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Tying Community Engagement With Appropriate Technology At The Last Mile: A Cluster Randomized Trial To Determine The Effectiveness Of A Novel, Digital Pendant And Voice Reminder Platform On Increasing Infant Immunization Adherence Among Mothers In Rural Udaipur, India

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Tying Community Engagement with Appropriate Technology at the Last Mile: A Cluster
Randomized Trial to Determine the Effectiveness of a Novel, Digital Pendant and Voice Reminder
Platform on Increasing Infant Immunization Adherence among Mothers in Rural Udaipur, India

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Thesis

Readers:

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University, School of Public Health

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For Alam,

who showed us his superpower of human connection

Abstract

Background: 500,000 children under the age of five die from vaccine preventable diseases in India every year. More than just improving coverage, increasing timeliness of immunizations is critical to ensuring infant health in the first year of life. Novel, culturally-appropriate, community engagement strategies are worth exploring to close the immunization gap. In this case, a digital pendant and voice call reminder system are tested for the effectiveness in improving DTP3 adherence within two monthly camps from DTP1 administration.

Methodology: A cluster randomized trial was conducted in which 96 village health camps were randomized to three arms: NFC sticker, NFC pendant, and NFC pendant with voice call reminder in local dialect across 5 blocks in the Udaipur District serviced by Seva Mandir from August 2015 to April 2016.

Results: The pendant and pendant with voice call reminder arms did not significantly improve adherence compared to the sticker group. Point estimates suggested that there was a higher odds of on-time completion in the pendant with voice call group compared to both the pendant group and the sticker group.

Conclusions: Despite the null results for adherence, the fact that the pendant was well retained and well accepted by the community suggests that the pendant can be a valuable social symbol and community engagement tool. Low power and short term follow-up may have masked true effects of the system. A larger randomized trial slated to begin in August 2016 will look to replicate and build off the study findings in the Udaipur district.

Chapter 1: Immunization in India: Determinants and Policies

Worldwide, 1.5 million children under the age of five die from vaccine preventable disease.[2] An estimated 500,000 of these children are from India.[1] Fully immunizing these children against tuberculosis, hepatitis B, polio, diphtheria, pertussis, tetanus, HiB, measles, mumps and rubella in the first year of life minimizes susceptibility to these diseases and mitigates the risk of infectious outbreaks.[2] Yet full immunization rates for children under 24 months in India nationally range from 60-80%, leaving 9.4 million children at risk annually.[1]

Sociocultural and geographical determinants pattern the immunization rates in India. Over half of these immunizations take place in outreach centers, with a 30 percentage gap in full immunization coverage from lowest to highest quintile of socioeconomic status, and the lowest rates of immunization take place among those Scheduled Tribe caste populations living in rural regions.[3] Geographic disparities in coverage have also been identified. Specifically, the Government of India is now targeting 201 "high focus districts" in 28 states to target for better uptake of timely and full immunization coverage through the first year of life.[1]

The drivers of under-immunization belie a complex narrative. After 10,542 mothers in India were interviewed as part of the UNICEF Coverage Evaluation Survey 2009, both demand-side and supply side factors were linked with partial and non-immunization. Among the top reasons cited by mothers for missing immunizations were "not feeling the need" and "not knowing about vaccines".[3] Reasons were further shown to vary by region and included a broader set of factors such as not knowing where to go, not having time or mutually convenient time, facing long wait times at the camp, having fear of side effects, and acting under misguided advice.[3] Others have cited that the expected job loss from tending to their child with DTP-induced fever serves as a deterrent to vaccination.[4,5] Conclusions from this comprehensive survey and other infield reports should not

discount supply side factors which may prevent access to routine immunization, but rather bring to light the importance of generating demand and awareness at the so-called "last mile."

The National Health Mission (formerly known as the National Rural Health Mission) situates the framework for health care delivery, including child immunization, to rural pockets of India. Decentralized outreach centers known as anganwaadi centers provide antenatal care and immunization services. Social link workers known as ASHAs (accredited social health activists) live in the villages and assist with tracking via due lists and facilitation via mobilization of mothers to come for receipt of maternal and child health care services at the nearest center. Auxiliary Nurse Midwives (ANMs) travel to the anganwaadi centers across multiple villages for their respective monthly scheduled camp days (typically Wednesday, Thursday, or Monday) where they may be supported by an Anganwadi Worker (AWW). ANMs pickup vaccines stored in refrigerators at the block level and return their vaccination box at the end of the day. Their task list also requires filling out the rural child health register for the patients that visited the center for that given day. The regularly scheduled camp days, also known as the Village Health and Nutrition Day, are established to improve common knowledge within the community around when services for maternal, infant, and early child health are accessible.[4] NGOs support parallel services in villages outside the majority reach of the government.

For immunization specifically, the GOI has executed programs such as Pulse Polio, and now more recently, Mission Indradhanush (MI). The pulse polio campaign, a perennial National Immunization Day, sees over 170 million children under the age of five vaccinated against polio virus each year. The large effort is supported by over two million vaccinators and over 8,000 community mobilizers in high focus districts.[6] Innovative campaigns were put in place to immunize nomadic populations with mobile teams on trains, bus stands, and market places. The massive human effort coupled with strong messaging and surveillance has been heralded as a success, with

India being declared polio-free for three years in 2014.[6] Mission Indradhanush can be considered a natural progression of the polio initiative. With an increased focus on educational messaging (both at the point of care and through broadband means), mapping of high focus districts, and generation of due lists and proper records at the micro-level, the campaign hopes to broaden the attention of immunization to those vaccines required in the first year of life. In its first phase, MI attempted to target 50% of India's partial and non-immunized children. Just recently, MI embarked on its third phase.[1]

Figure 1. Phase I Districts for Mission Indradhanush[1]

Moving forward and in conjunction with the recently announced Sustainable Development Goals 3.1 and 3.2[7] and the Global Every Newborn Action Plan[8], the GOI is redoubling its efforts to

address its gap in maternal and child health indicators, with its own Indian New Born Action Plan. Most recently the Call to Action Summit 2015 held in New Delhi, convened health ministers and leaders from 24 high focus countries to set the maternal and child health agenda, the "Delhi Declaration", to recognize the importance of maternal and child health in shaping sustainable societies.[9]

A focus on Rajasthan, Records

The state of Rajasthan is recognized as one of nine high priority states for immunization by the Ministry of Health and Family Welfare. Nine districts of Rajasthan were considered high priority in the first phase of MI. Under the second phase of MI, from October 2015, the health department has taken up another 15 mid-priority districts of Rajasthan. Udaipur, a predominantly tribal region where half of the administrative blocks fall in the high focus category, is the district in which our trial was conducted.[1]

Full immunization coverage in Rajasthan among rural populations is 72.6% and 74.2% overall according to the Annual Health Survey 2012-2013.[10] The data collected based on ANM reports is fed to a national e-health system. In the most recent complete financial year of reporting, the Pregnancy and Child Tracking Health Services Management System (PCTS) indicated that only 44.9595% of children were fully immunized.[11] This 2015-16 financial year the numbers are even lower – 36.1261%.[11] While the AHS data speaks to a representative sample of the state, the PCTS data comprises of individual ANM reports which are more granular, albeit restricted to those mothers within the catchment area of a government center.
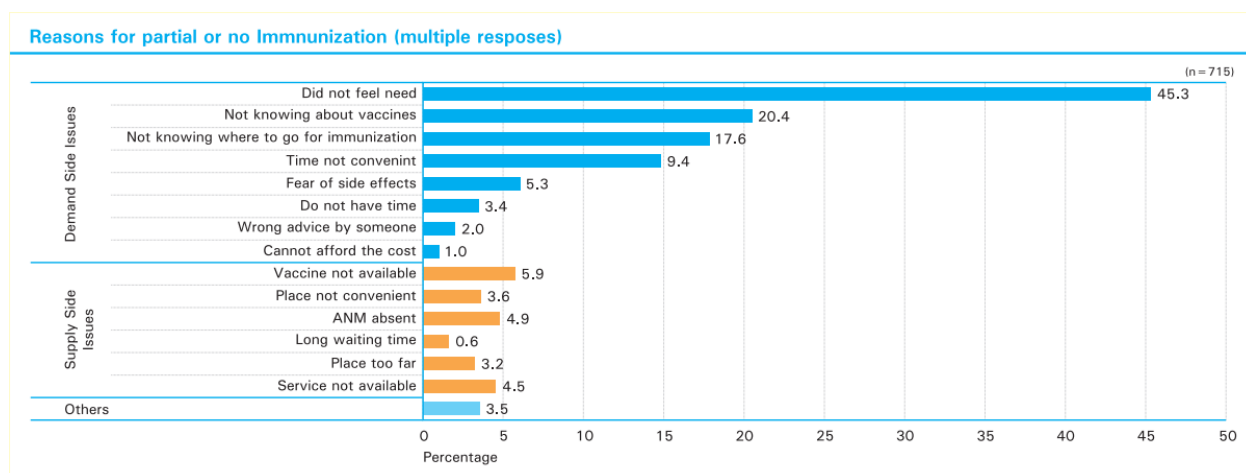
Reasons for partial or no Immnunization (multiple reponses)

(n = 715)

	Percentage
Demand Side Issues	
Did not feel need	45.3
Not knowing about vaccines	20.4
Not knowing where to go for immunization	17.6
Time not convenint	9.4
Fear of side effects	5.3
Do not have time	3.4
Wrong advice by someone	2.0
Cannot afford the cost	1.0
Supply Side Issues	
Vaccine not available	5.9
Place not convenient	3.6
ANM absent	4.9
Long waiting time	0.6
Place too far	3.2
Service not available	4.5
Others	3.5

Percentage

Figure 2. Mother explanations for missing child immunizations[3]

To their credit, Rajasthan, with PCTS, has taken a unique e-health systems strengthening approach to in part address the challenge of maternal and child health; through patient tracking and digital community engagement, they hope to improve coverage. Rajasthan is a recognized leader in electronic health and e-governance. Rajasthan's PCTS maintains online data of more than 13,000 government health institutions in the state, monitors a birth cohort of over 1 million children each year providing key information to health officials and demographers. A complementary Swasthya Sandesh Seva (SSS) text messaging platform reaches several hundreds of thousands of mothers every year as they go through pregnancy and the first 1000 days of birth.[11]

The Columbia Earth Institute conducted a gap analysis on the PCTS system in 2014. They found discrepancies in data filling from the forms filled by the frontline Auxiliary Nurse Midwives to errors in software calculation of calculated columns to unclear presentations of the data.[12] The completeness of the data, in areas where the government doesn't reach also casts doubt on the validity of the indicators, especially when complementary NGOs acting in the least accessible regions are not required and do not update patient-level data to the state system. Such drawbacks are not limited to the PCTS system used by the Rajasthan Department of Health but also extend to

other electronic health registries and tracking systems employed by the Indian public health system such as the MCTS (a national extension) and the Health Management Information System (a national initiative for reporting of health indicators).

Such indictments of data quality from the ground level to data entry operators have pushed the Rajasthan MOH to look towards digitization of data collection at the point of care itself. These new solutions must be rugged, deployable, and user friendly among a staff of ANMs that experiences low connectivity. The Rajasthan MOH is currently pursuing several e-health/m-health pilots: E-asha (from IIT Jodhphur), now known as E-Jan Swasthya is being piloted in the Badgaon block of the Udaipur district, and incrementally being rolled out into 10 other districts throughout the state.[13] But particularly when it comes to NGO-delivered mHealth proposals, there persists a plague and perception of *pilotisis*. Challenges still remain in ensuring proper training for staff, but more fundamentally on offering more universal accessibility when connectivity cannot be assumed, and where a population is known to migrate or even change villages upon delivery of a child.[14,15]

Udaipur and Seva Mandir

The proposed study site, the Udaipur district of Rajasthan, has lower immunization estimates than national levels while also performing poorly in other key developmental indicators with an IMR of 47 per 1000 (SRS Bulletin, 2014, GOI) live births and an MMR of 244 per 100,000 (MMR Bulletin, 2013) women of reproductive age.[*] The most recent immunization estimates for this area were assessed in 2013 by the DHLS-4 survey, but data is incomplete for villages outside of the government's catchment area. AHS 2012-13 reports immunization card retention at 63% among mothers in the Udaipur District for their children aged 12-23.[10]

To act as a stopgap for antenatal care and immunization coverage, a local NGO, Seva Mandir, began monthly immunization camps in 2004.[16] Seva Mandir, has had a long standing

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[*] See: http://nrhm.gov.in/nrhm-in-state/state-wise-information/rajasthan.html#health_profile for full profile

relationship with over 700 villages in Rajasthan, with nearly 100 villages participating in their monthly immunization program, which runs in parallel to complement the government's immunization services.[16] Their camps are situated in five administrative blocks in the Udaipur District: Badgaon, Girwa, Kherwara, Kotra, and Jhadol. While in some regions, geographical proximity gives mothers choice as to which health provider to seek, many villages are isolated from government services. These villages in most cases have used Traditional Birth Attendants known as *dai mas*, instead of ASHA's, along with other locally installed and trained paraworkers to keep track of infants and assist with safe deliveries.[16]

Between 2004 and 2007, Banerjee and colleagues from JPAL conducted a Randomized Control Trial in Seva Mandir's immunization camps to assess the effect of non-financial, food-based incentives on vaccine adherence.[17] Since the conclusion of the study, which found that treatment villages had four times the increase in full vaccination completion rates, Seva Mandir has incorporated the lentil-incentive program as standard practice across all camps. A recent endline study of the Seva Mandir immunization program which now incorporates lentil-based incentives shows Full Immunization Coverage rates for children 12-23 months near 60% in their camp catchment area.[16] The ability to rigorously evaluate strategies to increase the performance of immunization delivery and adherence makes Seva Mandir an outstanding and field-tested partner not only for the trial herein, but moving forward for testing future iterations of our intervention.

In summary, we have explored the vaccination context at the national, state, and district level from India to Udaipur. As a whole, there is a clear need to improve child health indicators, particularly around vaccination. Determinants of partial and non-immunization are well-researched, although a local context reveals contextual insights surrounding supply and demand-side factors of under-immunization. A dual area of concern is not just the low performance of indicators but the quality of data being reported from the last mile, which is needed both at the point of care and at

district levels for proper resource mobilization. The political context is ripe for innovation, and the GOI through its Ministry of Health and Family Welfare is seeking both vertical and health systems strengthening approaches to improve immunization

Chapter 2: Theory and Background Literature

Motivating preventative health seeking behavior, especially for vaccinations, has theoretical challenges. Not only does the mother face an tangible opportunity cost of lost wages, the cost is only magnified when considering economic models of future discounting.[18] Moreover, a mother unaware of vaccination-related effects has little incentive to see her child in distress without tangible knowledge of the future benefit – in this case omission of disease, which may be less obvious to perceive than disease that may result from incomplete immunization.[18] The SAGE working group attempted to establish a framework for these considerations around immunization. Their Vaccine Hesitancy Model integrates three key factors to vaccination uptake: convenience, complacency, and confidence.[19] Services must be accessible and affordable, rigorous adherence must be maintained, and trust must be established in these local communities around the services.

But before considering vaccination-specific behavior, a broader approach may look for insights from several models around behavior change itself. These models have attempted to capture the individual and ecological real world complexity that influences behavior change.[20] The Transtheoretic Model delineates a distinction in decision making between contemplation and action. This model serves as useful in considering the attitudes of newcomers or previous vaccination defaulters from seeking services for the first time. This thought process may be patterned by prior experiences with health workers during antenatal care or delivery. More importantly the impetus to act may be determined directly by the health status of the infant. A sick child may either prompt or prevent a mother from attending the monthly camp. The Theory of Planned Behavior is another model to consider. It focuses attention to how mothers must forego work, especially if the child will incur a fever after immunization and travel through tough terrain to reach services. This framework may also emphasize how mothers need to remember and plan for vaccination schedules and the subsequent response to keep immunizations on a fixed, predictable day of the month. Repeated

behaviors may become habit forming, having implications under this model for understanding adherence. For example, empirical work has shown that missing the first shot of DTP1 on time is associated with not completing downstream DTP3, let alone on schedule.[37] Finally, a health belief model is relevant, as caregivers in a community may be swayed be religious leaders or local superstitions which demonize the role of vaccines.[20]

One emerging theory comes from behavioral economics which implicates the importance of "social bandwagoning".[21] And here, specifically, understanding of social networks can play a useful role. Previous research has shown how even low uptake of behavior among influential nodes has had spillover effects in the extended graph of the surrounding community, for maternal and child health services.[21] Altogether the literature from social network theory suggests several key takeaways: connections in a social network are valuable predictors of health affecting behavior and information dissemination; sociocentric mapping of these communities is resource intensive, and a toolbox of heuristics (friendship nomination[22], gossiper nomination[23], geographic nomination[24]) for identifying individuals of varying social influence will need to be further explored; and that effective network targeting for diffusion of a contagion depends on the type of contagion – simple or complex - being spread (whether the contagion is latrine adoption[25], multivitamin use[22], information spread[23], or technological adoption[24]).

Rooted in these theories, several approaches have been widely accepted as fundamental to successful immunization campaigns. In particular, the role of the network-central social worker (e.g. ASHA), the presence of a reminder system, cost-free preventative care, the subsidies to account for lost wages, and strong educational messaging to promote pro-immunization health beliefs at the individual and importantly, at the community level.[26-29] In parallel, key determinants have been identified with regards to immunization adherence in LMICs: socioeconomic status, number of children under five, delivery at an institution, maternal education level, maternal age, and distance

from the camp.[30-35] The challenge moving forward is to find innovative yet locally appropriate approaches to increase positive behavior change towards immunization.

