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Impacts of a novel mHealth platform to track maternal and child health in Udaipur, India

October 2020

Impact Evaluation Report 129

Health

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About this report

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Cover photo: Khushi Baby

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Executive summary

Over 500,000 children die every year in India from vaccine-preventable disease. Khushi Baby is a solution built to change the way maternal and child healthcare is tracked and engaged in rural and remote communities. Our goal is to understand which mothers and children are falling through the cracks.

The Khushi Baby system centres on a novel health record for patients – the Khushi Baby pendant. This health record is digital, wearable, culturally symbolic, durable, biometrically secure and costs less than US$1. Health providers use the Khushi Baby mobile app to scan the Khushi Baby pendant, which allows them to both read and update the wearer's medical history, at the last mile, *without the need for prior data synchronisation*. The Khushi Baby app also acts as a decision-support tool for frontline health workers. Data from the app are synced to the Khushi Baby dashboard for health officials to see high-risk reports, supply-side gaps and health worker targets. The dashboard sends automated voice call reminders to individual families in the local dialect. Health workers and health officials discuss reports on Khushi Baby WhatsApp groups, and Khushi Baby monitors provide in-field support to health workers for follow-up visits.

3ie awarded Khushi Baby a grant to evaluate the impact of the platform, which has been used to track the health of over 25,000 mothers and infants to date. Through a rigorous, randomised controlled trial over the past two years, the Khushi Baby team has followed over 3,000 mothers and conducted nearly 10,000 interviews with mothers, frontline health workers, health supervisors and health officials. The unadjusted results of the trial showed Khushi Baby increased full infant immunisation rates by a factor of 2.03 and decreased infant moderate acute malnutrition rates by a factor of 0.23. Put differently, Khushi Baby increased full immunisation rates by 12.2 percentage points and decreased infant moderate acute malnutrition rates by 4 percentage points.

After adjustment for confounders, the final results showed the Khushi Baby system increased full infant immunisation by a factor of 1.66 and decreased infant moderate acute malnutrition rates by a factor of 0.26, both statistically significant and politically meaningful increases, when compared with the existing paper-based tracking system. The cost per 10 percentage-point increase in likelihood of full immunisation was US$0.68 (₹50) per beneficiary.

The Khushi Baby system retrieved data from the field in four hours, at an average cost of US$4.47 or just under ₹300 per additional beneficiary per year (inclusive of all costs of technology and human resources), and with a 4/5 star approval from the frontline health workers. The results were not statistically significant for decreasing hospitalisation rates or infant mortality.

These findings are particularly noteworthy for three reasons. First, the beneficiaries (mothers) receiving this intervention were only exposed after delivering their child. However, the Khushi Baby app is also used for tracking antenatal care, with automated community engagement of pregnant women as well. This additional early tracking and intervention may have resulted in even higher health behaviour outcomes during childhood, not measured in this trial. Second, these results were found despite frontline health workers still having to conduct double work on paper registers to comply with

mandated reporting protocols established by the state of Rajasthan. Third, these results are impressive considering the technical, financial, political and operational challenges faced to establish the organisation and build the intervention, and deploy the intervention at the last mile. As a result – and with the support of Dr Sanjeev Tak, the former chief medical and health officer of Udaipur district – the Khushi Baby intervention was given clearance to scale up from 350 villages in less than 5 administrative blocks to cover over 1,000 villages across the 5 blocks universally; and to cover the entire district's maternal and child health tracking and engagement operation by 2020. This scale-up is underway, and additionally the State Department of Health and Family Welfare has selected Khushi Baby's platform as a base to scale up across the state in multiple parallel districts in 2020–21.

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Abbreviations and acronyms

ANC	antenatal care
ANM	auxiliary nurse midwife
ASHA	accredited social health activist
BCMO	block chief medical officer
BPM	block program manager
CMHO	chief medical and health officer (district)
DEO	data entry operator
IFA	iron and folic acid
LHV	lady health visitor
LTF	loss to follow-up
MAM	moderate acute malnutrition
MCH	maternal and child health
MOIC	medical officer in charge
MUAC	mid-upper arm circumference
NFC	near field communication
PCTS	Pregnant Women and Child Tracking System
PENTA	pentavalent vaccine
PHC	primary health centre
RCH	reproductive and child health
SES	socioeconomic status
VHND	Village Health and Nutrition Day

1. Introduction

According to the Ministry of Health and Family Welfare, India sees an estimated 500,000 children die annually of vaccine-preventable disease (Saldanha, 2017). Despite much progress over the past decade, 30,000 mothers still die annually in India from preventable causes related to pregnancy and childbirth (UNICEF India n.d.). A variety of cost-effective solutions exist to avert this unnecessary maternal, neonatal and child mortality: immunisations, treatment of febrile illness, simple practices for newborn care and micronutrient supplementation for pregnant women stand out as successful interventions along the continuum of antenatal, intranatal and postnatal care. Increasing coverage of these essential services requires further attention (Horton and Levin 2016).

High rates of infant and maternal mortality in India are additionally concerning due to unreliable estimates from health surveillance systems. In the state of Rajasthan, 2.3 million mothers registered during pregnancy were lost to follow-up in the state's e-health registry between 2011 and 2016, according to a report from the Comptroller and Auditor General of India (Goswami 2017). Without first knowing which children (and mothers) are being left out, strategies to drive behaviour change for better uptake of essential maternal and child health (MCH) services would likely be non-specific and ineffective.

Consider the case of Udaipur, a 'medium-focus' district for immunisation coverage improvements in southwest Rajasthan.[1] The Annual Health Survey 2012–13 reported full immunisation coverage rates of 79.8 per cent in rural areas for children aged 12–23 months (Government of India n.d.a). However, conversely, the reputable National Family Household Survey conducted in 2015–16 found just 37.2 per cent of children of the same age in rural areas in the same district fully immunised (Government of India n.d.b). For the entire district of Udaipur, Rajasthan's Pregnant Women and Child Tracking System (PCTS) showed 44.5 per cent of children aged 12–23 months fully immunised in 2013 (Government of Rajasthan n.d.). Differences in denominators, sampling strategies and data quality might have resulted in this wide range of estimates. Multiple handoffs within the PCTS tracking system may have also contributed to discrepancies (Songara et al.2014-2015) .

Deficits in data quality noted at state and district levels reflect the current state of tracking at grassroots level – the villages, where failure to account for mothers and children results in the aforementioned estimates of infant and maternal mortality rates. The purpose of this evaluation is to rigorously investigate the merit of a novel, culturally tailored, data-vigilant, m-health platform for rural MCH tracking in India: Khushi Baby. Specifically, this evaluation addresses the effectiveness of a systematic multi-stakeholder, multi-component intervention on improvement in MCH data reliability and data retention; and, critically, improvement in data-driven engagements for patient care and delivery of health services to remote and rural communities.

[1] The 'medium-focus' district label was provided under the Mission Indradhanush campaign Phase II, a national campaign to improve child immunisation coverage (*Times of India*, 2015).

1.1 Context

Current protocols described by the National Health Mission and the Rajasthan Ministry of Health and Family Welfare outline health tracking across the MCH spectrum. First, newlywed couples (i.e. women who may soon enter pregnancy) should be identified by the accredited social health activist (ASHA) and given a serial number known as the 'eligible couple' number. During pregnancy, each mother attends an MCH nutrition camp in her village – also known as the Village Health and Nutrition Day (VHND) camp – and receives a pictorial, paper card – known as the MAMTA card – as a personal record for her pregnancy and her child's upcoming infancy.

The auxiliary nurse midwife (ANM), who services a subcentre catchment area of an average 5,000 individuals in plain terrain and 3,000 in tough terrain, is expected to see each mother four times during pregnancy and provide antenatal care (ANC) check-ups (recording any signs of high risk), maternal vaccines, iron and folic acid (IFA) tablets and deworming medications. During these ANC check-ups at the camp, the ANM is expected to fill in the mother's MAMTA card and her own reproductive and child health (RCH) register (a log of all patient data from the camp) with the same data. By the month's end, the ANM is expected to calculate totals for key health indicators that took place at her camps in central government-mandated Forms 6–8. The ANM also turns in her 'linelist' report from the RCH register, showing the individual details of each beneficiary who attends the camps, to the sector-level data entry operator (DEO).

The DEO enters this linelist report into the PCTS, a platform developed by the Government of Rajasthan. After copying values into the web portal for a given patient, the PCTS portal returns an ID for the mother or child known as the PCTS ID. These IDs, along with a due list of the next month's expected patients, are presented to the ANM by the DEO or lady health visitor (LHV). The ANM is expected to write the PCTS ID on the mother or child's MAMTA card at the next camp check-up. ANMs are salaried government staff, but are still evaluated on their ability to reach performance targets for various health indicators, such as registrations, ANC check-ups and immunisations given.

Primary health centres (PHCs) are mandated to have supervisory staff to conduct household 'spot checks' for 10 per cent of the beneficiary population to confirm whether mothers and children have indeed received services. Our observations from three years of field experience in rural Udaipur have revealed gaps not only in the process of delivery of services but also in the process of data collection. At health camp level, we have observed: ANMs not filling in all the required 130 columns of their RCH registers; ANMs skipping sections for past obstetric history; ANMs deliberately falsifying data for blood pressure values, blood sugar values and urine analysis results without performing tests; ANMs writing data in personal diaries in lieu of the official register; ANMs calling migrated patients and recording follow-up status over the phone for details that require an in-person check-up; ANMs only partially completing data on the patient's MAMTA card, particularly for immunisation dates; and ANMs holding the MAMTA card until completion of the last vaccine, instead of appropriately providing the card to the patient.

At PHC level, we have observed: DEOs receiving data to upload up to 30 days after the health camp; DEOs changing the dates of ANC check-ups and dates of the patient's last

menstrual period to bypass validations; ANMs summarising monthly indicators by hand; and ANMs manipulating data for month-end reporting for indicators uploaded into the PCTS portal. Similar findings have also been documented in a gap analysis of the PCTS system by Columbia University's Earth Institute (2015) for the district of Dausa, Rajasthan.

1.2 Innovation

In response to the challenges of paper-based tracking at field level, several solutions have been developed to digitally collect MCH data in rural healthcare settings. Solutions such as eJanSwasthya, Rajsangam, Medic Mobile, CommCare, mSehat and ANMOL (ANM online) are all mobile applications for health workers and share several features: the capacity to digitally collect structured health data in offline settings; validations to assist health workers to take actions; a mechanism to sync data to a cloud-based database; a reporting mechanism such as a dashboard for district health officials to see progress against key indicators; and, in some cases, use of SMS reminders for patients tracked with the system.

While these solutions have been used successfully to automate data collection, they remain vulnerable to several key limitations with respect to data accountability. Health workers may still create records offline without physically seeing beneficiaries. Furthermore, if beneficiaries move village, which is routine in Rajasthan in the last month of pregnancy, then the new health worker often has to create a duplicate record in the existing m-health solutions and has no insight into the beneficiary's past medical history on the digital platform. When the health worker enters the unique ID or name of the beneficiary to search the record, the beneficiary record may not be found because the data from where the beneficiary was initially registered were not synced to the current health worker's device.

The Khushi Baby platform was designed to advance the paradigm for m-health-based tracking by addressing the key issues of accountability and dependence on synchronised devices. The Khushi Baby pendant stores the medical history of the beneficiary, allowing them to carry their updated health record to any health worker in a digital format. The health worker cannot update or create a new health record without a beneficiary's biometrics and Khushi Baby pendant being scanned to match. The Khushi Baby platform was also designed to make culturally informed improvements to a technological approach, through community-inspired design of the wearable digital health record and with patient-specific, dialect-specific voice reminders for populations that are largely illiterate.

Ultimately, breaking through stagnation in infant immunisations will require addressing existing gaps in health system accountability, throughout the continuum of pregnancy through infant care, to drive behaviour change for both patients and the health workers who make up the health system in rural India. Our underlying hypothesis is that better–actionable and accountable – data can bring about better prevention and better care for mothers and children at the last mile.

1.3 Intervention

Khushi Baby is a system as an intervention designed to transform MCH at the last mile (Figure 1). The system's overarching objective is to better connect health workers with

beneficiaries and health officials with communities through data-driven engagements. To achieve these objectives, the Khushi Baby system has multiple components, targeted for multiple stakeholders (see Online Appendix to review the project and intervention evolution):

1. The Khushi Baby pendant *for beneficiaries.*
2. The Khushi Baby app *for health workers.*
3. The Khushi Baby analytics dashboard with automated voice calls *for health officials and families.*
4. Khushi Baby personal voice calls *for beneficiaries.*
5. Khushi Baby WhatsApp groups *for health worker teams.*
6. Khushi Baby field monitors *for health workers and beneficiaries.*

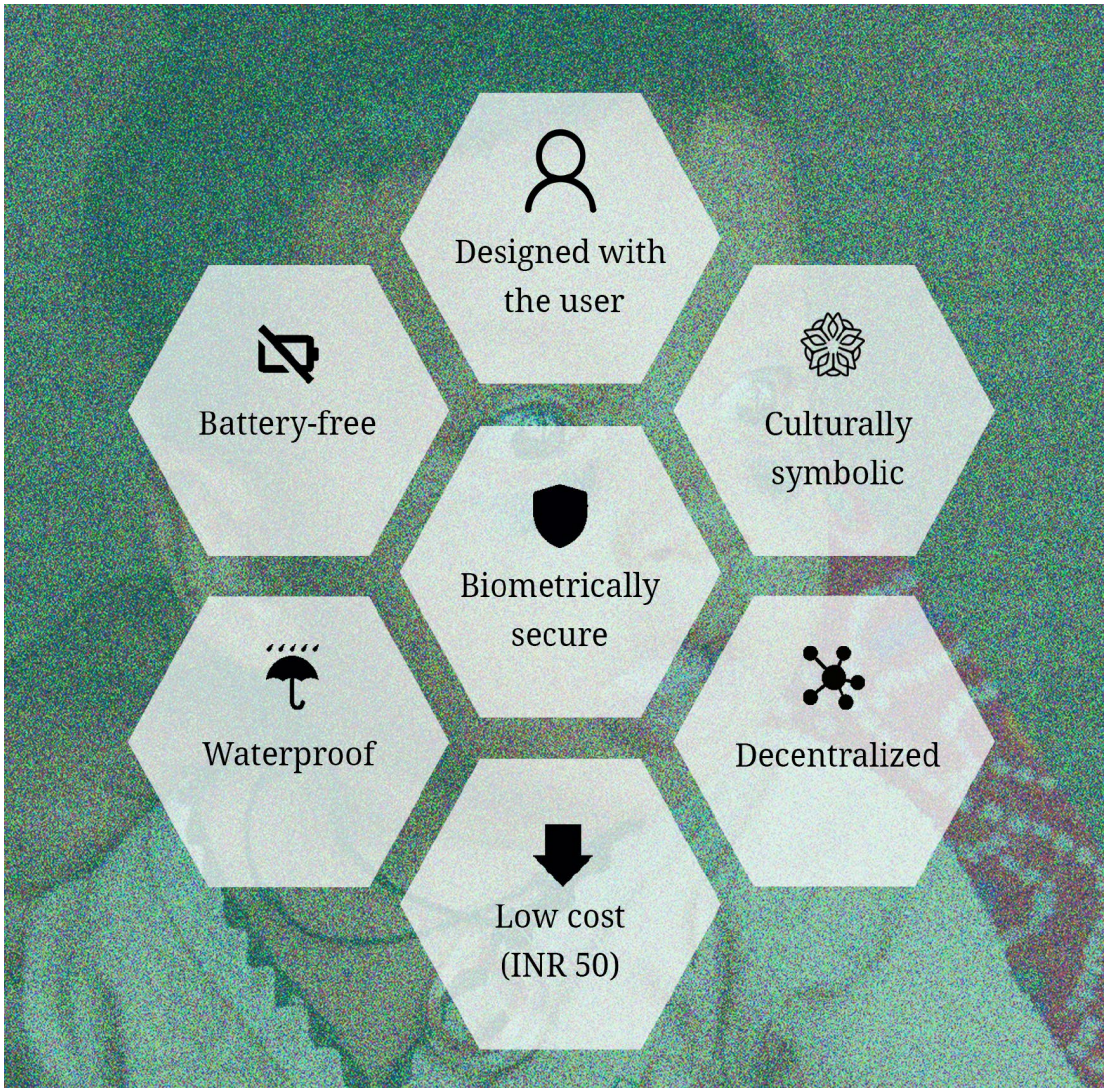
Figure 1: Khushi Baby intervention schematic

How it works: Mothers and children wear the Khushi Baby pendant. Health workers (ANMs) **scan** the pendant with the Khushi Baby app to retrieve and systematically **update** health information and plan for health camps. ANMs **sync** data when they return to areas with connectivity, so that health officials can **analyse** reports. Automated voice **calls** are sent to families to remind them of upcoming camps. High-risk patient reports are generated and sent via WhatsApp groups to health worker teams to **mobilise** on-the-ground action. Monitors support ANMs to facilitate high-risk follow-up.
Source: Khushi Baby Inc.

1.3.1 The Khushi Baby pendant

The pendant is a novel health record, which uses near field communication (NFC) technology to store unique IDs and the full health history of the mother and child. Importantly, this pendant has been designed with a culturally symbolic black thread, traditionally worn in these regions of India, to protect the child from the evil eye or *buri nazar*. By tapping the pendant with the health worker's tablet, and then scanning the beneficiary's fingerprint, the health worker can access and update the patient's most recent data without the need for connectivity.

Figure 2: Benefits of the Khushi Baby pendant



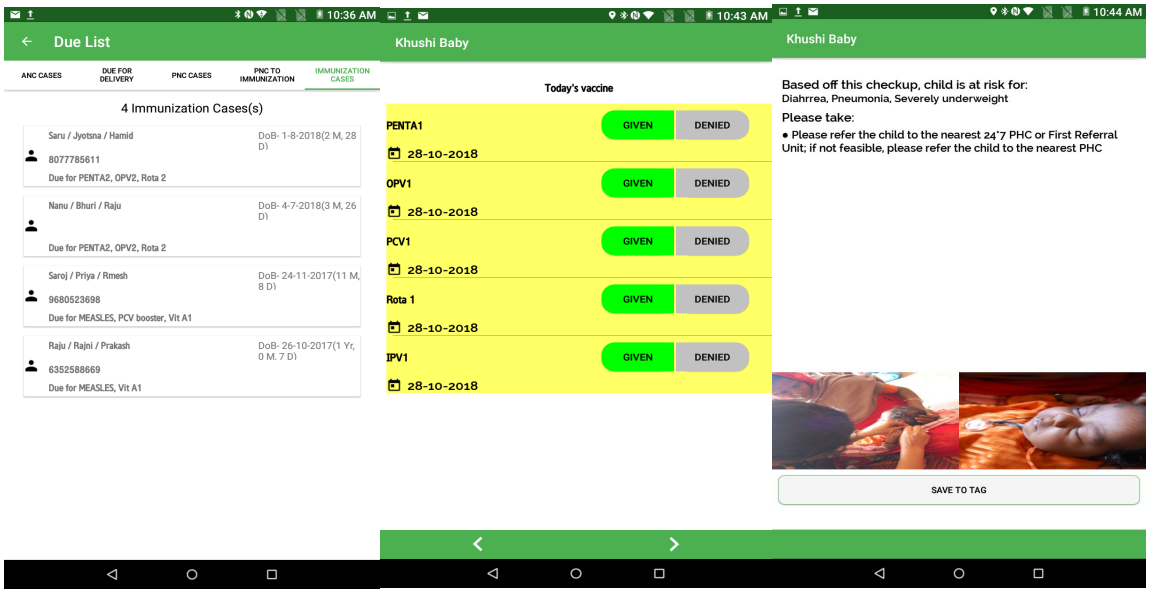
Source: Khushi Baby Inc.

1.3.2 The Khushi Baby app.

The app is an Android application (OS 4.4.3+), made for tablets, to be used by frontline health workers (ANMs). Features include: authenticated login with biometric authentication; health camp selection; GPS and time tracking to confirm attendance; pre-camp supply checklists; color-coded patient due lists for pregnant women and registered infants; data field validations and alerts; time taken per beneficiary tracking; check-up summary page with action items for the beneficiary; immunisations due for today; ability to report on reasons why vaccines, medications and tests were not administered; camp check-out summary with updated due list; and ANM summary statistics.

Using the Khushi Baby app, the ANM scans the beneficiary's pendant, and then their fingerprint to read and update their history. If the pendant is lost, there is a mechanism to search for the beneficiary by name in the tablet to issue a fresh pendant. All data collection fields are made to be compatible with Indian National Health Mission guidelines for RCH Register Sections II and III.

