for the first visit)						
	After Prescribed Date (N=130)		Within Prescribed Date (N=325)		Total (N=455)	
	#	%	#	%	#	%
Penta 1						
Yes	44	33.8	106	32.6	150	33.0
No	86	66.2	219	67.4	305	67.0
Penta 2						
	After Prescribed Date (N=198)		Within Prescribed Date (N=153)		Total (N=351)	
	#	%	#	%	#	%
Yes	73	36.9	48	31.4	121	34.5
No	125	63.1	105	68.6	230	65.5
Penta 3						
	After Prescribed Date (N=234)		Within Prescribed Date (N=74)		Total (N=308)	
	#	%	#	%	#	%
Yes	83	35.5	26	35.1	109	35.4
No	151	64.5	48	64.9	199	64.6

Follow-up visit wise availability of referral cards was inquired and observed by the research team across both the project locations (Table 6).

The results were bifurcated across those who arrived within the prescribed time frame. For Penta 1 visit, one-third of the respondents had a referral card with them. Similar proportions for the availability of referral card was observed for all the 3 follow-ups. This pattern was not markedly different across those who came within the given time frame for all the follow-ups and for those who came after the prescribed time frame.

Table 7: Children enrolled in VIR band study completing Penta 3, by gender of child						
	After Prescribed Date (N=234)		Within Prescribed Date (N=74)		Total (N=308)	
	#	%	#	%	#	%
Male	119	50.9	38	51.4	157	51.0
Female	115	49.1	36	48.6	151	49.0

Follow-up markers were analyzed across each of the visits with reference to the gender of the child (Table 7) and place of birth of the child (Table 8). These were analyzed to derive and identify any differential rate of vaccination across these indicators.

The pattern of frequency of follow-up across the sex of the child was consistent among the three follow-ups with both sexes having nearly equal and consistent representation for each of the band-based visit (*indicative results for Penta 3 follow-up only presented here*).

Place of birth for the child was considered as a proxy indicator for the health seeking behavior of study participants and also possibly an indirect marker of the economic status; where those having birth at a private facility and maternity home understood to be more affluent and having better health-seeking behaviors as compared to those who had birth at a government facility or home (Table 8).

	After Prescribed Date (N=234)		Within Prescribed Date (N=74)		Total (N=308)	
	#	%	#	%	#	%
At home	40	17.1	12	16.2	52	16.9
Government Hospital	9	3.8	2	2.7	11	3.6
Private Hospital	164	70.1	55	74.3	219	71.1
Maternity Home (LHW or TBA Home)	21	9.0	5	6.8	26	8.4

It was observed that there was no remarkable difference across those who arrived within the prescribed time frame and after the prescribed date for private hospital and maternity home categories. The similar consistent pattern across the within and after prescribed date categories was observed for those who had birth at home or the Government hospital/health facility. This finding can be used to infer that, there was no marked difference between those who returned late or within the prescribed time with reference to their healthcare seeking/utilization behaviors and their economic status.

	Pehalwan Goth (N=183)		Sachal Goth (N=314)		Total (N=497)		P Value
	#	C%	#	C%	C%	N	
Yellow							
Late return for follow-up	48	26.2	82	26.1	26.2	130	<0.001
Timely return for follow-up	131	71.6	194	61.8	65.4	325	
Lost to follow-up	4	2.2	38	12.1	8.5	42	
Purple							
Late return for follow-up	74	40.4	124	39.5	39.8	198	<0.321
Timely return for follow-up	62	33.9	91	29.0	30.8	153	
Lost to follow-up	47	25.7	99	31.5	29.4	146	

Aqua							
Late return for follow-up	88	48.1	146	46.5	47.1	234	<0.193
Timely return for follow-up	33	18.0	41	13.1	14.9	74	
Lost to follow-up	62	33.9	127	40.4	38.0	189	
<i>C% reflects column percentages</i>							

Table 10: Child returned for follow-up at the vaccination center with VIR band						
	Yellow (N=455)		Purple (N=351)		Aqua (N=312)	
	#	%	#	#	%	#
Yes	362	79.6	305	86.9	255	81.7
No	93	20.4	46	13.1	57	18.3

Table 11: VIR Band on child's ankle on follow up visits to the vaccination center						
	Yellow (N=362)		Purple (N=305)		Aqua (N=255)	
	#	%	#	#	%	#
Yes	334	92.3	280	91.8	238	93.3
No	28	7.7	25	8.2	17	6.7

Table 12: Status of VIR band among children visiting EPI center during follow up visit without/was not on child's ankle, VIR band						
	Yellow (N=121)		Purple (N=71)		Aqua (N=74)	
	#	%	#	%	#	%
At Home	18	14.9	5	0.7	15	20.3
Lost	69	57.0	45	63.4	40	54.1
In Hands	31	25.6	12	16.9	17	23.0
Child is vaccinated at another place	2	1.7	0	0.0	0	0.0
Don't know	1	0.8	9	12.7	2	2.7

A sub-analysis of field site-wise timeliness of those who returned for follow-up was conducted to understand similarities and differentials across the two field sites of Pehlwan Goth and Sachal Goth (Table 9). It was derived that across the two field sites the pattern of proportions related to timely follow-up was not statistically significantly different for the Purple and Aqua bands. A significantly higher proportion of study participants from Pehlwan Goth had a timely return for follow-up for the Yellow VIR band (p-value <0.001); hence reflecting better compliance rate among Pehlwan Goth participants.

7.3.3 VIR Band availability across follow-up visits

The respective VIR bands availability was recorded across the follow-up visits during the study. It was found that for the first follow-up nearly one-fifth of the children did not carry the VIR band. The availability of VIR bands was much better for the purple and aqua band, where a higher proportion as compared to the yellow band, had brought the baby with VIR band

	Yellow (N=455)		Purple (N=351)		Aqua (N=312)	
	#	%	#	#	%	#
Yes	319	70.1	258	73.5	233	74.7
No	80	17.6	57	16.2	45	14.4
DNK	56	12.3	36	10.3	34	10.9

Among those who came for follow-up, the vast majority (i.e., > 90%) across all the follow-up visits had the band on the ankle of the child (Table 11).

Status/current availability of VIR band was further explored for those children who did not have it during follow-up visits or it was not on their ankle.

It was reported that the highest proportion among this sub-group had lost the VIR band. The

	Yellow (N=80)		Purple (N=57)		Aqua (N=45)	
	#	%	#	%	#	%
VIR Band didn't function	44	55	25	43.9	20	44.4
Forgot to vaccinate	2	2.5	3	5.3	2	4.4
The child was sick	8	10	16	28.1	13	28.9
No one available at home to bring child to center	4	5	2	3.5	2	4.4
Band was lost temporarily	8	10	1	1.8	4	8.9
Vaccinator was not there	2	2.5	1	1.8	0	0.0
Child was out of town	12	15	8	14	4	8.9
Other	0	0.0	1	1.8	0	0.0

proportion of VIR band lost status was the highest for purple band (63.4%) followed by the Yellow band. It was interesting that nearly one fifth of the guardians/parents of the children in this sub-group had not lost the aqua band, but had forgotten it at home, while nearly one

quarter had brought the child for vaccination with the yellow and aqua bands in their hands and not on the ankles as per the study criteria (25.6% and 23.0% respectively) (Table 12).

During each follow-up visit, the specific segment of the quantitative questionnaire was used to collect data. The parents/caregivers were instructed at the time of enrollment and during each follow-up about the change of color as the cue for the due date for vaccination. During enrollment of an infant in the study the accompanying parent/caregiver was provided information about the correct age for each vaccine; however, when they were asked at each follow-up visit "did they think their child received the vaccine on time", nearly one-tenth responded across the yellow-purple-aqua bands responded as "did not know". One possible understanding derived from this finding is that possibly different caregivers/guardians were accompanying the child across the follow-up visits, and it was not necessarily the same parent/guardian who was educated during enrollment. Nearly one-sixth of the respondents at the subsequent follow-up visits reported that the vaccination of child was late.

The majority of those who came late for the follow-up vaccinations for the all the three bands reported malfunctioning of the VIR bands as "reason for delay". Those who reported that the vaccination was late, further inquiry was made about the reasons for the delayed follow-up visit (Table 14).

Table 15: Respondent's relationship with the child during each visit

	Yellow (N=455)		Purple (N=351)		Aqua (N=312)	
	#	%	#	%	#	%
Mother	282	62.0	231	65.8	197	63.1
Father	111	24.4	62	17.7	62	19.9
Grand Mother	32	7.0	37	10.5	28	0.9
Grand Father	2	0.4	0	0.0	3	0.1
Uncle	8	1.8	4	1.1	5	1.6
Aunt	16	3.5	12	3.4	15	4.8
Brother	1	0.2	2	0.6	1	0.3
Sister	3	0.7	3	0.9	0	0.0
Other	0	0.0	0	0.0	1	0.3

The sickness of the child was the second most common reason for the delayed visit for the purple band (third visit).

Relationship of the respondent with the child was asked at the time of each follow-up visits (Table 15).

Nearly two-thirds of the respondents across all the three band-based visits were mothers, followed by Fathers as the second most common respondent. A smaller proportion of grandparents were the respondents across the visits.

7.3.4 Functioning of VIR Band

The condition of the VIR bands across the follow-up visits was observed and recorded for each follow-up visits. This was done for infants who were brought to the vaccination center with VIR band on their ankle and for infants whose parents brought VIR band with them

	Yellow (N=386)		Purple (N=306)		Aqua (N=272)	
	#	%	#	#	%	#
Accurate	125	32.4	89	29.1	26	9.6
Ink leakage	20	5.2	6	2	3	1.1
Moisture	37	9.6	7	2.3	3	1.1
Broken	5	1.3	4	1.3	5	1.8
Time strip detached from the band	1	0.3	4	1.3	0	0.0
Serial number not visible	0	0.0	1	0.3	0	0.0
Missing	5	1.3	0	0.0	0	0.0
At home	9	2.3	4	1.3	9	3.3
Stopped	184	47.7	191	62.4	226	83.1

(though it was not at secured at the child's ankle). Nearly half of the yellow bands (47.7%), about two-thirds of the purple bands, and the vast majority of aqua bands (83.1%) had "timestrip" not working during the follow-up duration. Accurate working was recorded for one-third of yellow bands and purple bands (32.4% and 29.1%), while a very small proportion (9.6%) of the aqua band filled on time. (Table 16).