Chapter 3. Innovation & Intervention

Designing and implementing interventions to address a behavior change gap, in this case for uptake of immunization, requires incorporating an interdisciplinary understanding of the local landscape of health delivery and of behavior change theory models.[36] Many such interventions have been posed previously to generate demand with varying success[29]: text message reminders for surprisingly high mobile penetration rates in LMICs[37,38], non-financial, food-based incentives[17], ASHAs and social network activation[39], participatory action programs[28], vaccine defaulter tracing lists[28], health worker coaching[28], household immunization drives[28], vaccines on trains for migratory populations of Bihar[6], and even community filmmaking projects[28]. Health systems approaches to define a continuum of maternal and child care have integrated service delivery between antenatal care and routine immunization, recognizing that establishing behaviors during pregnancy can set precedents of adherence towards immunization later on.[29] Even new wearable bands (Vaccine Indicator and Reminder Band, Alma Sana) are being proposed to demystify the vaccine schedule in the eyes of mothers in Pakistan and Peru respectively.[40,41] Altogether, scoping reviews have shown the promise of technology and community engagement around immunization, but fail to see a diversity of approaches in the current literature around awareness generation.[29]

MHealth approaches, in particular SMS reminder systems and educational data collection apps for frontline health workers, have also been brought forward and are increasingly measured with respect to their effect on maternal and child care behavior change. Most systematic reviews show a large evidence gap and lack of strong methodology in evaluation.[42] But an increasing number of mHealth randomized evaluations are taking place in LMICs.[37,38,43,44] Recent reports on Dimagi's Commcare suggested providing their mHealth tool to community health workers in one district of

Bihar, resulted in increased frequency among mothers for their ANC visits[†] and PNC visits, consumption of IFA tablets during ANC, solid food introduction at 6 months and immediate breastfeeding after birth; the report however failed to find an immunization coverage or timeliness in particular.[45] And despite the aforementioned positive effects, the mechanism resulting from simply providing the health worker an app with a due list did not reveal itself through higher knowledge transfer to beneficiaries.[45]

A novel wearable and mobile health platform by the group Khushi Baby (KB) looks to advance a new community-centered intervention. This KB intervention accounts for the broader socioecological determinants of vaccination behavior and was designed alongside the community through a human-centered design framework.[46] The intervention began as a means to collect and track immunization records of children under the age of one in decentralized, connectivity-independent manner. The solution stores immunization records digitally on a Near Field Commmunication (NFC chip[‡]), which could be both read and updated by a custom Android smart phone application used by the community health worker instead of the traditional register. Data can therefore be digitized and decentralized at the point of care, before later being synced and packaged as real-time, analytics for health officials in the form of a dashboard. Similar concepts for storing data on the patient have evolved from QR codes in Lebanon[47] to RFID anklets posed by MIT researchers[48] to smart cards and NFC stickers elsewhere[49], showing some convergence towards the Khushi Baby concept validity. Of course, fit of the technology must also be deemed appropriate. After meeting with the communities serviced by Seva Mandir in the Badgaon block of Udaipur (village elders, community health workers, traditional birth attendants, local informers, health

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[†] Although this should be cautioned as authors concede that difference-in-difference was not taken despite differing baseline measurements for ANC frequency in treatment and control arms

[‡] The NFC chip can be contextualized in an evolution of techniques for off-grid storage: barcode, QR code, RFID, and now NFC. QR codes used to identify families in Lebanon for stock delivery could only record basic details about number of household members due to space limitations. Conversely, NFC chips being used here can store 888 bytes of data, facilitating storage of entire medical records, identifiers, biometric templates, and other possibilities.

officials and about 100 mothers), the Khushi Baby group was able to define the form factor to house this chip. A pendant wearable with black thread and chip in an amulet was selected among several options (all battery free and priced between $0.30 - $3): stickers, chips on bangles for mothers, chips embedded in silicon wristbands for children, anklets, and wristlets.
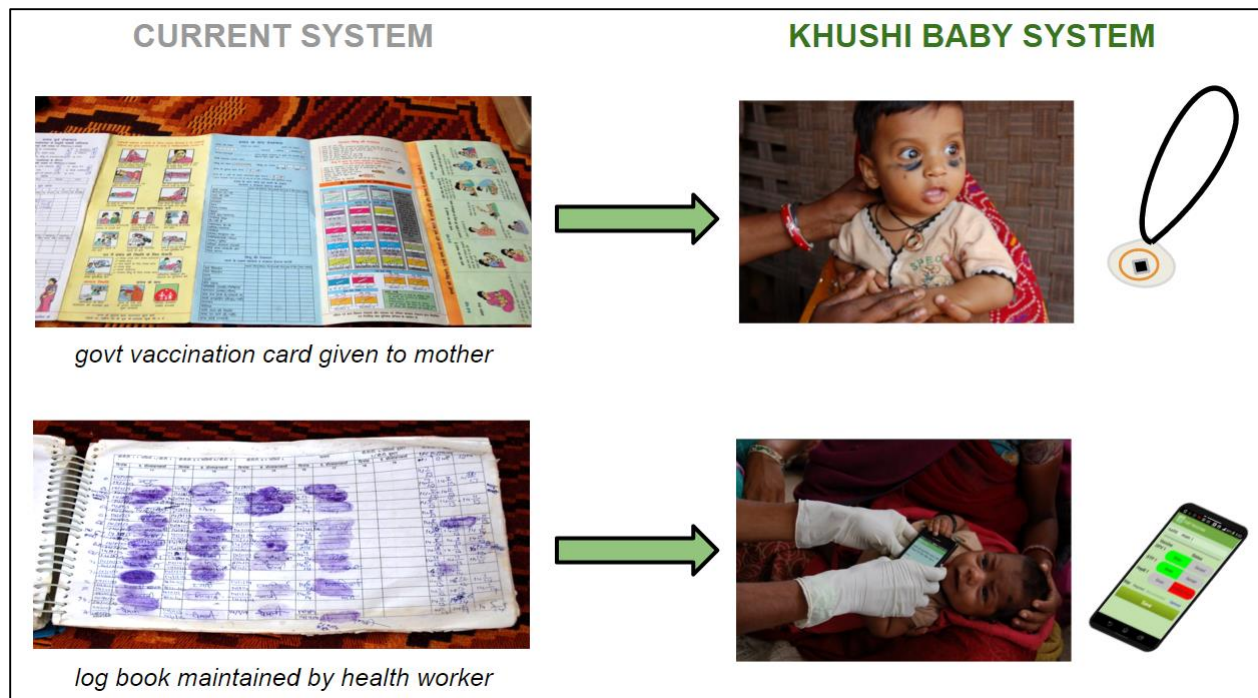

Figure 3. The KB approach redefines the interface of the provider-patient interaction around records at the point of care in remote settings.

Figure 4. A dashboard for health admins allows for resource management and call reminder placement

The Khushi Baby pendant provides two advantages over the existing government-distributed paper record or MAMTA card. The first strength is premised on the assumption that a wearable is less likely to be lost, and in this case more likely to be digitally filled out compared to the paper card. The second purported advantage derives from the color of the black thread (*kaalo dhaago*), which has a cultural significance of protecting the child from evil eye or *buri nazar*. [50-52] The significance of the black color is not unlike the significant difference associated with blue-colored bed nets in their adoption and proper use in Ethiopia over white bednets.[53] The KB pendant's cultural relevance speaks not only to the adoptability of the intervention at the point of care and beyond, but also in its potential marketability to those vaccine defaulters outside the camp who hold the same health beliefs. By symbolically protecting the child from disease, the pendant can thereby dually act as an educational tool for the health worker as well as a social signal generating a spillover effect within the community.

When compared to other mHealth platforms, the KB platform also provides several unique benefits. No other mHealth platform employs NFC wearables as a solution to address the barrier for patient record identification represented by inconsistent connectivity. The Cartilla Electronica de Vaccunacion has recently employed an NFC sticker in the child's immunization pamphlet[49], but again conforms to a paper card which can be lost. Additionally, the KB platform uniquely collects information on failed encounters of immunization and provides a workflow for health workers to select the reason for failed provision. This data on vaccination denials[§] allows for improved demand-side forecasting as a more complete dataset is passed on to the health official. Finally, while some mHealth platforms leverage push-based reminder systems, the KB platform uniquely implements heretofore untested dialect-specific voice-call reminders for those living in these last mile communities. This voice-call system stands to perform better than previous SMS and voice schemes

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[§] See Supplementary Appendix for vaccine denial reasons compiled over 15,000 immunization events tracked by the Khushi Baby system

that cannot reach the many mothers who are illiterate to Hindi, but instead could respond positively to the familiar voice of the local *dai ma*.

In summary, the KB system theory of change is multifactorial.[**] A retainable health record should facilitate proper receipt of vaccines at the immunization site, and the wearable could provide a sense of ownership around one's own record that begets awareness. The wearable could foster improved coverage within the community by acting as a social symbol or improved adherence by allowing the health worker to use the pendant as a means to establish better trust with the mother. The mobile application provides necessary in field decision making support for the health worker who may other have to guess or inappropriately administer vaccines. The mobile app further reduces the burden that may be faced through paper log systems and may potentially empower health workers to be more efficient and interactive in their patient encounters. The data collected via the app which is packaged into a dashboard, can catalyze action and responsiveness on the part of health officials, who may interrogate immunization denial reasons and track performance before monthly meetings with staff. Voice calls sent through the dashboard may spread awareness independently and reinforce the importance of maternal and child health in the household if the father holds the family phone. Altogether, the KB app extends what other community health apps attempt by providing a comprehensive wearable platform. This platform moves beyond data collection, and uses the local context to drive behavior change through design and timely feedback of complete data to both the health worker, health official, and mother. To test the potential mechanisms of the KB platform, the operationalization of the KB system would comprise of distribution of the KB pendant (wearable electronic record), training of health workers to use the app, and collection phone family phone numbers at the immunization camp site for the sake of the voice calls.

[**] See Supplementary Appendix for Full Theory of Change model

Table 1. Recent Innovations for Increasing Immunization in LMICs

	Khushi Baby	E-Jan Swasthya, ANMOL[13]	Dimagi / CommCare	MAMA, mMitra[54]	Medic Mobile[55]	PCTS[11] + SSS + Kilkarni + MAMTA card	VaxTrack[56]	VIR Band[57]	Alma Sana[58]	BMGF Records for Life[59]	Carlos Slim Carta Electronica de Vaccunacion[49]
Low Cost Physical Record (<$1)	✓					✓				✓	✓
Wearable Record	✓								✓		
Wearable Reminder	KB 2.0 – via bead tracking for mother							✓	✓		
Offline Mobile App	✓	✓	✓		✓	✓	✓				✓
Customized Dashboard	✓	✓	✓		✓		✓				✓
Locally Tailored	✓	✓	✓	✓					✓	✓	
Campaignable Symbol and educational talking point	✓								✓		
Unique Patient Identification	✓	✓	✓		✓	✓	✓				✓
Decentralized Patient Identification	✓										✓
Biometric Patient Record	KB 2.0						✓				
Decentralized Patient Record	✓								✓		✓
Alerts for Due Vaccinations for health worker	✓		✓	✓	✓	✓					✓
Automated Data Collection at point of care	✓	✓	✓		✓		✓				✓
Vaccination Event Linked to Vial	KB 2.0 – will be matched against camp end vial count						✓				
SMS Reminders to Mothers			✓	✓	✓	✓					✓
Voice Call Reminders	✓		✓	✓		✓					
Voice Call Reminders in Local Dialect	✓			✓							
Automated Voice Call Reminders	KB 2.0		✓	✓		✓					
Educational Calls from ANC	KB 2.0		✓	✓							

Chapter 4. Field Research

Khushi Baby scoping work commenced in summer of 2014 with three principal goals. Oriented with a human-centered design framework[46] the team sought out to understand the workflow of vaccine delivery in Seva Mandir outreach camps, learn about the pain points therein, and work with the community members and health workers to locally tailor a solution for the context on the ground. The ethnographic methodology that follows loosely condenses and parallels the approach taken by the Vaccine Delivery Innovation Initiative in Bihar, 2009.[4]

In this first phase, we observed the vaccination process in five villages, closely following three General Nurse Midwives (GNMs, Seva Mandir's nurse counterpart to the government's ANM) speaking with nearly 100 mothers in several focus group settings. We convened one focus group meeting among town leaders (*panchayat* members) in the village of Undithal. Furthermore we spent three weeks of focused time with the Seva Mandir Director of Child and Maternal Health and had a chance to hold a two hour discussion with the Seva Mandir CEO and her chief cabinet to gain feedback over our first proposal. From March to May the Khushi Baby team spent two months living in the various block offices, working with eight GNMs to understand the workflow as well as to train the GNMs on use of the Khushi Baby mobile app beta and to gauge the mother's response to an early voice call reminder system. Mothers and nurses were specifically surveyed to understand their satisfaction with the mobile app and pendant respectively. Preliminary work further investigated the population demographics of about 200 mothers during this period.

Seva Mandir immunization camps run from the first through the 24th of each month. The 100 villages are covered by a team of six to eight health workers. The process begins before the camp starts. A locally installed *dai ma*, or Traditional Birth Attendant trained by Seva Mandir, walks from household to household to remind mothers about the camp day (which is held on a fixed day of the month). The GNM leaves from the block office with vaccines and registers for mother, child,

and the lentil incentive program. The GNM typically travels on motorcycle and can travel for up to one and a half hours one way. Mothers leave from their home, the field, or from their daily job to reach the camp between 11:00 and 14:00. The GNM, dai ma, mothers, pregnant women, and in some cases local informers convene at a makeshift health camp site. Mothers present the government issued MAMTA card. Often this card is left unfilled and in other cases it is forgotten. Some mothers do take care to protect the card in plastic sleeves. Health workers check the card against their personal register and determine which vaccine the child is due for. In some cases, they have to guess the child's date of birth when the card is not present, for example by asking if the child was born before or after a key festival such as Holi or Diwali. For measles and BCG vaccinations, vials are not opened unless eight and five children respectively are due for the vaccine. While DTP and HepB injections are given to one child at a time, OPV may be given to multiple children all at once. After giving DTP, medications for fever-reduction are given to the mother. At Seva Mandir camps, the pentavalent vaccination has yet to be approved, so two injections (DTP and HepB) must be given on the same day. In some cases mothers deny the second injection after seeing their child in distress. The event is recorded in the Seva Mandir register and should also be recorded on the mother's MAMTA card. At the end of the month, register records are compiled by the GNMs and the Seva Mandir data entry operator. This process takes two to three days to complete.

In this process, several pain points undergirding the system were uncovered. The current record keeping process burdens health workers and the human-based reminder-system poses an unwieldy reliance on one dai ma for the physical household reminder. Incongruence with the new government MAMTA card has cornered Seva Mandir into providing photo copies of the older MAMTA card. In some villages like Dhar in Shankar Keda, Udaipur, the entire village repudiated immunizations. With no locally installed recruiter or informer, camps have been cancelled due to low turn up and limited resources. Preliminary work also showed a low understanding among

mothers about the number of required visits which are needed for full immunization in the first year as well as literacy rates as low as 20% among more than 200 sampled mothers from the villages serviced.

Figure 5. Process Prior to Immunization at a Seva Mandir Camp from community mobilization to travel to the camp site interaction

Figure 5. A child receives his OPV vaccine

Figure 7. A General Nurse Midwife records the vaccination in her register

Figure 6. NFC Form factors presented to mothers and health workers

From the workflow and pain points identified above, ideation over the intervention also took place with the stakeholders affected on the ground. The state of the medical record in a paper form suggested the need for a digital transition. A wearable form factor presented itself as advantageous to the paper record which could be lost, forgotten, or damaged. Mothers were presented one of six form factors and asked whether they would prefer to wear the wearable or to have their child wear the wearable. The overall consensus pointed towards the child wearing the black threaded pendant, with the black thread culturally familiar and symbolic of protecting the child from *buri nazar*. One child who had been given the pendant in July 2014 was still wearing the pendant upon receipt of his

measles shot in April 2015. The early reports provided confidence that mothers would both accept the pendant as well as retain it due to its symbolic significance. Health workers agreed that the time to identify a patient record was much improved when a patient came for follow-up when compared to the paper-based alternative.

Beyond the pendant, we were able to gain important insights on the implementation of a reminder system for mothers. The low literacy rates (26% of mothers in the March-May period) suggested that SMS-based reminders may be ineffective in this context. Rather, voice-based reminders, and dialect-specific reminders may increase the relatability of the intervention to the targeted mother.

Given the unexplored territory in applied Social Network Analysis for immunization adherence in developing world contexts, we decided to run a pilot observational study. The primary goals of the study were to:

1. Map the social network of reproductive age females (aged 14-45) representative villages in in the Badgaon District of Udaipur.

2. Identify central nodes within the aforementioned network

3. Associate network position (or proxies) with vaccination adherence. In the subsequent RCT, we were able to collect out-degree data and also determine whether or not the type of connection was tied to a previously determined central figure in the village such as the dai ma.

4. Understand how social network predictors compare to or confound other sociodemographic predictors of vaccination adherence in regression models.

There were several research directives that we were not completed in this pilot. We hope to consider these in future, larger scale studies.

1. We had additionally intended to use specific network centrality of Badgaon mothers to predict vaccination adherence in our RCT, making this a nested observational study. However fewer than 20 mothers in a sample of 214 ended up overlapping between this observational study and the follow-on RCT. In other words only 20 were both mapped sociocentrically and also had children that fit the eligibility criteria for the subsequent trial where we followed immunization behavior prospectively. Therefore, we could not impute centrality for the majority of the sample, despite collecting ego-centric measures such as out-degree.

2. Similarly, we hoped to understand how global network structure could predict adherence at the camp level in our RCT; egocentric mapping in the RCT disabled us from such analyses.

3. We had hoped to understand how the pendant or voice call reminder in the subsequent trial would diffuse through the sociocentrically mapped network through referral patterns. Again due to poor overlap, and lack of a household follow-up in the RCT, we were unable to determine which mother came to the camp due to a specific referral or because she saw another mother with the intervention.

The specific findings of our first four objectives and their methodology will be elaborated in the context of ego-centric mapping in the subsequent section discussing the Randomized Trial. For the nine villages we sociocentrically mapped in Badgaon, we used Trellis software developed by the Human Nature Lab. A team of 3 field staff and one manager would spend two days per village: the first day the field staff would conduct a photographic census of the village at the household level of any member above 14 years of age[††]; the second day the team would return to houses and specifically search for reproductive age females, aged 14-49, asking them a series of questions regarding their social ties in the village. These questions included but were not limited to: who do you go to for health advice, who comes to you for health advice, who do you go to the temple with, who reminds you of the vaccination camp, who do you go to the vaccination camp with, who in your community should be attending a vaccination camp but does not, and who in your community speaks out against vaccines. Mothers were able to nominate any of the previously census-registered individuals. To account for the inherent incompleteness in the census, an "other" option was also added to add a non-referenceable node as a relationship tie to the mother. One limitation of this

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[††] More technically the village referenced here is known as a hamlet. Each village has 1-5 hamlets. There are approximately 500 individuals in a given village. A Seva Mandir immunization camp catchment area could span multiple hamlets, not necessarily from the same village

approach was that the entire population was not defined to just mothers. By virtue of allowing non-potential mothers to be alters, the graph could not be considered as fully sociocentric. Not all reproductive age females who were referenced were also surveyed. Nevertheless, some insight was gained regarding mothers with high outdegree and higher than average in-degree (see RCT results section for further details).

While initially planning on mapping 12 villages in this manner, 9 villages were mapped due to resource and time constraints. Two representative villages where we believe the census covered at least 80% of households in the hamlet are shown as models.

Pilot Work: Baseline Survey of Full Immunization Coverage and Card Retention (July 2015)

To determine the baseline DTP3 coverage rate in SM camps, a 30 cluster, population-based probability sample survey was conducted prior to the start of the trial. 11 villages in the sample were in our first arm (control), 9 villages in the first treatment arm, and 10 villages came from the second treatment arm. We implemented a validated instrument to confirm immunization status either by examination of the MAMTA card or via verbal report using the NFHS survey as a basis with few modifications. 373 mothers were surveyed across 30 villages in 10 days. 75 (30.2%) had their immunization card. 148 (59.7%) said they had the card, but could not produce it at the time of the household survey. 25 (10.1%) were not in possession of a MAMTA card. DTP3 coverage in the sample was 49.5% (95 CI: 44.5-54.5%). This figure differs slightly from an independent SM conducted endline in 2015 (for the earlier JPAL study), which estimates the full immunization coverage at 60%.[16] An endline study will take place in late April to assess the change in DTP3 rate after the intervention across all villages in the study.