Figure 3: Beneficiary details on the Khushi Baby app

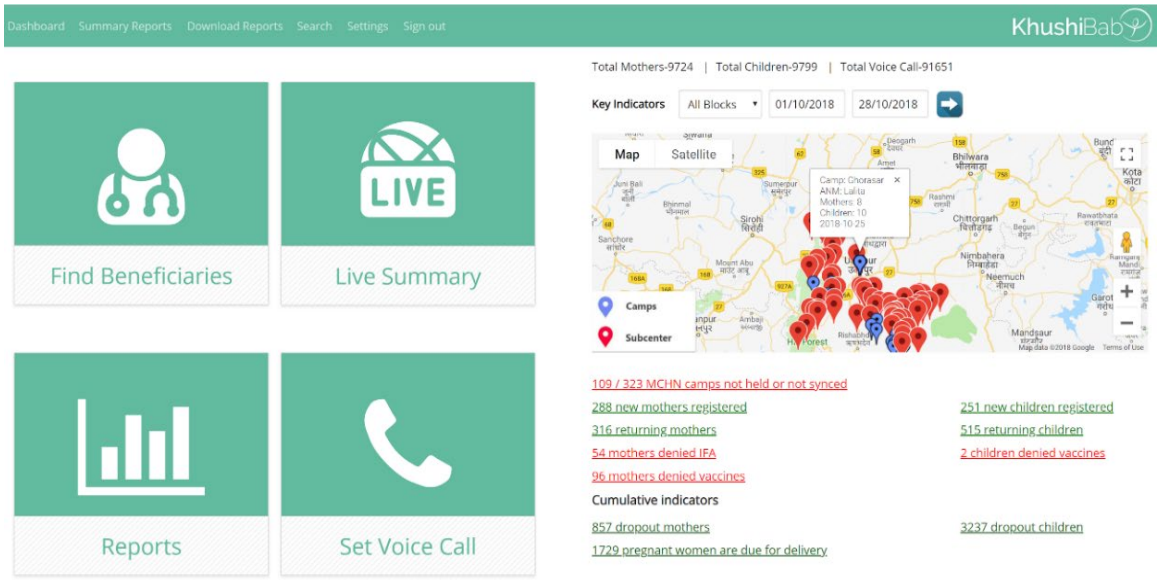


Source: Khushi Baby Inc.

1.3.3 The Khushi Baby dashboard.

The Khushi Baby dashboard presents real-time updated summary statistics, targeted to health officials. Reports are available in government formats for major indicators. Specialised reports are also available for health worker attendance, supply-side shortages and high-risk patients. Officials using the dashboard have the ability to drill down by geography to individual level (mother-child dyad) to track progress. The Khushi Baby mDash is an Android app under development, designed for officials to see actionable data distilled from the dashboard on their mobile phones while on the go.

Figure 4: Actions available through the Khushi Baby dashboard



Source: Khushi Baby Inc.

1.3.4 Khushi Baby automated voice calls.

Through the Khushi Baby dashboard, officials can schedule calls for camp reminders and for MCH education. These calls can be set for a specific time, specific geography and specific beneficiary group, such as those mothers who missed their child's last immunisation. More than 35, 30-second audio clips have been recorded in the regional dialect of Mewari.

1.3.5 Khushi Baby personal voice calls

One member from the Khushi Baby team is currently designated as the community engagement expert. She calls selected beneficiary groups, such as dropout mothers, high-risk mothers and mothers in their last month of pregnancy to provide timely advice and listen to concerns. Note that this component of the intervention was not rolled out to study participants.

Khushi Baby WhatsApp groups

ANMs and their block chief medical officer (BCMO) are added to WhatsApp groups. On a weekly basis, the Khushi Baby team shares high-risk patient reports with the ANMs. The groups are also used to share educational content related to specific MCH themes. ANMs use the groups to report back on high-risk patients from their catchment areas.

Khushi Baby monitors

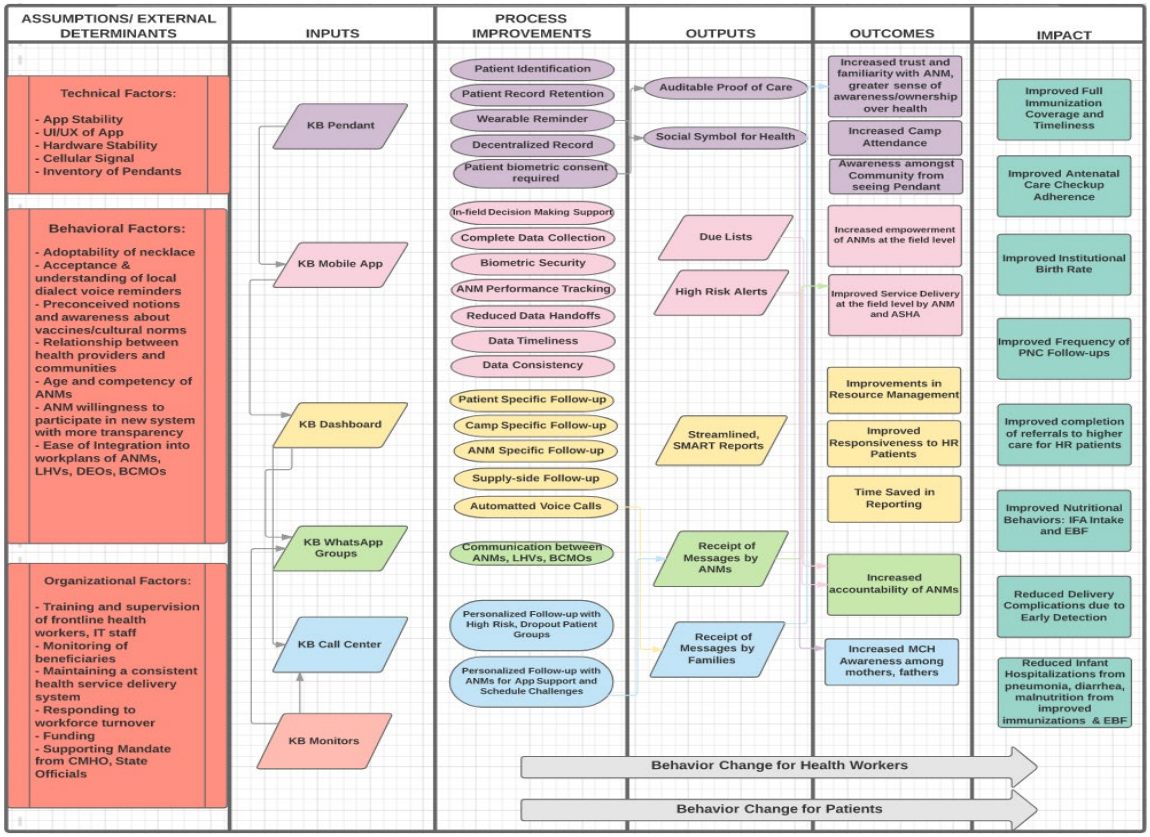
Khushi Baby field monitors are local staff who provide ANMs with training, in-field support and assistance in following up on high-risk and dropout beneficiaries.

Figure 5: Activities completed by Khushi Baby monitors

Source: Khushi Baby Inc.

1.4 Theory of change

Figure 6: Theory of change diagram



Source: Khushi Baby Inc.

Khushi Baby's theory of change (Figure 6)[2] is rooted in achieving the following specific aims:

1. To ensure an interface between frontline health worker, caregiver and child.
2. To streamline data collection on MCH indicators.
3. To enable better planning and clinical decision-making on the part of the frontline health worker.
4. To improve communication between the ANM and ASHA for care coordination.
5. To optimise management of limited health worker resources.
6. To identify high-risk and dropout beneficiaries.
7. To better educate and remind beneficiaries about the importance of ANC and immunisation
8. To change the culture of action and accountability among health workers and health officials.

[2] For a full description of our theory of change, see our Baseline Report (Nagar et al. 2017, pp.36–37).

2. Evaluation framework

2.1 Key evaluation questions[3]

1. Does the Khushi Baby system function robustly?
   a. What is the frequency of hardware- and software-related issues in the field?
   b. Does the Khushi Baby system deliver data on time?
   c. Do beneficiaries retain pendants more than MAMTA cards?
2. Can the Khushi Baby platform improve the quality of MCH data in rural Udaipur when compared with status quo processes?
   a. Are the data complete for minimum, mandatory fields for infant health tracking?
   b. Are the data consistent between the beneficiary and the backend source?
   c. Is there an impact on the check-up-related processes followed and/or the proportion of false fields entered?
3. If the Khushi Baby system works and generates higher-quality data, does the Khushi Baby system generate value or remain unused? Specifically, how does the Khushi Baby system generate differentiating data-driven engagement for better healthcare delivery and community engagement?
4. Does the collective Khushi Baby system lead to high rates of full and timely infant immunisation; and, if so, which factors are significant in predicting immunisation outcomes? Specifically:
   a. What factors contribute to full immunisation as defined by oral recall?
   b. What factors contribute to full immunisation as recorded on the official health card (MAMTA)?
   c. What factors contribute to full immunisation as recorded on the Khushi Baby pendant?
5. Are there any spillover effects of the Khushi Baby system on:
   a. Rate of severe acute malnutrition and moderate acute malnutrition (MAM);
   b. Infant hospitalisation rate; and
   c. Infant mortality rate when comparing treatment with control?
6. Comparing treatment with control, how have the attitudes, behaviours and awareness for mothers and fathers with respect to the healthcare of their child changed?
7. Comparing treatment with control, how have the attitudes, behaviours and practices changed for ANMs and ASHAs from baseline to endline?
8. What is the end user feedback on components of the system from mothers, ANMs, ASHAs and block program managers (BPMs) who have experienced the Khushi Baby pendant, app, automated voice calls and WhatsApp groups respectively?

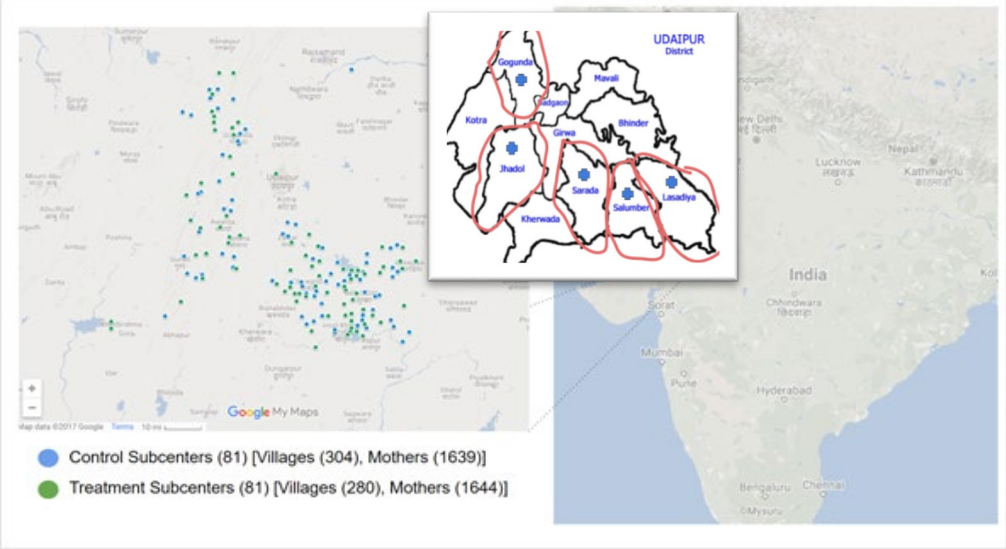
[3] See the Online Appendix for the Evaluation Design Framework (Appendix Table 1), Changes from Pre-Analysis Plan and Monitoring Plan (Appendix Table 2).

2.2 Study design[4]

A 162-subcentre, unblinded, cluster randomized controlled trial with two arms as treatment and control took place between September 2016 and August 2018. For a map of the Khushi Baby system treatment and control areas by subcentre, see Figure 7. In Udaipur, there are 627 subcentres, each covering a 5-kilometre radius and with an average population of 5,000, across 12 administrative blocks. Subcentres where earlier pilots had been rolled out in 2015–2016, and subcentres with other interventions such as eJanSwasthya, another m-health pilot, were excluded. The subcentres were further narrowed down by the district chief medical and health officer (CMHO) who allotted five administrative blocks from which we could select our treatment group. Of the remaining 252 subcentres, 162 were selected using a random number table.

The list of 162 subcentres was approved by the CMHO in August 2016. The subcentres were randomised to the Khushi Baby treatment and control groups using a stratified randomisation with blocking using STATA software. Randomisation was stratified on baseline full immunisation coverage, as determined by PCTS for the 2015–2016 financial year across three levels: 'high-performing' subcentres had reported full immunisation coverage of 90%+; 'mid-performing' subcentres 60–90%, and 'low-performing' subcentres below 60%. Randomisation checks were performed to ensure balance on the stratification factor. Randomisations were run until the difference in the stratification factor was no longer statistically significant between arms. The 81 subcentres randomised to treatment group were then visited by the Khushi Baby monitoring team to gather ANM contact details. ANMs who were about to retire or transition were excluded.

Figure 7: Map of treatment and control areas



Source: Google Maps.

[4] See the Online Appendix for the Evaluation Design Framework (Appendix Table 1), Changes from Pre-Analysis Plan and Monitoring Plan (Appendix Table 2).

2.2.1 Sample requirements

Sample requirements were calculated based on assumptions for Outcome 4A (full immunisation by oral recall), due to the relevance of the outcome to the grant thematic window; and due to the outcome having the largest projected sample size at the time of baseline for all the evaluation sub-questions. For two study arms, an alpha of 0.05, power of 0.8, minimum detectable difference of 10 percentage points from baseline rate of 0.5 to endline rate of 0.6 (which would be of programmatic significance), assumed loss to follow-up (LTF) of 10 per cent, and assumed inter-cluster coefficient of 0.15 (high inter-cluster homogeneity), the required sample size was 165 subcentres, with 20 eligible participants from each subcentre for a total target sample of 3,300 (Table 1). The baseline infant immunisation rate was 0.241, not 0.5. Therefore, the revised required sample for follow-up through endline was 2,480. The subgroup sample required for health record retention for those mothers who received a health record for their infant was 3,300, using the same assumptions as above and a measured baseline retention rate of 0.509. Other subgroup sample requirements were not calculated at baseline, due to limitations in the baseline coverage evaluation survey.

Table 1: Sample required and sample achieved

	Sample required for 10 percentage point minimum detectable difference	Sample enrolled	Eligible sample followed for outcome at endline
Full and timely immunisation at 12 months	2,480 (2,254 without 10% LTF)	3,283	2,243 (2,254 required)
Health record retention	3,300 (3,000 without 10% LTF)	3,283	2,145 (3,000 required)

LTF reasons varied by outcome. Most households were revisited during the endline exercise in both treatment (81/1,644 missed) and control areas (69/1,639 missed). LTF was due to mothers not being available at the endline visit, mothers having moved from the household, mothers having died, mothers refusing consent, and children having died after roll-out of the intervention. Health record analysis required receipt of a health record as a prerequisite. Mothers who did not receive the pendant or MAMTA card were excluded. Based on the endline sample achieved, health record retention as an outcome was underpowered to detect a 10 percentage point difference. Data completeness outcomes required a searchable patient ID. Mothers with duplicate Khushi Baby IDs or null PCTS IDs were excluded.

Full immunisation by recall excluded children under the age of 12 months or those who had died before the start of the intervention; whereas full immunisation by MAMTA card further excluded children with no corresponding MAMTA card. Children who did not meet the six-month age criteria were excluded from malnutrition outcomes, along with any who had died. Children who had died before the intervention start were excluded from the hospital admissions outcome and from the infant mortality outcome. For each outcome, an endline balance table was constructed to account for possible differential attrition between study arms. Differential predictors were adjusted for in the multivariate analysis where applicable. See Online Appendix for full consort flow diagram (Appendix Figure 1).

2.2.2 Sampling strategy

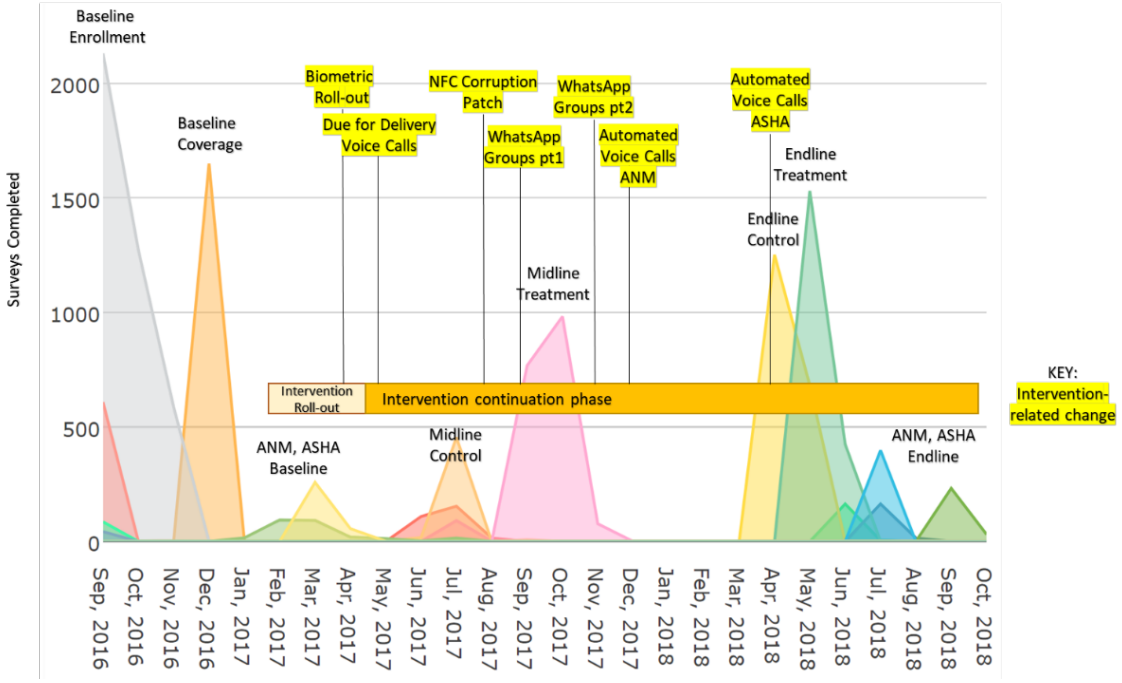
Figure 8 shows a detailed timeline of the evaluation and intervention stages. The following sections describe the sampling strategy for each stage of the evaluation.

Baseline enrolment

The purpose of the enrolment survey was to select the cohort of mothers to be followed longitudinally for our impact evaluation for up to 18 months. The enrolment sample, derived from the enrolment survey, was used to assess outcomes for: data retention; data completeness; data consistency; full immunisation coverage and timeliness; pentavalent coverage; severe and moderate acute malnutrition; infant hospitalisation and mortality; and changes in maternal attitudes towards healthcare. The enrolment survey collected important baseline indicators regarding mother's socioeconomic status (SES); mother awareness of maternal, neonatal and child health; and past medical history, which could serve as relevant covariates in models for the stated outcomes.

For each of the 162 control and treatment subcentres, lists of pregnant women ('linelists') were obtained from ANMs. Each mother in the linelist was visited at the household and individually invited to participate. This approach was used in order to avoid selection bias from sampling within subcentres, and to ensure the enrolment of pregnant women from all villages serviced by the subcentre. The target for enrolment per subcentre was 20 pregnant women. If the target could not be reached by recruitment of mothers on the linelist, mothers who were in the same village but not on the original linelist were invited to participate ('non-linelisters'). Mothers who had already delivered were excluded. Mothers not available at the household at the time of visit had their households revisited once.

Figure 8: Study timeline



Source: Khushi Baby Inc.

Baseline coverage
The purpose of the baseline coverage evaluation survey was to understand the immunisation rates at baseline of the average 12–23-month-old child in the control and treatment subcentres for randomisation stratification.

Of the 162 subcentres chosen for the study, 50 treatment and 50 control subcentres were selected using a random number generator procedure on STATA. Linelistings were obtained for all mothers with children aged 12–23 months from each of the 100 selected subcentres. As per 30-cluster sampling guidelines from the World Health Organization (WHO 2015), a required sample size of 13 respondents was targeted per subcentre (level of clustering), in order to have 95% CI, 5% margin of error, with an assumed true population baseline of full immunisation coverage of 70%. Systematic random sampling was conducted within the subcentre linelistings to determine which households to visit, and the process was continued until the target number of 13 was reached in each subcentre. Post-hoc analysis showed 12.43 respondents were surveyed per subcentre on average.

ANM Baseline
The purpose of the ANM baseline survey was to assess behaviors and attitudes of ANMs regarding the data collection process for MCH tracking, and for the routine work performed in general. Structured questionnaires were deployed to investigate ANM challenges, motivations, workflows and work conditions, as well as individual factors for each ANM, such as familiarity with mobile phone and years spent in training. All ANMs serving the 81 treatment and 81 control subcentres were selected for the ANM stakeholder sample (at baseline). In total, 166 ANMs were surveyed: 88 treatment and 78 control.

ASHA Baseline ASHA
The purpose of the ASHA baseline survey was to assess behaviors and attitudes regarding MCH tracking from the perspective of the ASHA, who plays a key role in recruiting mothers to the camps and in coordinating care with the ANMs. Structured questionnaires were deployed to investigate ASHA challenges, motivations, workflows and work conditions, as well as individual factors for each ASHA. A convenience sample of 2 ASHAs was targeted for each of the 81 treatment and 81 control subcentres. Each subcentre has approximately 4–5 villages serviced, each of which has an ASHA. A total of 310 ASHAs were surveyed.

Midline follow-up
The purpose of the midline survey was to follow up with the enrolment sample for health card retention, data completeness, data consistency and immunization coverage for OPV 1–3 (oral polio vaccine) and PENTA 1–3 (pentavalent vaccine), and to gather an intermediate time point for these indicators. All women in the treatment group were eligible. As part of a systematic random sample, every fourth respondent in the control group was approached.

Endline follow-up
The purpose of the endline survey was to gather data on all evaluation outcomes from the enrolment sample. Additionally, any variables missed during the baseline collection were also collected during the endline survey, such as distance to the health camp. All women originally enrolled were eligible for this survey.

Endline ANM survey
The purpose of this survey was to gather feedback from the ANMs on Outcome 7 (ANM and ASHA changes in attitudes, behaviours and practices). Topics addressed included comfort with and performance of the Khushi Baby system, confidence with conducting essential duties in the setting of the Khushi Baby system, and impact of the Khushi Baby system on camp attendance. All ANMs enrolled at baseline were eligible for this survey. 147 ANMs were surveyed in total.