A major setback to the VIR band intervention was the unacceptably high failure rate of the "timestrip" indicator encased in the silicone molding. Within the first 8 weeks after enrollment started the defect in the "timestrip" card was reported by parents. Our teams were in constant touch with the CHWs and started receiving feedback from the community as soon as the issue surfaced. The failure of the vast majority of "timestrip" was an emergency and required the urgent change in VIR band protocols. In our original plan skin rash/irritation to VIR band only was recognized as an adverse event but with feedback on the performance of the VIR band, any delay in child immunization due to the breakdown of the "timestrip" was also labeled as an "adverse event" based on epidemiological criteria. The research team decided to call back parents after two weeks if parents missed the due date. During the call, the parents were asked if the "timestrip" indicator had filled and in case of a negative response ("no") then parents were informed that the specified period had elapsed and that they should return to the vaccination center for the infant to receive his/her subsequent vaccine doses. In case the parent/caregiver did not receive the call on the first time (the phone was powered off or temporarily out of network) the team would call back at two different times. If the parents did not receive the call on the third time also, they were labeled as "loss to follow" for that specific vaccine. Cell phone numbers that were incorrect were followed-up by the address on the record. Moreover, in case no address was found, and if the infant was referred by CHW, the latter would be contacted to assist in reaching the parents. In case none of the strategies worked to reach the infant's parents/caregiver the case was labeled as "loss to follow". A

separate record was maintained of all the calls made to parents, and parent’s responses about VIR band/ “timestrip” status.

The research team shared the "timestrip" failure with the manufacturers as soon as communities reported it. Several rounds of discussion were carried out to identify possible remedial steps. The research assistants were given refreshers for adequate activation of the timestrip and the samples sent to manufacturers for lab investigations.

The difference in the proportion of VIR bands being accurate (filled completely and on time) among the three VIR bands indicates an unanticipated manufacturing flaw and not an issue with design performance of the VIR band and "timestrip" card. Among the VIR bands returned by the parents, the proportion of bands that were accurate was at, 42% among six weeks "timestrip" in Yellow VIR bands, 33% among four weeks "timestrip" in Purple bands and only 9% among four weeks "timestrip" in Aqua VIR bands.

Table 17: Parents/caregiver informed about the VIR band and immunization during visit to immunization center		
	(N=308)	
	#	%
Yes	280	90.9
No	1	0.3
Don't Know	27	8.8

The failure of the "timestrip" accuracy in the VIR band affected the results of Penta 1-3 timeliness. The Penta 1-3 timeliness can only be assessed for fully/accurately functioning VIR bands.

The parental experience with the VIR band was assessed during the study exit interviews. The biggest frustration of using the VIR band was the failure of the ink progression on the “timestrip” membrane (ink on the membrane did not fill on time/arrested progression). The parents reported that the failure of the ink to fill the membrane completely and on time caused the delay in their bringing their children on time.

Table 18: Parents/caregiver knowledge about the VIR band		
	(N=280)	
	#	%
Helps in reminding about the routine immunization on time	264	94.3
Doesn't cause any harm to the child	10	3.6
No unexpected reaction due to VIR band	2	.7
Don't remember	4	1.4

7.3.5 Knowledge, experience and opinions on VIR Band and Immunization

Respondents at the time of exit interviews were asked questions related to their knowledge about VIR band. These questions pertained to their knowledge levels based on information sharing-education on immunization and VIR band that was extended by the research team staff during the enrollment process, and during each of the follow-up visits (except the last/fourth visit). The vast majority of the respondents responded that they were informed about the VIR band (90.9%). The 9.1% exit survey respondents who did not know or said No

for this query, were found to be those guardians/parents who were not present at the time of enrollment and follow-up visits and some other family member or guardian had accompanied the child in the earlier visits¹².

Table 19: Parents/caregivers opinions about immunization (Multiple response)		
	(N=279)	
	#	%
Helps child's immunity against diseases	130	46.6
Prevents diseases	146	52.3
Makes the child healthier	16	5.7
Important for protecting children from disabilities	52	18.6
Cures diseases	52	18.6
Vaccinating the child on time protects the child	42	15.1
Not completing routine immunization schedule can cause diseases in child	1	0.4

When inquired about the details of VIR band, among those who knew about it, the majority (94.3%) reported that its primary benefit/function is to remind about getting the routine vaccination on time. These findings auger well for the VIR band study since the majority of those completing follow-up visits and hence the vaccination schedule up to the Penta III vaccine had right know-how about the VIR innovation, its usage, and benefits. The finding also augers well for possible second and larger phase testing for this innovation.

Table 20: Parents/caregivers opinion on VIR Band as a useful tool to remind about routine immunization		
	(N=308)	
	#	%
Yes	277	89.9
No	13	4.2
Don't Know	18	5.8

Knowledge about immunization and its importance was explored through querying this aspect from the exit survey participants. Nearly half of the interviewees shared that immunization protects children against diseases, while about one-sixth shared that immunization can prevent disabilities.

Table 21: Parents/caregivers opinion on how VIR band is beneficial as a reminder for immunization schedule		
	(N=277)	
	#	%
It reminds all the time	213	76.9
It is waterproof	14	5.1
It is easier to understand/comprehend and take care of	16	5.8

¹² Due to small numbers result not presented in table format

Timely reminder of child's vaccination schedule	33	11.9
Don't Know	1	0.4

Inquiry about usefulness and benefit of VIR band, revealed that the bulk of exit survey participants considered it to be useful (89.9%), (Table 20) while a very small proportion was not knowledgeable or did not share an opinion in this regard. Those who opined favorably about the VIR band were then asked about the views on the benefits of this reminder innovation (Table 21). Nearly three-quarters of the respondents opined that it is a continuous reminder, while about one-tenth of them shared that it gives "timely" reminder.

Table 22: Parents/caregivers response “they would recommend VIR band to family and friends”		
	(N=308)	
	#	%
Yes	289	93.8
No	10	3.2
Don't know	9	2.9

The vast majority of exit survey respondents shared favorable views for recommending this useful innovation to family and friends (Table 22).

When the said finding of favorable opinion was stratified across the field sites among exit survey participants, it was found that a statistically significantly higher proportion of these participants from Pehlwan Goth were carrying such opinion (p-value < 0.02).

Table 23: Parents/caregivers response “they would recommend VIR band to others”, in two study sites							
	Pehalwan Goth (N=121)		Sachal Goth (N=187)		Total (N=308)		P-value
	#	C%	#	C%	#	C%	
Yes	119	98.3	170	90.9	289	93.8	<0.020
No	2	1.7	8	4.3	10	3.2	
DNK	0	0.0	9	4.8	9	2.9	

Given that from the initially enrolled number of 497 participants, more than half (277/497 = 55.7%) recognized the benefits of VIR band and were in favor of recommending it to others (289/497 = 58.1%); these findings are encouraging keeping in view the short follow-up time frame for this pilot study. The finding also warrants a larger scale testing of this promising innovation to improve vaccination coverage and EPI schedule completion rates especially in poor and resource-constrained settings in the LMICs where the health system faces daunting challenges in improving immunization coverage rates among children.

7.3.6 Factors associated with follow-up visit wise adherence to timely vaccination

Cox regression - survival analysis with hazard ratio and Kaplan Meier curve outputs were derived to identify factors associated with compliance to vaccination schedule for VIR bands.

This analysis was conducted across three stages, where the first stage of univariate stage involved survival analysis for yellow band (i.e. based on time factor regarding follow-up

between BCG-Penta I), survival analysis for purple band (i.e. based on time factor regarding follow-up between Penta I-Penta II), survival analysis for Aqua band (i.e. based on time factor regarding follow-up between Penta II-Penta III). The stratification variable was field site (i.e., Pehlwan Goth and Sachal Goth). Kaplan Meier curves for each of these stages were generated (Figure 4-6).

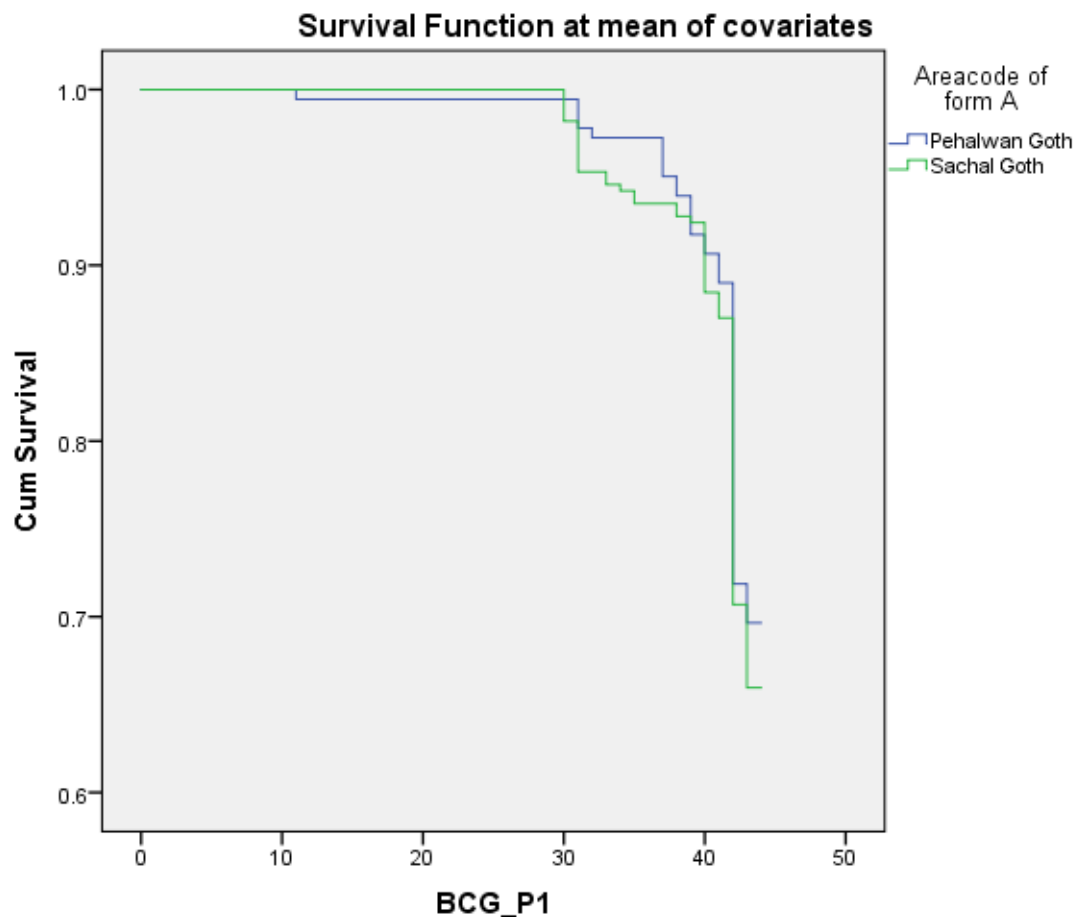


Figure 4: Survival function curve by field site for follow-up between enrollment and 2nd visit

As understood through descriptive analyses and univariate analysis, the rate of censoring was higher in Sachal Goth for each of the follow-up phases as compared to the Pehlwan Goth. This is reflected through a higher end-point value of green line in each of the graphs as compared to the blue line on the x-axis scale. The finding can hence be interpreted to reflect that there was a higher rate of attrition/loss to follow-up in Sachal Goth as compared to Pehlwan Goth.