Chapter 5. Randomized Evaluation

The following evaluation[‡‡] sought to address the public health impact of the Khushi Baby intervention. Specifically we examined whether or not the KB intervention improves timely health seeking behavior towards infant vaccination among mothers in rural Udaipur. While many health benchmarks and evaluations utilize primary outcome measures of DTP3 or full immunization coverage[29,37], timeliness is increasingly being recognized as standard, given the immunological and public health impacts of receiving delayed vaccines.[31,37,60,61] This evaluation conducted a three arm cluster randomized controlled trial where the unit of randomization is the Seva Mandir immunization camp, which has a catchment area of up to multiple hamlets from multiple villages. 96 camps were randomized evenly to three arms:

1. Control Arm: Near Field Communication (NFC) stickers are placed on the existing immunization card. These stickers serve as a digital record of the child's immunization but take the same form factor that the mother currently uses. The sticker can be updated via the Khushi Baby app and allows for consistent methodology of immunization data collection

2. Pendant Only: the immunization record is digitally stored on a pendant with black thread, worn by the child. Unlike the sticker, the form factor is visible, wearable, and culturally significant

3. Pendant + Voice Call Reminders: children received the pendant as described above and mothers received voice call reminders the day before and the day of the camp, along with either a thank you message or a missed camp message for mothers who failed to attend.

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‡‡ See Clinicaltrails.gov, ID: NCT02518178

Randomly selected members from this group were given a supplementary educational voice call message.[§§]

Primary Objective:

To determine if a pendant encoded with an electronic immunization registry, with or without voice message reminders would improve the proportion of children receiving DTP3 (third dose of diphtheria, tetanus toxoid, and pertussis containing antigens) by 20% two camps[***] after DTP1 (first dose of DTP vaccine) receipt as compared to control arm infants. Two camps were chosen instead of two months to account for supply-side cancellations of immunization provision, which would not be reflective of non-adherent health seeking behavior.

We hypothesized that the pendant may serve as a visual reminder of the child's impending vaccination schedule and that the pendant may function as a social signal to encourage immunization compliant behaviors. To our knowledge, voice reminders for immunizations (in locally specific dialects) have not been systematically tested within lower-and middle-income countries (LMICs) or in Udaipur in particular.

Secondary Objectives:

a. To determine if children randomized to pendant + voice reminders (Arm 3) would have higher timely DTP3 adherence at 2 camps after DTP1 than infants randomized to receive pendants only (Arm 2). In other words, does the voice call system make a difference?

[§§] Note in the original protocol, there was no provision for the educational voice call reminders, thank you messages, or missed camp messages; there was a 15 day reminder message which was removed in this implementation. These updates are pending and have yet to be reflected in the clnicaltrials.gov database

[***] Camps occur monthly; initially the protocol was originally slated to account for up to six camps after receipt of DTP1 at enrollment. Due to budget constraints for follow-up time, and after consideration of official guidelines from the Indian Academy of Pediatrics, a two camp period was deemed more appropriate and feasible, albeit stricter as a metric for success

b. To determine if the primary objective and first secondary objective would hold true for adherence two months after DTP1, after excluding those mothers who faced cancelled camps.

c. To determine if the primary objective and secondary objective A would hold true with respect to the outcome of DTP3 completion by 180 days after birth[†††]

d. To determine which other sociodemographic variables if any would be associated with adherence by 2 camps after DTP1, 2 months after DTP1, and 180 days from birth

A randomized evaluation was used to provide the closest causal evidence for the change in outcome measurement that can be directly attributed to the intervention after controlling for known and unknown confounders; a cluster randomized approach further allowed non-contamination of social-signaling interventions within the contacts of a given village.[62] Beyond the theory, a randomized approach would provide for us a more convincing, quantitative evidence base to present to government bodies for eventual scale up and complements the anthropologically focused pilot work that went into design of the intervention.

We chose a primary outcome of a 20% increase in timely DTP3 adherence because this would be significant from a public health standpoint and would improve the likelihood of bringing the KB intervention to scale. These treatment effects on adherence outcomes could be mediated by a set of covariates which were therefore collected for each mother in the study: years of education, caste, conditions of home (electricity, water, toilet), type of work, distance from immunization camps, number of children born at home vs. at the hospital, the age of the child upon receipt of DTP1, and social network covariates of the mother that assess number and type of friends (temple-

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[†††] The WHO cutoff differs from the IAP protocol, allowing for 8 week intervals between DTP vaccinations under a maximum threshold of 180 days from birth to finish the sequence; do note that the intervention was not started from birth, but rather from the first DTP shot

goer friends, health-advisor friends, health-advisee friends, friends who speak out against vaccines, friends who have children unvaccinated). In addition, we considered the calendar month of the child at enrollment and geographically based fixed and random effects at the block and camp level (unit of clustering) respectively. These covariates contain a mix of predictors that have been shown to be relevant, as well as some social network covariates that have been previously unexplored. While previous work has considered full sociocentric mapping, we look to examine whether less-resource intensive, ego-centric measures can act as independent predictors of our outcomes. Not included in this list were covariates for mother and father education level and previous antenatal care seeking behavior which have been previously shown as significant. [63]

The feasibility of this study was supported by the cooperation and experience of Seva Mandir, our partner health service implanting body and by the remote data collection facilitated through the KB app. Their previous experience with JPAL in studying lentils as immunization incentives from 2004-2007, following over 2000 children across their 130 villages continues to demonstrate a level of credibility in conducting longitudinal randomized evaluations. Further, Seva Mandir acted upon JPAL's findings, implementing the lentil program and translating the demonstrated evidence into program action. Seva Mandir thereby served and will continue to serve as a useful testbed for piloting this intervention and demonstrating evidence for future evaluations and scale-up if measured results can be demonstrated.

We randomized 96 SM camps (level of clustering) across five blocks in the Udaipur District to three treatment arms (sticker only, pendant, and pendant + voice call reminder). Randomization was conducted prior to enrollment. Mothers who attended camps under randomization were offered a chance to participate in the study.
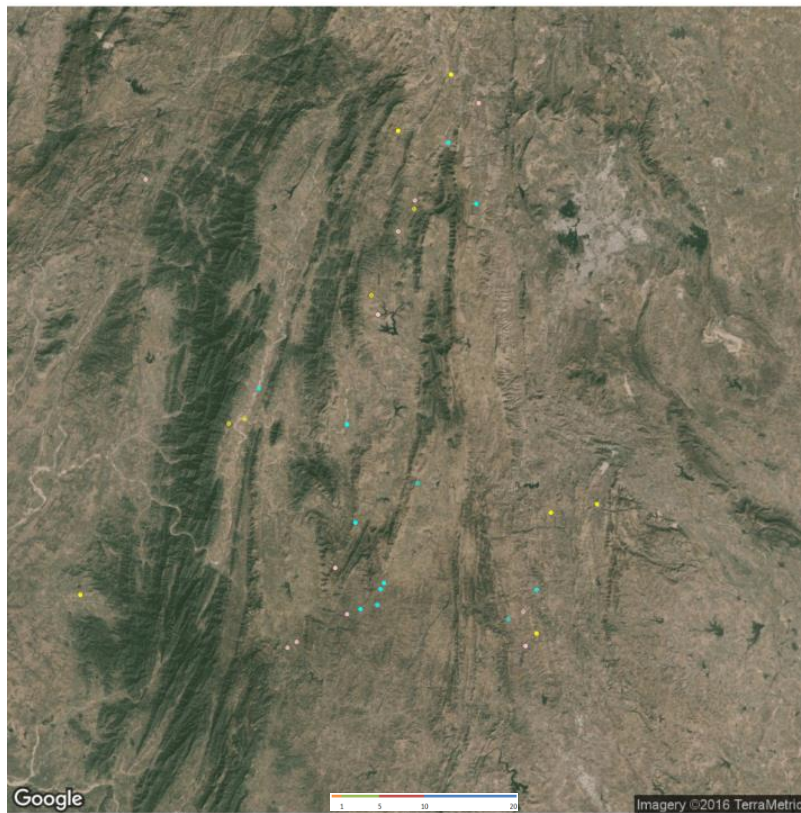
Figure 7. 34 of the 67 villages are mapped above: yellow (stickers), pink (pendants), and cyan (pendants with voice call)

During pilot work 24 camps had been offered a pendant. To minimize contamination a simple randomization was performed to evenly distribute these contaminated pendants evenly among the three arms. While we had initially planned to further restrict randomization so that average camp attendance would be evenly distributed, we were unable to trust Seva Mandir estimates for camp-wide attendance rates on which to do stratification. We chose a cluster randomized approach at the

camp level to minimize potential contamination of study arms as described by others (Hayes and Moulton et al.). For example, if two neighbors were enrolled in the study with infants of similar age where one caregiver received a pendant and the other did not receive a pendant, the control arm mother may be more likely to bring her child for immunization because she was, as a result of the other mother's treatment, influenced to attend the camp.

To achieve sufficient power to detect a minimum detectable difference of 20 percentage points in our clustered design, we targeted enrolling caregivers for three months, obtaining an average of at least three DTP-naïve children per camp in total (assuming 70% DTP3 on time adherence rate in control arm, 80% power, alpha of 0.05, 32 clusters, ICC of 0.15, 10% refusal rate). Of the 96 targeted camps, 67 camps had at least one enrollment during the three month window. The average number enrolled per cluster was approximately three. 24 clusters were in the control group, 21 clusters were in the pendant group, and 22 clusters were in the pendant with voice call reminder treatment group. Due to budget and implementation constraints, enrollment was confined for three months and held constant for all camps. In doing so, the resulting sample size was below the benchmark set for our starting assumptions, suggesting that the study could be unpowered to detect a meaningful difference between treatment arms.

Study Procedures:

Upon intake at the immunization camp, mothers/caregivers were informed of the study and allowed time to ask questions. Mothers/caregivers were then assessed for study eligibility using the following criteria for inclusion :

1. Caregiver has an infant less than six months old[‡‡‡]

2. Resides within one of the villages associated with the immunization camp

3. Willing to sign informed consent

4. In Pendant + Voice call camps, the mother must additionally be able to provide a phone number[§§§]

Mothers would be excluded if any of the following criteria were true:

1. Has received at least 1 dose of DTP vaccine

2. Has no intention to move in the next 6 months

Enrolled participants were expected to have a child less than six months of age and DTP naive (i.e. a child that has not received a single dose of DTP vaccine). This information was obtained by referencing the mother's MAMTA card, where available, or by asking the mother and taking a verbal report. If the mother agreed, she would be informed and consented. General information in some cases was presented at once to all mothers who attended the camp (about 10 per camp) by a village assistant or the camp surveyor. Every mother received an informed consent paper copy, which they either signed or thumbprinted. A separate copy of the informed consent copy signed by the mother was kept by project staff. After consenting, participants, regardless of study arm, were individually given an intake/enrollment survey to determine sociodemographic parameters (see "Baseline Survey" in the Supplementary Appendix for details).

[‡‡‡] Four students were mistakenly enrolled who were six months and one week of age; these children were not excluded from the analysis despite the slight deviation from protocol. All children mistakenly enrolled over this age were excluded (two in number).

[§§§] During the pre-work for the trial, community mobilization was conducted to collect phone numbers and to have them available in the surveyor register; in the case that the mother did not remember the phone number, the surveyor would reference the list of phone numbers previously collated. In doing so, selection bias for wealthier or more educated mothers who could better remember or present their phone numbers was averted. Note also the ownership and access of mobile phones was controlled for in the regression

The enrollment period had to be adjusted for the SM camp schedule. While the enrollment was slated to take place between mid-August to mid-October, camp cancellations in two blocks due to lack of a GNM delayed enrollment in some camps to October. Other camps were delayed in their enrollment due to a combination of Diwali related cancellations in November and the absence of a GNM in the Badgaon block in October and November. The final month of enrollment took place in December 2015. Mothers in the study were followed up till enrollment or completion of the trial, for a minimum of two camps after the enrollment camp. Mothers who finished their child's immunization after the two camp period were considered late and a failure to adhere as per the primary outcome, and mothers who did not finish DTP3 for the children by the end of the study outcome were considered a loss-to-follow up and a failure to adhere. Study follow up for these results concluded at the end of February 2016.

Workflow

A mother arriving at the camp would be screened by either the surveyor or the GNM to assess fit for inclusion in the study. Depending on the number of pregnant women and mothers with infants, this ascertainment process would vary. Generally, children would first visit the GNM where standard operating procedures would be performed to give due vaccines. This information would be relayed to the surveyor who would record the information of vaccine administration or denial (and the reason for denial) using the Khushi Baby mobile application.[****]

While GNMs were expected to collect digital records of non-enrolled patients on NFC stickers via their Sony Xperia M phones running the Khushi Baby application, this process was not adhered to due to high GNM turnover. As a result, non-enrolled patients continued for the most part to be recorded in the SM log book. Children of non-eligible mothers could also receive pendants in pendant or pendant + voice call camps if they asked for them, and in those cases the

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[****] The initial protocol called for the GNM to collect the vaccination information on the

GNM would go ahead and save the patient data to this tag. All children at immunization camps were afforded this opportunity to have access to either a pendant or a sticker to: help allow Seva Mandir to digitize their entire record keeping process. Additionally we avoided introduction of potential heterogeneity within the camp attendees by only including DTP naive children in our list of pendant recipients. A peer effect of some receiving the pendant could bias our results.

After finishing with the GNM, the mother, if a new enrollee mother would be sent to the camp surveyor who would conduct an enrollment screening, record the immunization event, and finish with conducting a baseline survey. The surveyors used a version of the Khushi Baby app which ran on a Nexus 7 tablet. The app provided a new patient workflow which required the camp surveyor to fill out identifying information such as name of the child, mother's name, date of birth, and village. These fields were required, although in some cases the child had not yet been given a name. These children had their nickname recorded which often roughly translated to "baby". From these aforementioned fields a unique ID would be generated for the child. The surveyor would copy this ID for later use. The surveyor would subsequently record the given or expected vaccines for that day after consultation with the GNM, and save the information on the NFC tag. If in a sticker camp, the tag would be initialized in the form of a sticker. If the camp was a pendant or pendant with voice call camp, the tag would take the form of a KB pendant. The NFC sticker would be placed on the mother's MAMTA card above the location for Tetanus Vaccination. In the case that the mother lost her card and there were no MAMTA cards at the camp, the sticker would be placed on the mother's consent form. The pendant would be given to the mother by the camp surveyor. The GNM with the assistant of the TBA would instruct the mother on safe tying technique. The TBA would assist the mother in putting on the pendant to ensure enough slack for the pendant to lie at the top of the sternum, but not too much slack so that the child could put the pendant in his/her mouth. The pendant was tied with a double knot to prevent the pendant from falling off the

neck. The pendants also came pre-strung around the pendant with a special double knot to ensure that the pendant will not fall from the thread. While tying the pendant the GNM would with the camp surveyor and dai ma's assistance, inform the mother about how the pendant was important for storing the child's data (comparing the device to a familiar SIM card), while referencing it's cultural significance.

After placing the pendant or sticker, the surveyor would conduct a baseline survey using the Trellis survey software developed by the Human Nature Lab. The child unique ID copied earlier from the Khushi Baby application was pasted in a labeled field so that mother survey data and child vaccination data could be consistently joined in the analysis phase. All newly enrolled patients would be maintained in a ledger by the camp surveyor.

Existing patients who were returning in months after enrollment would be referenced against the enrollment register by the camp surveyor. Again the mother would follow standard operating procedures to receive her child's vaccines for the day. To determine the due vaccine for today, the GNM would look to scan the NFC tag but could also check the mother's MAMTA card in case the tag was missing. The app would prompt the health worker and/or camp surveyor to examine and ask if the mother reported any problems with the pendant and if the mother would like it to be replaced or removed before proceeding to the aforementioned screens of due vaccines and the prompt to save the record onto the tag. If the mother forgot the tag (sticker or pendant), the camp surveyor and GNM could still retrieve the record by checking the tablet's local backup of patients and initialize a fresh tag with previous records. Throughout the study only three such instances occurred in which a tag was forgotten or not working and needed to be replaced with a fresh tag. Existing patients would receive one of two follow up surveys. The first follow up survey given for mothers coming to the camp for their child's second DTP dose. Mothers coming for the third and final dose would be given a separate, exit survey, again handled with the Trellis software.

There were no reports of vaccination denials for DTP1, 2, or 3 among the study participants, so each survey corresponded with the completion of one dose of the vaccine.

GNMs and camp surveyors would travel back to the block office together and were expected to sync the data both for vaccinations and surveys conducted at the end of each day. Due to internet issues at the various block offices, syncing was delayed at times of up to two to four weeks. The data synced to the cloud could be referenced by the research team as well as the Seva Mandir Director of Child and Maternal Health to see study progress via the Khushi Baby dashboard. This dashboard would also come into play for children randomized to pendant + voice call camps as voice calls were also launched from this dashboard, in this case by a research administrator. The initial intention was to leverage an automated system, but due to technical difficulties, individuals had to be called one at a time with the standardized messages. Families of children in the third arm would receive reminders the day before an immunization camp, the day of the immunization camp. They would additionally receive a thank you message if they were adherent for their next dose and a missed camp message if they failed to adhere. Randomly selected phone numbers were given an additional educational/informational message about the importance of vaccines for the child's health.

Mothers could choose to drop out at any time by removing their pendants outside of the camps, informing the GNM at the monthly meeting to dropout, or by informing the village TBA was tasked to compile a list with the camp surveyor of those deciding to no longer participate. No mother in the study dropped out explicitly due to concerns with the arm they were randomized to. Lastly, with the study in it's terminating phase, we expect to present our results and recommendations to the Seva Mandir key staff and advisors in April or May 2016. Midterm analysis conducted in January and February did not show evidence to support a decision to terminate the trial early in favor of any one of the three arms.

The source population was comprised of mothers who would visit a Seva Mandir camp for infant health care during the open enrollment window (Aug – December, varying based on the particular camp). Of the 300 targeted mothers we intended to enroll, we were only able to enroll 214 mothers (62 sticker mothers, 64 pendant mothers, and 77 pendant with voice call mothers) across 67 clusters (24 stickers, 21 pendants, 21 pendants with voice call reminder). All eligible mothers encountered were enrolled. 11 patients enrolled were not registered in the KB backend due to sync failures. On average 3 mothers were enrolled per cluster.

Twenty-nine percent of mothers enrolled were lost to follow-up (and also thereby non-adherent). Three mothers had children who died. Verbal autopsies were performed. One child exhibited signs of pneumonia, another child exhibited signs of seizures, and the final child exhibited symptoms of infection and was rushed to a hospital in Gujrat. 29 mothers faced interrupted camp schedules either due to Diwali or due to GNM turnover. 141 or 65.9% mothers completed their child's DTP3 sequence. The highest DTP3 completion rate was among those randomized to the sticker arm (74%). When considering timeliness however, only 84 mothers (35.9%) finished the DPT3 dose within two camps from DTP1.