Endline camp observation
The purpose of this survey was to observe the essential check-up processes and data entry processes performed by the ANM at the camp for Outcome 2C (data validity). Check-up processes for new and returning mothers and children were observed, along with subsequent data entry steps. All 147 ANMs at endline were eligible for this camp observation, but observation was completed before the full sample could be observed. However, the order of ANM observation was randomised. During each camp observation session, Khushi Baby monitors were given a target of observing one new mother, one returning mother, one new child and one returning child. In control subcentres, 31 ANMs who performed 32 mother check-ups and 35 child check-ups were observed. In treatment subcentres, 59 ANMs who performed 68 mother check-ups and 75 child check-ups were observed.

Endline focus groups – mothers
The purpose of this survey method was to gain a qualitative understanding of beneficiary feedback on various components of the Khushi Baby system, such as the pendant and voice calls, and their suggestions for how to improve these components moving forward. One facilitator and two observers were present to probe discussion topics and to capture, respectively, verbal and non-verbal responses from the group. For each of the five geographical blocks, a target was set of two to three focus groups at the village level. These villages were selected using a convenience sample accounting for geographical access, availability of the ASHA and availability of the beneficiaries who had received the Khushi Baby pendant. The survey was notably conducted during the maize harvest season, thereby reducing the availability of a certain set of beneficiaries. In total, 92 mothers were included in 11 focus groups, with a minimum of 2 focus groups from each geographical block.

Endline key informant interviews
The purpose of this set of interviews was to gain an understanding of the perspectives of LHVs, BCMOs, BPMs, medical officers in charge (MOICs), and the CMHO, who oversaw the treatment subcentres, on the impact of the Khushi Baby system, their individual interaction with the system to date, and their ideas for system improvement moving forward. A total of 36 LHVs, 36 MOICs, 5 BPMs, 5 BCMOs and 1 CMHO were concerned with the treatment area. A convenience sample was selected, with attempts to cover each block, and reach health officers who were both geographically near to and far from the Udaipur Khushi Baby headquarters. The target sample was 3 LHVs and MOICs from each block, and all 5 BPMs, BCMOs and the CMHO for a total sample of 41. In total, 27 interviews were conducted with 10 LHVs, 8 MOICs, 3 BCMOs, 5 BPMs and the CMHO.

Data collection and management
Data for all surveys except the endline focus group discussions and key informant interviews were collected on the SurveyCTO mobile app by a team of Khushi Baby field surveyors, hired as temporary contractors, and given an initial three-day workshop, with regular weekly meetings at the Khushi Baby headquarters. The Khushi Baby core team would evaluate the data collected daily and examine data for duplicates and missing mandatory fields. During the endline follow-up survey, it was noted that mid-upper arm circumference (MUAC) values were being reported with rounding bias on several hundred infants. Surveyors were informed to round to the nearest tenth as per the tape, and distribution of values improved over the next month and a half. Backchecks and spot checks were performed by Khushi Baby core team members after reviewing the weekly data. Data were merged using unique identifiers for respondents and subcentres.

2.3 Methods of analysis

2.3.1 Approach to quantitative analysis
Descriptive analyses were performed on all Outcomes 1–8 for frequencies and distributions. Differences between treatment and control groups were calculated on Outcomes 1C, 2A, 2B, 2C, 4A, 4B, 4D, 5A, 5B, 5C and 7, using parametric two-tailed, two-sample z-tests for proportions on an intent-to-treat basis. For Outcome 6, we compared distributions using a non-parametric, chi-square goodness-of-fit test between treatment and control groups, and made individual comparisons using appropriate parametric methods mentioned above.

For Outcomes 1C, 4A, 4B, 4D, 5A, 5B and 5C, those outcomes which had a significant difference between study groups were considered for regression analysis to adjust for potential confounders. Outcomes 4A, 4B, 4D and 5A (MAM) were considered for regression. Additionally, the treatment-specific Outcome 4C was regressed to corroborate the results from the analyses of 4A and 4B. Logistic regression was used on these binary outcomes, using their respective intent-to-treat sample, according to the following formulation:

$$Logit\left(Y_{ijkl,post}\right) = \alpha + \beta T_{kl} + \gamma X_{ijk} + \delta Z_{jk} + \rho W_k + \mu_{jk} + \varepsilon_{ijkl}$$

In this equation, $Y_{ijkl,post}$ represents the binary outcome at endline for the woman i in village j in subcentre k in block l. T_{kl} is a binary vector for subcentre k being in the treatment group. X_{ijk}, Z_{jk} and W_k, respectively, represent the vectors of individual-level, subcentre-level and administrative block-level covariates (only one categorical covariate for administrative block as a fixed effect). The subcentre-level error term is represented by μ_{jk}, and the individual-level error term is represented by ε_{ijkl}. Individual-level covariates included variables such as: age; marital status; education; caste; SES index; a maternal and child awareness index score; access to a mobile phone; distance to the health camp; child sex; child illness episodes; restrictions imposed by family members; frequency of ASHA visits; time spent waiting at camps; and number of intervention-related calls received.

Subcentre-level covariates were specific to the ANM, including (but not limited to) factors such as ANM age, education, distance to furthest camp, frequency of visit to the PHC, total requirement of reporting burden, and access to mobile phone. Subcentre-level

covariates also included number of external overlapping interventions, such as the Mission Indradhanush campaigns for immunisation. $\beta, \gamma, \delta, \rho$ represented coefficients for study group, individual-level, subcentre-level and block-level covariates, with β as the coefficient of interest, which represents the increase or decrease in the log-odds of the outcome for an average woman in a subcentre randomised to receive the intervention.

To build a parsimonious model, that is, a simple model with strong explanatory power, we had to select from over 260 measured variables related to the mother, the ANM, the ASHA, the geography and the components of intervention received. Our target model intended to include the 15 most significant covariates associated with the outcome.

The systematic approach to variable selection for the regression model was as follows:

1. List variables to be associated with the outcome based on theory and prior literature as the 'base model'.
2. Impute missing data using predictive mean matching for continuous and binary variables and mode substitution for categorical non-binary variables with the MICE package in R.
3. Reduce dimensionality via indices for SES and health awareness (see Online Appendix).
4. Assess differential distribution of measured variables between treatment and control groups at endline.
5. Assess the unadjusted, univariate association between each variable and the outcome.
6. Perform principal components analysis to further reduce dimensionality according to the methods described by Zhang and Castelló (2017).
7. Assess which top three principal components explained the largest degree of variation in the sample.
8. Assess which remaining principal components were most delineated by selecting those principal components that had at least one major loading with a covariate of |0.18|.
9. Assess which principal components were most statistically significantly associated with the outcome using a multivariate model built empirically, using forward selection.
10. Variables from steps 1, 7, 8, 4 and 5 were then sequentially added, with non-significant variables dropped (forward selection), to construct the final model, using the likelihood ratio test to assess difference between sequential models, and the objective Akaike Information criterion to determine the overall best fit model under the conditions for a parsimonious model, as described in Wahi (2017). The GLMER package in R was used for this step to specifically adjust for random effects of the cluster level and to check for highly multicollinear variables. For details on this statistical package implementation, see UCLA Institute for Digital Research and Education (2020).

Variables were included as categorical or continuous, based on the original method of measurement, unless there was a literature-based rationale for converting continuous variables into specific categorical bins. Continuous base model variables found to be non-significant in the final step were considered for categorical binning and retested against the model, if there was a non-linear trend seen between the variable and the outcome. Of note, treatment-specific Outcome 4C (full immunisation by Khushi Baby

pendant) followed the same procedure above with the exception of step 4, which was not applicable; and for step 10, GLM (not GLMER) was used. Both significant covariates from the final model and non-significant covariates from the base model are interpreted in section 3 on findings.

2.3.2 Approach to qualitative analysis

Individual quotes spoken in Hindi or Mewari by the mothers in the focus groups were recorded in Hindi or English by the Khushi Baby core team. Quotes were grouped according to each open-ended question-stem topic. Representative quotes were then selected for variety of role, level of detail, variety of opinion and uniqueness of response. Word and phrase frequencies were not quantitatively analysed. Key thematic areas from the full set of quotes and representative set of quotes were extracted and interpreted.

2.3.3 Approach to addressing sources of bias

From a quantitative standpoint, our objective was to provide an unbiased estimate of the effect of the Khushi Baby intervention on full infant immunisation, among other outcomes related to both data and health of the child. Several sources of bias were present in the study. First, the Khushi Baby team was responsible for designing the study, modifying the intervention, analysing the data and interpreting the results, which portends evaluator bias. An external organisation may have been able to conduct an impact evaluation with less of a vested interest in the role of the intervention on the outcome. Logistically and financially, this option was not feasible. Moreover, the degree to which an external agency may have been able to evaluate the project would likely be limited in comparison. Key to reducing bias was making the Pre-Analysis Plan and Baseline Report available, and justifying any deviations in intended analysis. Also, data collection was conducted by field monitors and surveyors hired as consultants through an external agency, A to Y Manpower. Detailed code and anonymised data will be made available through the supplement for others to replicate our analysis.

Sampling bias was addressed through the study design. Women chosen for the study were selected at the household level, not at the health camp level, and from an ANM linelist of each village. There was a possibility that the ANM- and ASHA-collected censuses of reproductive age women may have left out migratory populations or members from lower-caste groups, but our analyses found no differences in SES score, caste, or outcomes between linelisters and non-linelisters (see Online Appendix for details).

With respect to the data collected, several forms of bias may have contributed, including recall bias, especially with respect to Outcome 4A (full immunisation by oral recall), given also that the intervention population was already established to have a low baseline health literacy in the baseline coverage evaluation. To reduce recall bias, the survey questionnaire was designed to indicate the injection site and route of administration, using culturally relevant cues for the various vaccines modified from the National Family Health Survey.

With respect to Outcome 4B (full immunisation by MAMTA card), misclassification bias was a concern, given that ANMs were found to keep MAMTA cards to themselves, not always record the given status of the vaccine, or in some cases, record the given status without the date received. The effect of such misclassification would likely result in a

lower proportion of respondents completing the full immunisation requirements. At the same time, health incentives for ANMs to submit MAMTA cards showing full immunisation may have driven misclassification bias to overestimate the true coverage outcome. We expected the direction of misclassification to be equivalent in study groups given the randomised design. Outcomes 4A and 4B were included in the study design to corroborate findings from both approaches to measure full immunisation, and in doing so account for each method's own measurement bias.

Hawthorne effects from the Khushi Baby surveyors on the individual women enrolled were unlikely to have played a factor in the observed differences in outcomes. Women were approached and asked about the outcome at most three times: baseline, midline and endline. The effect of observation almost certainly played a role on ANMs, exclusively in the treatment subcentres, who received varying degrees of interaction and supervision from Khushi Baby field monitors. It is important to note, however, that outcomes were specific to the individual level and Khushi Baby monitors were part of the intended intervention being evaluated for scale-up.

John Henry effects of individuals in control groups, overcoming a known differential application of the intervention, were minimised by the clustered design, which ensured that individuals from the same subcentre (5 kilometres radius) would be relatively blinded to interventions in subcentres outside of the normal perimeter of their daily activities and less likely to cross over to the treatment group. Contamination of subcentres due to overlapping interventions was accounted for both in the randomised design and in the analysis phase, with specific attention to the Mission Indradhanush door-to-door vaccination campaigns that took place in select subcentres.

From a qualitative standpoint, the objective was to present a representative sample of impressions (positive, negative and group supported) of the intervention from various stakeholders and beneficiaries. In this case, Khushi Baby core team members were involved in these focus group discussions and in-depth stakeholder interviews. The room for evaluator bias was notable here, given that the Khushi Baby team was involved with the data collection process. To reduce bias in focus group discussions, a female member (who regularly calls high-risk mothers for personalised reminders) was selected as the facilitator, with two other members as silent observers. The facilitator would engage the women in ice-breaking activities to gain trust, and ask open-ended questions. When certain voices began to dominate the conversation, the facilitator would intervene to ask quieter members to share their thoughts as well. The facilitator would also probe women to share their thoughts in more detail. In both focus group discussions and stakeholder interviews, respondents were explicitly asked to suggest areas of concern and improvement to balance against any tendency to appease the evaluator.

2.4 Ethics and transparency

The study was approved by a local ethics board at the Centre for Operations Research and Training in Vadodara, Gujarat in July 2016, prior to the onset of the trial. Key ethical issues addressed included data privacy, extra burden placed on health workers, administrative burdens placed by randomisation, time required from survey participants who came from vulnerable populations, and concerns regarding safety of the necklace. Oral consent was taken from participants at the beginning of each survey process. Written

consent was also taken for participants in the baseline enrolment and coverage surveys. The study was registered online at clinicaltrials.gov with the following protocol ID: TW10.1078. Labelled anonymised datasets (without audio files) and statistical analysis code in R and Python with documentation are linked to the study's online summary.

3. Findings

3.1 Implementation fidelity

The initial target for implementation uptake was for 81 ANMs to use the Khushi Baby app, 5 BCMOs and 5 BPMs to use the Khushi Baby dashboard, 38 LHVs and DEOs to use the Khushi Baby dashboard, and for the CMHO to use the Khushi Baby dashboard.

The actual implementation uptake from February 2017 to June 2018 (the evaluation period) showed that the Khushi Baby app was used by 87 ANMs, although significant challenges were faced. Although trainings were provided to LHVs (90), DEOs (28) and medical officers (42), these health workers and officials did not consistently use the Khushi Baby dashboard over the evaluation period. Deviations in uptake from health officials may be principally attributed to the fact that our system did not collect data from all beneficiaries in the respective catchment areas (the block level) of these health officials due to the nature of our randomisation (at the subcentre level). Access to computers was not a barrier for many of these health workers, but in many cases, the computers of the health workers and officials were found to be largely unused (except for the case of DEOs).

We faced challenges increasing uptake of the mobile app among ANMs, especially between February and November 2017, for several reasons. First, many of the tablets used in the field had hardware failures. Second, some proportion of the replaced tablets, due to an error in the software library, caused several hundred records to be corrupted on the Khushi Baby pendant and Khushi Baby backend. These technical issues and other weekly crashes within the app directly caused many ANMs to express frustration and the desire to abandon the Khushi Baby app.

In particular, we observed that ANMs were less likely to use the Khushi Baby app without direct supervision from the Khushi Baby monitor. This was particularly notable in examining the synced data when field monitors were cross-covering for field surveyors during months with survey exercises and during summer months when heat would limit monitor travel. Of note, ANMs in the Lasadiya block were particularly resistant to using the system, despite over 10 visits to meet with them and their supervising medical officers. In Lasadiya, the CMHO could not enforce certain mandates as the local medical officer wields greater political power as an elected representative to the state assembly.

In total, 994 mothers received a Khushi Baby pendant, while 271 mothers did not receive a pendant – of whom 23 had never attended a health camp. This may be due to ANMs not using the app for each patient who visited the camp. Out of 1,189 mothers who had children alive during the intervention, 482 claimed to have received a Khushi Baby voice call, while 328 were confirmed to have received a voice call via the Khushi Baby backend. During baseline, 83.9% of mothers reported having access to a phone and 29.9% reported owning their own phone.

The proportion of mothers who received calls related to their infant's immunisation was closer to the proportion of mothers who owned their own phone, at 27.6%. The difference between the backend-verified confirmed calls and recall-reported received call counts could be attributed to recall bias on the part of the mothers. Field reports suggested that initially mothers were giving their husband's phone number (or the father's phone number) before more recently starting to give their own phone numbers.

Overall, major barriers to implementation fidelity included technical and organisational factors, as anticipated by the theory of change. Financial strain played a significant role. For a period of three months, field staff salaries had to be postponed due to a delay in two tranche disbursements of two separate grants. Limited staffing at the headquarters permitted technical hardware bugs to go unnoticed for two months before detection. It is possible to conclude that significant barriers were overcome through this process, but the challenges experienced in this first-time implementation likely limited the full potential for impact.

3.2 Khushi Baby system functionality

Table 2: Khushi Baby platform performance indicators

Key performance indicator	Value	Data source
ANMs who needed a tablet replacement	87	Field monitors
Pendants replaced due to corruption from software	200 (approximately) out of 20,000	Khushi Baby backend
Average weekly Khushi Baby app crashes	35 (approximately)	Fabric.io backend
Median time to sync data (hours)	Midline: 4.0 Endline: 3.75	Khushi Baby backend

Performance indicators (Table 2) were poor with respect to hardware stability and software stability, especially in the early stages when all tablets effectively had to be replaced. Nearly 200 app-related issues were identified and closed, with the remaining weekly crashes exclusively related to ongoing issues with custom software for handling the NFC module on the customised Datamini tablet that was sent as a replacement.

Other common issues reported by ANMs included crashes due to negative use cases in navigating between certain pages with complex page logic. Performance indicators were positive for the time to receive data synced from field after completion of camps with a median time of less than four hours per record from the time of creation or update at the health camp. With 93–98% crash-free sessions during endline months, app stability still has some room for improvement (Figure 9).

Figure 9: Khushi Baby app crash frequency

Source: Khushi Baby Inc.

Midline retention of health records in the treatment group was statistically significantly higher at the $p < 0.01$ level (Table 3). The proportion of health cards (pendants) retained in treatment was 82.4% (713/865) and 74.8% in the control (240/321); at endline, retention of the health record in the treatment group dropped to 78.3% (778/994), whereas for control, retention increased to 77.9% (896/1,150), which may be attributed to covering a larger sample than midline. The difference at endline was not statistically significant ($p = 0.840$).

Table 3: Patient health record retention at midline and endline

	Treatment			Control			
	Records retained	**Total received**	**Proportion**	**Records retained**	**Total received**	**Proportion**	**p-value**
Midline	713	865	0.824	240	321	0.748	0.0031**
Endline	778	994	0.783	896	1150	0.779	0.840

Note: ** = $p < 0.01$

3.3 Khushi Baby system data quality

Table 4: Data quality in treatment versus control subcentres

	Treatment			Control			
	Records correct	**Total**	**Proportion**	**Records correct**	**Total**	**Proportion**	**p-value**
Data completeness	5,375	5,446	0.9870	4,583	5,936	0.7721	< 0.00001
Data consistency	761	776	0.981	425	545	0.78	< 0.00001

Out of a total of 5,446 mandatory fields for infant registration[5] for patients who presented pendants, 5,375 were non-null (Table 4). The average data completeness for a mother in treatment was 21.6 per cent higher than that for a mother randomised to control, without adjustment for confounders, and this difference was statistically significant at the $p < 0.001$ level. Out of a total 776 infants with a Khushi Baby pendant, 761 pendant IDs (98.1%) were successfully matched on the Khushi Baby backend, compared with 81.0% matched between the MAMTA card PCTS ID and the PCTS backend. On average, data

[5] Mandatory fields include: mother name, child date of birth, child weight at birth, child sex, date of registration, BCG (Bacillus Calmette-Guérin, vaccine for tuberculosis) status, PENTA.

consistency was 17.1% higher in the treatment group without adjustment for confounders, and this difference was statistically significant at the $p < 0.001$ level.

Table 5: Data entry steps on MAMTA cards in treatment versus control subcentres

	Treatment			Control			
Data validity	**Steps**	**Total due**	**Proportion**	**Steps**	**Total due**	**Proportion**	**p-value**
Infants	132	504	0.262	66	245	0.27	0.830
Pregnant women	351	707	0.496	150	301	0.498	0.960

Table 6: Data collection and check-up processes followed by study group

	Treatment			Control			
Check-up processes	**Processes**	**Total due**	**Proportion**	**Processes**	**Total due**	**Proportion**	**p-value**
Infants	703	954	0.737	346	466	0.742	0.820
Pregnant women	722	1,059	0.682	321	426	0.754	0.00623**

Note: ** = p<0.01

Data validity was measured as the percentage of correct data entry steps on the MAMTA card out of the total required data entry steps for the check-up and confirmed by direct field observation of ANMs (Table 5). There was no statistically significant difference in the proportion of correct MAMTA card data entry in treatment versus control groups. Notably, correct data entry in the pendant versus the MAMTA card was not compared here because in order to save data onto the pendant the majority of the fields were required to have an entry.

Data collection and standard care processes were also recorded by field monitors (Table 6). There was no difference in child processes followed between ANMs in treatment and control subcentres, but ANMs in control subcentres were found to have a higher completion of required ANC data collection and check-up processes. This difference was statistically significant at the $p < 0.01$ level.

There was no statistically significant difference in new children and returning children for which check-ups were observed in the treatment and control groups. There was a statistically significant different distribution of new mothers and returning mothers between study groups, with more returning mothers observed for control ANMs, with a higher proportion of correct processes for returning mothers and common processes for new and returning mothers in control subcentres compared with treatment.