The second phase of Cox regression included the bi-variate stage of analysis for each phase of the follow-up. The co-variate uniformly deployed for this bi-variate stage was the age of respondent at each of the respective follow-ups, while the main bi-variate analyzed variable was the field site. A similar pattern of censoring was observed for this stage.

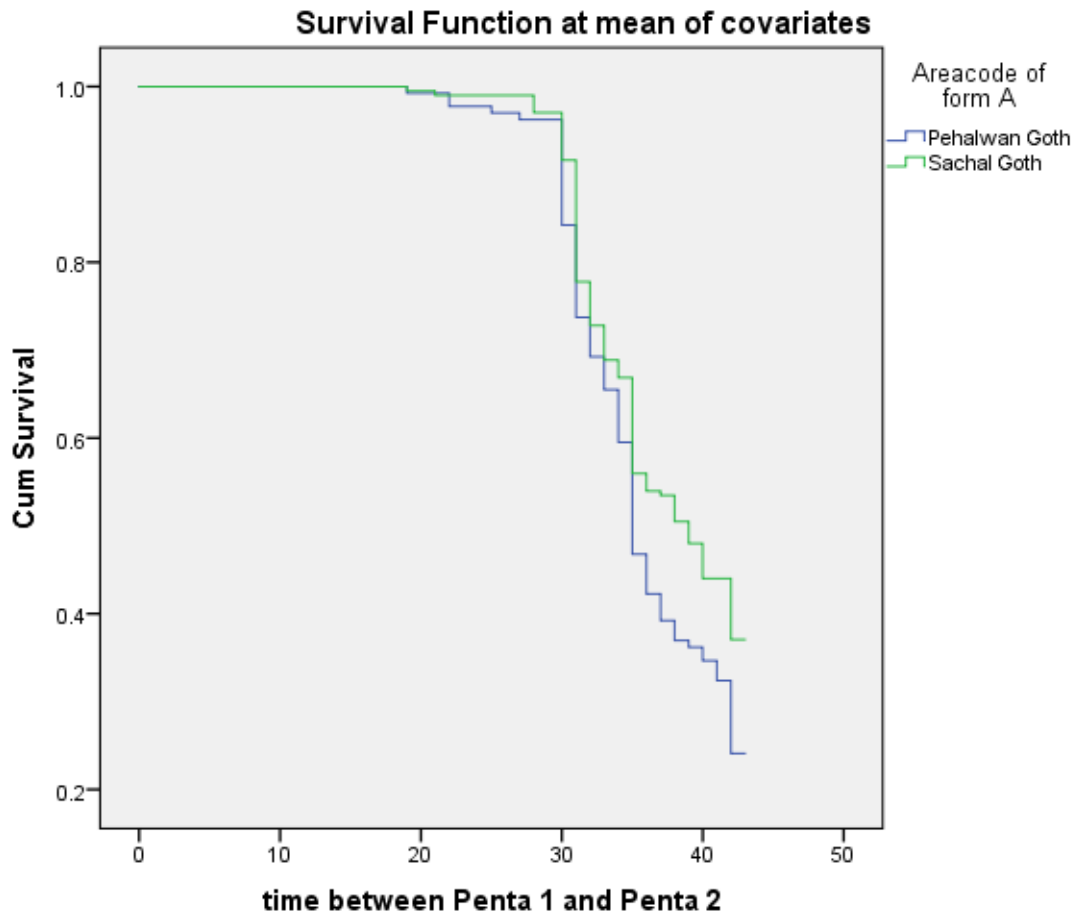


Figure 5: Survival function curve by field site for follow-up between 2nd and 3rd visit

Finally, the third stage of Cox regression involved multi-variate analysis in which the overall follow-up time between the time of enrollment till the fourth visit (i.e., BCG-Penta III) was adopted to be the time variable (graph not depicted here). Follow-up visit within the prescribed time frame was retained as the event of interest for Penta III vaccine. Parsimonious model building technique was used to develop a multivariate model that would best describe the compliance to vaccination schedule and presented through β coefficient, adjusted Hazard Ratios with respective 95% confidence intervals and Wald statistics-based p-values.

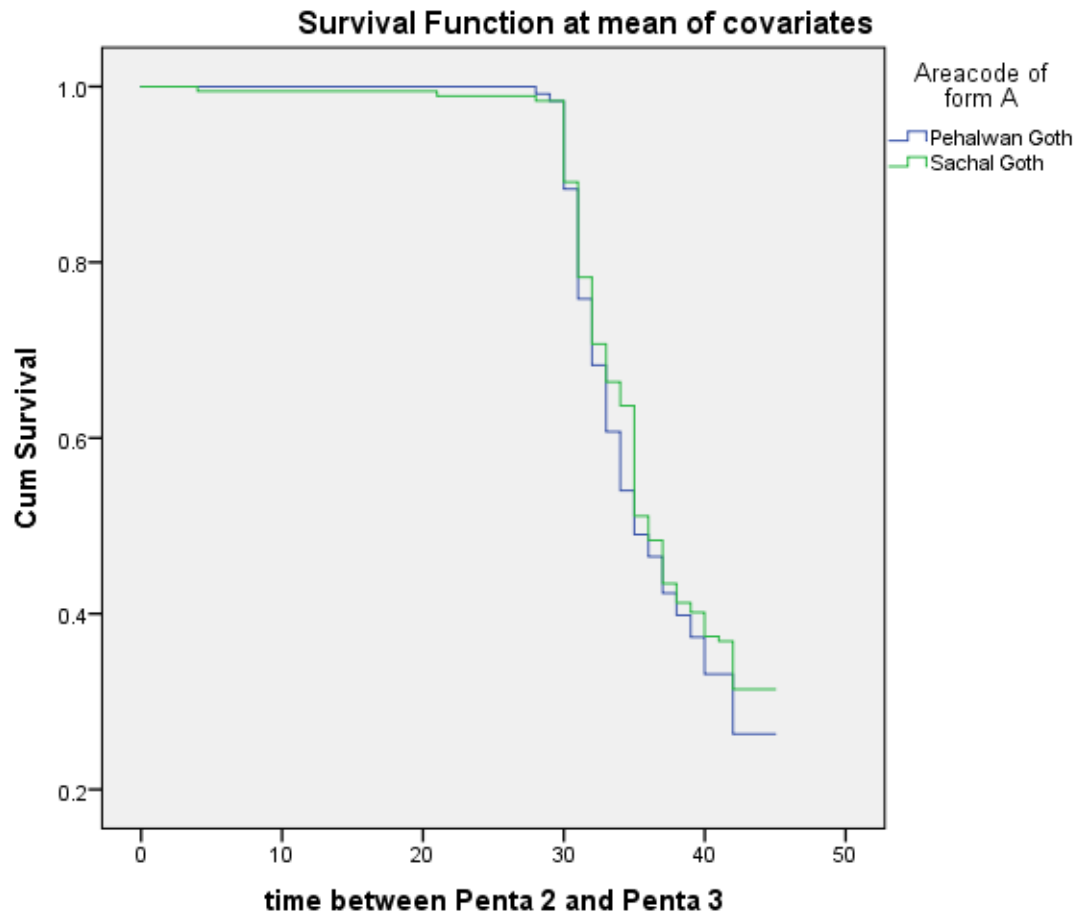


Figure 6: Survival function curve by field site for follow-up between 3rd and 4th visit

The variables included in the final multivariate model included the age of child (days) at the time of enrollment/BCG vaccine, Sex of the child, Respondent's age at the time of enrollment, Mother's education, Father's education, Place of birth of the child, field site and respondent's relationship with the child. Except for the continuous scale of the age of child and age of respondent, all other included indicator's variability had to be reduced to dichotomous level given the small numbers in this pilot study.

It was found that as the age of respondent at the time of enrollment increases by one year, the probability of compliance to completion of vaccination schedule increases by 1.02 times; thus reflecting that older parents/guardians are more likely to complete the vaccination schedule.

The latter significant finding if coupled with the RMNCH domain's already available empirical evidence in the country, that younger mothers/guardians are less likely to have favorable health-seeking behaviors, can be transcribed to encourage parenting at later ages to improve vaccination (and hence increase child survival) in a developing country like Pakistan.

All variables included in the final parsimonious model had no significant association with adherence to the vaccination schedule. This lack of statistical association is understood to be a reflection of the small number of participants in the study, as well as possibly attributable to a high rate of loss to follow-up/censoring across the 18 weeks. Given some indications through lower p-values for mother's education and field site, it is inferred that a larger powered study

to further test this tremendous innovation may bring out definitive evidence for associated factors related to VIR band associated compliance to vaccination.

Table 24: Final multivariate Cox regression model for factors associated with vaccination compliance based on VIR band reminder

Table 24: Final Multivariate Cox regression model for factors associated with Vaccination compliance based on VIR Band reminders				
Variable	β	Adjusted Hazard Ratio Exp (β)	95 % CI	p- value
Age of child at enrollment (days)	-0.011	0.99	0.93 – 1.05	0.73
Sex of Child Male Female	-0.11	0.896 1.00	0.56 – 1.43	0.65
Respondent’s age at enrollment (years)	0.02	1.02	1.01 – 1.01	0.01
Father’s education Educated Uneducated	-0.073	0.93 1.00	0.52 – 1.63	0.80
Place of Birth of child Private Hospital-Maternity Home Home – Government Hospital	0.069	1.07 1.00	0.61 – 1.87	0.81
Field Site Pehlwan Goth Sachal Goth	-0.33	0.72 1.00	0.45 – 1.16	0.18
Respondents Relationship with child Mother All other relations	0.13	1.14 1.00	0.98 – 1.33	0.09

Such a larger study (that accounts/controls for the nuances faced during this pilot study), should also be able to demonstrate that if the acceptability of bands is high (as demonstrated through this study as well), vaccination coverage rates in resource-constrained settings can be markedly improved through innovative, and user-friendly reminder approaches across the globe and especially in LMICs.

7.4 Discussion

The parental acceptance and compliance with use of VIR band is a significant predictor of the success of the intervention. The results of the enrollment data answered the primary research questions 1.1 through 1.4 and 2.1 through 2.3. The most reassuring finding of the VIR band intervention was the very high parental acceptance of not just the Yellow VIR band at vaccination initiation (100%) but agreeing to continue with the Purple (73%) and Aqua (86%) VIR bands at subsequent 2nd and 3rd visits. The high parental compliance with VIR band retention and returning it to the VIR team on subsequent visits indicate that the VIR band is considered as a valued item.

The “timestrip” card gives the VIR band the value-added advantage over other wearable vaccination reminders as it’s changing color serves as constant and active reminder, which is not observed with NFC pendants and silicon bands with symbols.

The parents who decided to opt out of the VIR band intervention mostly decided to do so because they reported vaccinating at another center or moving out of the intervention area. Only ten infants were moved out of the VIR band intervention because the husband/family refused to continue. There was no way of verifying the responses, and we do not have responses from among the loss to follow.