The pendant with voice call reminder arm had the highest percentage of timely DTP3 completion by the criteria outlined in the primary outcome of two camps after DTP1 (44.2%). Among those who did not have interrupted camps, 37.0% of sticker mothers, 38.6% of pendant mothers, and 42.3% of pendant with voice call mothers finished in two months, as recommended by the Indian Academy of Pediatrics. When considering the WHO definition of adherence, 41.9% of sticker mothers, 46.9% of pendant mothers, and 46.8% of Pendant with voice call reminder mothers finished DTP3 before their child turned six months of age. These unadjusted results would suggest that although sticker mothers had higher coverage, but pendant and P+V mothers had better overall

timeliness. It's important to note that there may be some overlap in the effect between pendants and P+V, as less than 50% of the reminder calls were reported as received by the intended mother before DTP2 and DTP3.

The ICC was calculated on using all outcomes individually by treatment arm. The ICC estimate was unreliable when taking the finished by 2 camps and finished by 2 months outcomes. Using the WHO cutoff, the ICC estimate was 0.136. The resulting effective sample size for an equivalently un-clustered sample would be 168 participants. The design effect and effective sample size due to clustering are shown below:

$$DE = 1 + (m\text{-}1)ICC$$

$$DE = 1 + 2(0.136) = 1.272$$

$$ESS = 214/1.272 = 168$$

Mothers who Visited a SM camp during open enrollment

214 Eligible
67 clusters

0 Refused

11 sync fail

Stickers Enrolled: 62
Pendants Enrolled:64
P+V Enrolled: 77

3 Pendants needed to be replaced

%44.2 did not receive a call for DTP3
%46.8 did not receive a call for DTP2

LTF: 62
S: 16
P: 22
P+V: 24

Death: 3
S: 0
P: 1
P+V: 2

Interrupted Camp: 29
S: 16
P: 7
P+V: 6

84 Received DTP3 within 2 camps of DTP1
S: 26 (41.9%)
P: 24 (37.5%)
P+V: 34 (44.2%)

69 Finished DTP3 in 2 months (IAP cutoff)
S: 17 (37.0%)
P: 22 (38.6%)
P+V:30 (42.3%)

92 Finished DTP3 by 180 days (WHO cutoff)
S: 26 (41.9%)
P: 30 (46.9%)
P+V: 36 (46.8%)

Stickers Exited: 46
Pendants Exited:42
P+V Exited: 53

Figure 8. Study Results Overview
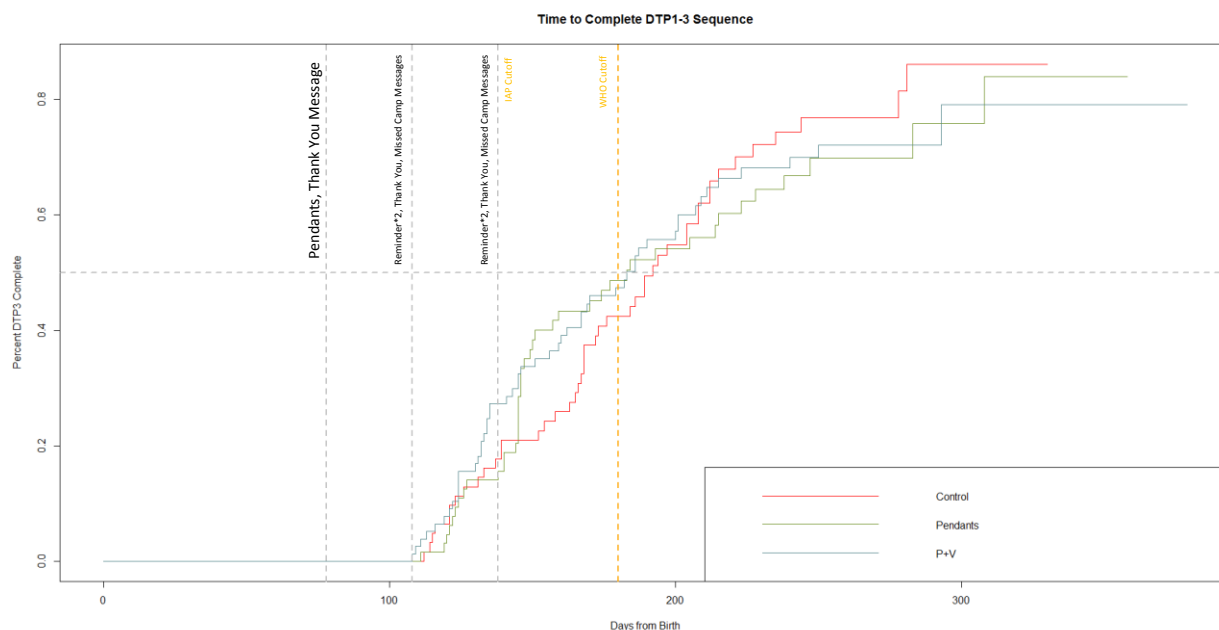
Figure 9. KM Curves for DTP3 completion from birth; median time for introduction of intervention is noted by gray vertical lines

Although pendant and pendant with voice call arms outperformed the sticker arm in the timeliness window defined by the IAP and WHO respectively, there was no statistically significant difference in the KM curves (given unadjusted and cluster adjusted analyses) from birth to DTP3 completion given the study's power and minimum detectable difference of 20%.

The descriptive analyses presented several important takeaways for the study population. Median time to camp: 30 minutes with a maximum of 180 minutes one way. Median number of children per household: 2 children with a maximum of 10 children. Median number of institutional births: 1, IQR:1-2, max = 8. Median marital age: 19 years. Median maternal age for this enrollment: 25.48 years. Median highest grade attended: 0 (IQR 0-5). Proportion of mothers who were able to cite a specific disease when asked about the importance of vaccination = 71.9% (147/214). 123 mothers identified as farmers, 154 as house wives, 108 as daily wage earners, and 159 as self-employed. The *dai ma* was confirmed as a central figure structurally in these villages and is the nodal member for vaccination reminders. Retention of the card was poor compared to the pendant. At enrollment: 53/177 = 29.9% lost or forgot their card at home. At first follow up: 13/175 = 7.4% lost or forgot at home. At second follow up: 31/159 (19.5%) lost or forgot at home. Among those with stickers, 11 forgot at home at enrollment, 4 at DTP2, and 3 at DTP3. On the other hand, 3/141 pendants (2.1%) needed replacement. Occupation was recorded for the husband as well in the baseline survey but is not presented here. Given the nature of flexible occupations, it was deemed that questions that would self-describe the mother would be more relevant form the analysis as she would be the caregiver at the camp being surveyed.

The Social Network Analyses demonstrated strong network centrality (proxied by in-degree) of the dai ma. Across treatment arms, the dai ma was nearly unanimously referenced when asked about which alter serves as the ego's health reminder. Smaller peaks may correspond to other mothers or locally established village leaders (such as balsakhis who assist the dai ma). This functional role cannot be confirmed from the data collected. The median outdegree for mothers in the RCT was 2 as was the median number of camp-related conversations with unique alters prior to the child's enrollment. Among camp attending mothers, no mother had an explicit tie to an anti-vaxer alter. Representative sociocentric networks for two hamlets in Badgaon are shown below.

Time to Reach Camp	Education Level of Mother	Age of Mother	Age of Mother at Marriage

Age of Child at Enrollment	Number of Children	Number of Prior Child Deaths	Number of Institutional Births
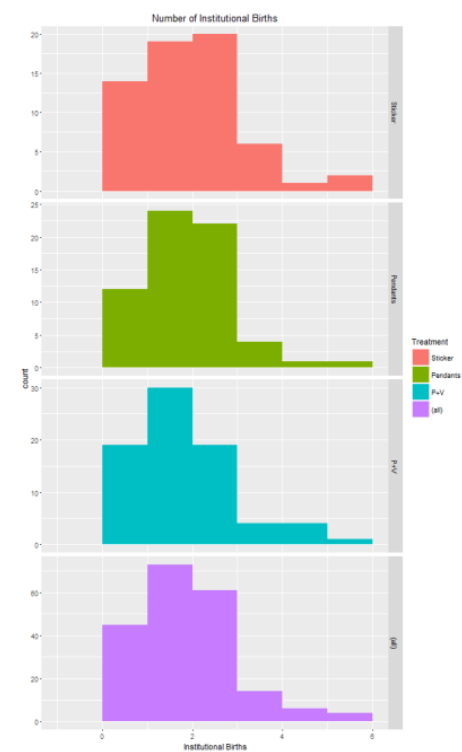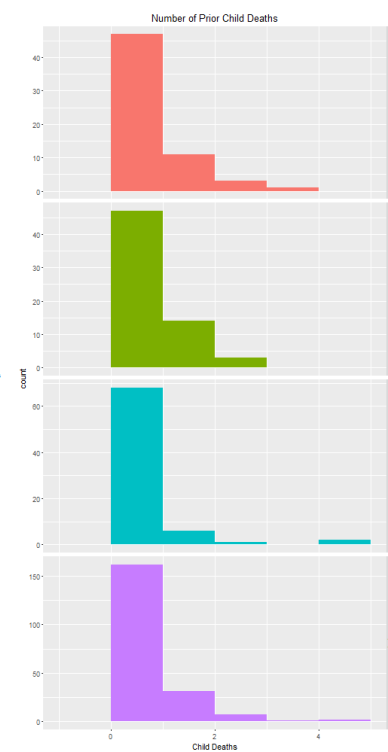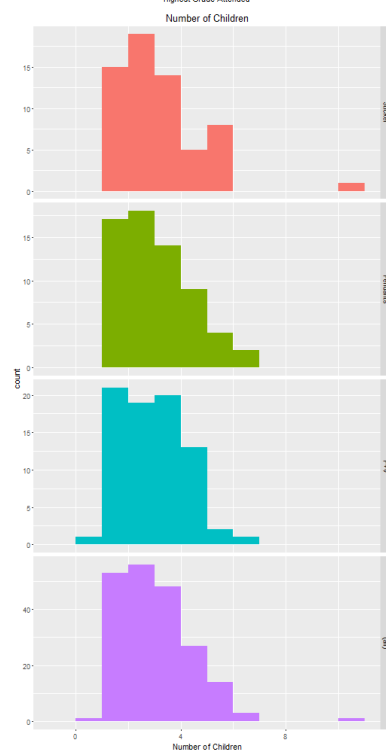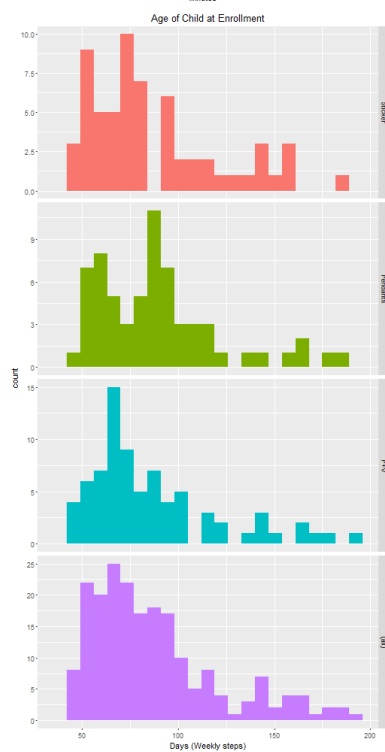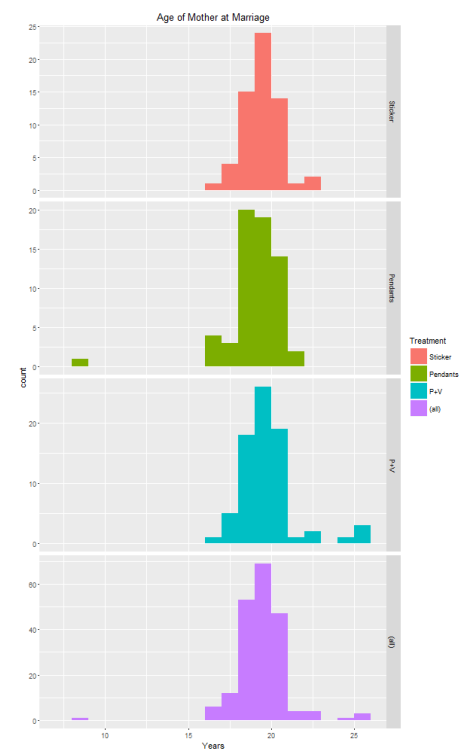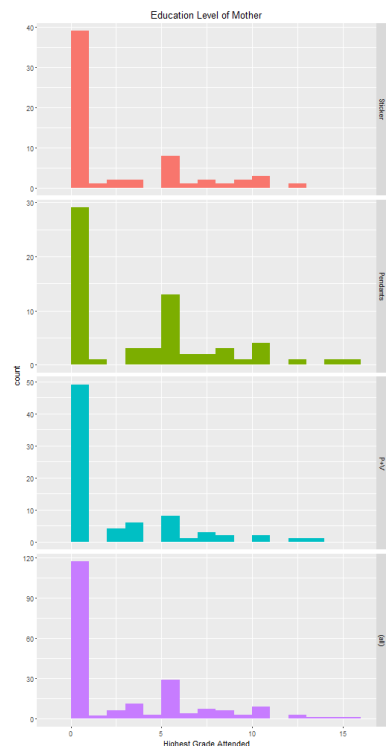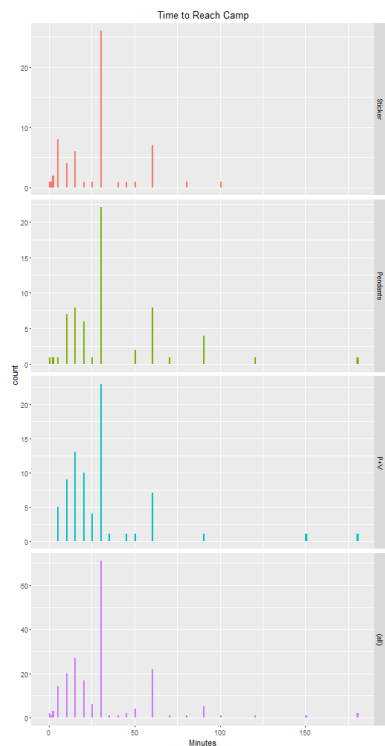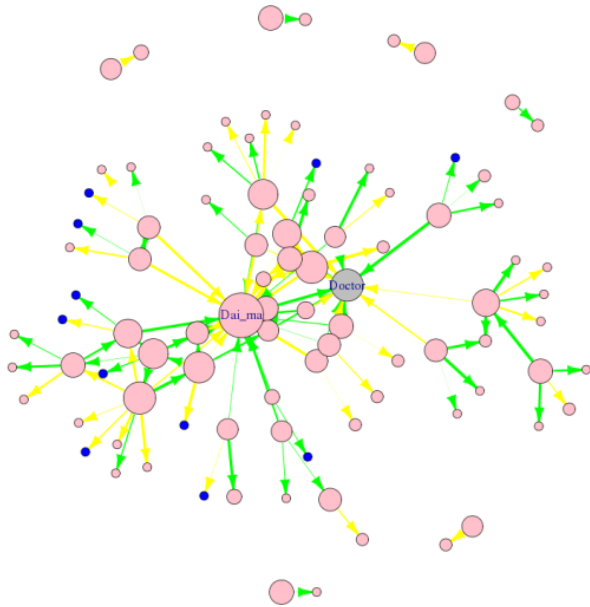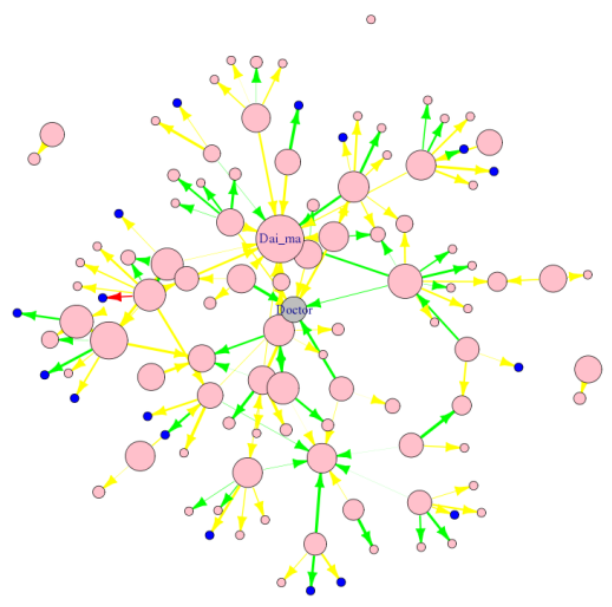
Figure 12. Representative Villages; Pink dots represent females, blue dots represent males. Green connections are health related ties; yellow connections are friendship ties; red connections are anti-health ties
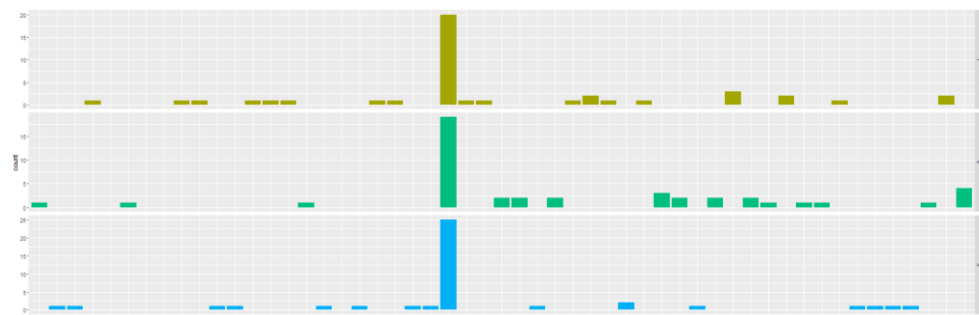
Figure 13. Dai ma's were common alters for the health advisor social tie question
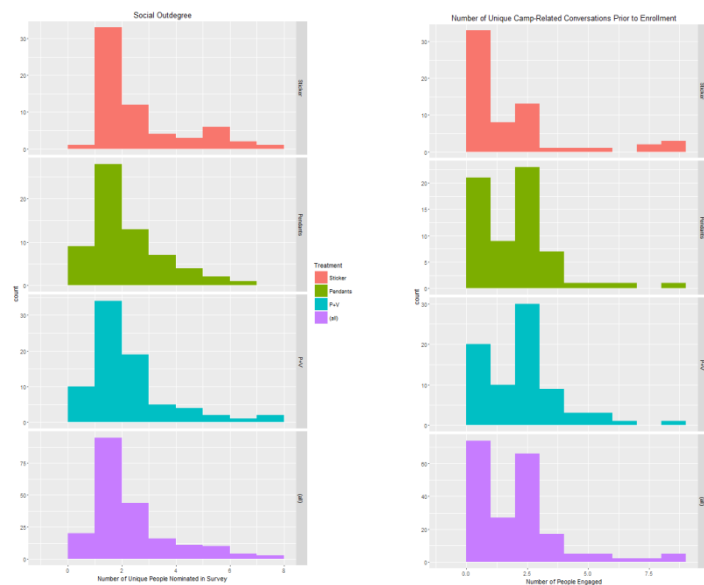
Figure 14. Social Outdegree was asymmetrically distributed

Randomization balance on variables of interest was checked among treatment arms. These variables included: highest grade in school attended by mother, caste of the mother, marital status of the mother, marital age of the mother, occupation of the mother, distance in minutes to the camp, mobile phone access or ownership, electricity type, bathroom type, water type, number of home births, number of institutional births, number of children, number of child deaths experienced, age of child at enrollment, gender of child, whether child received BCG or not, number of unique conversations about camp prior to enrollment, awareness of number of required vaccines, awareness of a specific vaccine preventable disease, social outdegree of mother, and whether the mother was connected to the village dai ma. To check the balance, the TableOne package (CRAN project) was implemented, which used three-way ANOVA and kruskal.wallis tests accordingly. Prior to that, each quantitative variable was categorized as normal or non-normal by inspection.