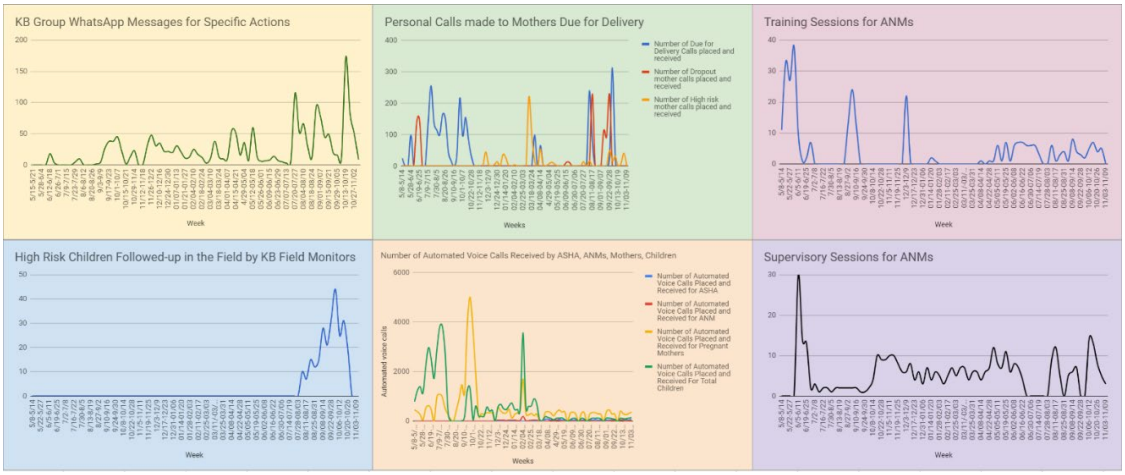
3.4 Khushi Baby system data for action

Table 7: Key performance indicators for data use for action

Indicator	Average per week	Total (May 2017–Nov 2018)
WhatsApp group messages for action	23.7	1,876
Trainings given to ANMs, LHVs, BCMOs	7.3	574
Automated voice call reminders received by pregnant women	539.8	42,468
Automated voice call reminders received by mothers of newborns	611.3	48,296
Calls to an ANM placed by a BCMO/LHV for equipment issues	0.7	54
Calls to an ANM placed by a BCMO/LHV for medication or vaccination stock-outs	0.5	42
Calls to an ANM placed by a BCMO/LHV for high-risk mothers	0.5	39
Calls to an ANM placed by a BCMO/LHV for high-risk children	1.0	78
Khushi Baby call centre calls received by mothers due for delivery	34.5	2,728
Khushi Baby call centre calls received by high-risk mothers or mothers with high-risk children	9.2	730
Khushi Baby call centre calls received by dropout mothers or mothers with children who are dropouts	13.2	1,050
Supervisory sessions held at low-performing camps	5.3	416
Focus groups with low-performing ANMs	0.3	27

The above key performance indicators for data for action (Table 7) come from a health worker team comprising a total of 36 LHVs, 36 MOICs, 5 BPMs, 5 BCMOs, 1 CMHO, between 81 and 87 ANMs, and approximately 350 ASHAs in the treatment area. Most engagement came from automated voice call reminders through the Khushi Baby dashboard, WhatsApp group messages exchanged by health worker teams, and personalised voice calls to high-risk and dropout mothers from the Khushi Baby call centre. More recently, there has been an increase in weekly WhatsApp engagement and high-risk follow-up in the field by Khushi Baby monitors. Figure 10 shows the time series progression of the key performance indicators.

Figure 10: Time series progression of key performance indicators for data-driven action



Source: Khushi Baby Inc.

3.5 Khushi Baby system effect on infant immunisation

3.5.1 Baseline coverage results

The baseline coverage survey included 1,243 participants with children aged 12–23 months. A balance table was constructed to assess differences in baseline complete immunisation rates between treatment and control subcentres, along with other relevant predictors (Table 8). Predictors considered included the broad categories of demographics, ANC factors, delivery factors and infancy and immunisation care factors. Specific indicators apart from those shown in Table 8 included: father's age; father's education; who was the primary caregiver of the child; whether the mother ever attended an ANC check-up; the number of ANC visits completed; locations at which the mother received ANC check-ups; time taken to reach the camp; time spent waiting at the camp; time spent with the ANM during examination; whether there was someone to remind the mother of ANC check-ups; which people and which formats for reminders were received by the mother during pregnancy; if the mother was ever prevented from attending health camps by family members; with what frequency check-up data was recorded on the MAMTA card; whether the ANM did not answer questions during a check-up; who assisted with the delivery; and whether incentives were received after delivery.

Table 8: Baseline coverage balance table[6]

	Control	**Treatment**	**p**	**test**
n (survey block distribution)	612	631		
Demographics				
Mother's age (median [Inter Quartile Range])	25.00 [23.00, 28.00]	25.00 [23.00, 28.00]	0.322	Non-normal
Mother's education (%)			0.0246	
Never went to school	350 (57.2)	339 (53.7)		
Grades 1–5	98 (16.0)	127 (20.1)		
Grades 6–8	86 (14.1)	88 (13.9)		
Grades 9–10	39 (6.4)	40 (6.3)		
Grades 10–12	29 (4.7)	18 (2.9)		
Graduate	9 (1.5)	7 (1.1)		
Postgraduate	1 (0.2)	6 (1.0)		
Mother's caste category (%)			0.0150	
General	49 (8.0)	51 (8.1)		
OBC	46 (7.5)	54 (8.6)		
SC	23 (3.8)	49 (7.8)		
ST	258 (42.2)	262 (41.5)		
Distance to health camp (%)			0.484	
0–0.5 km	194 (32.4)	167 (26.9)		
0.5–1 km	213 (35.6)	237 (38.2)		

[6] We used the tableone library for R, which automates comparisons between secondary exposure variables, depending on the variable type and distribution. Categorical variables were compared with chi-square test, continuous variables normally distributed were compared with one-way ANOVA (i.e. student's T test), and non-normal continuous variables compared with a Wilcoxon signed-rank test.

	Control	Treatment	p	test
1–1.5 km	100 (16.7)	123 (19.8)		
2–4 km	38 (6.3)	39 (6.3)		
4–6 km	5 (0.8)	5 (0.8)		
ANC history				
ASHA visit frequency in weeks during pregnancy (median [IQR])	3.00 [2.00,4.00]	3.00 [2.00,4.00]	0.0298	Non-normal
Any digital/voice-based reminder for ANC = Yes (%)	44 (7.3)	37 (6.0)	0.619	
Ever received MAMTA card = Yes (%)	289 (92.9)	270 (90.0)	0.250	
MAMTA card present at baseline (%)			0.317	
No	310 (50.7)	300 (47.5)		
Yes	301 (49.2)	331 (52.5)		
At least 4 ANC visits completed (%)	90 (14.7)	106 (16.8)	0.530	
Ever received TT vaccine (%)			0.994	
No	18 (3.0)	19 (3.1)		
Yes	560 (94.6)	575 (94.6)		
Ever received IFA tablets = Yes (%)	566 (95.6)	579 (95.2)	0.861	
Ever hungry during pregnancy = Yes (%)	24 (4.0)	31 (5.0)	0.486	
Delivery history				
Child birth location (%)			0.0373	
Home	78 (13.0)	92 (14.8)		
In transit (to hospital)	1 (0.2)	3 (0.5)		
Subcentre	12 (2.0)	6 (1.0)		
PHC	163 (27.2)	128 (20.6)		
CHC	257 (42.9)	277 (44.7)		
Private clinic	23 (3.8)	29 (4.7)		
Other (specify)	4 (0.7)	1 (0.2)		
Child gender = male (%)	305 (49.8)	309 (49.0)	0.804	
Pregnancy complications requiring hospital visit = Yes (%)	97 (16.2)	104 (16.8)	0.845	
Any post-birth hospital visits for the infant = Yes (%)	67 (11.2)	90 (14.5)	0.0989	
ASHA home visits post-pregnancy (median [IQR])	2.00 [0.00,2.00]	1.00 [0.00,2.00]	0.00467	
Colostrum given after birth = Yes (%)	543 (90.7)	548 (88.4)	0.232	
Infant care and immunisation history				
Exclusive breastfeeding duration (%)			0.210	
Till end of first month	14 (2.3)	16 (2.6)		
Till end of second month	9 (1.5)	13 (2.1)		
Till end of third month	27 (4.5)	21 (3.4)		
Till end of fourth month	53 (8.8)	79 (12.7)		
Till end of fifth month	143 (23.9)	132 (21.3)		
Six or more months	310 (51.8)	330 (53.2)		
Immunisation_reminder_method_family_member (%)	35 (6.1)	37 (6.2)	1	
Immunisation_reminder_method_any_other_health_worker (%)	19 (3.3)	17 (2.9)	0.793	
Immunisation_reminder_method_ASHA_came_to_home (%)	512 (88.7)	526 (88.4)	0.931	
Immunisation_reminder_method_ANM_or_by	36 (6.2)	43 (7.2)	0.577	

	Control	Treatment	p	test
_ASHA (%)				
Immunisation_reminder_method_SMS_of_phone (%)	13 (2.3)	24 (4.0)	0.115	
Immunisation_reminder_timings_everytime_before_ camp (%)	547 (96.0)	558 (95.4)	0.734	
Immunisation_reminder_timings_sometimes (%)	24 (4.2)	25 (4.3)	1	
Immunisation_reminder_timings_after_missing_immunisation (%)	1 (0.2)	2 (0.3)	1	
Polio_count (median [IQR])	3.00 [2.00, 3.00]	3.00 [2.00, 3.00]	0.365	Non-normal
BCG_administration (%)			0.509	
PENTA_count (%)			0.154	
1 dose	112 (19.9)	109 (18.8)		
2 doses	268 (47.6)	251 (43.3)		
3 doses	183 (32.5)	220 (37.9)		
Measles_administration (%)	525 (86.9)	542 (88.3)	0.761	
Full immunisation without birth doses = Yes (%)	138 (22.5)	160 (25.4)	0.259	exact

Note: OBC = other backward caste; SC = scheduled caste; ST = scheduled tribe; TT = tetanus toxoid; BCG = Bacillus Calmette-Guérin; CHC = community health centre.

There were no predictors differentially distributed between treatment and control groups prior to sample enrolment, as per the modified significance testing threshold of 0.000725 (determined through the Bonferroni correction to adjust for 69 tests). Baseline coverage results show higher proportions of mothers in the control group were educated past the sixth grade compared with mothers in the treatment group (26.9% versus 25.2%). A higher proportion of mothers in the treatment group were part of the scheduled caste category compared with mothers in the control group (7.8% versus 3.8%). A higher proportion of children in the treatment group were born outside of facilities compared with children in the control group (15.3% versus 13.2%). There were fewer home visits for postnatal care in the treatment group when compared with the control group. Health behaviour outcomes were balanced when considering seeking ANC check-ups, receipt of tetanus vaccine and IFA tablets, breastfeeding, immunisations (although there were more PENTA 3 shots in the treatment group than the control group).

3.5.2 Full infant immunisation status using recall at endline

Table 9: Baseline and endline differences in full immunisation status from recall

	Treatment			Control			
	Immunised	**Eligible**	**% (95% CI)**	**Immunised**	**Eligible**	**% (95% CI)**	**95% CI (difference)**
Baseline coverage sample[7]	160	631	25.4%	138	612	22.5%	-1.93–7.54%
Endline enrolment sample	837	1,152	72.7%	629	1,091	57.7%	11.1–18.9%
Difference (endline to baseline)			+47.3% (43.0–51.6%)			+35.1% (30.7–39.5%)	
Difference-in-difference			+12.2% (3.5–20.9%)				

Note: differences are unadjusted.

The unadjusted mean proportion of infants fully immunized per recall was 72.7% in the treatment group and 57.7% in the control group at endline, representing a respective increase from baseline of 47.3 percentage points and 35.0 percentage points (Table 9). The unadjusted difference-in-difference in full infant immunisation was 12.2 percentage points higher in the treatment group, which was both programmatically meaningful and statistically significant as per the cluster-adjusted, minimum detectable difference threshold at the $p < 0.05$ level. The unadjusted odds ratio for the treatment group was 2.03 (95% CI 1.60–2.58). Randomisation by design serves to balance both measured and unmeasured confounders between the study group, to isolate the true effect of the intervention on the outcome of interest. However, by chance, randomisation assignment may lead to differential distributions of secondary exposures which may confound the relationship between study group and outcome.

The abbreviated baseline randomisation group is provided in full in the Online Appendix (Appendix Table 1). Notable differences at baseline between the randomized groups included: electricity at home, income bracket, land ownership, self-ownership of mobile phone, roof type, latrine type, and ownership of various fixed assets. These variables were summarised in the SES index and used to adjust for the outcome in the final model. The sample followed for the recall outline did face attrition. To check for differential attrition in the outcome-specific sample on any particular covariate, a second balance table was made for endline, also including potential differences related to ANMs (Table 10).

[7] Note that the baseline coverage sample was distinct from the baseline enrolment sample (from which the endline enrolment sample was derived). See section 2.2.2 for clarification on the difference in samples.

Table 10: Endline differences in study groups for full immunisation status by recall

	Control	Treatment	p-value[8]
Study participants at endline	**1,091**	**1,152**	
ANM factors			
Demographics			
ANM caste			3.0E-12
General	338 (31.0)	271 (23.5)	
SC	272 (24.9)	451 (39.1)	
ST	481 (44.1)	430 (37.3)	
ANM marital status			2.0E-7
Live-in, divorced	4 (0.4)	8 (0.7)	
Married	1,037 (95.1)	1,096 (95.1)	
Never married	23 (2.3)	47 (4.1)	
Widowed	27 (2.5)	1 (0.1)	
Phone use			
ANM access_to_smartphone_true = 1 (%)	404 (37.0)	593 (51.5)	8.0E-12
Mobile_app_use: SMS = 1 (%)	85 (7.8)	0 (0)	-
Mobile_app_use: WhatsApp = 1 (%)	251 (23.0)	448 (38.9)	7.0E-16
Mobile_app_use: YouTube = 1 (%)	837 (76.7)	693 (60.2)	6.0E-17
Work processes	**Treatment**	**Control**	**p-value**
Hours_per_camp_baseline (mean (sd))	6.11 (1.12)	5.71 (1.06)	2.0E-17
Time_to_furthest_camp_1_2hour_cat = 1 (%)	132 (12.1)	257 (22.3)	2.0E-10
Time_to_furthest_camp_over2hour_cat = 1 (%)	50 (4.6)	18 (1.6)	5.2E-5
Time_to_PHC_from_house_1_2hour_cat = 1 (%)	150 (13.7)	246 (21.4)	3.1E-6
Transport_to_camp_method_bike_cat = 1 (%)	65 (6.0)	142 (12.3)	2.8E-7
Transport_to_camp_method_privatevehicle_cat = 1 (%)	60 (5.5)	14 (1.2)	2.7E-8
Connect with ASHA frequency			2.0E-13
Daily	186 (17.0)	109 (9.5)	
Weekly	88 (8.1)	193 (16.8)	
Biweekly	817 (74.9)	850 (73.8)	
Drop_out_tracking_method: ASHA list = 1 (%)	738 (67.6)	673 (58.4)	7.6E-6
Duties_outside_camp: facility-based care provision = 1 (%)	677 (62.1)	602 (52.3)	3.5E-6
ANM_RCH_number_columns (median [IQR])	20.00 [13.00, 36.00]	25.00 [15.00, 40.00]	8.6E-8
Patient_list_preparation_time (median [IQR])	30.00 [15.00, 30.00]	30.00 [25.00, 90.00]	1.0E-24
Reports that she has completed high-risk list prepared = 1 (%)	1,063 (97.4)	1,066 (92.5)	2.2E-6
Intervention-related factors			
ANM received at least 1 call from KB = 1 (%)	0 (0.0)	482 (41.8)	-
Endline average_ANM_call_duration_cont (median [IQR])	0.00 [0.00, 0.00]	0.00 [0.00, 36.00]	-

[8] Cells with '-' correspond to a p-value of less than 1E-10 per the tableone R library.

	Control	Treatment	p-value[8]
Prefer_KB_true = 1 (%)	999 (91.6)	1,142 (99.1)	2.0E-17
Mother factors	**Control**	**Treatment**	**p-value**
Monthly income in ₹ (%)			4.0E-23
< 1,000	27 (2.5)	3 (0.3)	
1,000–2,000	98 (9.0)	20(1.7)	
2,001–4,000	146 (13.4)	105 (9.1)	
4,001–6,000	468 (42.9)	489 (42.4)	
6,001–10,000	253 (23.2)	400 (34.7)	
10,000+	99 (9.1)	135 (11.7)	
Monthly_saving (median [IQR])	750.00 [0.00, 1,500.00]	1,500.00 [250.00, 1,500.00]	2.0E-10
Latrine: jungle/field = 1 (%)	983 (90.1)	965 (83.8)	1.2E-5
Asha_visit_after_birth distribution (%)	2.00 [0.00,2.00]	1.00 [0.00,2.00]	5.1E-8
ASHA visit frequency (%)			1.9E-5
Every day	7 (0.6)	5 (0.4)	
Every week	74 (6.8)	36 (3.1)	
Every 15 days	180 (16.5)	137 (11.9)	
Every month	707 (64.8)	823 (71.4)	
Sometimes	119 (10.9)	147 (12.8)	
Never	4 (0.4)	4 (0.3)	
Birth place (%)			8.4E-8
Home	143 (13.1)	163 (14.1)	
In transit	8 (0.7)	9 (0.8)	
Subcentre	26 (2.4)	52 (4.5)	
PHC	387 (35.6)	317 (27.5)	
CHC	299 (27.4)	435 (37.8)	
Government hospital	165 (15.1)	132 (11.5)	
Private clinic	61 (5.6)	43 (3.7)	
Delivery_incentive: medicines = 1 (%)	286 (26.2)	623 (54.1)	-
Delivery_incentive: supplementary food = 1 (%)	254 (23.3)	593 (51.5)	-
Waiting time at health camps (%)			2.0E-6
Less than 5 minutes	115 (10.5)	51 (4.4)	
5–10 minutes	344 (31.5)	363 (31.5)	
10–20 minutes	256 (23.5)	280 (24.3)	
20–30 minutes	157 (14.4)	189 (16.4)	
30 minutes to 1 hour	129 (12.2)	174 (15.1)	
More than 1 hour	90 (8.2)	95 (8.2)	
TT_vaccine (mean (sd))	1.86 (0.53)	1.74 (0.47)	5.0E-9
Child_age (mean (sd))	15.40 (2.10)	16.29 (1.98)	-
Intervention-related factors			
Endline average_child_call_duration from backend (median [IQR])	0.00 [0.00, 0.00]	0.00 [0.00, 17.00]	-
Endline total_child_calls from backend (median [IQR])	0.00 [0.00, 0.00]	0.00 [0.00, 2.00]	-
Endline total_child_duration from backend (median	0.00 [0.00,	0.00 [0.00,	-

	Control	Treatment	p-value[8]
[IQR])	0.00]	37.25]	
How_many_voice_calls from recall (median [IQR])	0.00 [0.00, 0.00]	0.00 [0.00, 5.00]	-
Mother of child received at least 1 call = 1 (%)	1 (0.1)	324 (28.1)	-
Outcomes	**Control**	**Treatment**	**p-value**
PENTA_1 = 1 (%)	998 (91.5)	1,112 (96.5)	6.6E-7
PENTA_3 = 1 (%)	768 (70.4)	949 (82.4)	-
OPV_3 = 1 (%)	760 (69.7)	947 (82.2)	-
Full_immunisation = 1 (%)	629 (57.7)	837 (72.7)	-

Note: SC = scheduled caste; ST = scheduled tribe; TT = tetanus toxoid; KB = Khushi Baby; CHC = community health centre.

As described previously, a systematic model selection approach was applied to arrive at the final model, which included adjustment for these unbalanced secondary exposures, which could potentially confound the relationship between study group and outcome. Base model covariates considered were: study group; maternal age; SES score; access to mobile phone; number of ANC check-ups; whether the mother received the tetanus vaccine in pregnancy; maternal awareness score; child awareness; child sex score; distance to camp; average time spent waiting at the camp; household visit frequency of the ASHA; geographic block; voice calls received by the mother; ANM age; voice calls received by the ANM; and subcentre.

Significant base model covariates, associated with increased full immunisation rates in the final model, were: study group; higher SES score; access to mobile phone; distance to camp less than 0.5 kilometres; higher child awareness score; higher maternal awareness score; ASHA visit frequency every week; and higher number of voice calls received by the mother (from recall) (Figure 11). Being in the Lasadiya block was associated with a decreased full immunisation rate. Other significant final model variable covariates associated with increased full immunisation included: higher number of IFA tablets consumed during ANC; higher number of months spent exclusively breastfeeding; no family member ever prevented immunisation; ANM having knowledge of high-risk patients; ANM having received at least one Khushi Baby call; and ANM having a mobile phone and being near to the PHC.

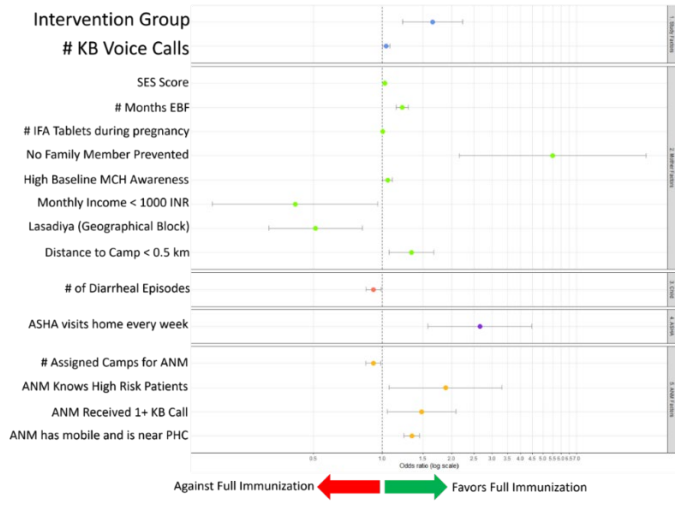
Covariates associated with decreased full immunisation included: monthly income less than ₹1,000; number of diarrhoeal episodes of the child; and number of assigned camps to the ANM. Although more endline surveys were conducted in June and May for the treatment group (as opposed to April and May for the control group), temporal confounding was not found to be significant (see Temporal confounding analysis in the Online Appendix for further details).

Without adjustment, those randomised to the treatment group were 2.03 (95% CI 1.60–2.58) times more likely to be fully immunised. After adjusting for confounders and the effects of clustering, mothers randomised to subcentres that received the Khushi Baby intervention were 1.66 times (95% CI 1.23–2.24) as likely to report full infant immunisation at the endline survey than those mothers randomised to control subcentres.