During the household survey and pretesting of the VIR study enrollment forms the parents got suspicious when they were asked about their household income and showed reluctance to participate in the study. To avoid any suspicion among parents the economic/household income data was not collected during the VIR band enrollment study. Therefore, we cannot comment on the distribution of the VIR band intervention sample and parental acceptance and compliance by wealth quintiles. All the data is segregated by sex of child, ethnicity and parental educational status. The qualitative data gathered during IDIs, FGDs and feedback from healthcare providers and policymakers during formal and informal meetings show that all major stakeholders value the utility of the VIR band and are optimistic about its large-scale implementation. The primary constraint to large-scale implementation is lack of funding by the public sector. The government program managers expect that donor agencies fund any largescale implementation of the VIR band intervention. The accuracy of the "timestrip" card of the VIR band was compromised due to an unanticipated manufacturing flaw, resulting in only 42% of the Yellow VIR bands, 33% of Purple and 9% of Aqua VIR bands filling completely and in the specified period. The success of the VIR band intervention suffered a major setback due to the performance failure of the "timestrip" to accurately indicate the elapsed time and serve its purpose of an active reminder to parents to revisit the vaccination center. Among children who received a Yellow VIR band, 73% (361) returned to the vaccination center for Penta-1 vaccine and among these 40% (199) received their due vaccine within one week of the prescribed date.

The encouraging fact is that despite experiencing flaw in the Yellow and Purple bands, the parents continued to accept the intervention and returned to the center with the band on subsequent 2nd, 3rd and 4th visits. Parent/caregivers were asked at each follow-up visit "how the VIR band was an effective reminder" and the most frequent response was that "it changed color". The VIR band is an innovative concept and a viable option for effectively reminding parents of the due time to revisit the vaccination centers.

The process of the VIR band intervention was closely monitored through fortnightly updates from the field staff, monthly update of the work plan, and monthly meeting of the VIR band team meeting and follow-up on the minutes of the previous meeting. The progress of the intervention, challenges faced and lessons learned was shared by the team during each monthly meeting and reports were generated for each quarter. Activities were planned for each month and the quarter and their completion checked accordingly.

The SEEP activities were also tracked and reported for each quarter along with the means of verification for each activity. All the activities included in the initial work plan (March 2016) and the revised work plans were completed with delays due to various reasons, details mentioned under section study timeline, but were completed within the revised timelines in the final work plan. There was no difference between actual and budgeted cost even though the study cycle was extended beyond the initial 18 months period. The VIR band intervention was not

implemented at the household level, but household level data was collected during the baseline survey. The team with the support of the community gatekeepers were able to complete the HHS in the specified time frame. Part of the VIR band community engagement and communication plan was to place plaques in front of houses where all children were fully immunized and up-to-date for their immunization. The study team was allowed by all homeowner to place the plaque except where the house was rented. The VIR band team also re-visited households which had reported during the HHS that the household head was against vaccination. All these households met with the PI and team and showed no hostility toward the team or VIR band intervention. The team probed the reasons for not vaccinating children or being against vaccination and found that the main reason for not vaccination was previous negative experience after vaccinating. One grandmother stated that despite vaccination, one of her grandchildren had passed away. In the same household there were vaccinated and non-vaccinated children, depending on the parent's decision. Since the VIR band team had developed a good rapporteur with the community at large, the healthcare workers and community volunteers, the team left a positive impression in the community.

At the community level arranging a large group session was a challenge as the notables promised to gather large groups for orientation session but only small groups attended. The community members would be more interested in attending the session when refreshments were provided. The original plan was to distribute the VIR band into the community among newborn infants through the LHWs, and the NBC approved the proposal for this design. In the original ToC assumption was that CHWs have deep connections with the communities they serve so involving LHWs would increase vaccination timeliness among infants. However, with feedback form LHWs during social mapping, the protocol was changed to giving them referral cards only. This design turned out to be a better option as LHWs participation turned out to be very low, they made only 2% of the referrals. Our assumption was also refuted, and we need to understand the low level of participation by LHWs in future studies.

The community health workers namely the FCV actively participated in disseminating the VIR band messages and successfully referred infants to the vaccination centers. They were reimbursed, and the VIR team regularly meet with them in person which was vital to their continued support during the cohort recruitment phase. Due to the high cost of living and limited earning opportunities, monetary incentives play a significant part in CHWs participation, however, in our experience the LHWs were not very active even with paid incentives. The LHW program performance is not uniform across various districts, and even at union council, there are differences in service delivery by this cadre of CHWs. For more than a decade the LHWs are the focus of every primary healthcare interventions by development partners leaving the LHWs to underperform their job of promoting family planning. Fatigue among LHWs can be prevented if development partners recruit other cadres of community volunteers.

The vaccine delivery system in Pakistan is managed by three different partners working in cellos with some integration. The district healthcare system runs the primary healthcare facilities housing the vaccination services provided by the EPI. The second partner, LHWs are part of a different vertical program, are tasked with community outreach. The third player, the development partners like WHO and UNICEF provide technical support and facilitate the supplementary immunization activities and hires the FCVs. Only now the different partners are trying to create linkages and integration at various points of services delivery. The VIR band intervention had to coordinate with all different stakeholders in the vaccine delivery

system making sure each partner was informed and aware of the activities. Getting buy-in from the provincial health department was a significant challenge as there was frequent change in top management. The midlevel management has no system in place to track the record of visits and documents shared with the department. For this, the VIR band field coordinator's monthly and quarterly work plans included the task to meet with all stakeholders at the sub-district (Tehsil) level on a monthly and the district level at quarterly intervals. The study PI made a point to meet with provincial program managers at least once every six months.

TVI was always able to bring on board motivated, and energetic team members but staff turnover was a major concern and at times a setback. The field coordinator was replaced twice, research supervisor three times and research assistants more than five times. This created disruptions in the program as new team members had to be familiarized with different activities and in understanding their job descriptions. The difference in education, training and field experience varied between team members, resulting in delay in important tasks like online data entry, data cleaning and detailed reporting of field challenges.

During the VIR band intervention, the team developed, tested, verified several tools and implemented plans and designed mechanisms. The documents were developed in coordination with the research team and implementation partner grant and financial managers.

The qualitative findings were used in the development of quantitative tools, and the later were used to verify the findings of the former. The VIR band intervention used new tools like social mapping which is not used commonly by health programs. Even large-scale interventions in the province have not conducted social mapping of their intervention sites as detailed as those carried out during the VIR band intervention. The social mapping exercise was used to identify the key community stakeholders who were then approached for the qualitative IDIs.

The SEEP template and Progress and Learning formats provided by 3ie greatly facilitated reporting to the agency as well as internal planning and reporting within the team. The introduction of technological advancements like the use of CAPI android based survey tools and online digital record keeping of the study participants posed challenges of usability among field team members. At the same time, quality control measures and real-time reporting was facilitated. Information Technology is one field that needs to be vigorously integrated into public health interventions particularly immunization. The lack of IT professionals trained in Public Health is becoming more and more imperative as we move towards digitalization and automation of health services.

The use of mobile-based transfer of funds to female CHWs was faced with resistance initially as many had never used it before. The team members repeatedly met with them and provided assurance, so once the process was streamlined the ease, and timely transfer of funds was very encouraging. The FCV work in teams visiting homes in the community and would make referral together, but since the mobile-based transfer was possible to one person at a time they were told to figure a way to share the incentive money. The TVI institutional knowledge and staff expertise proved very useful in the design and implementation of all tools, mechanisms, and plans.

Implications of formative study findings

7.5 Implications for the intervention

Revised intervention design

1. The VIR band has been successful in getting the attention of development partners as an effective intervention for improving vaccination timeliness and completion. The UNICEF country office in Pakistan has provided the team with letter of intent to support if the VIR band effectiveness is tested in a higher-powered study.
2. The VIR band evaluation/ Phase II RCT study is recommended to be carried out in a health and demographic surveillance system (HDSS) settings. This will greatly reduce the cost of implementing the intervention as the HDSS studies have mechanism in place to collect data on all women, mothers to be and newborn infants in the catchment area
3. The enrollment of infants close at birth in the VIR band RCT will be facilitated if the study is done in the HDSS setting. This will ensure timely initiation of RI and include children who would otherwise have delayed RI initiation.
4. In low resources setting the VIR band intervention can be implemented in conjugation with other programs that also have the objective of improving immunization coverage. One such example is the UNICEF Urban Slum intervention which is focused on increasing Measles I and II immunization. The UNICEF Urban Slum program has engaged CSOs for community mobilization during Measles vaccination campaigns.
5. Rapid social mapping to identify all health resources available to the community and service providers coming into direct contact with newborn children and their parents/caregivers should be part of VIR band intervention. Social mapping exercises are already being conducted by UNICEF during the SIA for Polio and Measles. The UNICEF social mapping takes count of every child under five years of age in the community. The most time-consuming component of the social mapping exercise in the VIR band study was the household line listing and identifying children under two years of age. UNICEF can be approached to share data of social mapping of communities covered by their program. The VIR band team can focus on identifying each and every cadre of healthcare provider working in the community and mapping all health producing resources available to the community.
6. The VIR band intervention would try to engage, train and incentivize service providers and healthcare cadre most active in the community to refer infants for RI soon after birth.
7. Extensive community engagement and communication campaign should precede VIR band enrollment phase. The major stakeholders would include community gate keepers, EPI program field and center staff and healthcare workers and providers most active in the community. During the social mapping exercise, the key stakeholders in each community can be identified and engaged prior to roll out of the VIR band intervention.
8. The VIR band would integrate technology such as use of android app on a palm held device for enrollment of infants into the VIR band intervention.

The original plan to distribute the VIR band to infants through LHWs and CMWs was changed at the beginning of the intervention as LHWs refused to distribute the VIR bands to mothers because they did not want to come into conflict with mothers of infants who did not meet the enrollment criteria. This change proved to be very useful in several ways, first, community midwives though present on paper were not functional in the catchment area, secondly the LHWs despite their enthusiasm for the VIR band during engagement accounted for only 2% of the referrals and finally since the VIR band was distributed only at the centers there was minimum wastage and loss.

In any future VIR band intervention the cadre of CHWs most active in a given community, birthing assistants (TBAs and trained) and pediatric healthcare providers will be engaged and incentivized to refer infants to the vaccination centers soon after birth. In larger powered VIR band study, number of referrals made by each cadre of providers will be shared among them as well as with the larger community on a quarterly basis. Areas where the FCV are not active and after the end of FCV program, CHWs engaged with other programs, like nutrition and community volunteers willing to participate in the intervention will be engaged. The Child Health Ambassadors (CHA) engaged and trained by the VIR band team are another cadre of workers who can promote timely initiation and completion of RI.

Any new intervention, especially when it is an innovation that has not been tested elsewhere needs a more rigorous launching campaign for maximum uptake and minimize chances of misinformation. Prior to rolling the VIR band intervention robust and systematic community engagement and communication activities have to be undertaken. The VIR band formative study originally did not have the “Community Engagement and Communication Plan” (CECP) but with feedback from 3ie to include the stakeholders right from the beginning, the plan was developed and implemented. During the implementation of the CECP the team realized the utility of this component and reached out to as many community members as possible during the VIR band enrollment period.