Table 2. Randomization Balance	Stickers	Pendants	P+V	p-value
n	62	64	77	
Clusters	24	21	22	
Highest Grade Attended (mean(sd))	2.24 (3.43)	3.55 (3.99)	2.00 (3.22)	0.027
Caste Category (%)				<0.001
GEN	5 (8.1)	1 (1.6)	1 (1.3)	
OBC	2 (3.2)	9 (14.1)	4 (5.2)	
SC	2 (3.2)	15 (23.4)	7 (9.1)	
ST	53 (85.5)	39 (60.9)	65 (84.4)	
Percentage of Mothers "Married"	62 (100.0)	62 (96.9)	71 (92.2)	0.059
Marital Age of Mother (mean(sd))	18.93 (1.12)	18.51 (1.78)	19.25 (1.70)	0.023
Age of Mother (mean(sd))	26.95 (4.51)	26.15 (3.53)	27.73 (3.19)	0.176
Mother Occupation = Wage Earner (%)	38 (61.3)	31 (48.4)	39 (50.6)	0.299
Mother Occupation = House Wife (%)	46 (25.8)	44 (68.8)	64 (83.1)	0.13
Mother Occupation = Farmer (%)	42 (32.3)	31 (48.4)	50 (64.9)	0.052
Mother Occupation = Self Employed (%)	52 (16.1)	47 (63.4)	60 (77.9)	0.362
Time to camp in minutes (mean(sd))	27.98 (20.47)	36.12 (30.79)	29.48 (27.67)	0.188
Mobile Phone (%)				0.002
no/neither	14 (22.6)	11 (17.2)	2 (2.6)	
yes, access	40 (64.5)	47 (73.4)	71 (92.2)	
yes, own	8 (12.9)	6 (9.4)	4 (5.2)	
Electricity (%)				0.01
no/neither	24 (38.7)	38 (59.4)	28 (36.4)	
yes, line	34 (54.8)	18 (28.1)	43 (55.8)	
yes, solar	4 (6.5)	8 (12.5)	6 (7.8)	
Bathroom (%)				0.192
covered	0 (0.0)	1 (1.6)	2 (2.6)	
open	62 (100.0)	61 (95.3)	70 (90.9)	
ventilated	0 (0.0)	2 (3.1)	5 (6.5)	
Water Source = Well (%)	35 (56.5)	51 (79.7)	50 (64.9)	0.019
Water Source = Bore Well (%)	57 (91.9)	62 (96.9)	66 (85.7)	0.065
Water Source = Hand pump (%)	36 (58.1)	52 (81.2)	52 (67.5)	0.018
Water Source = Waterfall (%)	0 (0.0)	1 (1.6)	1 (1.3)	0.633
Number of Institutional Births (mean(sd))	1.47 (1.18)	1.39 (1.02)	1.31 (1.14)	0.714
Number of Children (mean(sd))	2.66 (1.61)	2.55 (1.36)	2.43 (1.24)	0.62
Number of Prior Child Deaths (mean(sd))	0.32 (0.65)	0.31 (0.56)	0.21 (0.71)	0.504
Number of Home Births (mean(sd))	1.44 (1.68)	1.19 (1.44)	1.12 (1.25)	0.414
Age of Child at Enrollment in Days (mean (sd))	86.55 (34.60)	88.03 (31.77)	85.74 (33.69)	0.92
Proportion of Children who received BCG	28 (45.2)	20 (31.2)	15 (19.5)	0.005
Gender = Male (%)	36 (58.1)	33 (51.6)	38 (49.4)	0.578
Aware that more than 7 Vaccines required (%)	8 (12.9)	7 (10.9)	10 (13.0)	0.921
Aware of specific vaccine preventable disease (%)	9 (14.5)	24 (37.5)	24 (31.2)	0.012

Outdegree (mean (sd))	2.10 (1.64)	1.67 (1.35)	1.73 (1.51)	0.223
Social Tie with Dai Ma = 1 (%)	47 (75.8)	52 (81.2)	60 (77.9)	0.755
MAMTA card status at Baseline (%)				0.312
no never received	7 (11.3)	7 (10.9)	14 (18.2)	
no, lost the card	1 (1.6)	4 (6.2)	3 (3.9)	
yes	43 (69.4)	40 (62.5)	39 (50.6)	
yes but at home	11 (17.7)	13 (20.3)	21 (27.3)	
Camp Satisfaction at Baseline (%)				0.175
not satisfied	3 (4.8)	3 (4.7)	0 (0.0)	
satisfied	37 (59.7)	39 (60.9)	40 (51.9)	
very satisfied	22 (35.5)	22 (34.4)	37 (48.1)	
Number of Conversations with Others before first camp (%)	1.35 (2.17)	1.55 (1.55)	1.79 (1.57)	0.345
Block (%)				
				<0.001
Badgaon	15 (24.2)	8 (12.5)	9 (11.7)	
Girwa	17 (27.4)	10 (15.6)	4 (5.2)	
Jhadol	10 (16.1)	6 (9.4)	12 (15.6)	
Kherwara	4 (6.5)	29 (45.3)	31 (40.3)	
Kotra	16 (25.8)	11 (17.2)	21 (27.3)	
Starting Month (%)				0.182
August	8 (12.9)	6 (9.4)	14 (18.2)	
Sept	24 (38.7)	16 (25.0)	15 (19.5)	
Oct	18 (29.0)	21 (32.8)	31 (40.3)	
Nov	6 (9.7)	12 (18.8)	11 (14.3)	
Dec	6 (9.7)	9 (14.1)	6 (7.8)	
Number of Camp Cancellations (mean(sd))	0.26 (0.44)	0.17 (0.58)	0.08 (0.27)	0.057
Proportion of Camp interruptions (%)	16 (25.8)	7 (10.9)	6 (7.8)	0.007
Proportion of Child Deaths (%)	0 (0.0)	1 (1.6)	2 (2.6)	0.45

Potential confounders due to significant differential associations with treatment arm included: caste category, marital age, mobile phone ownership, electricity source, water source, proportion of children who received BCG, proportion of mothers aware of specific vaccine preventable disease, geographical block and proportion of camp interruptions.

Regression modeling took place on three outcomes: first, completion of DTP by 2 camps after enrollment. second, completion of DTP by 2 months after enrollment (where children who faced an interrupted camp were excluded from the analysis), and third, completion of DTP3 by 180 days of birth. To select covariates for our models we considered several factors: was the covariate associated with the outcome independently? Was the covariate differentially distributed among treatment arms to a significant degree? Finally, even if the first two criteria were not met, we considered a theoretical basis that would justify inclusion of the covariate. Models generated were also designed to be parsimonious in construction. With 200 data points, we limited the number of covariates to 10 and levels of all covariates to 20. The regressions were based on an intention-to-treat approach, thereby conducting an analysis consistent with the original randomization. We had no evidence of contamination due to drop-in or drop out from intervention to control arms based off the data collected.

Table 3. Significant Unadjusted associations between exposure and outcome

Variable with Theoretical Importance	By 2 camps	By 2 months	By 180 days	Differentially Distributed?	Causal Pathway
Pendant	No; 1.48 (.70-3.20)	No; 1.07(0.48-2.41)	No; 1.22(0.60-2.48)	Yes	Being tested
Pendant + Voice	No; 1.69 (.83-3.53)	No; 1.25(0.59-2.70)	No;1.22(0.62-2.40)	Yes	Being tested
Caste	No	No	No	Yes	No
Maternal Age	No	No	No	Yes	No
Marital Age	No	No	No	Yes	No
Child received BCG prior to enrollment	No	No	No	Yes	No
Mother aware of vaccine preventable disease at baseline	No	No	No	Yes	No
Mobile Phone access or ownership	No	No	No	Yes	No
Electricity source (line)	2.09 (1.13-3.92)	2.25(1.18-4.36)	No	Yes	No
Water source	No	Handpump: 0.53(0.26-1.04)	Handpump: 0.54(0.29-0.98)	Yes	No
Mother Occupation = Wage earner	2.72(1.51-5.00)	2.09(1.13-3.93)	No	No	No
Whether a camp was interrupted	0.05(0.003-0.26)	n/a		Yes	No
Age of the Child at enrollment in weeks	Almost 0.95(0.88-1.01)	0.82(0.86-9.99)	0.73(0.65-0.81)	No	No
Gender of the Child	1.72(0.96-3.12)	2.04(1.10-3.83)	1.83(1.05-3.22)	No	No
Outdegree of Mother	0.82(0.65-1.01)	No	No	No	No
Whether mother referenced Dai Ma as social connection	No	No	No	No	No
Number of Prior Children	No	No	No	No	No
Geographical Block	No	Jhadol: 0.19(0.04-0.74)	Jhadol: 0.15(0.04-0.48)	Yes	No
Start Month compared to August October November	November: 3.93(1.28-13.3)	October 3.27(1.20-10.07) November 3.93(1.28-13.3)	October 2.66(1.08-6.94)	No	No
Number of Prior Child Deaths	No	No	No	No	No

These covariates were then compared to the model output which optimized through backward selection. Covariates were also checked for multicollinearity (for example block and start month showed high correspondence because certain blocks only started in a given month – e.g. Jhadol). Final models for the three outcomes are shown below with their outputs.

Covariates with significant unadjusted associations included: electricity, water source as hand pump, occupation of other as wage earner, age of the child at enrollment, gender of the child, outdegree of the mother, geographical block and start month of enrollment. These variables along with those differentially distributed were kept for subsequent backwards selection

Covariates without differential distribution or significant unadjusted associations included: prior child deaths, number of children, and social connection to the dai ma. These covariates were excluded from the backwards selection models moving forward.

Model 1: Finished by two camps after enrollment

Backwards selection drops the following variables using AIC criteria: block_id, caste category, mobile phone ownership/access. Marital age of the mother as also dropped due to high multicollinearity with the intercept term. The remaining variables were regressed, adjusting for random effects of the camp (unit of clustering) using the LME4 package (CRAN project). The results and final model are shown below:

$Formula: adherent1to3 \sim I(Treatment == \text{P+V}) + I(Treatment == \text{Pendants}) + maternal.$
$age + bcg.status + vaccine.prevent.disease.knowledge + electricity + water$
$(handpump) + occupation.mother(wageearner) + interrupted.camp + child.age.at.$
$enrollment + child.gender + outdegree + start.month + RandomEffect(1 | camp\_id),$
$data = mydata, family = binomial(logit)$
AIC: 227.6

Table 4. Relative Risks after adjustment

Pendants with voice call	1.57 (0.59-4.20)
Pendants	1.48(0.5-4.37)
Significant at the 0.01 level	
Mother Occupation = NOT Wage Earner	3.05(1.32-7.05)
Interrupted Camp = True	0.053(0.006-0.48)
Start month = November	7.88(1.66-37.5)
Significant at the 0.05 level	
Electricity (line)	2.88(1.78-7.04)
Start month = October	4.29(1.03-17.8)
Significant at the 0.1 level	
BCG status = True	2.17(0.88-5.36)
Vaccine Preventable Disease Awareness = False	0.42(0.16-1.08)
Child age at enrollment in weeks	0.93(0.85-1.01)
Child Gender = Male	2.34(0.96-5.73)
Outdegree of Mother	0.79(0.60-1.04)
Start month = September	3.33(0.78-13.92)
Start month = December	5.31(0.99-28.4)

When changing the reference group from Sticker to Pendant, the relative odds of adherence in the voice call group was 1.06 (0.42-2.63) times the odds of that in the pendant only group.

Model 2: Finished by 2 months

Backwards selection drops the following variables using AIC criteria: block_id, caste category, mobile phone ownership/access. Missed camps was dropped as a covariate as this cohort was limited to those who had not faced interrupted camps. Marital age of the mother as also dropped due to high multicollinearity with the intercept term. The remaining variables were regressed, adjusting for random effects of the camp (unit of clustering) using the LME4 package (CRAN project). The results and final model are shown below:

Formula: $adherent1to3 \sim I(Treatment == P+V) + I(Treatment == Pendants) + bcg.statatus + vaccine.prevent.disease.knowledge + electricity + water.handpum + occupation.mother\ (wage\ earner) + childweeks + child.gender + outdegree + start.month + RandomEffect(1 \mid camp\_id)$
Data: $noint, family = binomial(logit)$
AIC = 228.9

Relative Risks after adjustment

Pendant with voice call reminder	1.46(0.57-3.78)
Pendant	1.29 (0.45-3.73)
Significant at 0.01 level	
Occupation Mother = NOT Wage Earner	3.42(1.53-7.65)
Significant at 0.05 level	
Start Month = November	4.82(1.19-19.4)
Electricity = line	2.39(1.02-5.55)
Significant at 0.10 level	
Intercept	0.14(0.018-1.14)
Vaccine preventable disease knowledge = NO	0.43(0.17-1.10)
Child age at enrollment	0.92(0.85-1.00)
Child gender = Male	O 2.16(0.90-5.18)
Outdegree	0.77(0.58-1.01)

Model 3: Finished by 180 days ~

Backwards selection drops the following variables using AIC criteria: block, caste category, mobile phone ownership/access. Marital age of the mother as also dropped due to high multicollinearity with the intercept term. The remaining variables were regressed, adjusting for random effects of the camp (unit of clustering) using the LME4 package (CRAN project). The results and final model are shown below:

Formula: $adherent1to3 \sim I(Treatment == "P+V") + I(Treatment == "Pendants") + bcgstatus + vaccineawareness\_why.prevents.specific.disease. +$
$electricity + water.handpump.y + occupation\_mother.wage.earner.y + missX + childweeks + child\_gender + outdegree + maternalage + start\_month + (1 \mid camp\_id)$
Data: $mydata, Family = binomial\ (logit),$
AIC = 227.6

Relative Risks after adjustment

Pendant with voice call reminder	1.57(0.58-4.20)
Pendant	1.48 (0.45-3.73)
Significant at 0.01 level	
Occupation Mother = NOT Wage Earner	3.05(1.32-7.05)
Interrupted Camp	0.05(0.0059-0.48)
Start Month = November	7.88(1.66-37.5)
Significant at 0.05 level	
Electricity = line	2.87(1.17-7.04)
Start Month = October	4.29(1.04-17.7)
Significant at 0.10 level	
Intercept	0.14(0.018-1.14)
Vaccine preventable disease knowledge = NO	0.43(0.17-1.10)
BCG Status	2.17(0.88-5.36)
Child age at enrollment	0.92(0.85-1.01)
Child gender = Male	2.34(0.96-5.73)
Outdegree	0.77(0.58-1.01)
Start Month = September	3.33(0.80-13.9)
Start Month = December	5.31(0.99-28.4)

Across all three outcome models of adherence, the predictors were more or less consistent. After adjusting for potential confounders, pendant and pendant with voice call reminder groups had positive odds estimates compared to the sticker group, but these estimates were not statistically significant; similarly, the pendant with voice call group had a higher odds estimate than the pendants only group, albeit the estimate was not significant.

Significant positively associated covariates with the adherence outcomes after adjustment included: the occupation of the mother not being a daily wage earner, having line-powered electricity, and being enrolled in October or November. Significant negatively associated covariates with the adherence outcomes after adjustment included: having an interrupted camp and interestingly, and having a higher out-degree. We failed to find a theoretical basis for significant interactions based off Baron and Kenny criteria. Given our low power and non-significant main effects, interactions were not explored with the treatment group.

The main finding of the study is a null result with regards to the effectiveness of the intervention, both pendant and voice call on improving timely adherence from DTP1 through DTP3 for the infant. Although coverage estimates are higher, timeliness still has much room for improvement. This novel approach for moving the needle on timeliness may have fallen short due to no true effect. On the other hand, a low sample size may have reduced the study's power, thereby making the study unable to detect a small yet meaningful difference. Furthermore, it is possible that the latency of the effect was not captured in the first few months where adherence may already be relatively high. A better indication of timely adherence could be gauged upon completion of measles. Finally, it's important to note that all point estimates were positive for the intervention arms, according to original expectations. So there is no reason to favor a hypothesis with the inverse relationship between intervention and outcome.

We originally predicted that the KB pendant arm would perform better for adherence, satisfaction, and awareness outcomes. We also anticipated that the KB voice call with pendant arm would improve satisfaction, adherence, awareness (both for mother and at home) compared to the controls and pendant only arms. We postulated several mechanisms that still may hold true. Pendants via vis their symbolic value could build trust at the inception of care. This initial impression could affect future behavior and relationships, which would affect follow up and adherence. The more personal nature of tying the pendant on to the child may affect how the health worker communicates information about the upcoming immunization schedule on an interpersonal level as well, thereby affecting awareness and satisfaction with the experience as well. In other words the pendant could have been used as an educational prop at the camp site. Pendants being a visible piece of jewelry could attract gossip among non-attending mothers or future mothers-to-be and thereby contribute towards formation of social norms predicated on going to the immunization camp. We further anticipated that the phone calls could serve to not only maintain proper behavior but also increase awareness in the household. As the husband often possess the phones, it could have been possible that they may have been more attuned to the developments of their child's immunization progress.

Considering the data not presented here, and discussed further in Venkat's thesis, there is statistically significant evidence to support that the pendant is widely accepted and discussed throughout the camp. Few pendants were lost, and many mothers who were not in the cohort opted for a pendant as well. The awareness and attitude of the mother and paternal grandmother toward the pendant and immunization camps faired positive at the exit survey. Nearly half of individuals cited the pendant as a relevant factor in their camp attendance and tool that could be used for future recruitment. Given the benefits of a better retained medical record, and the potential benefits on improvement in health behavior, further studies should and will be conducted to narrow the

precision of the intervention effect estimate. Parallel effects on health worker decision making as guided through the mobile app and health worker performance in relation to the paperless workflow further justify future evaluation. Before such evaluation can take place, improvements the KB system itself are in order. With fewer than 50% of intended calls being placed from a manually-operated voice call reminder system, the intervention arm could be further optimized compared to its trial implementation. In particular, in looking to scale, the call reminders would need to be standardized and automated. Further pilot work around messaging and timing will need to be conducted before a subsequent trial.