For every additional voice call received from the Khushi Baby system, mothers were 3.8% (95% CI 1.6–7.7%) more likely to have their child complete full immunisation after adjusting for relevant confounding variables. For every 10-point increase on the SES index of the mother (range 5–84), there was an associated 22.6% increase (95% CI 14.6–30.7%) in odds of full immunisation of the child. For every additional 100 IFA tablets consumed during pregnancy, the likelihood of the child completing full immunisation increased by 0.26% (95% CI 0.03–0.49%). For every additional month spent breastfeeding, the likelihood of the child completing immunisation increased by 22.1% (95% CI 15.0–29.9%). Mothers who were not prevented from having their child immunised by a family member were 5.50 times (95% CI 2.16–14.0) more likely to have the child complete full immunisation. For every point increase in MCH awareness score at baseline (principal component score), there was an associated 5.38% increase (95% CI 0.44–10.6%) in full immunisation rate. Mothers who had a monthly income less than ₹1,000 had 0.417 times (95% CI 0.182–0.953) the chance of completing full immunisation for their child when compared with mothers making more than ₹1,000. Mothers living in the Lasadiya block had 0.512 times (95% CI 0.320–0.820) the chance of completing full immunisation of their child when compared with mothers from other blocks. Mothers who lived within 0.5 kilometres of the health camp had 1.34 times (95% CI 1.07–1.68) the chance of completing full immunisation for their child when compared with mothers living further than 0.5 kilometres from the camp.

For every additional diarrhoeal episode a child experienced, the child was 8.85% (95% CI 2.2–15.1%) less likely to complete full immunisation. Mothers who had ASHAs visiting their home weekly were 2.66 times (95% CI 1.58–4.48) more likely to have their child fully immunised. For every additional camp assigned to the ANM of the mother, the child was 8.8% (95% CI 1.8–15.4%) less likely to be fully immunised. Mothers with ANMs who reported knowledge of their high-risk patients were 1.88 times (95% CI 1.07–3.31) more likely to have their child fully immunised. Mothers of ANMs who received at least one voice call from the Khushi Baby system were 1.48 times (95% CI 1.05–2.09) more likely to have their child fully immunised. Mothers with ANMs with mobile phones and near the PHC were 1.34 times (95% CI 1.24–1.45) more likely to have their child fully immunised.

Figure 11: Significant covariates associated with full immunisation (recall)



Source: Khushi Baby Inc.
Note: KB = Khushi Baby; EBF= exclusive breastfeeding.

Sensitivity analysis was performed by comparing the results for full immunisation by 9 months of age between the treatment and control groups; and by running the same analysis using MAMTA card data for both immunisation at 12 months and 9 months of age (Outcome 4B), and by repeating within-treatment analysis for data from the pendant group (Outcome 4C) (Table 11). Results consistently demonstrated that being randomised to the treatment group resulted in the mother having a higher chance of her infant completing full immunisation when compared with mothers randomised to the control group, under an intent-to-treat analysis framework.

It is worth noting that there were differences in the point estimates for the full immunisation rate between recall and the MAMTA card. The lower immunisation rate on MAMTA cards could be explained by multiple factors. For example, ANMs may have forgotten to fill in the details of the encounter on both the MAMTA card and in the RCH registers. Oral recall on the other hand may have been influenced by the selective memory of the mother, who may have been more likely to exaggerate services received to avoid stigma or perceived repercussions for failure to receive all required services.

Table 11: Full infant immunisation by recall and MAMTA card

	Treatment			**Control**			
	Immunised	**Eligible**	**%**	**Immunised**	**Eligible**	**%**	**Difference (95% CI)**
Full immunisation at 12 months (recall)	837	1,152	72.7%	629	1,091	57.7%	11.1–18.9%
Full immunisation at 12 months (MAMTA card)	632	921	68.6%	468	815	57.4%	6.66–15.7%
Full immunisation at 9 months (recall)	849	1,173	72.4%	649	1,127	57.6%	10.9–18.7%
Full immunisation at 9 months (MAMTA card)	643	938	68.6%	480	847	56.7%	7.41–16.4%

Subgroup analysis was performed for the following strata: SES quartiles (derived from our index, which was verified for normal distribution); baseline maternal health awareness halves; baseline child awareness halves; and distance to camp (Table 12). Interaction terms were chosen using two necessary criteria: that the individual interaction terms must be independently significantly associated with the outcome; and that the rationale for a synergistic effect must be justified conceptually. In this case, it was hypothesised that mothers in the highest quartile might receive higher benefits from the intervention than those in the lowest quartile, due to the fact that mothers in the highest quartile might be more educated and willing to learn; and more likely to have a mobile phone to receive calls, and which would be charged due to electricity being present at home. Similarly, it was hypothesised that mothers with a higher baseline MCH awareness score would be more able to learn and respond to community engagement efforts and that mothers closer to the camps would be more likely to attend the camp when they received a reminder.

Table 12 demonstrates the strata-specific proportions of outcomes between the treatment and control groups with the odds ratio, confidence interval and p-value of the interaction term when added to the model. None of the interaction terms reached significance. Mothers with higher maternal health awareness in the treatment group were 1.48 times more likely to have their child immunized than mothers in the control group with low baseline maternal health awareness (p = 0.058). As such, there was insufficient evidence to suggest that the effect of the treatment was partial to any of the mentioned subgroups below.

Table 12: Subgroup analysis for full immunisation status by recall

Subgroup	**Treatment**			**Control**				
x = Immunized ***X = Eligible***	**x**	**X**	**%**	**X**	**X**	**%**	**Odds ratio (95% CI)**	**p-value**
SES quartile 1	175	273	64.1%	151	304	49.7%	*	*
SES quartile 2	215	307	70.0%	173	307	56.4%	0.988 (0.587–1.66)	0.964
SES quartile 3	208	272	76.5%	124	223	55.6%	1.41 (0.801–2.48)	0.234
sSES quartile 4	239	300	79.7%	181	257	70.4%	0.814 (0.458–1.45)	0.486
Maternal awareness bottom 50%	435	625	69.6%	359	612	58.7%	*	*
Maternal awareness top 50%	402	527	76.3%	270	479	56.4%	1.48 (0.987–2.21)	0.058
Child awareness bottom 50%	411	584	70.4%	304	570	53.3%	*	*
Child awareness top 50%	426	568	75.0%	325	521	62.4%	0.741 (0.493–1.11)	0.149
Distance to camp ≥ 0.5 km	575	807	71.3%	423	765	55.3%	0.849 (0.548–1.32)	0.465
Distance to camp < 0.5 km	262	345	75.9%	206	326	63.2%	*	*

Note: Comparators are marked by asterisks.

3.5.3 Full infant immunisation status by MAMTA card at endline

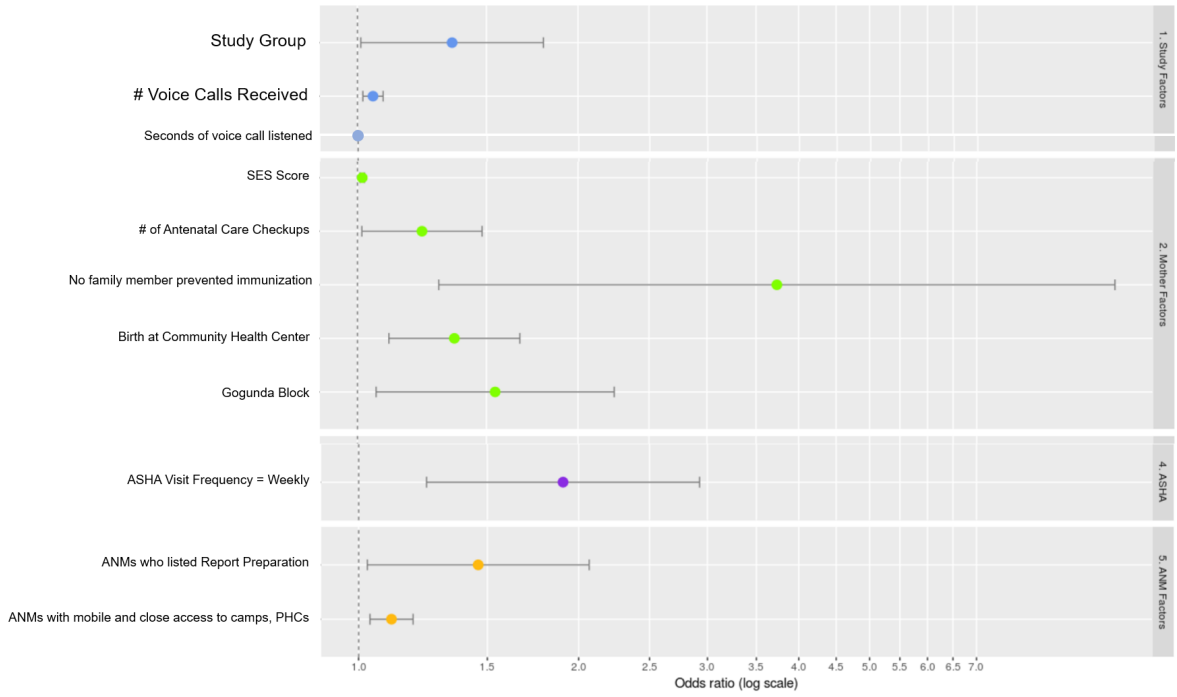
The purpose of this analysis was to corroborate the outcome estimates and conclusions of study group differences with another common approach to measuring full immunisation: use of the government-issued MAMTA card. Mothers who received and retained their MAMTA card until endline were eligible for this analysis. Randomisation balance was checked for the endline sample. Notable differences can be seen in the Online Appendix (Appendix Table 2). A systematic model selection approach was applied to arrive at the final model, which included adjustment for these unbalanced secondary exposures which could potentially confound the relationship between study group and outcome. The same base model variables included in Outcome 4A (full immunisation by oral recall) were considered here.

Without adjustment for confounders, mothers in the treatment group were 1.70 times (95% CI 1.27–2.28) more likely to have their child fully immunised (Figure 12). After adjusting for confounders and the effects of clustering, mothers randomised to subcentres that received the Khushi Baby intervention were 1.35 times (95% CI 1.10–1.67) more likely to report full infant immunisation at the endline survey than those

mothers randomised to control subcentres. For every additional voice call received from the Khushi Baby system, mothers were 5.0% (95% CI 1.8–8.4%) more likely to have their child complete full immunisation after adjusting for relevant confounding variables. For every additional minute the mother spent listening to a Khushi Baby-generated voice call (as verified by the Twilio database), there was an 8.27% increase (95% CI 3.12–13.4%) in the likelihood of the child being fully immunised by endline.

For every 10-point increase on the SES index for the mother (range 5–84), there was an associated 15.5% increase (95% CI 8.8–22.2%) in the chance of the child being fully immunised. Mothers living in the Gogunda block had 1.54 times (95% CI 1.06–2.24) the chance of completing full immunisation of their child compared with mothers from other blocks. Mothers who had ASHAs visiting their home weekly were 1.90 times (95% CI 1.24–2.93) more likely to have their child fully immunised. For every additional ANC check-up completed by the mother, the child was 22.5% (95% CI 1.44–48.0%) more likely to be immunised. If the child was born at a community health centre, the child was 1.35 times (95% CI 1.10–1.67) more likely to be fully immunised compared with children born elsewhere (home, transit, PHC or hospital). Mothers who were not prevented from having their child immunised by a family member were 3.74 times (95% CI 1.29–10.8) more likely to have the child complete full immunisation. Mothers who had ANMs who listed report preparation as a duty outside of camp were 1.46 times (95% CI 1.03–2.07) more likely to have a child with a full immunisation status as per the MAMTA card. Mothers who had ANMs who were closer to camps or PHCs, and had access to a mobile phone (principal component group score) were 1.09 times (95% CI 1.04–1.19) more likely to have their child immunised.

Figure 12: Adjusted odds covariates associated with full immunisation (MAMTA)



Source: Khushi Baby Inc.

Subgroup analysis was intended for the same strata as mentioned in Outcome 4A (full immunisation by oral recall) (Table 13). However, maternal awareness, child awareness and distance from camp were not significantly associated with the outcome as independent strata, so only the interaction between SES quartile and study group was considered. The interaction term was again not found to be significant and resembled findings from Outcome 4A.

Table 13: Subgroup analysis for full immunisation by MAMTA card

	Treatment			**Control**				
x = Immunised ***X = Eligible***	X	X	%	X	X	%	Odds ratio (95% CI)	p-value
SES quartile 1	133	273	48.7%	105	304	34.5%		
SES quartile 2	161	307	52.4%	123	307	40.1%	0.798 (0.481–1.32)	0.388
SES quartile 3	148	272	54.4%	100	223	44.8%	0.749 (0.436–1.28)	0.292
SES quartile 4	190	300	63.3%	140	257	54.5%	0.692 (0.404–1.19)	0.180

3.5.4 Full infant Immunisation status by Khushi Baby pendant at endline

We also conducted analysis of full immunisation status by Khushi Baby pendant (Outcome 4C; Table 14), the purpose of which was to corroborate Outcomes 4A and 4B (full immunisation by oral recall and MAMTA card, respectively) with treatment-specific data. As seen in Outcomes 2A and 2B (data completeness and consistency, respectively), the data stored on the pendant were more likely to be complete and consistent with the Khushi Baby backend.

By design, vaccination status also contained the date of administration automatically, which was not the case with the MAMTA card. Compared with recall (72.7% and 72.4% for 12 months and 9 months, respectively) and MAMTA card (68.6% for both 12 and 9 months), full immunisation coverage was lower roughly by 5–10% on the pendant. When just looking at the 778 respondents with pendants, 601/778 (77.2%) reported full immunisation by recall and 479/778 (61.5%) were fully immunised as per the MAMTA card at 12 months.

Table 14: Full immunisation status by Khushi Baby pendant

	Immunised	**Eligible**	**%**
Full immunisation by 12 months (pendant)	481	754	63.8%
Full immunisation by 9 months (pendant)	488	767	63.6%

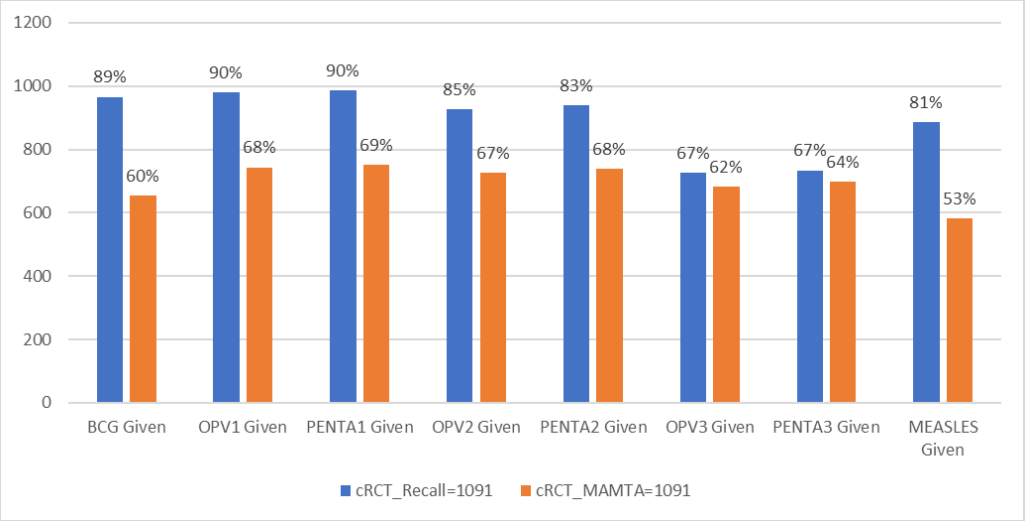
The sample considered for regression analysis consisted of mothers who had received pendants and were able to present the verified pendant at endline. Because this was a treatment-specific analysis, randomisation balance was not needed. A systematic model selection approach was applied to arrive at the final model.

After multivariate regression, for each additional voice call received by the mother as per the Khushi Baby backend, the likelihood of completing full immunisation was a 1.06 times (95% CI 1.01–1.11) higher. A 10-point increase in SES score was associated with a 14.7% increase (95% CI 0.089–28.9%) in the likelihood of full immunisation. For every additional pneumonia episode experienced by the child there was a 12.1% (95% CI 0.08–21.2%) decrease in the likelihood of full infant immunisation. For every grade

increase in the ANM's education, the likelihood of the outcome was 1.33 times (95% CI 1.17–1.50) higher. Mothers who had ANMs who faced difficulty arranging the register were 40.4% (95% CI 9.7–60.7%) less likely to complete immunisation. Mothers with ANMs who tracked dropout lists with the RCH register were 45.2% (95% CI 14.1–65.0%) less likely to complete full immunisation.

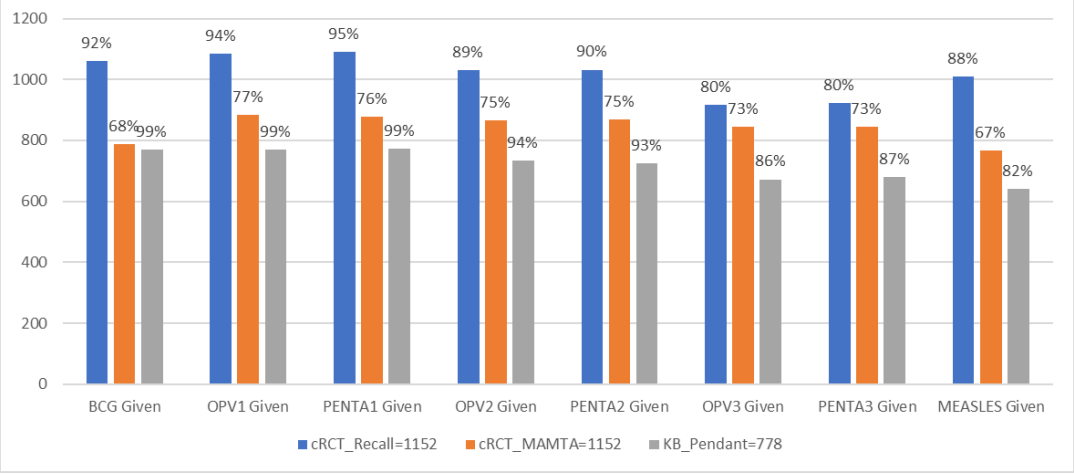
When considering the differences between immunisation rates across all three methods, Figures 13–15 demonstrate the higher rates of immunisation in the treatment group (Figure 14) compared with the control group (Figure 13) across individual rates of vaccines. Highest dropouts take place between PENTA 3 and measles for both the control and treatment groups using MAMTA card data, but between PENTA 2 and 3 using Khushi Baby pendant and Khushi Baby backend data (Figure 15).

Figure 13: Immunisation coverage rates by MAMTA card, recall in control subcentres



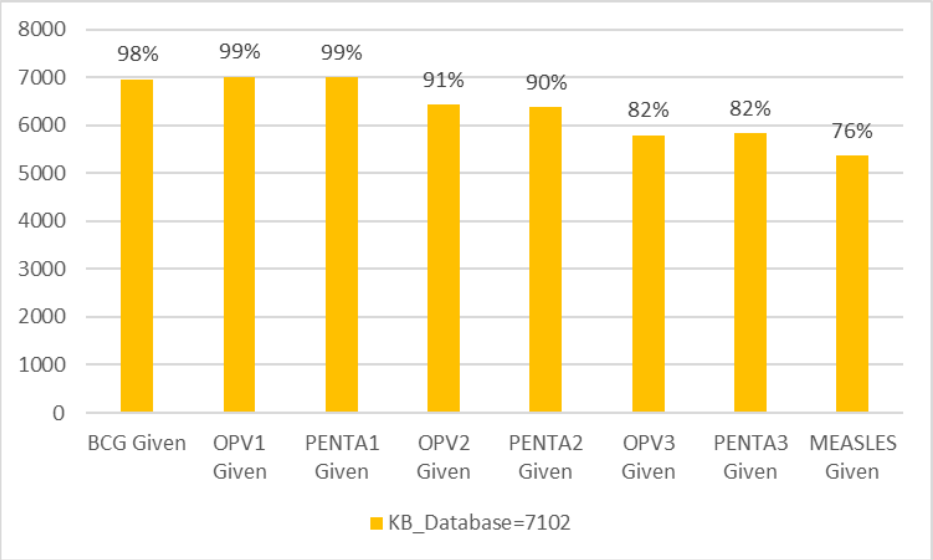
Source: Khushi Baby Inc.

Figure 14: Immunisation coverage rates by MAMTA card, recall and pendant in treatment subcentres



Source: Khushi Baby Inc.

Figure 15: Immunisation coverage rates by Khushi Baby backend from February 2017 to October 2018



Source: Khushi Baby Inc.

3.5.4 PENTA 1–3 coverage by recall

Table 15: PENTA 1–3 completion status by recall at endline

	Treatment			**Control**			
	Immunised	**Eligible**	**% (95% CI)**	**Immunised**	**Eligible**	**% (95% CI)**	**Difference (95% CI)**
Baseline							
PENTA 1–3 coverage (recall)	220	631	34.9%	183	612	29.9%	-0.23–10.2%
Endline							
PENTA 1–3 coverage (recall)	910	1,152	79.0%	716	1091	65.5%	9.7–17.0%
PENTA 1,2	1,032	1,152	89.6%	940	1,091	86.1%	0.72–6.1%
PENTA 1	1,090	1,152	94.6%	986	1,091	90.3%	2.1–6.4%
PENTA 1–3 dropout	180	1,152	15.6%	270	1,091	24.7%	-12.4–5.8%
Difference (endline to baseline)			+48.5% (39.7–48.5%)			+39.7% (31.1–40.3%)	
Difference-in-difference			+8.4% (-0.59–17.4%)				

Note: Differences are unadjusted.