From a design perspective, timely initiation of RI is also important for the success of the VIR intervention. The VIR band silicon band length is designed for infants 0-5 months, any delay in initiation and increase in age and ankle circumference will pose a challenge to enroll older infants. Detailed social mapping was not part of the original proposal approved by 3ie, but once in the community, as the VIR band team had to locate healthcare, birthing and vaccine providing facilities, it realized the need to identify all stakeholders and community health workers to promote timely initiation of RI and introduce the VIR band intervention. The social mapping exercise enabled the team to list all the health producing resources available to the community and note any accessibility challenges in accessing vaccination centers. The information gathered during the social mapping exercise proved useful throughout the VIR band intervention, especially during the design of the community engagement and communication plan and its rollout. The social mapping exercise at the subdistrict level can be completed within two weeks with the use of Autocad for map making.

A “MySQL” based program was used to enter the enrollment and follow-up information of all infants enrolled in the VIR band study. The software allowed all the 4 devices (laptops) to be connected via internet to each other, to avoid duplication and facilitate data entry even if infants visited different vaccination centers for their three follow-up visits. The custom designed enrollment form was only accessible on a laptop and at the enrollment centers all the 4 teams always faced challenges with adequate space to place the device. In the next phase the enrollment form will be designed on a palm held device to facilitate filling information and carrying it in a shoulder sling to allow for mobility of the team during enrollment.

7.6 Revised theory of change

Most of the assumptions listed in the ToC were validated, like community acceptance of vaccination and interventions for improving vaccination timeliness. Public vaccination services were easily assessable and acceptable to the community. The assumption that monetary incentive will encourage LHWs to actively follow-up on new born infants for timely RI initiation was partially met. In the future studies the intervention cannot rely solely on CHWs to reach

to infants. Communication and engagement activities will have to be intensified to reach infants close at birth.

7.7 Anticipated timeline

The completion of the formative evaluation was largely delayed by main components of the study. The first delay was due to the re-design process, following the finding that the “timestrip” indicator performance was compromised due to the silicon molding. The second delay was due to the low turnover of infants to the vaccination center in the first two months of the enrollment phase. The plausible explanation for this is the very high temperatures and the parents observing Ramadan¹³ during May and June. The anticipated changes in the timeline are based on the fact that the VIR band in the second phase will be a fully tested and manufactured device ensuring 99% accuracy of the “timestrip” indicator. Secondly enrollment may get slow due to extreme temperatures during summer and winter and month-long religious festivities keeping families occupied. Accounting for these two delays the second phase of study of enrolling cohort of 1500 children and following them for 18 weeks, will be completed in 15 months.

7.8 Implications for future research

The VIR band is an innovation with high community acceptance and parental compliance, as well as recognized by stakeholders as a viable option for improving vaccination timeliness and completion among children. The VIR band formative evaluation study has generated evidence that the intervention is doable at a larger scale and well accepted by families and stakeholders alike. Provided the accuracy of the “timestrip” card in the VIR band is guaranteed the intervention qualifies for a randomized control trial (RCT). The objective of the RCT will be to test the efficacy of the VIR band in reminding parents of due time of 2nd, 3rd and 4th visits to vaccination center to improve timeliness and completion of Penta 1-3 vaccine doses. The primary outcome variable will be the proportion of children with up-to-date immunization at 20 weeks of age.

8. Major challenges and lessons learned

The VIR band study team downloaded the Pakistan National Bioethics Committee (NBC) application packet from the official website and submitted it in February 2016. The application was returned, and the team was required to resubmit on a new format which was not updated on the NBC website. The study team had to comply and resubmit and received ethical approval and no changes were required for the research objectives, survey instruments, and study design. Though the resubmission did not delay field planned activities for the second quarter the process consumed time and effort on the part of the team.

The study team secured approval from the NBC and the EPI program to enroll children up to 30 days of age, but this was unacceptable to the district health officer (DHO)/manager and vaccinators in the field sites. The VIR band team had to comply with the requirements imposed by the DHO and EPI field staff to gain permission for conducting the study in their centers and secure cooperation of their staff.

On ground presence of health workers is at times different from reported figures, the VIR band intervention planned on engaging two government-employed cadres of community health workers; Lady Health Workers (LHW) Program and Community Midwives (CMW) hired by the National Commission for Maternal, Neonatal and Child Health (NCMNH). During the social

¹³ Note: May 26-June 24, 2017, Muslim religious obligatory one month of fasting from dawn to dusk

mapping exercise, we could not locate the two officially designated CMWs posted in the two intervention communities. The team inquired about the designated CMWs from local Union Council members, primary healthcare center in-charge and community members, yet no one knew about them. As the study team never located this cadre in the intervention community, they could not be engaged or provided training of any sort as defined in the original protocol.

During social mapping, the study team inspected the mandatory community health journals/records maintained by Lady Health Workers. The LHWs provide several key primary health care interventions, but our team observed that their record keeping was not up to date and they were not aware of all new births in the community.

During social mapping the team identified another cadre of community health workers, the female community volunteers (FCVs) hired by WHO/UNICEF for supplementary immunization activities (SIA) to eradicate polio. This cadre is utilized for SIA activities only, but they are a valuable asset for reaching to the community. Of the 162 infants referred to the VIR study, 98% were sent by FCVs.

Traditional Birth Attendants (TBA) though not utilized by the health programs for message dissemination nor given recognition by the government are an essential cadre of CHW. They influence parental decision making and can spread the message of timely initiation where they are actively providing birthing services.

It was a challenge for the VIR band team to engage with male community members during the usual working hours of 9AM-5PM as most men would be out attending to their jobs. The operating hours of all the public vaccination centers 9am-2pm also posed a challenge for reaching to the men and disseminating the key VIR band messages to them. The VIR band male team members often had to stay back after 5 PM to meet with community influential and decision makers of child health.

The VIR band intervention was using three technology-related products; the first was the Timestrip, second was the data collection apps and third the online immunization registry. Each was important in implementation and had to be custom built for the study. Each of the three technologies posed major challenges to the team.

The "timestrip" silicon molding unexpectedly disrupted its performance, and the team is working closely with the manufacturer to overcome this issue. Developing an Android based CAPI app was another challenge as the team did not have the in-house capacity and had to depend on Aga Khan University technical staff for the task. The research team aimed at doing the entire intervention on a paperless basis, where all data collecting and reporting tools would be digital. However, the delays and repeated system errors in the Android app discouraged the team from digitizing all reporting tools. The local market for app development is very limited and with fewer developers having experience working in the health sector. The cost of international developers is very high therefore any technology related product has to be adequately budgeted early on and with larger timeframes for unexpected delays.

VIR Band's online enrolment system's front end is PHP (Personal Home Page) and HTML (Hypertext Markup Language) based, and backend has MySQL (My Structured Query Language) server for database operation. Though it was developed to be user-friendly, still the field staff struggled with understanding and easy data entry. Few team members were able to master the database entry process thus they ended up doing most of the data entry. Hard copies of the HHS forms and enrollment forms were developed as a backup plan in case

of software/electricity failure, the team members preferred to use the paper tools due to familiarity which added to their workload and doubled data entry.

The field staff also faced issues with net connectivity and power outages in enrollment centers. The space provided to the VIR band team at the enrollment centers was limited, and where vaccinations were taking place, there was no separate table for the research associates to keep their laptops. The team faced issues keeping their laptop with them during enrollment and activation of VIR band. Though there were two team members at all times, one to engage with parents and the other to record data, the later was always a challenge. Our learning is that any time field-based data entry is involved it is highly advised to use lightweight, long battery life, palm held devices.

The team during the social mapping and household exercise were thought to be part of the polio team or revenue board, and in both instances, the locals did not want them to visit the community. The VIR team had to wear their ID badges at all times to differentiate themselves from other program workers.

The data quality control was maintained through biweekly checks for completeness and correct entry. Since the database was MySQL based and data was analyzed in Stata, each time the database had to be imported and made sure that string variables were imported correctly. The checks and limits placed by the database programmer required several variables to be recoded once the data was imported into Stata and SPSS for analysis. The VIR band enrollment data analysis was all performed in SPSS.

Maintaining strict adherence to the planned timeline was a challenge due to frequent turnover of the key and field staff members and unavailability of skilled staff when the team needed one. Data analysts and PhDs in Biostatistics are not always available. The development of CAPI app and digital database resulted in delays in initiation of second and third phase of the intervention, but once activities were initiated each was completed within three months of specified times. The most significant delay in start of enrollment phase was due to the long time it took over repeated testing of the VIR band form and function and the manufacturing of accurate and efficiently performing "timestrip" cards. The industry partners of the VIR band were supportive, but the task of developing the VIR band did not receive top priority as compared to the for-profit and high yielding commercial products.

The VIR band study team had to strictly observe the bureaucratic hierarchy when approaching healthcare managers and policymakers. To secure Letter of Understanding from the Lady Health Workers Program and District Health Officials the team had to first secure formal approval from the Provincial Health Secretary. The vertical programs like EPI are autonomous, but with increasing integration, they too recommend approval from the highest health official in the province.

Building rapporteur with mid-level health managers is essential as they are easily accessible and can be instrumental in reaching out to higher/senior health officials. Regularly attending different health seminars, meetings and dissemination events of different health programs is an effective way to network and build alliances with program managers and policymakers. The EPI Program Director arranged the VIR band team meeting with the Provincial Health Secretary and upon his request the Secretary Health signed the final approval letter.

The VIR band received support and encouragement from all major community stakeholders, RI, LHWs and FCV program manager, and health policymakers. The key lesson learned was

to continually engage with all stakeholders identified in the SEEP document and share results at every stage and different forums.

Continued sharing of results at diverse platforms and engagement with non-health stakeholders is also key to being recognized. The VIR band presence on social media is maintained on its "Facebook" page which is regularly visited, liked and shared within the contacts and list shared. The VIR band intervention has been appreciated not only by health planners but also highlighted on the Radio, TV and print media.

The major challenge that nearly sabotaged the entire VIR band study was the high product failure rate of the "timestrip" indicator, the details of band breakdown have been explained in the results section. Before the start of the study the VIR band was pretested in several rounds and only when 99% accuracy of the timestrip card was established that the final design was approved and order for 3000 bands manufacture was finalized. Despite all these efforts and the manufacturer's quality control measures something went wrong during processing of the timestrip card into the silicon band. As soon as the first batch of Yellow VIR band were reported as defective (delayed filling) by parents, the manufacturer was informed, and they ran required tests to figure out what went wrong. The cards were laser dissected and inspected under the microscope but no apparent damage to the Timestrip was detected.

The design and manufacturing team at PDC are working on ensuring to get the final design and manufacturing process details to ensure that future VIR band does not have any manufacturing defects.