Beyond the treatment effects of the intervention, this study further elucidated predictors of immunization adherence. Prior studies have suggested low SES, low maternal education, high number of home births, high number of children under 5 (not measured here), younger maternal age (estimated here), presence of Vaccination Reminder System, further Distance from Health Provider, and child birth at home are all associated with poorer adherence outcomes. While education and camp time were not considered in the regressions, in other post-hoc analyses the aforementioned predictors were either consistent with or showed a null result in our models. One predictor that stood out was outdegree of the mother. We would expect outdegree, a proxy for centrality, to be associated with higher adherence as more socially connected mothers would both be more likely to follow the herd and to be more aware of available services. The estimate however showed that increased outdegree corresponded with a drop in adherence, perhaps explained by a possible echo-chamber like effect, where egos must get confirmation from multiple social connections before themselves committing to an action. Alternatively, given that the relationship-identifying name-generator questions were only validated for Honduras and not formally validated in the Udaipur context, it is possible that the series of questions asked did not confer appropriate construct validity, and therefore failed as an instrument.

The above model results must be contextualized based on their internal and external validity. Internal validity of course may have been affected by non-equivalent camp distribution among the arms, due to lack of stratified randomization with blocking. Failures in implementation of the phone call intervention as well may have also biased the analysis comparing the third arm. Furthermore, the study may have been challenged by Hawthorne effects; in other words the act of observation may have resulted in differential or non-differential exposure on subjects. In this case, with up to 7 months of follow-up, increased interaction with a surveyor may itself have an effect on RI awareness, independent of the intervention itself. The presence of the surveyors, could have increased the nurse work load, the waiting times, and increasing engagement, which may have provided incentives for mothers to return more often. Conversely, discomfort with the presence of unfamiliar male surveyors or from the additional time from participating in the survey may have detracted caregivers from attending camps and adhering to the RI schedules. As there were 8 different surveyors, there could have been differential effects unmeasured in the analyses above. It is worth noting that the surveyors were not blinded to the treatment arm and may have been biased towards data collection or follow-up of treatment mothers. Therefore the reported odds ratio may be even over-inflated, further decreasing the likelihood of significance in this underpowered study.

John Henry Effects may have resulted with caregivers who were geographically proximate to intervention targeted villages that are given the KB pendant (social symbol). In the case that such a caregiver was able to notice that pendants are being distributed outside their control group, they may have foregone their village's designated immunization camp site to receive immunizations from a nearby intervention camp. These effects would have to an extent been mitigated as only new registrants and village residents will be included in the study as per the eligibility screen. Health workers could also have identified if the mother/caregiver had previously been enrolled by identifying the presence of an NFC sticker on the mother's MAMTA card (the control treatment).

In our case, we did not find any reports of such contamination, however villages with different camp assignments were within walking distance (1-5km). For example, one mother who faced three interrupted camps attended three separate nearby camps to finish DTP3 immunization in two successive months.

The overall study strengths and weaknesses can be summarized in Table 5 below:

Strengths:
- First RCT to test this novel intervention systematically
- Randomized design minimized confounding
- Clustering minimized chance of contamination within village
- RCT was conducted on a shoe-string budget of less than $16,000
- Mix of quantitative and qualitative methods was employed, including human-centered design research and sociocentric mapping
- Did not rely on vaccination card or verbal vaccination report for determination of vaccine receipts as interactions were collected through the KB app
- Collection of vaccination denial reasons may be used to further elucidate provider-patient interaction

Weaknesses:
- Small sample size
- Follow-up was limited to those who were camp attenders; house hold survey would be needed to see both spillover to non-target camp attenders and camp-defaulters
- Supply Side failures led to camp cancellations, differentially distributed among treatment arms
- Failure to deliver intervention protocol in Pendant + Voice call arm to a majority of sample participants
- Surveyors nor GNMs were blinded to the treatment arms leading to differential treatment effects
- Data collection had gaps
  - 9 children were not in the KB backend
  - 2 children were in the KB backend but had no registered vaccines
- Failure to adjust for seasonal trends beyond starting month, father education, and ANC adherence (the latter two of which are known predictors of timeliness and coverage)
- Inability to measure longer term / latent effects on health behaviors

When considering external validity or generalizability of the results and intervention, one must consider the study context first. Udaipur again is a high focus district, with low rates of immunization coverage and timeliness. When compared to similar districts or geographies in Northern India, one cannot make broad generalizations about either the culture or beliefs. As mentioned previously, the UNICEF CES 2009, reasons for under-immunization also differed by region. That being said, the cultural appropriateness of the KB pendant may be more generalizable. Similar concepts were proposed through ethnographic and human-centered design approaches in Bihar for example.[4] We believe the intervention has scope throughout Rajasthan and generally in North India where practices of wearing a kaalo dhaaga to protect against "evil eye" are prevalent.[4,50] Broadly speaking, amulet wearing practices can be found in cultures around the world.[52] We acknowledge that the social signaling of any particular form factor will vary from community, but we hope we allow communities to self-tailor the pendant to confer upon it commensurate value. When it comes to considering a universizable approach, we are also including NFC stickers as a potential form factor and one of our treatment arms. This form factor can conform to any government-issued MCH card, costs less 0.15 USD at bulk, and is readily scalable and already available off-the-shelf. Recent discussion with the Carlos Slim Foundation has shown that they are also testing and preparing to scale an NFC sticker model for immunizations in Mexico. For these reasons, we do not believe the form factor of this intervention, whichever form factor does succeed, will prevent cross-application to other regions and contexts, but we do recognize that local adaptation will happen when such a transfer does occur.

Chapter 6. Future Directions

Originally designed as a last mile data collection platform for immunization tracking, the KB pendant and its supporting digital platform promises more in terms of potential to generate attention, awareness, and hopefully demand towards critical, life-saving immunizations for infants in rural India. Premised off designing an innovation that would be locally relevant (symbolic thread color or dialect-specific voice calls), the intervention makes a strong case for affecting local health seeking behavior in these last mile villages. Of course multiple interventions will be needed to address this complex behavior change, which is predicated on sustained behavior affected by local health beliefs and lifestyle conditions. Yet the local signature of the intervention speaks to its potential adoptability just as its low cost (for both pendants and voice calls) suggests promise for scale up and integration with government maternal and child care delivery and tracking systems.

A larger evaluation in villages serviced by the Udaipur district government, incorporating the intervention from antenatal care onwards will begin soon after this study to continue to seek answers and questions that evolve from this approach. The intervention will look to be strengthened in several facets: introducing a stronger educational component to the mobile health app used by the health worker, incorporating a biometric field for stronger identification in the case of tags that are transferred or stolen, and even a pendant designed for mothers, with mothers that incorporates a visual system such as color beads to demonstrate progress and a timeline of checkup requirements on the mother's person.

Additionally, methodological limitations of the current study will be addressed to gain precise unbiased estimates of the effects of the intervention. In particular, the sample will explicitly include those who may not initially be camp attending by following-up with randomly selected mothers at the household level at baseline and endline. Moreover, stratified randomization with blocking will be employed to ensure greater numerical balance and even randomization between

known strata that bear influence such as SES, camp size, or presence of an ASHA. The social network analyses call for a deeper dive into investigating network targeting strategies beyond the dai ma as part of the behavior change package of the KB intervention. There may be multiple influential nodes undergirding the dai ma within the community as evidenced by the preliminary work in Badgaon. And when considering the process outcome of gossip of the camp intervention through such influential nodes, one may anticipate that the distribution of the pendant may interact with the ability to recruit non-attending mothers, more-so if the wearable were not being introduced. In other words, perhaps having a pendant to demonstrate encourages mothers who attend to talk more and advertise their experience to others in the community turning the pendant into a potential social marketing or social campaign tool. Finally, we will incorporate more mixed methods approaches with a focus on in depth interviews of multiple key informants as well as cost benefit analyses relevant for government policy construction.

Ultimately, even if the pendant confers little marginal value compared to the sticker, policy makers can still look to adopt NFC stickers and other form factors which are over three times cheaper but similar in functionality. Indeed that NFC sticker approach is currently be tested by the Government of Mexico. On the other hand, if this pendant even turns into a catalyst for immunization adherence of the beneficiary or her neighbor, we must continue to interrogate and measure how much progress can be made. At present, Khushi Baby is working with the Rajasthan State Ministry of Health and Family Planning, UNICEF Innovation, and Bill and Melinda Gates to validate and transition this innovation to scale throughout Rajasthan and will continue evaluation in its upcoming and scaled-up randomized trial. At the very least, this wearable NFC concept is new and presents an incremental push of the mHealth frontier. At the most, Khushi Baby presents a new, worthwhile paradigm for the interface between patient and provider. And perhaps in the future, the Khushi Baby pendant may provide more than personal comfort from *nazar* but also act

as a digital key to a gamut of NFC enabled health and social security services, pushing us towards a

more connected, healthier India, and a more vigilant, accessible world.

Glossary

Abbreviation	Term
3ie	International Initiative for Impact Evaluation
ANM	Auxiliary Nurse Midwife
ANMOL	ANM Online
BCG	TB Vaccine
BMGF	Bill and Melinda Gates
cRCT	cluster Randomized Control Trial
DE	Direct Effect
DTP	Diphtheria Tetanus and Pertussis
ESS	Effective Sample Size
GNM	General Nurse Midwife
GOI	Government of India
IAP	Indian Academy of Pediatrics
ICC	Intercluster Correlation Coefficient
KB	Khushi Baby
KM	Kaplan-Meier
MAMTA	Maternal and Child Health Tracking Paper Record
MCH	Maternal and Child Health
MCTS	Mother and Child Tracking System
mHealth	Mobile Health
MOH	Ministry of Health
MOHFW	Ministry of Health and Family Welfare
NFC	Near Field Communication
OPV	Oral Polio Vaccine
P+V	Pendant and Voice Call Arm
PCTS	Pregnant Mother and Child Health Tracking and Management System
RCT	Randomized Controlled Trial
SM	Seva Mandir
SNA	Social Network Analysis
SSS	Swasthya Sandesh Sayog
TBA	Traditional Birth Attendant
VDII	Vaccine Delivery Innovation Initiative
WHO	World Health Organization

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My mother and father have sacrificed their lives for me to be in a position to have the best education in the world. A simple footnote could never do justice to what their support means for me in Khushi Baby and all other life endeavors.

Supplementary Appendix
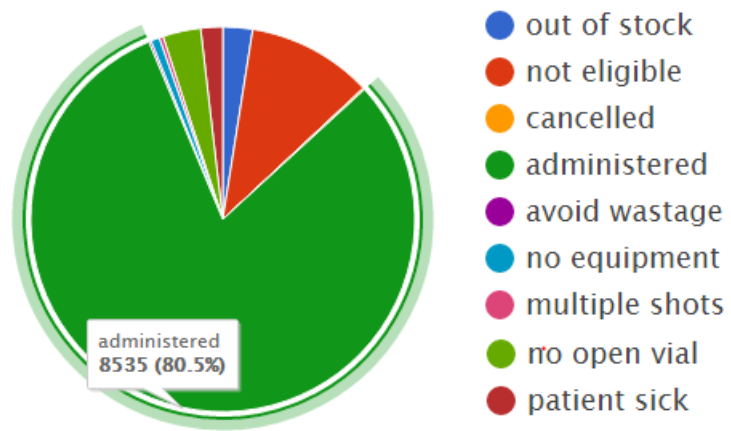
S1. Vaccination Denial Reasons collected by the Khushi Baby system
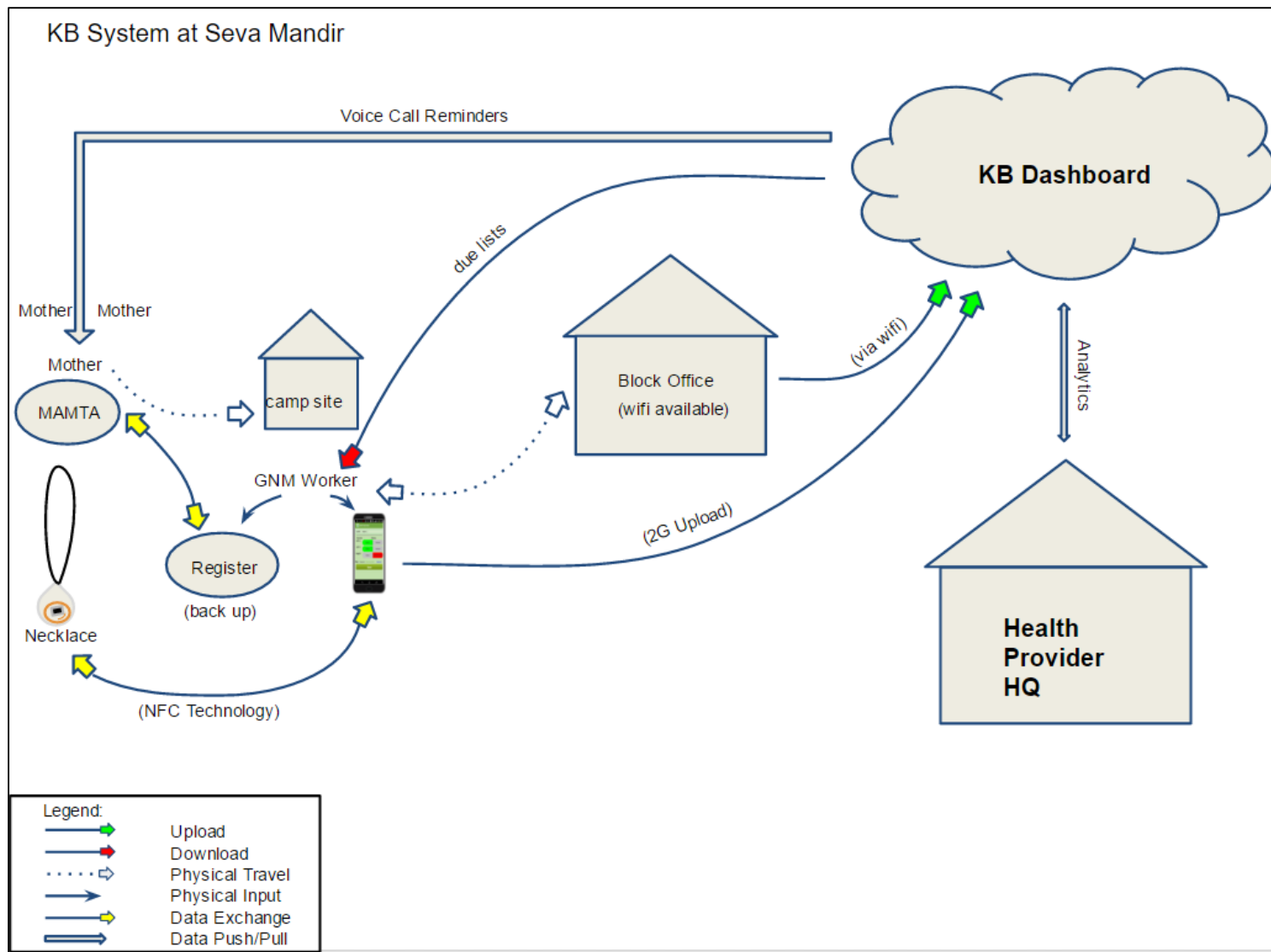
S2. Seva Madir Workflow with KB System overlayed

ToC Flowchart

INPUTS
- KB pendant
- KB mobile app
- KB dashboard
- KB voice calls

ASSUMPTIONS/EXTERNAL DETERMINANTS

Technical Factors
- Data syncing
- User interface/technical skill required to use mobile app & dashboard
- Cell signal coverage
- Hardware management

Behavioral Factors
- Adoptability of the necklace
- Acceptance & understanding of local dialect voice reminders
- Preconceived notions and awareness about vaccines/cultural norms
- Relationship between health providers and communities

Organizational Factors
- Training and supervision of frontline health workers, IT staff
- Monitoring of beneficiaries
- Maintaining a consistent health service delivery system
- Responding to workforce turnover

PROCESS IMPROVEMENTS
- Data Collection
- Data Decentralization
- In-field Decision Making Support
- Standardization of Immunization protocols
- Resource management
- Empowerment of health workers with greater accountability
- Community Engagement
- Frontline-Mother interaction and Education
- Remote Education and Reminders

OUTPUTS
- Real-time, granular data
- Increased communication between health providers and beneficiaries
- Increased communication between beneficiaries
- Digitized, searchable information system

OUTCOMES
- Full, on-time immunization completion
- Completion of all antenatal care check-ups and vaccines
- Greater MCH and RI awareness
- Increased efficiency and accuracy of data collection processes
- Cost-effectiveness in data collection and vaccine delivery processes

IMPACTS
- Healthier children
- Healthier mothers
- Increased sense of empowerment with regard to family health
- Increased educational awareness

Figure 10. Theory of Change for the KB System

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Supplemental Research Objectives

Several research objectives are being investigated in parallel analyses by MOHammed Shahnawaz and Preethi Venkat. While key results may be referenced here, the methodologies behind those results will not be discussed in detail:

a. To determine if the overall camp turn up difference in camps assigned to treatment arms increased during the intervention compared to the difference in the camps which received the control

b. To determine the retention of the wearable pendant compared to the immunization card

c. To determine the likelihood of spreading knowledge of the medical record to others in the community in treatment vs. control arms after accounting for confounders

d. To determine the satisfaction of mothers towards the medical record in treatment vs. control arms

e. To determine the error rate of the KB system, proxied by: number of sync failures, replacement tags needed, number of duplicated or incomplete records (when referenced against the logbook and/or MAMTA card)

<u>Voice Notes</u>

- Camp Day Message: नमस्ते, टीकाकरण आपके बच्चे के अच्छे स्वास्थ्य के लिए जरूरी है। कृपया आप अपने बच्चे को आज सेवा मंदिर द्वारा आयोजित टीकाकरण केंद्र पर ज़रूर लाएं। टीकाकरण आपके बच्चे के अच्छे स्वास्थ्य के लिए जरूरी है। कृपया आप अपने बच्चे को आज सेवा मंदिर द्वारा आयोजित टीकाकरण केंद्र पर ज़रूर लाएं। धन्यवाद /namaste, teekaakaran aapake bachche ke achchhe svaasthy ke lie jarooree hai. krpaya aap apane bachche ko aaj seva mandir dvaara aayojit teekaakaran kendr par zaroor laen. teekaakaran aapake bachche ke achchhe svaasthy ke lie jarooree hai. krpaya aap apane bachche ko aaj seva mandir dvaara aayojit teekaakaran kendr par zaroor laen. Dhanyavaad

- One day before camp: नमस्ते, टीकाकरण आपके बच्चे के अच्छे स्वास्थ्य के लिए जरूरी है। कृपया आप अपने बच्चे को कल सेवा मंदिर द्वारा आयोजित टीकाकरण केंद्र पर ज़रूर लाएं। टीकाकरण आपके बच्चे के अच्छे स्वास्थ्य के लिए जरूरी है। कृपया आप अपने बच्चे को कल सेवा मंदिर द्वारा आयोजित टीकाकरण केंद्र पर ज़रूर लाएं। धन्यवाद /namaste, teekaakaran aapake bachche ke achchhe svaasthy ke lie jarooree hai. krpaya aap apane bachche ko kal seva mandir dvaara aayojit teekaakaran kendr par zaroor laen. teekaakaran aapake bachche ke achchhe svaasthy ke lie jarooree hai. krpaya aap apane bachche ko kal seva mandir dvaara aayojit teekaakaran kendr par zaroor laen. Dhanyavaad