The purpose of this analysis (Table 15) was to investigate whether the results for full immunisation were consistent when considering PENTA series coverage. The PENTA series is typically due for completion by 180 days after birth and serves as a prerequisite

to achieving the full immunisation outcome. Like the results for full infant immunisation, summary statistics demonstrated that the treatment group performed significantly higher than the control group with respect to PENTA 1–3 completion (14.5 percentage point increase) and PENTA 1–3 dropout (9.1 percentage point decrease). Results showed an increase in PENTA 1–3 completion for the treatment group from an unadjusted difference-in-difference comparison, which factored in the change from baseline in each study group (8.4 percentage points). These results were comparable with the findings for full immunisation (12.2 percentage point difference-in-difference).

Several variables were differentially distributed between the study groups, such as child age (15.99 months in the treatment group versus 15.04 months in the control group), birth place (greater proportion in community health centre for treatment versus PHC in control); ANM caste composition; ANM access to network (greater proportion in treatment); monthly income of ₹1,000–2,000 (greater proportion in control); and waiting time at health camp less than five minutes (greater proportion in control). Covariates independently associated with the PENTA coverage outcome included: being visited midline; not being prevented by a family member; caste category; being exclusively breastfed; higher number of IFA tablets consumed; higher education score; higher husband education score; higher transportation score; and higher SES score.

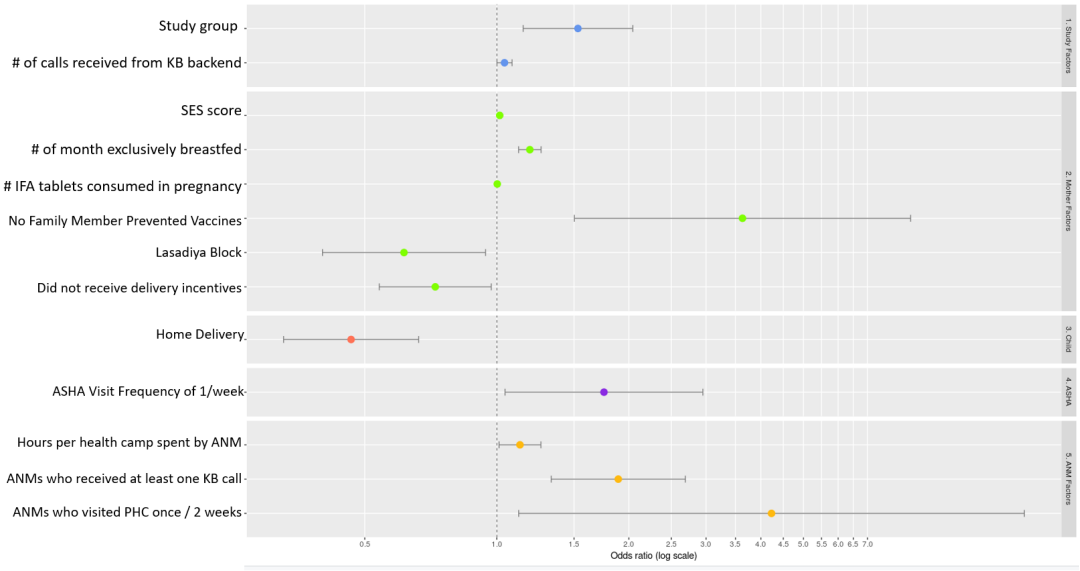
The unadjusted odds of mothers in the treatment group completing full PENTA coverage was 2.04 times (95% CI 1.57–2.64) that of mothers in the control group completing full PENTA coverage (Figure 16). After adjusting for confounding in the multivariate regression model, mothers randomised to the treatment subcentres were 1.53 times (95% CI 1.15–2.04) more likely to have completed the PENTA series when compared with mothers in control subcentres. For every additional voice call received by the mother (confirmed by the Twilio backend), the chance of PENTA series completion increased by 4.12% (95% CI 0.07–8.34%).

For every 10-point increase in the SES score of the mother there was a 15.4% increase (95% CI 7.64–23.4%) in the chance of PENTA immunisation. Mothers who exclusively breastfed were 1.19 times (95% CI 1.12–1.26) more likely to complete the PENTA series for their child. For every additional 100 IFA tablets consumed by the mother during pregnancy, the chance of PENTA vaccination increased by 2.51% (95% CI 0.22–4.80%). Mothers who did not have a family member prevent vaccination were 3.63 times (95% CI 1.50–8.78) more likely to complete the PENTA series for their child. Mothers who did not receive incentives during the time of delivery were 0.724 times (95% CI 0.540–0.971) more likely to have completed the PENTA series.

Mothers from Lasadiya were 0.614 times (95% CI 0.401–0.942) more likely to have completed the PENTA series. Mothers who had home births were 0.465 times (95% CI 0.327–0.664) more likely to have completed the PENTA series. Mothers with ASHAs who visited once per week were 1.75 times (95% CI 1.04–2.95) more likely to complete the PENTA series. For every additional hour spent on camp activities by the ANM, the mother was 12.9% (95% CI 1.21–26.1%) higher. Mothers who were randomized to ANMs who visited the PHC on a fortnightly basis were 4.23 times (95% CI 1.12–15.9) more likely to have completed the PENTA series than those who had ANMs visiting on a different schedule.

Mothers randomised to ANMs who received at least one voice call from the Khushi Baby backend system (confirmed via the Twilio database as received by the user) were 1.89 times (95% CI 1.33–2.69) more likely to complete the PENTA series compared with their counterparts. Subgroup analyses for SES quartile, maternal and child awareness scores, camp distance, and being part of the baseline ANM linelist were all found to be not significant for effect modification.

Figure 16: Adjusted odds ratios for covariates significantly associated with PENTA 1–3 completion by recall



Source: Khushi Baby Inc.
Note: KB = Khushi Baby.

3.6 Khushi Baby system effect on health outcomes

Table 16: Health outcome differences between treatment and control groups

	Treatment			Control			
	Immunised	**Eligible**	**%**	**Immunised**	**Eligible**	**%**	**p-value**
Infant mortality rate	23	1,243	18.50	21	1,192	17.62%	0.870
Moderate acute malnutrition (MUAC 11.5–12.5 cm)	156	1,122	13.9%	187	1,045	17.9%	0.011*
Severe acute malnutrition (MUAC < 11.5 cm)	54	1,122	4.8%	57	1,045	5.5%	0.498
Hospital admission of the infant	1,009	1,189	84.86%	971	1,148	84.58%	0.851
Hospital admission due to diarrhoea	786	1,243	63.2%	753	1,187	63.4%	0.917
Hospital admission due to suspected pneumonia	479	1,243	38.5%	448	1,187	37.7%	0.687

Note: * = $p < 0.05$

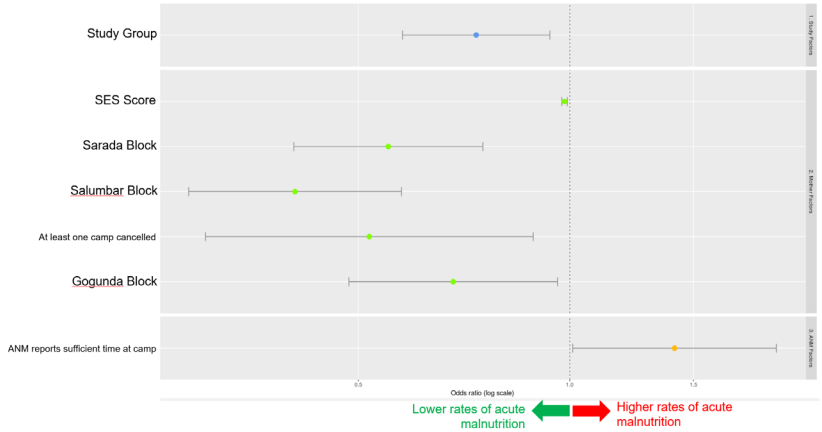
Both endline treatment and control groups reported comparable rates in infant hospitalisation (84.86%, 84.58%), hospitalisation diarrhoea (63.2%; 63.4%) and hospitalisation pneumonia (38.5%; 37.7%), respectively (Table 16). There was a statistically significant difference between groups for MAM, with children in treatment subcentres having a MAM rate of 13.9% compared with children in control subcentres having a MAM rate of 17.9% (p = 0.011). The unadjusted odds ratio for the treatment group on the MAM outcome was 0.766 (95% CI 0.582–1.009), which approached significance.

To check for confounders between the study group and MAM outcome, a randomisation balance table was made. Notable differences in differential distribution of secondary exposures can be found in the Online Appendix (Appendix Table 3). The same systematic approach for Outcomes 4A and 4B was applied to narrow the list of covariates included in the final regression model, used to determine the pure fixed effect of the study group.

Without adjustment for confounders, mothers randomised to treatment were 0.766 times (0.582–1.01) less likely to have infants who had MAM (Figure 17). After adjusting for confounders and effects of clustering, mothers randomized to subcentres that received the Khushi Baby intervention were 0.736 times (95% CI 0.577–0.937) more likely to have children who had MAM at endline. Mothers living in Sarada block were 0.551 times (95% CI 0.404–0.752) more likely to have a child with MAM. Mothers living in Salumbar block were 0.406 times (95% CI 0.286–0.576) more likely to have a child with MAM.

Mothers in Gogunda block were 0.682 times (95% CI 0.484–0.961) more likely to have a child with MAM. For every one-point increase in SES score of the mother, there was an associated 1.7% (95% CI 0.8–2.6%) decrease in the likelihood of the child having MAM. Surprisingly, mothers who faced at least one cancelled camp were 0.518 times (95% CI 0.303–0.887) more likely to have a child with MAM. In addition, it was surprising to observe that mothers with ANMs who reported that they had sufficient time at their health camp to perform required activities were 1.41 times (95% CI 1.01–1.97) more likely to have a child with MAM.

Figure 17: Adjusted odds ratios for covariates significantly associated with moderate acute malnutrition



Source: Khushi Baby Inc.
Note: Acute malnutrition in the figure above refers to MAM.

Subgroup analysis was intended for the same strata as mentioned in Outcomes 4A and 4B (full immunisation by oral recall and MAMTA card respectively; Table 17). However, maternal awareness, child awareness and distance from camp were not significantly associated with the outcome as independent strata, so only the interaction between SES quartile and study group was considered. The interaction term was again not found to be significant and resembled findings from Outcomes 4A and 4B.

Table 17: Subgroup analysis for moderate acute malnutrition

	Treatment			**Control**				
x = Immunised ***X = Eligible***	x	X	%	x	X	%	Odds ratio (95% CI)	p-value
SES quartile 1	43	261	16%	60	281	21%	*	*
SES quartile 2	53	298	18%	50	290	17%	1.57 (0.852–2.92)	0.146
SES quartile 3	33	272	12%	49	224	22%	0.725 (0.375–1.40)	0.337
SES quartile 4	27	291	9.3%	27	249	11%	1.46 (0.705–3.00)	0.309

Note: * = comparator

In summary, the significant effects of assignment to the Khushi Baby arm (i.e. study group) on health behaviour and health outcomes can be found in Table 18. We can observe for all outcomes that the adjusted odds ratio estimate was less in magnitude when compared with the unadjusted odds ratio estimate, suggesting that other confounders within the multivariate model helped to explain the association. The exception to this pattern would be the MAM outcome, where after adjusting for covariates, the effect size of the odds ratio is increased, and becomes statistically significant, suggesting that the control group had confounders that were otherwise protective against the outcome of MAM.

Many covariates in the multivariate models were shared across outcomes, further corroborating their significance. The number of voice calls received, SES score, geographical block, ASHA visit frequency, higher MCH awareness (higher IFA consumption, delivery at hospitals and exclusive breastfeeding), ANM use of mobile phones and ANM proximity to PHCs were all found to be significant factors in multiple outcome models.

Table 18: Summary of effect sizes of study group on outcome (intent to treat)

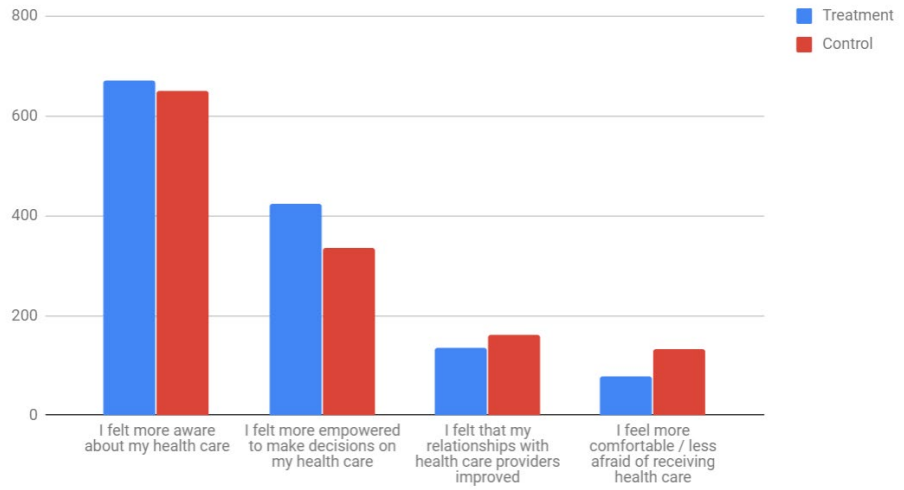
	Unadjusted odds ratio of study group			
Outcome (measurement tool)	Effect size	95% CI	Standard error	p-value
Full immunisation (recall)	1.95	1.66–2.33	0.09	1.18E-13
Full immunisation (MAMTA)	1.28	1.37–1.912	0.0851	1.59E-08
PENTA 1–3 (recall)	1.95	1.616–2.343	0.095	2.08E-12
Moderate acute malnutrition (based on MUAC)	0.745	0.591–0.94	0.118	0.013
	Unadjusted odds ratio of study group, accounting for clustering			

Full immunisation (recall)	2.03	1.60–2.58	0.122	6.70E-09
Full immunisation (MAMTA)	1.70	1.27–2.28	0.149	0.00033
PENTA 1–3 (recall)	2.04	1.57–2.64	0.132	6.67E-08
Moderate acute malnutrition (based on MUAC)	0.766	0.582–1.01	0.14	0.06
	Adjusted odds ratio of study group, accounting for clustering and multiple covariates			
Full immunisation (recall)	1.66	1.23–2.24	0.153	0.000998
Full immunisation (MAMTA)	1.35	1.011–1.794	0.146	0.0420
PENTA 1–3 (recall)	1.53	1.15–2.04	0.147	0.00370
Moderate acute malnutrition (based on MUAC)	0.736	0.577–0.937	0.123	0.0130
Covariates included in the multivariate models:				
Full immunisation (recall)	study group, # of voice calls (self-report), SES score, # IFA consumed, # months breastfeeding, whether family members prevented immunisation, maternal child awareness index, monthly income less than ₹1,000, geographical block, frequency of ASHA visits, ANM self-report of having high-risk patient list, ANM receipt of voice reminders from the KB system, ANM possession of mobile phone and distance to PHCs			
Full immunisation (MAMTA)	study group, # of voice calls (KB backend), # of minutes listened to KB voice calls (KB backend), SES score, # of ANC check-ups completed per self-report, whether family members prevented immunisation, delivery location, geographical block, frequency of ASHA visits, ANM who listed report preparation as a duty outside of camp, ANM possession of mobile phone and distance to camps and PHCs			
PENTA 1–3 (recall)	study group, # of voice calls (KB backend), SES score, # IFA consumed, # months breastfeeding, whether family members prevented immunisation, geographical block, receipt of incentives during delivery time, delivery location, frequency of ASHA visits, ANM reported hours spent at health camp, ANM receipt of voice reminders from the KB system, ANM frequency of visiting PHCs			
Moderate acute malnutrition (based on MUAC)	study group, # of voice calls (self-report), SES score, geographical block, experience of a camp cancellation, ANMs who reported spending sufficient time at the camps			

Note: KB = Khushi Baby.

3.7 Khushi Baby system effect on attitudes and perceptions of beneficiaries

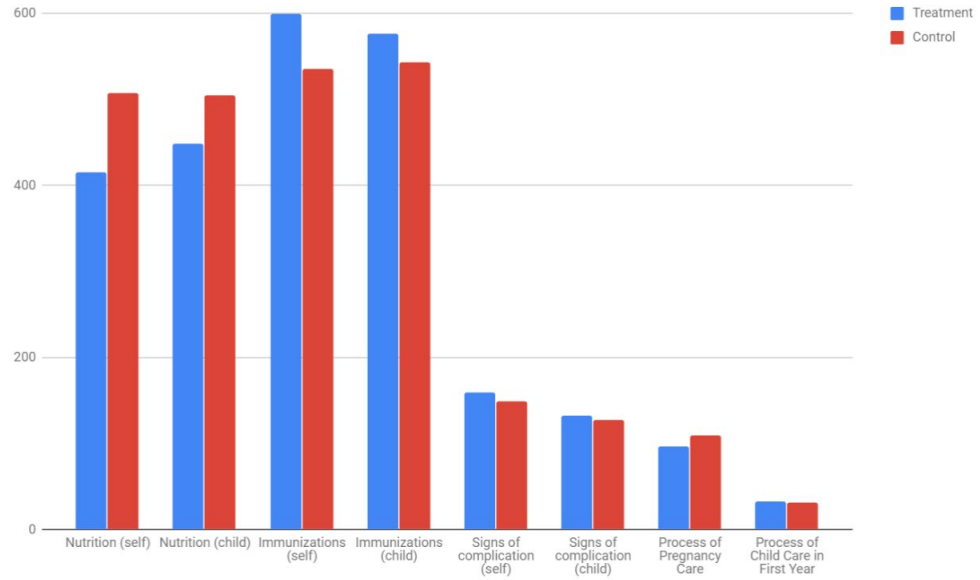
Figure 18: Attitudes and perceptions of mothers with positive experiences (infancy)



Source: Khushi Baby Inc.

Distributions for the types of positive experience mothers perceived differed significantly between study groups ($p < 0.00001$, $X^2 = 27.2$) (Figure 18). Proportionally, more mothers in the treatment group felt empowered to make decisions about their healthcare ($p = 0.00052$), whereas proportionally more mothers in the control group reported feeling more comfortable receiving healthcare ($p < 0.00001$). There were no significant differences in the underlying distributions of the mothers who felt more aware or the mothers whose relationships with healthcare providers improved between study groups.

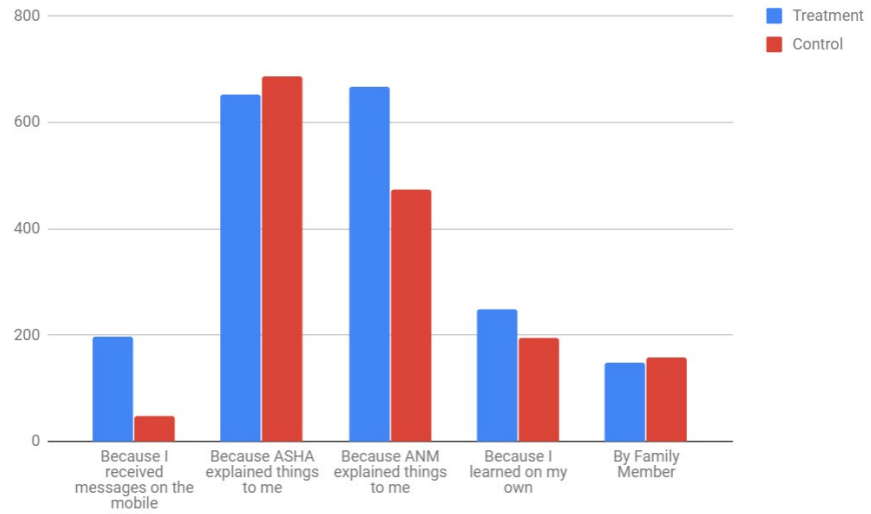
Figure 19: Topics for which mothers reported positive awareness change at endline



Source: Khushi Baby Inc.

Distributions significantly differed for the types of awareness change (p = 0.0126) (Figure 19). Mothers in the treatment group were more likely to report higher awareness of maternal immunisations than the control group (p = 0.01208). Mothers in the control group were more likely to report higher awareness of maternal nutrition than the control group (p = 0.00228).

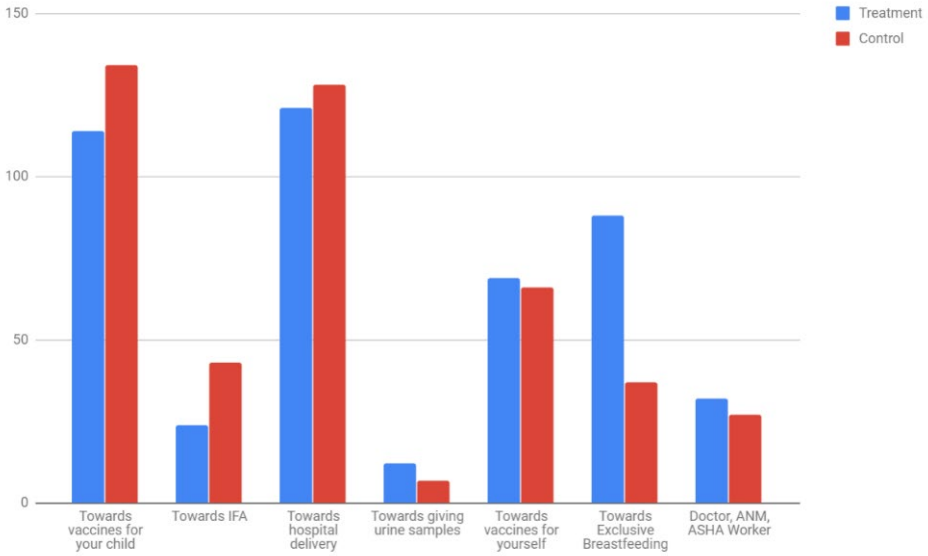
Figure 20: Reasons driving positive awareness change reported by mothers at endline



Source: Khushi Baby Inc.