The frequent turnover of vertical program directors namely the LHWs and EPI the team had to constantly visit new officers. The EPI program director was changed twice during the VIR band formative evaluation study. During the report writing phase the EPI had an acting program director who refused to make any commitments or provide letter of intent to support. A new program director took charge of the EPI program in September 2018 and now he is reluctant to provide the VIR band team a letter of support despite repeated visits by VIR grant manager. Efforts are being made by the grant manager and PI to secure a letter of intent of support from the EPI program director. It is encouraging that UNICEF provided the VIR band a letter of intent of support which will be used to convince the EPI program to do the same.

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10. Annexures

Additional Tables

Table 25: Parental compliance, VIR band on the ankle of child during follow-up visits in the two sites, Karachi, Pakistan

		VIR band on the ankle of child during follow-up visit in the two sites, Karachi, Pakistan					
		Pehalwan Goth		Sachal Goth		Total	
		#	%	#	%	#	%
Yellow	Yes	129	90.8	205	93.2	334	92.3
	No	13	9.2	15	6.8	28	7.7
	Total	142	100.0	220	100.0	362	100.0
Purple	Yes	111	89.5	169	93.4	280	91.8
	No	13	10.5	12	6.6	25	8.2
	Total	124	100.0	181	100.0	305	100.0
Aqua	Yes	96	92.3	142	94.0	238	93.3
	No	8	7.7	9	6.0	17	6.7
	Total	104	100.0	151	100.0	255	100.0

Table 26: Accuracy of "timestrip" and parental response "VIR band" as effective reminder, Karachi, Pakistan

Accuracy of the "timestrip indicator" in Karachi, Pakistan

	Proportion	Frequency	Total
Yellow VIR bands filled on time (six weeks)	41%	157	386
Purple VIR bands filled on time (four weeks)	33%	101	306
Aqua VIR bands filled on time (four weeks)	9%	25	272

VIR band as an effective reminder of vaccine due date, parental response, Karachi, Pakistan			
	Yellow	Purple	Aqua
Parents reported that the VIR band reminded them for vaccination due date	283 (73%)	227 (74%)	177 (65%)
Parents reported that the effective way to remind about routine immunization	277 (89.9%)	263 (89.7%)	271 (90.03%)
Parents reported that the VIR band is an effective reminder as it changes color	170 (60.0%)	138 (60.7%)	70 (39.55%)

Table 27: Socio-Demographic characteristics of children enrolled in the VIR band study, Karachi, Pakistan

	Frequency	Proportion
Mean Age days (SD)	9.3 (3.9)	
Median	9	
Time of visiting the immunization center for children enrolled in VIR study		
<= one week	130	26.2%
1 - 2 weeks	299	60.2%
At 15 days	68	13.7%

Has the child visited the center with a referral card

Yes	162	33%
No	335	67%

Who has given the referral card?

FCV	158	98%
LHW	4	2%

Age of respondent

Mean (SD)	34.4 (13.7)	
Median	30	
< 20 Years	35	7%
20 – 30	241	49%
31 – 40	104	21%
41 – 50	56	11%
>50	61	12%

Respondent relation with the child

Mother	167	34%
Father	93	19%
Grand parents	116	24%
Aunt	92	19%
Sister/Brother	11	2%
Uncle	15	3%

Child's gender

Female	235	47%
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Male	262	53%
Child's place of birth		
At home	88	17.7%
Government Hospital	17	3.4%
Private Hospital	353	71.0%
Maternity Home (LHW or TBA Home)	39	7.8%
Child's ethnicity		
Urdu Speaking	51	10.3%
Sindhi	261	52.5%
Punjabi	29	5.8%
Baloch	15	3.0%
Pakhtoon	72	14.5%
Siraiki	59	11.9%
Hindko	5	1.0%
Kashmiri	2	0.4%
Other	3	0.6%
Child's mother's education		
Uneducated	192	38.6%
Primary	64	12.9%
Middle	49	9.9%
Matric	97	19.5%
Intermediate	42	8.5%
Graduation	34	6.8%
Masters	7	1.4%

Religious Education	11	2.2%
DNK	1	0.2%

Child's father's education

Uneducated	113	22.7%
Primary	46	9.3%
Middle	54	10.9%
Matric	127	25.6%
Intermediate	58	11.7%
Graduation	56	11.3%
Masters	37	7.4%
Religious Education	4	0.8%
DNK	2	0.4%

10.1 Annexure A: Roles and responsibilities of governmental and non-government health personal involved in the delivery of the VIR band intervention

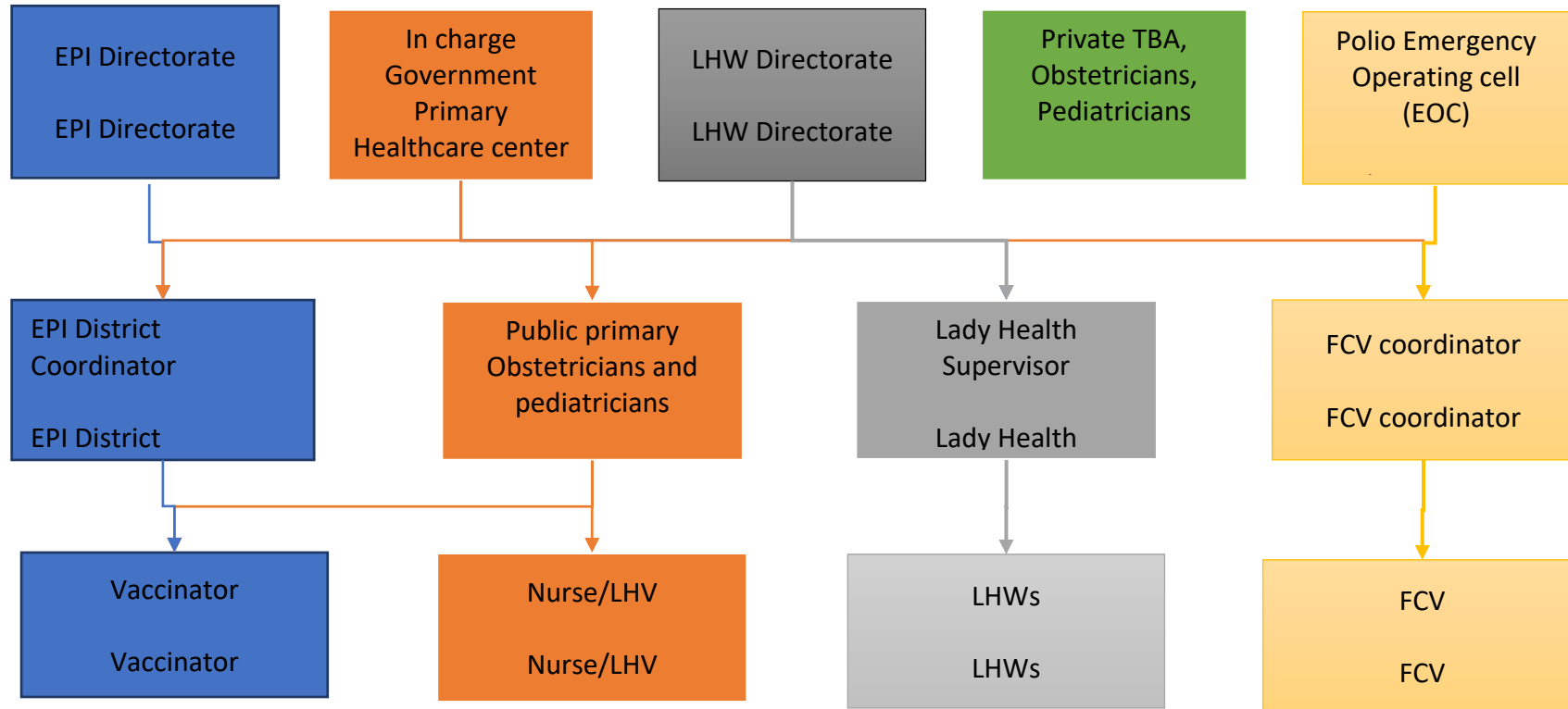
Acronym	Full Description	Employer	Position created by intervention	Specific additional tasks in the intervention	Part /Full time	Remuneration
LHW	Lady Health Workers	Sindh Lady Health Workers Program for Family Planning and Primary Health Care	No	Give referral cards to newborn infants on routine home visits	Part time	Reimbursement for every successful newborn referred for BCG vaccine within 2 weeks of age
LHS	Lady Health Worker's Supervisor	Sindh Lady Health Workers Program for Family Planning and Primary Health Care	No	Give referral cards to newborn infants on routine home visits	Part time	Reimbursement for every successful newborn referred for BCG vaccine within 2 weeks of age
CMW	Community Midwives	National Commission on Maternal, Neonatal and Child Health	No	The team was not able to locate this cadre of community health worker in the intervention area	N/A	N/A
FCV	Female Community Volunteers	UNICEF/ Polio Eradication Program	No	Give referral cards to newborn infants on routine home visits	Part time	Reimbursement for every successful newborn referred for BCG vaccine within 2 weeks of age
TBA	Traditional Birth Attendants	Private	No	Give referral cards to newborn infants after assisting delivery	Part time	Reimbursement for every successful newborn referred for

						BCG vaccine within 2 weeks of age
N/A	Obstetrician/ Trained Birthing Assistants (Nurse, Lady Health Visitor)	Private and Public sector	No	Provide counseling to parents for timely initiation	N/A	Provided with custom printed prescription pads
N/A	Pediatrician	Private and Public sector	No	Provide counseling to parents for timely initiation	N/A	Provided with custom printed prescription pads
DHO	District Health Officer	Health department: GoS	No	Monitoring visits of the VIR band study activities	N/A	N/A
N/A	Vaccinators	Expanded Program on Immunization	No	Vaccinate children and at the fixed EPI sites Direct parents to VIR team	Full time	N/A
GM	Grant manager	TVI	No	-Oversee the financial and logistics management -Timely fund disbursement - Financial report	Part time (2 hours a day)	Monthly salary by TVI
FC	Field coordinator (1)	VIR band grant/Trust for Vaccine and Immunization	Yes	-Oversee the performance of the VIR field team and all field activities -Engage and share updates with community/healthcare stakeholders -Evaluation Progress and learning report writing	Full time	Monthly Salary by TVI