- When a camp day is missed: नमस्ते, आपके बच्चे का समय पर लगने वाला कुछ टीका छूट गया है और टीका नहीं लगने के कारण आपका बच्चा बीमार हो सकता है। कृपया अपनेबच्चे को स्वस्थ और मज़बूती से बढ़ने के लिए सेवा मंदिर द्वारा आयोजित अगले टीकाकरण दिवस पर ज़रूर लाये। धन्यवाद /namaste, aapake bachche ka samay par lagane vaala kuchh teeka chhoot gaya hai aur teeka nahin lagane ke kaaran aapaka bachcha beemaar ho sakata hai. krpaya apanebachche ko svasthy aur mazabootee se badhane ke lie seva mandir dvaara aayojit agale teekaakaran divas par zaroor laaye. Dhanyavaad

- Thank you message: नमस्ते आज सेवा मंदिर द्वारा आयोजित टीकाकरण केंद्र पर आपके बच्चे का जानलेवा बीमारी से बचाने के लिए और स्वस्थ बने रहने के लिए टीका दिया गया इसके लिए सेवा मंदिर आपका धन्यवाद करता है। namaste aaj seva mandir dvaara aayojit teekaakaran kendr par aapake bachche ka jaanaleva beemaaree se bachaane ke lie aur svasthy bane rahane ke lie teeka diya gaya isake lie seva mandir aapaka dhanyavaad karata hai

- Educational message on DTP-related fever: नमस्ते आज सेवा मंदिर द्वारा आयोजित टीकाकरण केंद्र पर आपके बच्चे का जानलेवा बीमारी से बचाने के लिए और स्वस्थ बने रहने के लिए टीका दिया गया इससे बुखार आ सकता है इससे घबराये नहीं और अगले टीकाकरण दिवस पर अपने बच्चे को अवश्य लाये Inamaste aaj seva mandir dvaara aayojit teekaakaran kendr par aapake bachche ka jaanaleva beemaaree se bachaane ke lie aur svasthy bane rahane ke lie teeka diya gaya isase bukhaar aa sakata hai isase ghabaraaye nahin aur agale teekaakaran divas par apane bachche ko avashy laaye

- Standard educational message: नमस्ते, आपके बच्चे का स्वास्थ्य समय पर होने वाले टीकाकरण पर निर्भर करता है। पर यह ज़रूरी है की टीकाकरण के लिए सेवा मंदिर द्वारा आयोजित अगले टीकाकरण दिवस पर अपनेबच्चे को ज़रूर लाएं। अधिक जानकारी के लिए अपने गाँव की बालसखी स्वास्थय कार्यकर्ता से मिले। धन्यवाद | namaste, aapake bachche ka svaasthy samay par hone vaale teekaakaran par nirbhar karata hai. par yah zarooree hai kee teekaakaran ke lie seva mandir dvaara aayojit agale teekaakaran divas par apanebachche ko zaroor laen. adhik jaanakaaree ke lie apane gaanv kee baalasakhee svaasthay kaaryakarta se mile. dhanyavaad

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Survey Questions

To see the survey details, see:

https://docs.google.com/spreadsheets/d/1HXurMW2RcPPo5xyvhCmpJHl1MRunprQ2ZE4MMSqK-os/edit?usp=sharing

Question (Hindi)	Question Type	Relationship Type	Multiple Choice?	Question (English)	Answer 1 English	Answer 2 English	Answer 3 English	Answer 4 English			
आपके पास आपका मम्ता कार्ड है?			Yes	Do you have your MAMTA card	Yes	Yes but at home	No lost	No never received			
आपके कितने बच्चे है?	Numerical Textboxes			How many children do you have							
आपके सारे बच्चे सही से पैदा हुए या कोई बात भी हुआ है?	Numerical Textboxes			How many of your children have died							
कितने बच्चों का जन्म अस्पताल में हुआ है?	Numerical Textboxes			How many children have had hospital births							
आपकी शादी हुई तब आप कितने साल की थी?	Numerical Textboxes			At what age were you married							
आपके परिवार की जाति का नाम क्या है?	Comment/Essay Box			To what caste do you associate							
आपने कितनी कक्षा तक पढ़ाई की है?	Numerical Textboxes			Till what grade in school have you studied							
आप किस तरह का काम करती है?	Multiple Answer		Yes	What line of work do you do	wage earner	Self employed	housewife	farmer	Other		
आपके पति किस तरह का काम करते है?	Multiple Answer		Yes	What line of work does your spouse do	wage earner	migrant worker	self employed	farmer	govt job	private job	
क्या आपके पास मोबाईल है?	Single Answer		Yes	Do you own or have access to a mobile phone	yes,own	yes,access	neither				
क्या आपके घर में बिजली आती है? किस तरह की?	Multiple Choice		Yes	What type of electricity source do you have	yes, solar	yes, line	no				
आप पानी कहाँ से लाती है ?	Single Answer		Yes	From where do you retrieve water	handpump	well	bore well	pipe water	waterfall		
आप किस तरह का बाथरूम इस्तेमाल करती है?	Single Answer		Yes	Where do you go to the bathroom	open	covered	ventilated				
आप किस तरह का ईंधन इस्तेमाल करती है?	Multiple Answer		Yes	What fuel do you use for cooking	wood	dung	grass or crop	charcoal	coal	kerosene	LPG	biogas
आपके घर की छत किस सामन से बनी है?	Multiple Answer		Yes	What material is used for your roof	grass thatch clay	plastic polythene	tiles	burnt brick	stone slate	metal	cement
क्या आपको पता है कि आपके बच्चे के जन्म के बाद पहले साल में कितने टीके लगने चाहिए?	Numerical Textboxes			How many shots does your child need in first year of life							
आप अपने बच्चे को टीके लगवाने कहाँ लेकर जाती है?			Yes	Who provides you vaccine service	SM camp	govt hospital	ANM clinic	Private clinic			
आप अपने बच्चे को टीका क्यों लगवाती है?			Yes	Why does your child need vaccines	prevents disease	prevents specific disease	improves health	because others do it	Don't know		
आपको टीका लगवाने की तारीख कौन याद दिलाता है?		Yes		Who reminded you of the camp							
आप कैम्प में किसके साथ जाती है?		Yes		Who did you come with to the camp							
आपने आज के कैम्प में भाग लेने से पहले कितने मालओं के साथ बात की?	Numerical Textboxes			How many mothers did you speak to about the camp							
आपको टीका नहीं लगवाना चाहिए क्या ऐसा कोई कहता है?		Yes		Who if anyone told you not to come to the camp							
आपको कैम्प तक पहुचने में कितना समय लगता है? (मिनट में)	Numerical Textboxes			How long in minutes does it take to reach the camp							
आप मेडा मंदिर टीका कैम्प से कितने संतुष्ट है?			Yes	How satisfied are you with the camp	not satisfied	satisfied	very satisfied				
क्या आपके पास आपका मम्ता कार्ड है?			Yes	Do you have your MAMTA card	Yes	Yes but at home	No lost	No never received			
क्या आपने इस स्टीकर के बारे में किसी और माँ /महिला को बताया है?		Yes		Have you shown your sticker to anyone, if so who?							
आप कैम्प में किसके साथ आई है?		Yes		Who did you come with to the camp							
दाई के अलावा, क्या आप कैंप के बारे में किसी और से बात करती है?		Yes		In addition to the dai ma, who else publicizes the camp							
क्या आपको आज की शिविर के बारे में याद दिलाने के लिए कोई फोन कॉल आया था?			Yes	Did you receive a phone call reminder	Yes	No					
आज के कैंप के बारे में याद दिलाने के लिए आपको कितने फोन कॉल आये थे?	Numerical Textboxes			How many times did you receive a phone call reminder							
क्या आपने फोन कॉल के बारे में किसी और माँ /महिला को बताया है?		Yes		Who did you tell about the phone call reminders							
क्या आप कोई ऐसी किसी को जानती है जो हर महीने कैंप में नहीं जाती हो?		Yes		Do you know any mothers not attending camps regularly, if so who							
क्या आपने यह हार किसी को दिखाया है? अगर दिखाया है तो किसको दिखाया है।		Yes		Did you show your necklace to anyone, if so who							
क्या लटकन से आपको किसी तरह की परेशानी आई?			Yes	Did you experience any problems with the pendant	yes	no	Not relevant for sticker				
अगर आप कैम्प ये हर महीने नहीं जा पाती है तो ज्यादातर क्या वजह होती है?			Yes	Why have you missed a camp	camp is too far	cant go alone	due to poor health	had work at home	forgot about camp	Dai ma (TBA) did not inform	prevented by family	camp is hard to reach
क्या आपको पिछले कैम्प के बाद किसी भी परेशानी का सामना हुआ?			Yes	Have you had any issues after the camp							
यह कैंप किस प्रकार का है ?			Yes	What treatment arm is this camp	Sticker	Pendant	P+V				
क्या आपके पास मम्ता कार्ड है ?			Yes	Do you have your MAMTA card	Yes	Yes but at home	No lost	No never received			
आप कैम्प में किसके साथ आई है?		Yes		Who did you come with to the camp							
दाई के अलावा, क्या आप कैंप के बारे में किसी और से बात करती है?		Yes		In addition to the dai ma, who else publicizes the camp							
क्या आपको आज की शिविर के बारे में याद दिलाने के लिए कोई फोन कॉल आया था? (केवल P+V कैंप में पूछे)			Yes	Did you receive a phone call reminder	yes	no					
आज के कैंप के बारे में याद दिलाने के लिए आपको पिछले महीने कितने फोन कॉल आये थे ?	Numerical Textboxes			How many times did you receive a phone call reminder							
क्या आपने इस स्टीकर/पेंडेंट के बारे में किसी और माँ /महिला को बताया है?		Yes		Have you shown your sticker/pendant to anyone if so who							
कितने लोगो को आपने ये पेंडेंट (लटकन)/ स्टीकर दिखाया है ? (कैंप के अनुसार यह सवाल पूछे)	Numerical Textboxes			How many people did you show it to							
इस पेंडेंट (लटकन) को देखने पर लोगो की आम प्रतिक्रिया किया थी ? (केवल P+V कैंप में पूछे)			yes	What was their general reaction to the pendant/sticker	Very good	Good	Bad	Vey Bad	No reaction		
क्या बच्चे/बच्ची के पिता ने ये लटकन देखा ?			yes	Has the father seen the necklace	yes	no					
क्या दिए गये फोन रिमाइंडर (टीकाकरण के लिए फोन कॉल) प्राप्त किया या उन्हें इसके बारे में पता है ?			yes	Is the father aware of the voice call reminders	yes	no					
नियमित टीकाकरण के लिए आप बच्चे को केंद्र तक लाने से क्या इनके पिता का नजरिया बदला है ?			yes	How has the father's attitude towards vaccines changed	Negative	no reaction	positive				
क्या बच्चे/बच्ची के दादी ने ये लटकन देखा ?			yes	Has the grandmother seen the pendant	yes	no					
नियमित टीकाकरण के लिए आप बच्चे को केंद्र तक लाने से क्या बच्चे की दादी का नजरिया बदला है ?			yes	How has the grandmother's attitude changed	Negative	no reaction	positive	No more Grand Mother m			
वो कौन से कारक है जिनके कारण आप बच्चे को नियमित रूप से बच्चे को टीकाकरण के लिए केंद्र तक लाती है? (कई जवाब संभव है)	Multiple Answers		yes	What factors were important in influencing camp turn up	TBA	Phone call	Pendant	GNM	Other mothers	Husband	Mother in Law
आपके तीन में दस में से कितने परिवार में एक साल से छोटा बच्चा है ?	Numerical Textboxes			How many out of ten have infants							
और उनमे से कितने बच्चे नियमित रूप से टीकाकरण के लिए हर महीने कैंप नहीं आते है ?	Numerical Textboxes			How many mothers with infants are not coming out of 10?							
क्या आप किसी प्रकार से, जो माँ अपने बच्चे को टीकाकरण कैंप ले कर नहीं आती है , उन तक पहुँच कर, उनसे बात करके , उन्हें समझा कर कैंप ला सकती है?			yes	Do you have the ability to recruit nonattenders	Yes	No	Don't Know				
यदि नहीं, तो आपके कौन मित्र/ दोस्त/ साथी उन तक पहुँच कर उन्हें समझा सकता है ?		Yes		Do you have friends who have the ability to recruit nonattenders if so who							
आपको क्या लगता है किस प्रकार की प्रतिक्रिया वो बच्चे की माँ देगी यदि हम उन्हें यह पेंडेंट देते है ?			Yes	How do you expect nonattenders to react to the necklace	Negative	no reaction	positive				
यदि आपको किसी माँ को यह समझाना परे की बच्चे को कैंप लाना है तोह आप किस तरह उन्हें समझाएंगी ?	Multiple Answers		Yes	What is the best way to convince non-attenders mother to attend	Need for good health	Lentils as incentive	Pendant	better care for children	Follow up call reminders		
आप बच्चे को खसरे से बचने का टीका लगवाने कब आओगे ?			Yes	At what age should your child get vaccinated with measles	9 months	12 months	15 months	Dont Know			

<u>Model Selection Output:</u>

```
Step:  AIC=227.46
adherent1to3 ~ I(Treatment == "P+V") + I(Treatment == "Pendants") +
        maternalage + maritalage + bcgstatus +
        vaccineawareness_why.prevents.specific.disease.y +
        electricity + water.handpump.y + occupation_mother.wage.earner.y +
        missX + childweeks + child_gender + outdegree + connected_to_dai ma +
        start_month

                                                          Df Deviance    AIC
- maritalage                                               1   187.47 225.47
- connected_to_dai ma                                      1   187.47 225.47
- maternalage                                              1   187.66 225.66
- I(Treatment == "Pendants")                               1   188.08 226.08
- I(Treatment == "P+V")                                    1   188.43 226.43
- water.handpump.y                                         1   189.34 227.34
<none>                                                         187.47 227.47
- bcgstatus                                                1   189.82 227.82
- start_month                                              4   196.23 228.23
- outdegree                                                1   190.59 228.59
- childweeks                                               1   190.75 228.75
- child_gender                                             1   191.00 229.00
- vaccineawareness_why.prevents.specific.disease.y         1   191.07 229.07
- electricity                                              2   193.62 229.62
- occupation_mother.wage.earner.y                          1   194.31 232.31
- missX                                                    1   199.32 237.32
```

Marital age was also dropped due to high multicollinearity with the error term

```
Generalized linear mixed model fit by maximum likelihood (Laplace Approximation) ['glmerMod']
 Family: binomial  ( logit )
Formula: adherent1to3 ~ I(Treatment == "P+V") + I(Treatment == "Pendants") + maternalage + bcgsta
tus + vaccineawareness_why.prevents.specific.disease.y +  electricity + water.handpump.y + occupa
tion_mother.wage.earner.y + missX + childweeks + child_gender + outdegree + start_month +
(1 | camp_id)
   Data: mydata

     AIC      BIC   logLik deviance df.resid
   227.6    289.5    -94.8    189.6      173

Scaled residuals:
    Min      1Q  Median      3Q     Max
-2.5247 -0.6628 -0.2466  0.7082  5.4092

Random effects:
 Groups   Name        Variance Std.Dev.
 camp_id (Intercept) 0.05948  0.2439
Number of obs: 192, groups:  camp_id, 66

Fixed effects:
                                 Estimate Std. Error z value Pr(>|z|)
(Intercept)                      -3.14612    1.76283  -1.785  0.07431 .
I(Treatment == "P+V")TRUE         0.44930    0.50266   0.894  0.37140
I(Treatment == "Pendants")TRUE    0.39094    0.55264   0.707  0.47932
```

maternalage	0.01917	0.05135	0.373	0.70888	
bcgstatus1	0.77637	0.46013	1.687	0.09155	.
vaccineawareness_why.prevents.specific.disease.yNo	-0.87151	0.48363	-1.802	0.07154	.
electricityyes, line	1.05637	0.45667	2.313	0.02071	*
electricityyes, solar	-0.12704	0.68011	-0.187	0.85182	
water.handpump.yNo	0.55459	0.43393	1.278	0.20122	
occupation_mother.wage.earner.yNo	1.11659	0.42686	2.616	0.00890	**
missXyes	-2.92732	1.12092	-2.611	0.00901	**
childweeks	-0.07699	0.04452	-1.729	0.08378	.
child_genderm	0.85010	0.45702	1.860	0.06287	.
outdegree	-0.23803	0.14095	-1.689	0.09128	.
start_month9	1.20348	0.72959	1.650	0.09904	.
start_month10	1.45638	0.72536	2.008	0.04467	*
start_month11	2.06477	0.79506	2.597	0.00940	**
start_month12	1.67006	0.85601	1.951	0.05106	.