Distributions significantly differed for the drivers of awareness change between study groups (p < 0.00001) (Figure 20). Mothers in the treatment group reported in higher proportions that their awareness was increased by mobile messages (p < 0.00001) and by ANM interaction (p = 0.00438). Mothers in the control group reported in higher proportions that their awareness was increased through conversations with the ASHA (p < 0.00001).

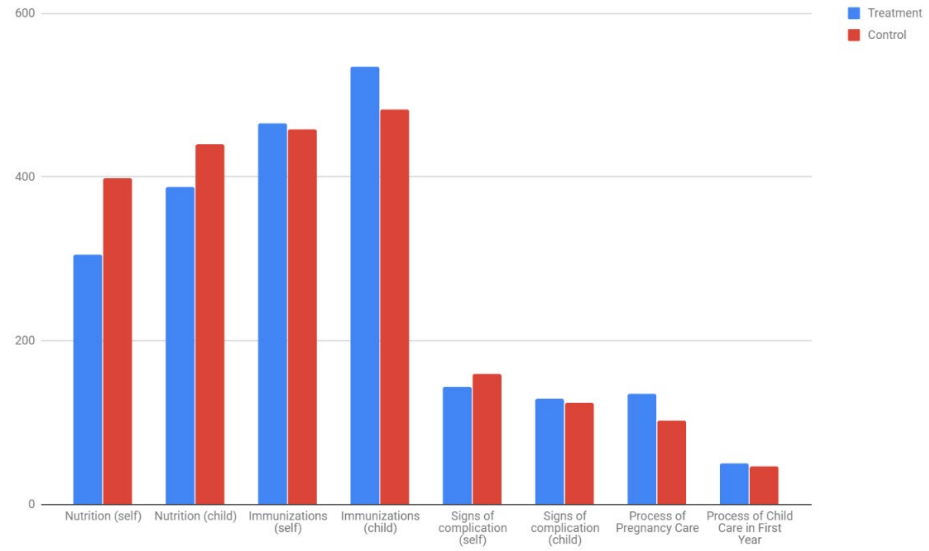
Figure 21: Areas in which mothers felt more comfortable toward MCH at endline



Source: Khushi Baby Inc.

There were significantly different distributions in the areas where mothers felt more comfortable between the study groups ($p < 0.00005$) (Figure 21). Mothers in the treatment group reported in significantly higher proportions that they felt more comfortable with exclusive breastfeeding ($p < 0.00001$).

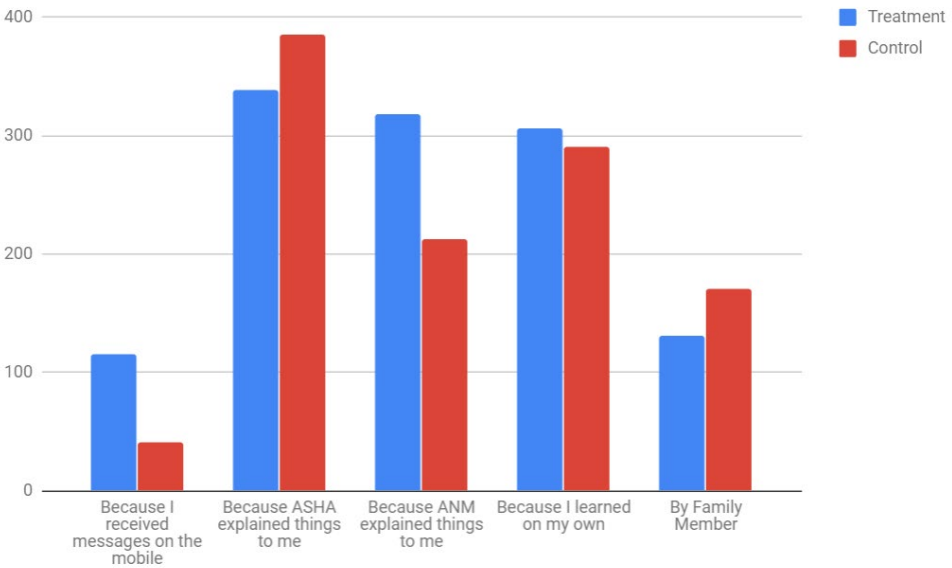
Figure 22: Topics for which mothers reported that the husband's awareness had improved



Source: Khushi Baby Inc.

There were significantly different distributions in the topics where the husband/father's awareness had increased between the treatment and control groups ($p = 0.00014$) (Figure 22). Mothers in the control group reported in higher proportions that their husbands had a higher awareness of maternal nutrition ($p = 0.00052$). Mothers in the treatment group reported higher rates of the husband's awareness of child immunisations, but this only approached significance ($p = 0.0164$).

Figure 23: Reasons driving awareness change in husbands/fathers



Source: Khushi Baby Inc.

Distributions significantly differed for the drivers of awareness change in husbands/fathers between study groups ($p < 0.00001$) (Figure 23). Mothers in the treatment group reported in higher proportions that their husband's awareness was increased by mobile messages ($p < 0.00001$) and by ANM interaction ($p = 0.0006$). Mothers in the control group reported in higher proportions that their husband's awareness was increased through conversations with the ASHA ($p = 0.00026$) and through family members ($p = 0.00084$).

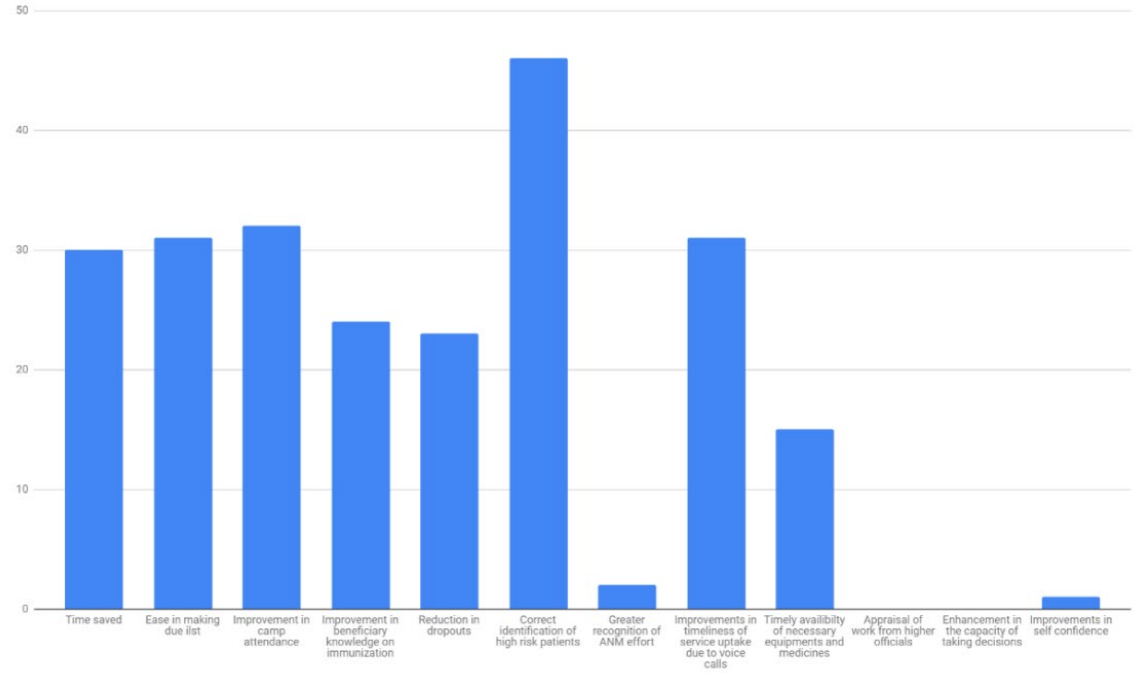
Focus group discussions with mothers generated feedback around three thematic areas: voice calls, the Khushi Baby pendant and biometrics, and future ideas and suggestions. While some mothers appreciated the voice call messages, others had perceptions that the call frequency was inconsistent or easily mistaken for an advertisement. Some mothers found the pendant to be convenient and customisable, while others felt that the reason why the pendant needed to be worn was not properly explained. Others found that the whole Khushi Baby process, with the pendant scan, may have increased the time spent at the camp. Ideas for improvement included guidance on foods to eat during pregnancy, the ability to customise the pendant, and access to more educational content with local-language videos. Representative quotes can be found in the Online Appendix (Appendix Table 3).

3.7.1 Khushi Baby system effect on attitude, perceptions and practices of health workers

At baseline, the highest frequency of self-reported duties included facility-based care, report preparation, coordination with the ASHA and special government programs. At endline for the treatment group of ANMs, the highest frequency of self-reported duties included report preparation, home-based visits for postnatal care, attending trainings and meetings, and performing sterilisation. The self-reported role at baseline differed from that at endline, with more ANMs at endline describing their role as a coordinator with health providers (46.4% in endline versus 35.6% in baseline), and fewer as an educator (7.3% versus 36.8%) or social worker (73.9% versus 82.8%).

With respect to confidence in carrying out camp procedures, ANMs in the treatment and control groups had distributions that were not significantly different for ability to communicate with mothers; ability to record data into the RCH register; decision-making for medication administration; decision-making for camp-based tests; and decision-making for vaccine administration. There was no statistically significant difference between time spent per camp among treatment ANMs (5.48 hours) and control ANMs (5.45 hours).

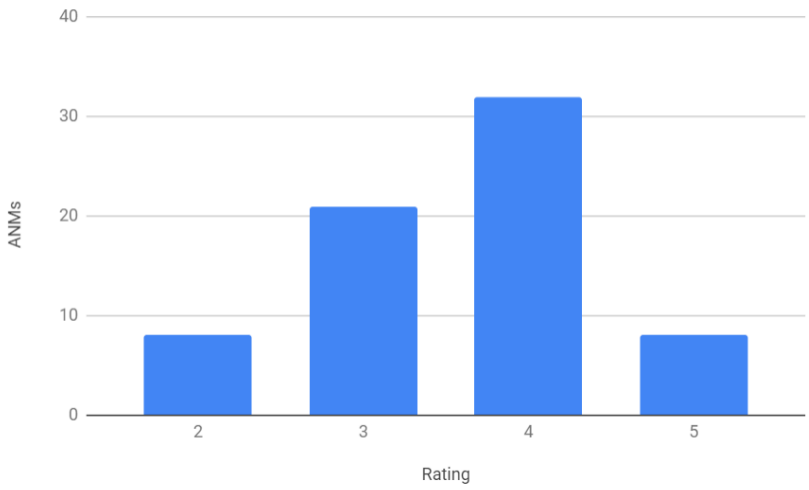
Figure 24: Benefits from Khushi Baby system reported by ANMs



Source: Khushi Baby Inc.

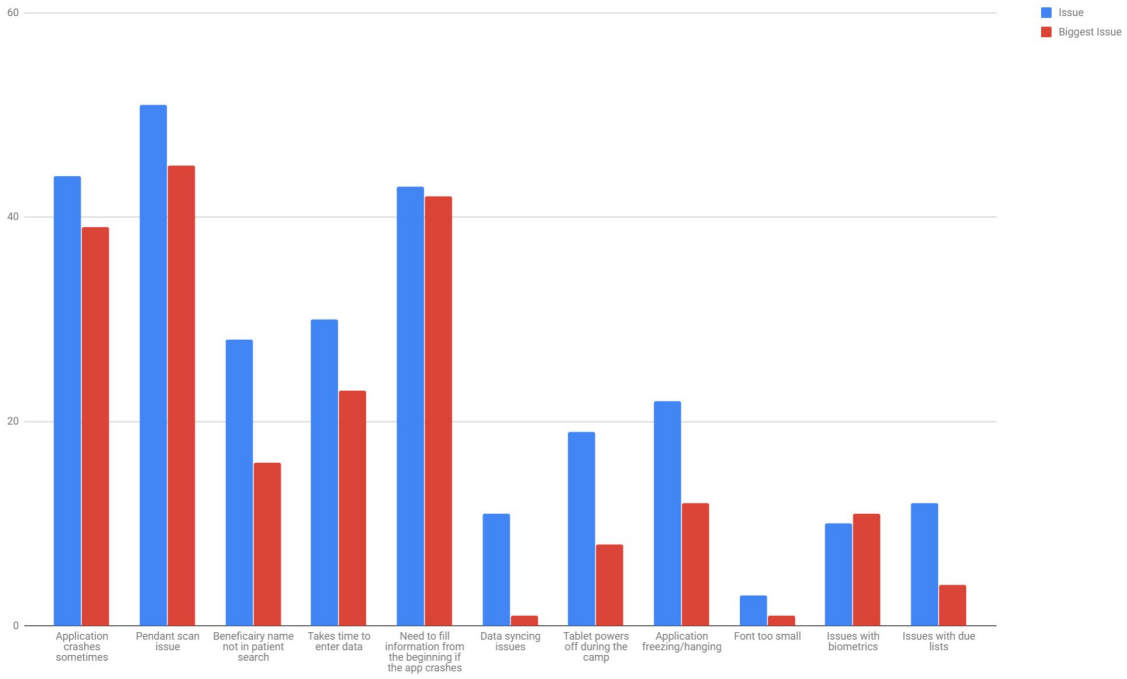
When presented with an open-ended question without suggested options regarding the system's positive aspects, 46/69 ANMs reported that the Khushi Baby system helped them to correctly identify high-risk patients (Figure 24); 32/69 ANMs attributed the Khushi Baby system with an improvement in camp attendance by beneficiaries; 31/69 ANMs reported that the Khushi Baby app assisted them with making their due list; 62/69 (90%) of ANMs who used the app reported that they would prefer to continue to use the system moving forward; and 68/77 (88%) of ANMs in the control subcentres who did not use the Khushi Baby system also reported that they would prefer to use the Khushi Baby app moving forward. The average rating from ANMs in the treatment group was 4/5 stars (Figure 25).

Figure 25: App ratings from ANMs using the Khushi Baby app



Source: Khushi Baby Inc.

Figure 26: Issues with the Khushi Baby app as reported by ANMs



Source: Khushi Baby Inc.

The most prevalent issues reported by ANMs using the Khushi Baby app included: having to re-enter data after an app crash (60.9%); having issues with scanning the pendant (65.2%); issues with the app crashing (56.5%); and time required to enter data (33.3%) (Figure 26). From our field observations, common concerns included: charging the tablet; app crashes; new registrations taking time; not having all peer ANMs use the app; differences in high-risk classification; inability to edit the LMP date; and the fact that tablets had been changing hands frequently. Representative quotes from the ANMs can be found in the Online Appendix (Appendix Table 4).

The majority of ASHAs reported that they found the system beneficial. In particular, the voice call feature reduced their workload as they reported that mothers would come on their own, call them to check if the camp was taking place after receiving the Khushi Baby voice call, and even come before the camp started. They attributed the voice call to benefitting the ANC check-up coverage, institutional delivery rate and full immunisation rates in their communities. They reported that people liked the pendant and asked questions about where to get pendants that they as ASHAs would wear. They also appreciated how many of the due lists that they were responsible for tracking were autogenerated in the ANM's tablet. Representative quotes from the ASHAs can be found in the Online Appendix (Appendix Table 5).

Feedback from health officials was largely positive regarding increased turn-up at camps and access to data, with specific references to WhatsApp and voice calls. Officials commented on how the system could be strengthened with direct integration into the PCTS backend; collection of additional data (e.g. vaccine logistics); uniform district-wide scale-up; additional content for WhatsApp group messaging and voice calls; and a focus on simplified, actionable views for the dashboard. Representative quotes from health officials can be found in the Online Appendix (Appendix Table 6).

"I used to walk 5km to inform mothers to come to vaccination camps. Now because of the Khushi Baby voice calls, mothers themselves will call me and tell me that they have been informed of a camp." – Pepu Kuwar, ASHA, Ruao Subcenter, Salumbar Block

"The best feature in the Khushi Baby App is the Checkup summary. Sometimes we are in a rush filling the details of the ANC. But the checkup summary shows me all of the high risk conditions and the action steps I need to take in one place, so I find this very helpful"
ANM Rekha Garg
Salumbar Block

3.8 Cost analysis

We sought to assess the financial costs of the system (incurred and averted) to provide policy makers with data to inform budgets for continued or scaled implementation. We used a back-of-the-envelope methodology developed by J-PAL (Abdul Latif Jameel Poverty Action Lab) to list the ingredients-wise costs for the programme over the entire study duration (July 2016 to July 2018). Incurred costs were determined from receipts of real expenditures, as opposed to initially planned budgets, and classified as upfront or recurring. Opportunity costs were included in the averted cost analysis.

Where costs were left unmeasured, assumptions were made. We assumed no costs for targeting of beneficiaries to the intervention, given that implementation of such a system within established VHND camps would not trigger new targeting activities prior to implementation in a real-world sense, nor did we target beneficiaries in this study. We also assumed no additional costs to the participant (i.e. the mother/primary caregiver) outside what they would already incur for attending regularly scheduled VHND camps.

This assumption is aligned with current government policies surrounding free provision of care to beneficiaries receiving services from VHND camps, irrespective of the data collection or community engagement methodologies employed. We assumed no additional cost to health workers for implementing the solution, given that the technology provision would not be borne by them, and that the use of the system (and trainings therein) would serve to complete their mandated scope of work currently being compensated by their government employer.

Table 19 outlines the incurred costs (both upfront for project establishment and the recurring costs throughout the duration of the study), as well as summarising the assumed averted costs (Appendix Tables 7–9 in the Online Appendix give full details of the assumed averted costs). Table 20 summarises the cost per beneficiary for the pilot and from the perspective of marginal costs moving forward, should the system be adopted by a government implementing body.

Table 19: Cost ingredients for cost analysis

	Base year	Reporting year	Notes/Assumptions
	2016	2018	The costing period considered was from July 2016 to July 2018. Specific activities have time periods mentioned below
Programme administration and staff costs (July 2016–July 2018)	₹3,222,214	US$48,093	*Staff costs:* **US$20,651 (recurring)** Includes: 25% time contribution for the chief operating officer, the technical programme manager and the field data manager; 100% time contribution from the field implementation manager, field communication lead and field supervisor *Programme administration costs:* **US$27,442** Includes: rent and utilities for headquarters **(US$11,369, recurring)**, mobile phone talk-time, software subscriptions and web server hosting subscriptions **(US$3,379, recurring),** indirect costs and office expenses, including laptops, chairs, desks, stationary (**US$12,694, upfront)**
Targeting costs			All reproductive-age women and mothers with children are already known to be eligible for the intervention, which takes place at the VHND site. In a real implementation of this system, there would not be pre-intervention targeting of users. Just as was the case in this study, no additional costs were given to target beneficiaries towards VHND camps with the intervention
Staff training costs (February 2017–July 2018)	₹98,289	US$1,467	This activity includes costs for training the primary users of the intervention, primarily ANMs (87). No formal trainings were held for supporting staff (LHVs, DEOs, MOICs, BCMOs). Although supporting staff members were also visited and provided with demos, these costs were included under the 'monitoring costs' activity as they were performed by field monitors during their regular activities
Participant training costs			There were no costs associated with training the beneficiaries
Implementation and program materials costs (July 2016–July 2018)	₹10,555,448 (actual) ₹11,627,448 (with tablet)	US$157,544 (actual) US$173,544 (with tablet cost)	*Technology costs (funded by multiple agencies):* - Tech development: **US$63,550** over the first 6 months **(upfront)** - Tech maintenance: **US$36,000** over the next 18 months **(recurring)** *Procurement costs:* - NFC pendants: **US$21,792**; includes shipping and handling and customs fees over the total

	Base year	Reporting year	Notes/Assumptions
			study period **(upfront)** - Tablets: US$0 **(provided by IDEMIA's CSR)** In case of purchase, we assumed **US$16,000** for a total of 80 tablets at US$200/unit based on recent negotiated rate with tablet provider Datamini over the total study period **(upfront)** *Implementation costs:* **US$36,202** Includes: transportation and logistics costs related to initial deployment across 365 villages **(US$32,789, upfront)** and data plans for ANMs to sync data from February 2017 to July 2018 (**US$3,233, recurring)**
User costs	-	-	We assumed no cost to the user. There was no evidence that the user spent more time on the Khushi Baby system at endline
Averted costs (July 2016–July 2018)	₹356,335 (assumes no time savings) ₹7,234,773 (assumes time savings)	US$5,318 (assumes no time savings) US$107,982 (assumes time savings)	Detailed description in Appendix Tables 7–9
Monitoring costs (July 2016–July 2018)	₹4,464,612	US$66,636	This category includes salaries for field monitors and travel for field monitors over the study period. Field monitoring was a core component of the intervention. This category does not include costs related to baseline, midline or endline surveys
Total upfront costs	₹9,837,275	US$146,825	Includes office expenses for establishment, upfront costs for development, equipment and goods costs related to tablets and pendants, and initial costs of deployment in the field
Total recurring costs	₹4,773,951	US$71,253	Includes programme staff costs, rent and utilities costs, maintenance costs for the technology platform, costs of syncing and monitoring costs
Total program cost	₹11,427,793 (assumes time savings) ₹18,306,230	**US$273,227** (assumes no time savings) **US$170,564** (assumes time savings)	Total programme costs = (programme administration and staff costs + targeting costs + staff training costs + participant training costs + implementation and program materials costs + user costs + monitoring costs) – averted costs. In both cases, tablet costs are included.

Note: CSR = corporate social responsibility.