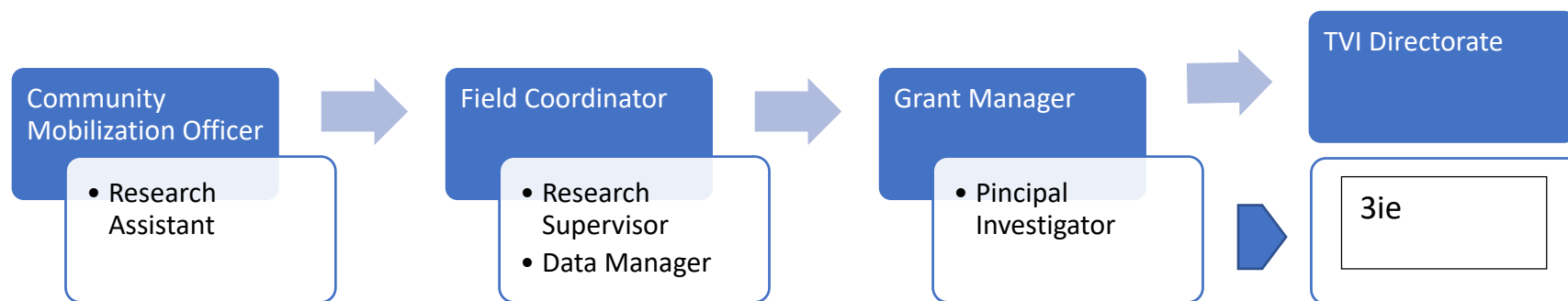
RS	Research supervisor (1)	VIR band grant/Trust for Vaccine and Immunization	Yes	-Oversee the protocols, tools, reporting procedures -SEEP report writing	Full time	Salary by TVI
N/A	Data manager (1)	VIR band grant/Trust for Vaccine and Immunization	Yes	-Household survey data management -VIR band enrollment database development, management and quality control	Full time	Salary by TVI
CMO	Community mobilizer officer (2)	VIR band grant/Trust for Vaccine and Immunization	Yes	-Engage community members and conduct sessions -Arrange field activities Facilitate FC -Report challenges faced in the field and their solutions	Full time	Salary by TVI
N/A	Research Associate (2)	VIR band grant/Trust for Vaccine and Immunization	Yes	-Facilitate CMO in all activities -Arrange field activities -Report challenges faced in the field and their solutions	Full time	Salary by TVI
RA	Research Assistants (8)	VIR band grant/Trust for Vaccine and Immunization	Yes	Facilitate CMO Engage and communicate with community Enroll and follow up children in the VIR band study	Full time	Salary by TVI

CHA	Child Health Ambassadors	Community Volunteers	Yes	Promote the VIR band message	Part time	Certificate of appreciation, CHA logo shirt and cap
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10.2 Annexure B: Health personal reporting organogram in the VIR band study in Karachi, Pakistan



10.3 Annexure C: VIR Band Team reporting organogram for the formative evaluation in Karachi, Pakistan



10.4 Annexure C: Logical Framework Table for the VIR band study in Karachi, Pakistan

Logframe				
Categories of Planned Work and Intended Results	Narrative Summary/ Timeframe	Indicators	Means Verification	of Assumption
Long-term Outcome	RI timely completion seen as social obligation 2 years	<ul style="list-style-type: none"> 90% infants with timely initiation and completion of RI 	Household survey/ Digital immunization registry Third party evaluation	
Intermediate Outcome	1 years	<ul style="list-style-type: none"> 10,000 infants receive VIR band intervention Penta-1,2,3 timeliness and completion Parental prioritization of timely initiation of RI 	End-line household survey/ Digital immunization registry Evaluation by study team	VIR band is scaled at the district level VIR band intervention conducted in HDSS setting Infants enrolled at home in HDSS setting Higher power RCT with multiple arms and control
Short-term Outcome	Parental acceptance and compliance with VIR band and returning	<ul style="list-style-type: none"> 40% of cohort received Penta 1 vaccine within 1 week of prescribed age 	Enrollment database: Form E Form C, D, E Form F	VIR band intervention graduating to next phase of funding by 3ie/Gavi VIR band form and function enhanced to 99% accuracy

to vaccination center within 3 days of “timestrip” filling/visual cue

May—2017 to Feb—2018
9 months

- 61% of cohort received Penta 3
 - 61% parents at exit interview reported others inquired about VIR band
 - 84% parents at exit interview said they would recommend VIR band to family and friends
 - 98.5%, 96.2% and 93.4% of respondents correctly identified age for Penta 1, 2 and 3 vaccines
 - EPI policy makers supporting VIR band
 - Feedback from community, healthcare providers about utility of VIR band
 - Difference between budgeted and
- Letter of understanding from EPI supporting the VIR band intervention
 - Healthcare provider dissemination meeting minutes
 - Community dissemination meeting minutes
 - Financial report Submitted to 3ie
-

		actual implementation cost		
Outputs	<p>-The processes are streamlined and team works to complete tasks detailed in the work-plan in specific time period</p> <p>-Research and implementation team work synchronized</p> <p>January 2016—December 2017</p> <p>24 months</p>	<ul style="list-style-type: none"> National Bioethics Clearance Certificate Letter of Understanding with EPI and District Health Department and Lady Health Workers Program Baseline study reports (Social Mapping, Qualitative Study, Household Survey) Cohort of 497 infants enrolled in VIR band study and followed for 18 weeks Evaluation progress and learning quarterly reports Online immunization 	<p>-Copies of Official letters</p> <p>-Baseline *Qualitative study report,</p> <p>*Social Mapping Report</p> <p>*Household Survey Report</p> <p>-Quarterly *Evaluation Progress and Learning Reports</p> <p>*SEEP -Reports</p> <p>-Final report major challenges and learning</p> <p>Submitted to 3ie by research and implementation team</p>	<p>Assumption: -CHWs are very active in the community and have up-to-date information about newborns in the community</p> <p>-CHWs will send maximum referrals which will facilitate early completion of enrollment of 500 infants</p> <p>Learning:</p> <p>-LHWs made only 2% referrals</p> <p>-CMW none functional</p> <p>-FCVs and TBAs most active in community</p> <p>-Enrollment of 497 infants completed from May—September 2017</p> <p>Assumption: Engagement and incentive for CHWs would increase timely initiation of RI schedule</p> <p>Learning:</p> <p>-Not all children visiting the enrollment center were from VIR band study catchment areas where CHW were engaged</p> <p>-Main reason for parental delay of BCG vaccine/timely initiation is parents being busy/mother not fully recovered from delivery</p> <p>-Parents assumption that infant is too weak for getting vaccines</p>

records of 497
infants

- 162 referrals by
CHWs
- SEEP activities over
a period of 24
months
- SEEP quarterly
reports
- Facilitators and
barriers to VIR band
implementation at
household,
community,
healthcare workers
and health policy
level
- Problems faced by
the field staff in
implementing the
VIR band
intervention
- Dissemination of
the VIR Band
Community
Engagement
Intervention

-
- FM105, National Radio Show “Men not allowed but gentlemen are” with Shreen Aktar
 - Ajj TV, Social Roundup Show with Alina Memon
 - Sindh TV Show
 - EPI Partners of Sindh “Annual Meeting”, Karachi, Sindh
 - VIR Band included in the Johns Hopkins Bloomberg School of Public Health Centennial Time Capsule (May 2017)
 - VIR band nominated for display at the Vaccine Delivery team at the Bill & Melinda Gates Foundation Visitor Center, Seattle,
-

Washington, United States (September 2017)

- Shaheed Zulfikar Ali Bhutto Institute of Science and Technology “Social Behavior Change Communication Seminar”, Karachi, Pakistan
 - National Health Service Academy, Annual Public Health Conference, Islamabad, Pakistan
 - UNICEF Country Office, Health Team, Islamabad, Pakistan
 - JHPIEGO Research Seminar in Karachi, Pakistan
 - VIR Band Community engagement and Communication
-

Plan Paper poster presentation at “International Social Behavior Change Communication Summit”, Nusa Dua, Indonesia

<p>Activities</p>	<p>VIR band team work in intervention sites with support from the respective communities</p> <p>July 2016—April 2017</p> <p>9 months</p>	<ul style="list-style-type: none"> • Social Mapping Exercise: • Development and verification of detailed maps of the catchment area • Line listing of all structures in the catchment area • Identification of households with children under two years of age in the catchment area • Identification of all health, vaccination and birthing providers/centers and education 	<p>Quarterly</p> <p>-SEEP Report</p> <p>-Evaluation Progress and Learning Reports</p>	<p>Assumption: Detailed maps will be developed in two weeks’ time and Social mapping exercise completed in one month by and report ready by second quarter</p> <p>Learning: VIR team members had no prior mapping experience and there were no detailed maps available with the district or local government. The detail maps development, verification and digitalization completed in third quarter</p> <p>Assumption: The “Timestrip” in the VIR bands will have 99% accuracy</p> <p>Learning: a major drawback negatively affecting the VIR band effectiveness was the findings a “timestrip” failure rate above 15%</p> <p>Despite 100% success rate of “timestrip” indicator during close testing</p> <p>The failure was higher for Aqua bands compared to Purple and Yellow bands</p>
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<p>institutions in the catchment area</p>	<p>Assumption: Community support during Social mapping and household survey</p>
<ul style="list-style-type: none"> • Identification of community resources and stakeholders (parks, community centers, CSOs, NGOs, government institutions, business, political parties and religious centers) 	<p>Learning: community support during social mapping and maps verification and 0% non-refusal rate during HHS</p>
<ul style="list-style-type: none"> • Qualitative study on community perceptions about vaccination and VIR band: 	<p>Assumption: Qualitative study and HHS informed high acceptance rate for VIR band</p>
<ul style="list-style-type: none"> • 6 FGDs with LHW and Parents 	<p>Learning:</p>
<ul style="list-style-type: none"> • 28 IDI with community stakeholders 	<p>-100% Yellow VIR band acceptance among eligible children</p>
<ul style="list-style-type: none"> • Baseline household survey: 	<p>-73% Purple VIR band acceptance (among children who returned)</p>
<ul style="list-style-type: none"> • 500 respondents' knowledge, attitude 	<p>86% Aqua VIR band acceptance (among children who returned)</p>
	<p>Assumption: community receptive of VIR band messages</p>
	<p>Learning: only one refusal by school administration and none by religious centers, community centers and community healthcare providers for VIR band message session</p>
	<p>Assumption: policy makers and program managers supportive of VIR band intervention</p>
	<p>Learning: VIR band received full support by major stakeholders at every platform it was presented. The VIR Band study details were presented at the Annual EPI partners of Sindh Meeting, JHPIEGO</p>

and practice
regarding vaccines

- Immunization history of 500 children up-to 30 months (youngest child in the household)
- Immunization history of 62 other children up-to 30 months in the household
- VIR band brochure testing:
- VIR band intervention messages and VIR band study details comprehension and relevance by community members
- VIR band close testing:

End of Project Research Seminar and Meeting with Health and Nutrition staff at UNICEF Country Office, Pakistan

-
- Assessing the accuracy of the “Timestrip” indicator
 - Parental feedback on the VIR band form and function
 - Health providers/CHW/TBA / community volunteers’ engagement
 - One-day training workshop for 32 LHWs, FCVs and vaccinators
 - Referral mechanism setup
 - Two-day training workshop for 24 Community Volunteers (termed as Child Health Ambassadors)
 - Screening 789 and enrollment of 497 infants visiting the EPI centers where
-