Signif. codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Correlation of Fixed Effects:

```
            (Intr) I(T=="P+ I(T=="P" mtrnlg bcgst1 v_.... elct,l elct,s wtr..N o_...N mssXys chldwk chld_g outdgr strt_9 str_10 str_11
I(T=="P+V") -0.320
I(T=="P")TR -0.250  0.617
maternalage -0.725  0.088     0.040
bcgstatus1  -0.246  0.217     0.076    0.014
vccnw_....N  0.070 -0.135    -0.256    0.050  0.017
elctrctyy,l -0.335  0.114     0.333    0.171 -0.070 -0.326
elctrctyy,s -0.101 -0.064    -0.032    0.073 -0.132 -0.034  0.323
wtr.hndpm.N -0.152 -0.090    -0.165   -0.085  0.056 -0.089  0.127  0.111
occptn_...N -0.177  0.036     0.086    0.027  0.183 -0.370  0.134 -0.047  0.016
missXyes     0.026 -0.007    -0.021    0.055 -0.199  0.020 -0.042  0.022 -0.028  0.074
childweeks  -0.307  0.016     0.050   -0.084  0.058  0.049  0.010 -0.010  0.035 -0.103 -0.009
child_gndrm -0.355  0.223     0.180    0.042  0.274 -0.062  0.139 -0.155 -0.080  0.188 -0.120  0.221
outdegree    0.012  0.063     0.043   -0.090 -0.149  0.014 -0.016  0.112 -0.028 -0.190 -0.040  0.008 -0.164
start_mnth9 -0.227  0.037    -0.059   -0.134  0.088 -0.114 -0.106 -0.084  0.149  0.072 -0.074  0.021  0.001  0.002
strt_mnth10 -0.262 -0.004    -0.072   -0.153  0.197 -0.064 -0.104 -0.044  0.126  0.058 -0.151  0.088  0.095 -0.061  0.760
strt_mnth11 -0.326  0.039    -0.073   -0.018  0.229 -0.073 -0.020  0.016  0.131  0.089 -0.070 -0.007  0.100 -0.115  0.677  0.736
strt_mnth12 -0.214  0.100     0.040   -0.143  0.102 -0.336  0.075  0.018  0.101  0.087 -0.062 -0.019  0.119 -0.065  0.652  0.681  0.629
convergence code: 0
Model failed to converge with max|grad| = 0.00465497 (tol = 0.001, component 1)
```

	Est	LL	UL
(Intercept)	0.04301875	0.001358643	1.3621045
I(Treatment == "P+V")TRUE	1.56721994	0.585135173	4.1976255
I(Treatment == "Pendants")TRUE	1.47836498	0.500450221	4.3671936
maternalage	1.01935613	0.921760429	1.1272852
bcgstatus1	2.17357788	0.882068355	5.3560937
vaccineawareness_why.prevents.specific.disease.yNo	0.41831777	0.162118077	1.0793969
electricityyes, line	2.87591281	1.175029068	7.0388680
electricityyes, solar	0.88070081	0.232226107	3.3399945
water.handpump.yNo	1.74123415	0.743854965	4.0759241
occupation_mother.wage.earner.yNo	3.05440924	1.323044670	7.0514745
missXyes	0.05354051	0.005950206	0.4817625
childweeks	0.92590337	0.848532490	1.0103291
child_genderm	2.33987529	0.955361975	5.7308293
outdegree	0.78818221	0.597920382	1.0389865
start_month9	3.33167624	0.797303383	13.9220112
start_month10	4.29038564	1.035270700	17.7802858
start_month11	7.88346570	1.659404573	37.4526095
start_month12	5.31246938	0.992305534	28.4411706

Start AIC: 225.94

```
Step:  AIC=214.21
adherent1to3 ~ I(Treatment == "P+V") + I(Treatment == "Pendants") +
    maternalage + maritalage + bcgstatus + vaccineawareness_why.prevents.spec
ific.disease.y +
    electricity + water.handpump.y + occupation_mother.wage.earner.y +
    childweeks + child_gender + outdegree + start_month
```

	Df	Deviance	AIC
- maritalage	1	178.29	212.29
- I(Treatment == "Pendants")	1	178.35	212.35
- maternalage	1	178.59	212.59
- I(Treatment == "P+V")	1	178.90	212.90
<none>		178.21	214.21
- bcgstatus	1	180.47	214.47
- water.handpump.y	1	180.87	214.87
- vaccineawareness_why.prevents.specific.disease.y	1	181.10	215.10
- start_month	4	187.11	215.11
- childweeks	1	181.47	215.47
- electricity	2	183.63	215.63
- outdegree	1	181.81	215.81
- child_gender	1	182.38	216.38
- occupation_mother.wage.earner.y	1	185.14	219.14

```
Generalized linear mixed model fit by maximum likelihood (Laplace Approximati
on) ['glmerMod']
 Family: binomial  ( logit )
Formula: adherent1to3 ~ I(Treatment == "P+V") + I(Treatment == "Pendants") +
bcgstatus + vaccineawareness_why.prevents.specific.disease.y +
    electricity + water.handpump.y + occupation_mother.wage.earner.y +      c
hildweeks + child_gender + outdegree + start_month + (1 |      camp_id)
   Data: noint

    AIC      BIC   logLik deviance df.resid
  228.9    282.6    -97.5    194.9      157

Scaled residuals:
    Min      1Q  Median      3Q     Max
-2.5334 -0.6845 -0.3399  0.8078  3.2689

Random effects:
 Groups  Name        Variance Std.Dev.
 camp_id (Intercept) 0.03084  0.1756
Number of obs: 174, groups:  camp_id, 63

Fixed effects:
                                                Estimate Std. Error z value Pr(>|z|)
(Intercept)                                     -1.94858    1.06040  -1.838  0.06612 .
I(Treatment == "P+V")TRUE                        0.38164    0.48319   0.790  0.42963
I(Treatment == "Pendants")TRUE                   0.25557    0.54121   0.472  0.63676
bcgstatus1                                       0.68221    0.43850   1.556  0.11976
vaccineawareness_why.prevents.specific.disease.yNo -0.83440  0.47345  -1.762  0.07800 .
electricityyes, line                             0.86926    0.43106   2.017  0.04374 *
```

```
electricityyes, solar                          -0.22324   0.66578  -0.335  0.73739
water.handpump.yNo                              0.58761    0.42150   1.394  0.16328
occupation_mother.wage.earner.yNo              1.22912    0.41068   2.993  0.00276 **
childweeks                                     -0.07973    0.04278  -1.864  0.06235 .
child_genderm                                   0.77028    0.44667   1.724  0.08462 .
outdegree                                      -0.26277    0.14387  -1.826  0.06778 .
start_month9                                    0.74330    0.64410   1.154  0.24849
start_month10                                   0.89469    0.61570   1.453  0.14619
start_month11                                   1.57207    0.71129   2.210  0.02709 *
start_month12                                   1.16419    0.75781   1.536  0.12448
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1


Correlation of Fixed Effects:
           (Intr) I(T=="P+ I(T=="P" bcgst1 v_.... elct,l elct,s wtr..N o_...N chldwk chld_g outdgr strt_9 str_10 str_11
I(T=="P+V") -0.390
I(T=="P")TR -0.317  0.613
bcgstatus1  -0.304  0.233    0.075
vccnw_....N  0.099 -0.143   -0.255    0.058
elctrctyy,l -0.252  0.092    0.335   -0.107 -0.319
elctrctyy,s -0.041 -0.080   -0.035   -0.128 -0.039  0.309
wtr.hndpm.N -0.261 -0.108   -0.233    0.011 -0.033  0.082  0.092
occptn_...N -0.183  0.043    0.089    0.161 -0.361  0.103 -0.055 -0.046
childweeks  -0.570  0.031    0.042    0.051  0.072  0.008 -0.016  0.010 -0.119
child_gndrm -0.459  0.215    0.173    0.270 -0.020  0.075 -0.170 -0.109  0.177  0.227
outdegree   -0.075  0.079    0.051   -0.158  0.018 -0.005  0.106 -0.035 -0.223 -0.004 -0.197
start_mnth9 -0.404  0.024   -0.077    0.042 -0.097 -0.141 -0.104  0.146  0.063  0.000 -0.032 -0.007
strt_mnth10 -0.447 -0.022   -0.095    0.119 -0.010 -0.166 -0.057  0.069  0.024  0.067  0.035 -0.069  0.703
strt_mnth11 -0.396  0.008   -0.105    0.180 -0.039 -0.081 -0.001  0.107  0.066 -0.023  0.065 -0.144  0.610  0.670
strt_mnth12 -0.348  0.085    0.028    0.032 -0.336  0.050  0.014  0.052  0.062 -0.057  0.051 -0.074  0.579  0.592  0.543
```

	Est	LL	UL
(Intercept)	0.1424767	0.01782833	1.138615
I(Treatment == "P+V")TRUE	1.4646868	0.56812298	3.776132
I(Treatment == "Pendants")TRUE	1.2912031	0.44700173	3.729752
bcgstatus1	1.9782524	0.83757242	4.672411
vaccineawareness_why.prevents.specific.disease.yNo	0.4341345	0.17163879	1.098078
electricityyes, line	2.3851438	1.02467962	5.551892
electricityyes, solar	0.7999202	0.21693383	2.949620
water.handpump.yNo	1.7996851	0.78779367	4.111313
occupation_mother.wage.earner.yNo	3.4182331	1.52834381	7.645084
childweeks	0.9233625	0.84909602	1.004125
child_genderm	2.1603794	0.90015730	5.184915
outdegree	0.7689202	0.57998608	1.019401
start_month9	2.1028625	0.59503840	7.431505
start_month10	2.4465653	0.73192238	8.178028
start_month11	4.8165944	1.19475714	19.417822
start_month12	3.2033143	0.72533183	14.146935

Start: 232.37

Step: AIC=225.47

```
adherent1to3 ~ I(Treatment == "P+V") + I(Treatment == "Pendants") +
    bcgstatus + vaccineawareness_why.prevents.specific.disease.y +
    electricity + water.handpump.y + occupation_mother.wage.earner.y +
    missX + childweeks + child_gender + outdegree + maternalage +
    maritalage + start_month
```

	Df	Deviance	AIC
- maritalage	1	187.47	223.47
- maternalage	1	187.67	223.67
- I(Treatment == "Pendants")	1	188.11	224.11
- I(Treatment == "P+V")	1	188.44	224.44
- water.handpump.y	1	189.34	225.34
<none>		187.47	225.47
- bcgstatus	1	189.82	225.82
- start_month	4	196.31	226.31
- outdegree	1	190.62	226.62
- childweeks	1	190.78	226.78
- child_gender	1	191.00	227.00
- vaccineawareness_why.prevents.specific.disease.y	1	191.09	227.09
- electricity	2	193.97	227.97
- occupation_mother.wage.earner.y	1	194.35	230.35
- missX	1	199.36	235.36

```
Generalized linear mixed model fit by maximum likelihood (Laplace Approximati
on) ['glmerMod']
 Family: binomial  ( logit )
Formula: adherent1to3 ~ I(Treatment == "P+V") + I(Treatment == "Pendants") +
bcgstatus + vaccineawareness_why.prevents.specific.disease.y +
    electricity + water.handpump.y + occupation_mother.wage.earner.y +      m
issX + childweeks + child_gender + outdegree + maternalage +      start_month
+ (1 | camp_id)
   Data: mydata
```

AIC	BIC	logLik	deviance	df.resid
227.6	289.5	-94.8	189.6	173

Scaled residuals:
```
    Min      1Q  Median      3Q     Max
-2.5247 -0.6628 -0.2466  0.7082  5.4092
```

Random effects:
```
 Groups  Name         Variance Std.Dev.
 camp_id (Intercept) 0.05954  0.244
Number of obs: 192, groups:  camp_id, 66
```

82

```
Fixed effects:

                                                   Estimate Std. Error z value Pr(>|z|)
(Intercept)                                        -3.14630    1.76280  -1.785  0.07429 .
I(Treatment == "P+V")TRUE                           0.44917    0.50266   0.894  0.37155
I(Treatment == "Pendants")TRUE                      0.39077    0.55264   0.707  0.47951
bcgstatus1                                          0.77628    0.46013   1.687  0.09158 .
vaccineawareness_why.prevents.specific.disease.yNo -0.87158    0.48363  -1.802  0.07152 .
electricityyes, line                                1.05626    0.45666   2.313  0.02072 *
electricityyes, solar                              -0.12711    0.68011  -0.187  0.85175
water.handpump.yNo                                  0.55461    0.43393   1.278  0.20121
occupation_mother.wage.earner.yNo                   1.11662    0.42687   2.616  0.00890 **
missXyes                                           -2.92722    1.12089  -2.611  0.00901 **
childweeks                                         -0.07697    0.04452  -1.729  0.08382 .
child_genderm                                       0.84999    0.45697   1.860  0.06287 .
outdegree                                          -0.23806    0.14096  -1.689  0.09123 .
maternalage                                         0.01918    0.05135   0.374  0.70880
start_month9                                        1.20363    0.72961   1.650  0.09901 .
start_month10                                       1.45663    0.72538   2.008  0.04463 *
start_month11                                       2.06500    0.79507   2.597  0.00940 **
start_month12                                       1.67020    0.85603   1.951  0.05104 .
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1


Correlation of Fixed Effects:
           (Intr) I(T=="P+ I(T=="P" bcgst1 v_.... elct,l elct,s wtr..N o_...N missXys chldwk chld_g outdgr mtrnlg strt_9 str_10 str_11
I(T=="P+V") -0.320
I(T=="P")TR -0.250  0.617
bcgstatus1  -0.246  0.217    0.076
vccnw_....N  0.070 -0.135   -0.256    0.017
elctrctyy,l -0.335  0.114    0.333   -0.070 -0.326
elctrctyy,s -0.101 -0.064   -0.032   -0.132 -0.034  0.323
wtr.hndpm.N -0.152 -0.090   -0.165    0.056 -0.089  0.127  0.111
occptn_...N -0.177  0.036    0.086    0.183 -0.370  0.134 -0.047  0.016
missXyes     0.025 -0.007   -0.021   -0.199  0.020 -0.041  0.022 -0.028  0.074
childweeks  -0.307  0.016    0.050    0.058  0.049  0.009 -0.010  0.035 -0.103 -0.009
child_gndrm -0.355  0.223    0.180    0.274 -0.061  0.139 -0.155 -0.080  0.188 -0.120  0.221
outdegree    0.012  0.063    0.043   -0.149  0.014 -0.016  0.112 -0.028 -0.190 -0.040  0.008 -0.164
maternalage -0.725  0.088    0.040    0.014  0.050  0.171  0.073 -0.085  0.027  0.055 -0.084  0.042 -0.090
start_mnth9 -0.227  0.037   -0.059    0.088 -0.114 -0.106 -0.084  0.149  0.072 -0.074  0.021  0.001  0.002 -0.134
strt_mnth10 -0.262 -0.004   -0.072    0.197 -0.064 -0.104 -0.044  0.126  0.058 -0.151  0.088  0.095 -0.061 -0.153  0.760
strt_mnth11 -0.326  0.039   -0.073    0.229 -0.073 -0.020  0.016  0.131  0.089 -0.070 -0.007  0.100 -0.115 -0.018  0.677  0.736
strt_mnth12 -0.214  0.100    0.040    0.102 -0.336  0.075  0.018  0.101  0.087 -0.061 -0.019  0.118 -0.065 -0.143  0.652  0.681  0.629
```

	Est	LL	UL
(Intercept)	0.04301102	0.001358493	1.3617643
I(Treatment == "P+V")TRUE	1.56701192	0.585054253	4.1970917
I(Treatment == "Pendants")TRUE	1.47811408	0.500368022	4.3664286
bcgstatus1	2.17338043	0.881998930	5.3555422
vaccineawareness_why.prevents.specific.disease.yNo	0.41829046	0.162106582	1.0793325
electricityyes, line	2.87558983	1.174925693	7.0379063
electricityyes, solar	0.88063867	0.232205926	3.3398134
water.handpump.yNo	1.74126710	0.743868173	4.0760060
occupation_mother.wage.earner.yNo	3.05452752	1.323087164	7.0517942
missXyes	0.05354594	0.005951266	0.4817745
childweeks	0.92591588	0.848546002	1.0103403

```
child_genderm                                    2.33963382 0.955368146  5.7296095
outdegree                                        0.78815342 0.597897979  1.0389495
maternalage                                      1.01936191 0.921764770  1.1272927
start_month9                                     3.33220021 0.797398374 13.9247314
start_month10                                    4.29147702 1.035504282 17.7853200
start_month11                                    7.88531752 1.659735331 37.4627395
start_month12                                    5.31325452 0.992418953 28.4463265
```

Institutional Committee for Ethics and Review of Research

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Manager, Library, IIHMR, Jaipur

Ex-officio Member
Dean (Research), IIHMR, Jaipur

Member Secretary
Dr Nutan P. Jain
Professor, IIHMR, Jaipur

1	Serial No. of Institutional Committee for Ethics and Review of Health Management Research office		June 20		1				
1	Project Title	Khushi Baby (KB): Efficacy and Impact Assessment of Novel Mobile Health Solution for Vaccination Record Keeping in rural Udaipur, Rajasthan, India							
2	Name of Faculty In-charge/ Project coordinator		Md Shahnawaz						
3	Date of Submission to the Committee		2	2	0	5	1	5	
4	Date of Submission to the Agency								
5	Review Category of the Proposal								
	Expedited Review								
	Full review		✓						
6	Date of Review		2	0	0	6	1	5	
7	Reviewers' Name	Dr Shashikant, Dr Malabika Roy, Dr Suresh Joshi, Dr Vinod K SV, Dr Arindam Das, Dr Rajeshwari Gupta, Dr Nutan P Jain, Mr Kamlesh, Chand Sharma							
8	Reviewer's Feedback (Please tick the following, if you are								
8.1	Respect for person		✓						
8.2	Fair subject selection		✓						
8.3	Informed consent		✓						
8.4	Maintaining privacy		✓						
8.5	Maintaining confidentiality		✓						
9	Final Comment								
	Approved without suggestions								
	Approved with suggestions		✓						
	Sent back for revision and re-submission								
	Not approved								
10	Signature of the reviewer								

Yale University

To:	Nicholas Christakis
From:	Human Subjects Committee
Date:	05/05/2015
HSC Protocol #:	1504015677
Study Title:	Social network analysis of the Khushi Baby data collection system
Committee Action	**Expedited Approval**
HSC Action Date:	05/05/2015
Approval Date:	05/05/2015
Expiration Date:	05/04/2016
Submission Type:	**Initial Application**

The above-referenced protocol was approved following expedited review by the Human Subjects Committee. The project was found to be of minimal risk and to meet the approval requirements under University IRB policy and 45 CFR 46 as applicable.

_____

Review Comments:

- The HSC considers the study to be minimal risk and can be approved for one year under 45 CFR 46.111
- The HSC acknowledges and approves the following submitted documents: protocol.

It is the Principal Investigator's responsibility to obtain review and continued approval before the expiration date. You may not continue any research activity beyond the expiration date without approval by the Institutional Review Board.

Adverse Reactions: Investigators are required to promptly report any unanticipated problems or complaints to the committee. If necessary a member of the IRB will be assigned to look into the matter. If the problem is serious, approval may be withdrawn pending IRB review.

Amendments: If you wish to change any aspect of this study, such as the procedures, the consent forms, or the investigators, please communicate your requested changes to the Human Subjects Committee. The new procedure is not tobe initiated until the IRB approval has been given.

Please keep this memo with your copy of the approved protocol.

Yale University

To:	Ruchit Nagar
From:	Human Subjects Committee
Date:	08/07/2015
HSC Protocol #:	1508016259
Study Title:	Khushi Baby (KB): Efficacy and Impact Assessment of Novel Mobile Health Solution for Vaccination Record Keeping in rural Udaipur, Rajasthan, India
Committee Action	**Expedited Approval**
HSC Action Date:	08/07/2015
Approval Date:	08/07/2015
Expiration Date:	08/06/2016
Submission Type:	**Initial Application**

The above-referenced protocol was approved following expedited review by the Human Subjects Committee. The project was found to be of minimal risk and to meet the approval requirements under University IRB policy and 45 CFR 46 as applicable.

Review Comments:

- The HSC has determined that this protocol presents minimal risk to subjects.

- The PI is reminded to please fill out the HSC specific renewal form for next year, which can be found on our website at http://www.yale.edu/hrpp/forms-templates/behavioral.html.
- This approval is for secondary data analysis only.
- The HSC acknowledges receipt of and approves the following documents: secondary data analysis protocol

It is the Principal Investigator's responsibility to obtain review and continued approval before the expiration date. You may not continue any research activity beyond the expiration date without approval by the Institutional Review Board.

Adverse Reactions: Investigators are required to promptly report any unanticipated problems or complaints to the committee. If necessary a member of the IRB will be assigned to look into the matter. If the problem is serious, approval may be withdrawn pending IRB review.

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The following CRAN packages were used:
TableONE, HMisc, plyr, igraph, CRTsize, ICCest, survival, ggplot2

Statistical Analyses were conducted on R 3.2 for Windows