		<ul style="list-style-type: none"> VIR band teams were stationed Community engagement and communication activities (detail given in CECP table/report) SEEP activities 		
Inputs	<ul style="list-style-type: none"> -Development of Formative evaluation protocol by Principal Investigator in collaboration with TVI team -Review and approval of formative evaluation protocol by 3ie technical team -3ie Technical comments addressed by research team 	<ul style="list-style-type: none"> VIR Band team hiring and training National Bioethics Board application Meetings with Program Director Expanded Program on Immunization (EPI), District Health Officer/Taluka Health Officer for approving the VIR band implementation VIR band design refinement and production 	<ul style="list-style-type: none"> -Quarterly Financial summary report -Letter of confirmation of receiving application -Meeting minutes -3D design and graphics -SEEP document submitted to 3ie -Gantt/work-plan submitted to 3ie -CECP submitted -Details of digital database provided 	<p>Assumption</p> <ul style="list-style-type: none"> -Revision of VIR band design for form and function accuracy achieved within 3 months <p>Learning: This assumption was misinformed as there was unanticipated high failure rate of the “timestrip” indicator once it was encapsulated in the silicon casing</p> <ul style="list-style-type: none"> -The android based CAPI survey questionnaire would be developed and ready for use within three months <p>Learning: the CAPI app took six months to complete due to which household survey (HHS) was also delayed accordingly. The HHS was planned to be conducted in the first phase along with the qualitative data collection but the team decided to conduct the HHS two months prior to VIR enrollment study to get a more accurate picture of the vaccination status of infants in the community</p>

<p>January—June 2016 6 months</p>	<ul style="list-style-type: none"> • Stakeholder Engagement and Evidence up-take Plan (SEEP) • Detailed work plan/Gantt chart • Community Engagement and Communication Plan • Net connected digital database development • VIR band brochure development • Social mapping tool • CAPI household survey questionnaire • Qualitative study guide • Research Assistants field manual • Community Health Workers and 	<ul style="list-style-type: none"> -Copies of -English and Urdu VIR band brochure -Social mapping protocol -CAPI IP -Training manuals -Referral mechanism details -Lease Agreement documents 	<p>The gap between the household line listing and HHS was almost six weeks so the eligibility criteria for “index child” (youngest child in the household) was changed from 24 months to 30 months of age.</p>
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community
volunteers training
modules

- Referral and reimbursement mechanism for CHW
 - Setup of VIR Band field office
-

10.5 Annexure C-2: Theory of Change framework for the implementation of VIR band in Karachi, Pakistan

Program stages	Theory of Change (ToC)	Monitoring and Evaluation Indicators	Quantitative and qualitative findings and ToC assumptions met/not met
<p>Context:</p> <p>-Caregivers are not aware of the importance of vaccination timely initiation and completion</p> <p>-Caregivers don't have access to an accurate reminder system for timely vaccination.</p>	<p>-Giving active reminders to parents of due visits for vaccination will increase parental compliance for timely completion</p> <p>-Imparting information to caregivers and communities on the importance of RI timely initiation and completion will bring a change in behavior at the household level and will create a social demand for vaccination services.</p> <p>Assumption:</p> <p>-Public vaccination services are accessible</p> <p>-Parents who initiate immunization are willing to complete the immunization schedule on time</p> <p>-There are no vaccine refusals due to misconceptions (prevalent misconceptions that vaccine cause sterility in</p>	<p>Baseline survey to assess:</p> <p>1) Vaccination timeliness and completion rates among children</p> <p>2) Factors associated, with vaccination timeliness and completion:</p> <p>-Access (availability and knowledge of vaccination services), -Accessibility (distance, travel time, transport, transport and consultation cost)</p> <p>Parental knowledge and attitudes</p> <p>Social mapping to assess:</p> <p>-Quality of services at EPI centers,</p> <p>-Programs and CSOs/NGOs for child health working in the target community</p>	<p>Assumption met: Public vaccination services are accessible.</p> <p>Finding:97% of respondents knew that vaccines are provided free of cost, 90% of respondents reached the vaccination center within 15 minutes and 87% of respondents said it cost them no money to reach the vaccination center.</p> <p>Reference: VIR band intervention baseline household survey report, Table 6</p> <p>Assumption met: no vaccine refusals due to misconceptions (vaccine cause sterility in children when they are adults)</p> <p>Finding: Only 18(3.6%) of the respondents stated that household decision makers “not in favor of vaccines” and only half of them (9 respondents) stated vaccines are harmful for child.</p>

	children when they are adults). Community acceptance of VIR intervention	-Health and education resources available in the community	Reference: VIR band intervention baseline household survey report, Table 5
Intervention:	1) Community engagement and communication activities for vaccination for timely initiation and introduction of the VIR band 2) LHW/CMW/FCVs refer every newborn they attend to in the community to visit EPI center within 15 days of birth 3) Eligible infants enrolled and VIR band activated at the vaccination center once child receives BCG/first dose of vaccine 4) Digital vaccination record is created for every enrolled child 5) Every child followed for 18 weeks	1) Number of Focus group discussions/counseling sessions with parent/caregiver and VIR band brochures distributed about vaccination timeliness and completion and VIR band key messages 2) Number of CHW (LHW/CMW/FCV/TBA) engaged and trained for the sending referrals From the online database: 3) Number/proportion of eligible children enrolled in the study 4) Number/proportion of children who visit the vaccination center within 15 days of birth 5) Number of children who visit vaccination center with referral card 6) Referrals by each CHW cadre	Assumption partially met: Monetary incentive to CHWs for every child they refer for a VIR band and whose parents visits the vaccination center soon after birth/within 15 days of birth will form the incentive for success. Findings: All the community health workers engaged and consulted during the focus group discussion agreed to refer families for early vaccination and enroll in the VIR band study but only FCVs sent most of referrals Parents who came without referral also agreed to enroll in the VIR band study Reference: Social mapping report VIR band enrollment online database Assumption not met: Communication activities will promote timely initiation Finding: Large proportion of infants initiate RI at age of more than 15 days

6) Study completion/exit interview (in-person/telephonic) conducted with parents of enrolled children	<p>every newborn even in the poorest communities</p> <p>Assumption:</p> <ul style="list-style-type: none"> -Rewards to CHWs for every child they refer for a VIR band and whose parents visits the vaccination center soon after birth/within 15 days of birth will result in acceptance and timely enrollment of study sample - Mothers/caregivers value the benefits of vaccines and overcome barrier to timely RI initiation and completion 	7) Refusal rate at Yellow, Purple and Aqua VIR band	Reference: VIR band enrollment online database
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Output: Cohort 497 infants enrolled into the VIR band intervention	<p>-The VIR band on the ankle of the child will be a constant reminder to every household member to vaccinate the child and the timestrip indicator will provide visual clues to vaccination due dates</p> <p>Assumption: VIR band made up of silicon band and the timestrip time indicator both function as designed</p>	<p>Each child followed for up to 18 weeks and information collected on</p> <ol style="list-style-type: none"> 1) Vaccine administration date 2) Record keeping of ink progression indicated on the timestrip 3) Age of the child at Penta 1-3 4) Loss to follow-up 	<p>Assumption met during pre-testing: Proportion of VIR band made up of silicon band and the “timestrip” time indicator both function as designed withstanding environmental conditions.</p> <p>Findings: the VIR band was tested in controlled and community setting during a period of one year and the Gen III VIR band proved its functional accuracy and sturdiness.</p>
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	withstanding environmental conditions.	5) VIR bands lost 6) VIR bands removed by caregivers 7) Reason for VIR band removal 8) Mal-functioning "timestrips"	Reference: VIR band controlled testing reports and prototypes Assumption partially met during intervention rollout: proportion of "timestrip" indicator reach at end point on time in: 42% Yellow bands, 33% Purple bands and 9% of Aqua bands Reference: Online database
Short term Outcome: Enrolled cohort complete their vaccination schedule on time	-Individual and group counseling of parents/caregivers, discussion at the household level, promotion by community health workers reinforce among communities the importance of timely initiation and completion -VIR band acting as a constant reminder of vaccine due dates facilitates families to remember to take their children for vaccination on time -99% of VIR bands accurate	1) Number of children completing the study 2) Number of children initiated the vaccination schedule immediately soon/within 15 days of birth 3) Number of children received three doses of Penta-valent vaccine on recommended age 4) Number of children completed all three doses of Penta-valent vaccine 5) Caregiver acceptance/compliance with and recommendation of the VIR band	Assumptions not met: Parental side delays in vaccination timeliness among accurately performing VIR bands "timestrip" indicator breakdown causing delays in Penta 1-3 vaccines

<p>Impact: Childhood RI timely initiation and completion becoming a community norm</p>	<ol style="list-style-type: none"> 1) The VIR band innovation reinforced by community engagement and communication promoting timely initiation and completion of RI timeliness 2) Community members holding themselves and families accountable for timely vaccination of children and following the vaccination status of every child 3) VIR band high power RCT conducted 4) VIR RCT conducted in HDSS setting 5) Infants enrolled at home to capture children who might otherwise miss vaccination 	<p>Vaccination timeliness and completion rate in the community at or above 90%</p> <p>Post intervention rate 90%: $\frac{\text{Children up to date for vaccines}}{\text{Total number of births in the community} - (\text{number of children migrated out} + \text{refusals} + \text{infant deaths})} * 100$</p> <p>qualitative data on 1) caregivers' knowledge and positive attitudes towards vaccination timeliness and completion</p> <p>2) Caregivers acceptance and demand for VIR band</p> <p>Government officials support of VIR band</p> <p>And introduction of the VIR band in EPI RI program</p> <p>3) Third party evaluation of the VIR band intervention</p>	
<p>Sustainability:</p> <p>1) The VIR band costs 2US\$ and this will be</p>	<p>1) Government supported initiatives integrated with the national data base will have a</p>	<p>1) VIR band adopted by the Sindh department of Health and expanded program of immunization and to be</p>	<p>1. Assumption-not yet met: Gavi, WHO and UNICEF will support the VIR band vaccination reminders since</p>

brought down even further during mass production

2) The government instated vaccination staff already generate paper records thus transitioning into Digital Vaccination Records will be smooth

3) Integrating vaccination records with national database will create the demand and ensure supply for the intervention

4) LHWs and CMWs programs are well established and funded by the Government for more than a decade

mass appeal and acceptance by the communities

Assumptions:

1) Gavi, WHO and UNICEF will support the VIR band vaccination reminders since they are already funding SMS reminders which cost more the VIR band

2) Government and Expanded Program of Immunization Pakistan implementing the program as a national public health intervention

3) Availability of open access digital software for digital vaccine registry

4) Donor support and government funds for incentives for LHWs and CMWs

introduced in low income union councils of Karachi, Pakistan

2) Community mobilization replicated and conducted by the provincial health department and expanded program of immunization in target communities

they are already funding SMS reminders which cost more the VIR band.

2. Government and Expanded Program of Immunization Pakistan implementing the VIR band as a public health intervention at the national level.
3. Availability of open access digital software for digital vaccine registry.
4. Donor support and government funds for incentives for LHWs and CMWs to refer every child they attend to in the community and sent their birth history to the vaccination center.

Findings: Yet to come

10.6 Annexure C-3: Diagram Theory of Change; VIR Band Formative Evaluation Study, Karachi, Pakistan