Averted costs are defined as costs that would have otherwise been borne by the payer if not for the intervention. The payer in this case is the district government, which receives

funds from the state. We estimate the averted costs that come from three sources: increased immunisations rates (for PENTA 1–3 and measles vaccines); decreased cases of MAM; and time and supplies saved (Appendix Tables 7–9).

Averted costs from immunisations are estimated by multiplying the disease-specific incidence in India by the vaccine attributable risk reduction by the increase in vaccination proportion in the treatment by the total costs of disease treatment and the process of seeking treatment. To estimate for longer-term net benefits, the averted costs from disease treatment and the process of seeking treatment is multiplied by 1.67 in accordance with the results published by Gavi (Ozawa et al. 2016). These estimates may be considered conservative given that the benefit from increased BCG (Bacillus Calmette-Guérin, tuberculosis vaccine) and OPV (oral polio vaccine) was not accounted for due to lack of available costing data.

Averted costs from the decreased rate of MAM were calculated by multiplying the difference in MAM incidence proportion by the number of children in the treatment group by aggregate cost of treating a child for MAM, based on data from a recent study in Mumbai slums (Goudet et al. 2018). This is likely a conservative estimate given that the broader economic benefits of a well-nourished child who is more likely to meet developmental and learning milestones were not accounted for in this estimate.

Finally, averted costs from time and supply savings were calculated using a series of assumptions. These time and supply savings were likely not realised during the study period due to lack of a state mandate to integrate Khushi Baby data directly from the treatment-randomised subcentres. However, we have made estimates from our experience working with local stakeholders on time saved; in particular, on monthly reporting tasks, currently on paper, which would be automated via the Khushi Baby app. Such averted costs can be relatively large in comparison with the health benefits, and therefore represent an optimistic or best-case scenario should the Khushi Baby platform be universally deployed.

Table 20: Aggregate costs for cost analysis

	Local (₹1 = US$0.015)	US dollars (US$1 = ₹67)	Notes
Total programme cost	₹4,491,663	**US$273,227** (assumes no time savings) **US$170,564** (assumes time savings)	
Number of total beneficiaries during the study period	19,811	Beneficiaries (mothers and babies)	Total beneficiaries tracked for ANC, postnatal care, high-risk follow-up and immunisation. Although the system was active between February 2017 and July 2018 (18 months), we conservatively assume that this total target achieved represents the actual target achieved over the 24-month total study duration, rather than extrapolating the beneficiary count to fit the total study timeline
Average cost per beneficiary over the full 24-month study period	₹924	**US$13.79** (assumes no averted costs from time savings or supplies)	The average cost divides the total programme cost as defined in Table 19 by the total number of beneficiaries served during the study duration. This includes both the upfront and recurrent costs during the study period
	₹577	US$8.61 (assumes averted costs from time savings and supplies)	
Marginal cost to add a beneficiary per year	₹376.54	US$4.47	NFC pendant, customs, transportation = US$0.80 per year assuming 1 pendant for the mother during pregnancy and 1 pendant for the child during infancy Voice calls, 7 reminder voice calls per year at US$0.03 per voice call = US$0.21 Tablet amortised over 1,000 patients per ANM in a 2-year span = US$0.04 in total or US$0.02 per year Tech maintenance = US$36,000 over 18 months for 19,811 beneficiaries * 12 months = US$1.21 per year Monitoring: US$66,366 over 18 months for 19,811 beneficiaries * 12 months = US$2.23 per beneficiary per year * Cost of data plans for ANMs and data hosting was not included given the availability of existing government cellular networks and servers that can be leveraged for the purpose if/when the system is scaled up

Using J-PAL's basic cost collection template, it was determined that the average cost per beneficiary during the study period (24 months) was US$13.79 (or US$6.90 per year) in the conservative scenario with no assumed averted costs from time savings and US$8.61 over the two-year period (US$4.30 per year) in the optimistic scenario, with included averted costs from projected time savings. The marginal cost to add a beneficiary per year to the system was US$4.47, assuming the conservative case with no averted costs, which is our preferred estimate moving forward as it relies on the fewest assumptions. If averted costs are included without projected time savings, then the marginal cost to add a beneficiary per year is estimated to be US$3.73 less (US$0.74).

If averted costs are included with projected time savings, then the marginal cost to add a beneficiary per year is estimated to be US$5.45 less (US$0.98 net profit). Notably, tablet costs were included in all estimates, even though not part of actual costs borne by the team. At scale, existing tablets for which an investment has already been made could be repurposed for this use case. The yearly averted cost calculation also makes assumptions, which were not directly proven in this study.

3.8.1 Cost-effectiveness analysis

We used a cost-effectiveness analysis method described by Borkum and colleagues (2015) in their similar but smaller study of an m-health app for community health workers in Bihar, under a similar randomised controlled design. They defined cost-effectiveness as the cost per beneficiary per year for a 1 percentage point absolute increase in the outcome compared with the baseline. And due to multiple outcomes being evaluated, they suggested their estimate was a high-end cost per utility estimate compared with a scenario in which all resources of the intervention were vertically focused on a single outcome as opposed to a set of multiple outcomes. We took forward the same assumption given that: (a) our intervention's combined focus on MCH made it arbitrary to separate costs for any particular outcome (immunisation versus nutrition for example); and (b) it was the most conservative approach to assume that all the resources (and therefore costs) were focused on the primary outcome of interest – immunisation.

Because at baseline, recall data were collected on immunisation status, a difference-in-difference was calculated for an unadjusted mean average difference in absolute percentage points as a result from the baseline of 12.2 percentage points (95%CI 3.5–20.9 percentage points). Using this metric, the cost-effectiveness analysis for this unadjusted estimate could be interpreted as US$4.47 per additional beneficiary, divided by a 12.2 percentage point absolute increase in full immunisation rate or US$0.37 (95% CI US$0.21–1.28) per beneficiary per year per 1 percentage point absolute increase in full immunisation rate.

Borkum and colleagues (2015) used adjusted differences, so a direct comparison is not appropriate. But as a reference point, they found a US$1.02 cost per beneficiary per year per 1 percentage point absolute increase in mothers receiving full tetanus vaccine coverage, which serves as the closest proxy indicator. Their study did not show a significant yield for improvement in full infant immunisation.

Using this study's adjusted effect estimates, the cost-effectiveness can alternatively be calculated by looking at cost per percentage change in relative risk. In this case, the

cost-effectiveness would be US$4.47 per additional beneficiary, divided by a 66% (95% CI 23–124%) relative increase in full infant immunisation or US$0.68 (95%CI US$0.36–1.94) per 10% relative increase in the likelihood of full infant immunisation.

To determine the cost per additional child fully immunised, we divided the total programme cost (US$273,227 without time savings and US$170,564 with time savings) by the additional number of infants in the treatment arm fully immunised compared with the control arm (12.2 percentage points or 140 infants). This results in a cost per additional child fully immunissed in the initial roll-out phase of US$1,950 (95% CI US$1,150–6,860) where time and supply savings are ignored and US$1,220 (95% CI US$710–4,280) where time and supply savings are assumed. These are conservative estimates which assume that the entire benefit of the intervention was derived from the increase in immunisation. This cost-effectiveness estimate does not include the overlapping cost of program activities that led to improvements in infant malnutrition; or of the services received by out-of-sample mothers who were impacted by the intervention during the study period but not considered for the final outcome.

To calculate the average cost per additional vaccine, we first found the difference in average vaccinations between the treatment and control groups using recall data as 0.52 (95% CI 0.34–0.70). This difference was multiplied by the total endline treatment sample size to determine the number of total additional vaccines received: 600 (95% CI 390–810). The total program cost was divided by the total additional vaccines received to obtain the cost per additional vaccination: US$460 (95% CI US$340–700) with no time savings included and US$280 (95% CI US$210–440) with time savings included.

The estimates above serve as a rough calculation of the cost-effectiveness of the pilot-stage roll-out. After initial deployment, the cost of subsequent beneficiary enrolment drops from US$6.90 to US$4.47, due to gains from efficiencies of scale in technical management and operations balanced by increased admin costs.

4. Discussion

4.1 Challenges and lessons learned

There were significant challenges faced in the implementation of this project from financial, political, technical, operational and intra-team domains.

This project was initially funded by a grant from 3ie, which was circumscribed to impact evaluation. At the time the grant was received, however, the intervention to be tested had yet to be developed. We severely underestimated the costs of technical development of our 2.0 system (Khushi Baby app and dashboard), which would cover the MCH tracking requirements laid down by government health officials. The significant costs related to technical development ended up being more than US$100,000 over what we had originally projected.

These costs were coupled with delays in receiving anticipated funding from two granting agencies. For three months, key field staff and core team members went without a salary in the summer of 2017, while we had to seek bridge loans until payment of our next funding tranche was resolved.

Access to capital was also limited by the fact that, as an Indian non-profit organisation, we experienced barriers to receiving funds from international agencies abroad. As an independent entity and early stage start-up, we were not successful in convincing the local district to put forth a financial stake. We should have either requested more money or planned for a smaller trial. But a smaller trial would have risked not having adequate analytical power due to the necessary clustering required to avoid the health worker from using both the Khushi Baby system and the paper intervention in different camps.

We found a way forward with timely receipt of other grants to fill the deficits from the tranche delays and by having the core team defer their salary so we could focus on technical development. Beyond technical development, the 3ie grant also went towards establishing a headquarters and hiring our first full-time staff. Due to budget limitations, the staff initially comprised four members who were managing a team of over 40 surveyors during the baseline survey exercise. Lack of financial stability early on certainly affected the execution of the project.

Multiple political hurdles were overcome in this impact evaluation. It took over a year of engagement with the CMHO to convince him that the organisation was serious and here to stay, as opposed to other pilots which had worked with the local government in the past. In one case, our chief operating officer had to track down the CMHO on the highway after almost daily visits to the chamber seeking approval during which the CMHO did not have time to see the system fully. The CMHO initially was insistent that the evaluation be conducted using a quasi-experimental design with all ANMs from one block receiving the intervention to avoid administrative burdens from the randomisation. After much persuasion, the CMHO acquiesced to the current study design.

Even with the CMHO's support, there was no official written mandate or memorandum of understanding from the district that established that ANMs had to adhere to the Khushi Baby study or intervention protocols. This proved to be especially challenging with respect to the ANMs in Lasadiya, who were increasingly resistant to adopting the new system. The local health officer there also had political clout and turned a blind eye despite multiple visits in which the team informed him of poor acceptance by ANMs in his area. We were ultimately unable to change the minds of some 5–10 ANMs. We also failed to regularly engage health officials and supervisors at various levels. And with officials changing every few months, we did not have a policy manager in place to maintain relations with the new appointees. We have now hired someone to fill the position and have activated our field monitors and core team to regularly track and participate in block- and district-level meetings with local officials.

One way our lack of engagement translated into the study was by means of the health officials not using the dashboard. This lack of use may be most attributed to the fact that our system was not rolled out through an entire catchment area, thereby only providing partial data for action. Moreover, the health officials and ANMs had to submit data according to the state-mandated PCTS system. And because of this, ANMs were still bound to the double work of filling paper forms both at the camp and on a monthly basis.

The way we handled these challenges was by adapting the reports of the dashboard into a format accessible on WhatsApp. This proved to get various health workers engaged, although the quality of responses towards high-risk patients still left room for

improvement among ANMs and supervisors alike. For double work, we introduced features like the patient search and summary, which allows the ANM to have quick views of all the beneficiaries they have seen in a month.

There were many substantial technical hurdles at play, both in the development and maintenance phases of the project. The system was developed without the guidance of a professional designer by the core team and, as a result, many elements of the user interface and experience were not optimised. Certain features of the technical architecture were also particularly weak, including handling of backend database joining, optimisation of backend memory usage, and handling of NFC reading and writing. We were unfortunately provided with over 80 tablets that had unreliable hardware components, which necessitated replacement.

Four months after starting, we discovered data corruption issues due to the faulty hardware that we had replaced, which had us backtracking to solve the issue for over 200 beneficiaries with corrupted data. Some of the technical errors may have been averted had we been able to hire in-house developers earlier who were closer to the field issues and who could more readily communicate with our testers. We later developed systematic processes for documenting our testing of each build and reached stability after a year of iteration in the field. Yet we still have persistent issues with some of the hardware-specific software for NFC handling. We look to resolve these issues in our next 3.0 system with new hardware and a newly built platform, which will also be one carefully designed with the users in mind, led by our newly hired lead designer.

Operationally, this was a very challenging project for several reasons. With our headquarters centralised in Udaipur, we were still having to oversee a radius of up to 150 kilometres, which included the hilly terrain of the Aravalli Range. Maintaining regular communication with our own field monitor team took time, as we first had to identify appropriate network points near each of the nearly 600 villages in the study. Field monitors and the core team were heavily involved in coordinating syncing of data from the field at these network points, as well as coordinating replacement of faulty tablets. If a tablet was causing issues, getting data to understand the root cause required going to great lengths to retrieve that tablet and bring it to the headquarters. The team also had to battle through the elements in the monsoon season when bridges were broken and in the hot dry season when temperatures would climb to over 45°C (113°F) for most of the day.

Our team was responsible for designing and testing the project, working closely with developers, training, deploying and providing in-field support, monitoring and evaluating the project, and interacting with stakeholders. With limited funds, we did not always have the full capacity to address these technical issues in house. With limited staff in the early stages, there were periods when staff were severely overworked and there were concerns that several members would leave the organisation for new jobs. Many of the team members volunteering globally also became occupied with various other obligations and could no longer be held to the same level of accountability as they could when the project had started. Despite these challenges, our organisation has grown from 4 full-time members at the study start to over 20 full-time staff today, including new technical talent in data analysis, design and development.

Future challenges can be mitigated with proper planning. Financially, we would like to ensure an 18-month runway with our funders and to schedule large field deployments or procurements after receiving a new tranche of funding for the allocated activity. Conservative impact estimates and timelines will be made to donors to avoid no-cost grant extensions.

Technically, we will recruit in-house talent. A technical program manager will use project management tools for agile app design. Weekly code and progress reviews will take place with a senior technical lead. A hardware senior contact person will be appointed by the vendor and deployed to the field site during the launch phase. Prior to development, a rigorous design process will take place, defining the information architecture for the overall application, preparing high-fidelity visual mock-ups of each screen, and gaining feedback from ANMs.

Politically, we will increase our engagement with the district and state levels by having biweekly meetings with concerned decision-makers and policy influencers; and by participating in working groups for health information system integration.

4.2 Substantive findings from impact evaluation

With respect to Khushi Baby system functionality, there were initial hardware and software challenges faced, during which all tablets had to be replaced. By endline, among the 87 ANMs, the last 90 days shows 93.7 per cent crash-free sessions and 75.4 per cent crash-free users, showing reasonable stability with room for improvement; and the median time to receive health updates was 3.45 hours (compared with a maximum time of 30 days as mandated by the existing paper-based process). Retention of the health record was greater for the pendant (82.4%) when compared with the MAMTA card (74.8%) at midline ($p = 0.0031$) but was not significantly different at endline (78.3% versus 77.9%). Higher retention of the health record at any time point is meaningful for ensuring proper receipt of services at the camp site.

For those children who did retain their health records, data completeness (98.70% versus 77.11%, $p < 0.00001$) and consistency (98.1% versus 81.0%, $p < 0.00001$) were increased among those who had the Khushi Baby pendant. By design, in the Khushi Baby system records cannot be created without passing certain validations, so a high rate of data completeness was expected for the Khushi Baby system, provided it functioned according to plan. With respect to the validity of the data entered on the MAMTA card, 27 per cent of the fields were correctly recorded (as opposed to skipped or falsely entered) for children, and 49.8 per cent for mothers. There were no significant differences in the child or ANC check-up processes conducted or the rates of correct data entry on the MAMTA card when comparing treatment and control camps. Altogether, these findings suggest that the Khushi Baby system's data had higher overall quality, but there may be room for improvement with respect to check-up and data-filling processes.

The data collected from the Khushi Baby system were used for new forms of substantive action in the field, particularly through WhatsApp groups, automated voice call reminders, in-person voice call outreach and high-risk child follow-up house visits. On a weekly basis, over 20 WhatsApp messages were exchanged and over 1,100 voice call

reminders were automatically sent to mothers on average. While health officials did not use the dashboard as intended, reports from the dashboard were sent by the Khushi Baby team members on the WhatsApp groups, where health officials and health workers responded to specific high-risk patient follow-ups.

With evidence for new data-driven actions from the Khushi Baby system, we looked to investigate the impact on health behavior outcomes, principally in relation to immunisations. Knowing that the data quality of the common measurement tools for full immunisation were subject to incomplete and false entry, we sought multiple methods of corroborating vaccination status: both from recall and by examining the MAMTA card.

We found that mothers randomised to the treatment subcentres were 1.66 times (95% CI 1.23–2.24) more likely to have their children fully vaccinated when compared with mothers from control subcentres, irrespective of whether they reported receiving the intervention, by way of recall and after adjusting for potential confounders under a conservative intent-to-treat framework. This result remained consistent when looking at MAMTA cards in treatment and control groups (odds ratio 1.35, 95% CI 1.10–1.67), and when considering full immunisation by nine months for both methods and improvements in PENTA 1–3 coverage. There was a 12.2 percentage point difference-in-difference in absolute full infant immunisation rate between treatment and control groups from baseline to endline.

The benefit of the intervention was not partial to any subgroup on the basis of SES quartile, distance to camp or baseline maternal child health awareness. Among covariates, factors independently associated with a higher full immunisation rate included: the number of reported Khushi Baby calls received; SES score; ASHA visit frequency; ANM proximity to the PHC; and whether a family member prevented vaccination and geographic block, with Lasadiya block performing worst among its peers. These results are particularly noteworthy even though the research cohort only began to receive voice calls during the infancy period. The full potential of receiving the intervention during ANC, which is the standard for non-sample mothers, was not captured in this study.

With improvements in full immunisation outcomes, we looked to investigate how health behaviours may have contributed to improved health outcomes. We found that infants of mothers randomised to treatment subcentres were 26.4% (95% CI 6.3–42.3%) less likely to have MAM (MUAC between 11.5 cm and 12.5 cm) compared with children of mothers randomised to control subcentres, irrespective of whether they reported receiving the intervention, and after adjusting for confounders. This result was particularly significant because, unlike data reported on the MAMTA card or by recall from the mother, the data for the outcome were measured directly by using a MUAC tape. There were no significant differences found for rates of severe acute malnutrition, 24-hour hospitalisations of the infant, hospitalisations due to diarrhoea, hospitalisations due to suspected pneumonia, or overall infant mortality, although the study was not powered for these outcomes.

To understand the underlying drivers for the observed health behaviour outcomes, we asked mothers at endline about their attitudes to and perceptions of their recent health journey. Notably, more mothers in the treatment group felt empowered to make

decisions about their healthcare ($p = 0.00052$), whereas proportionally more mothers in the control group reported feeling more comfortable with receiving healthcare ($p < 0.00001$). However, more mothers in the treatment group felt comfortable with exclusive breastfeeding practices ($p < 0.00001$). This may be of consequence for the lower rates of MAM found above.

As expected, a higher proportion of mothers attributed their increase in awareness and their husband's increase in awareness to mobile messages they received during the intervention period ($p < 0.00001$). Mothers reported that they received the messages, listened to the messages and understood the messages. They also reported having been asked by others in the village about where they received their pendant. They felt empowered when the ANM took their biometrics to access their health history.

We were also concerned with how this system would affect our users. Feedback from our ANMs, the key users of the Khushi Baby app, has been positive. 62/69 (90%) of ANMs who used the app reported that they would prefer to continue to use the system moving forward. 68/77 (88%) of ANMs in the control subcentres who did not use the Khushi Baby system also reported that they would prefer to use the Khushi Baby app moving forward. The average rating from ANMs in the treatment group was 4/5 stars. ANMs cited benefits including ease of identifying high-risk patients, automatic generation of due lists, time saved at the camp, and noticeable improvement in camp turn-up from voice calls.

ASHAs were indirect beneficiaries of the system. Although they did not use the app, they strongly reported that due to Khushi Baby voice calls they had seen improvement in uptake of ANC, hospital delivery and child immunisation. Before Khushi Baby, they would have to go repeatedly to certain households to remind them of upcoming camps. Now, instead, mothers and pregnant women are receiving the Khushi Baby call, calling the ASHA to confirm the camp the next day, and coming themselves, in some cases before the camp even starts.

Health officials and supervisors strongly appreciated the system, particularly the WhatsApp groups through which they reported that they saw an improvement in how the ANM was addressing high-risk and dropout beneficiaries. There were calls to have the system expanded and integrated into the Rajasthan State Ministry of Health's PCTS database, by the CMHO of Udaipur, Dr Sanjeev Tak, who appreciated how individual elements of the Khushi Baby system – from the pendant to the app to the high-risk reports, voice calls and WhatsApp group – fit into a theory of change for health outcomes.

Altogether, the findings above represent strong evidence from a large, randomised, prospective trial that, even without the full scope of the Khushi Baby app in play and despite challenges, there were significant improvements in data quality, health behaviour outcomes, health outcomes supported by health workers and health official satisfaction.

4.3 Comparisons with existing literature

The study was conceived as an extension of a prior randomised controlled trial by the Khushi Baby team in 96 villages of Udaipur with a partner NGO, Seva Mandir, for which an under-powered sample failed to show significant differences in timely immunisation

coverage through DTP 3 (three-dose diptheria-tetanus-pertussis vaccine), but which did show significant increases in the levels of discussion concerning the pendant versus the MAMTA card (Nagar et al. 2018). The impact evaluation discussed here is unique in that it is the first of its kind to test a combination of several novel components for community engagement, including but not limited to the wearable,[9] culturally symbolic, NFC-based pendant[10] and dialect-specific voice calls,[11] for MCH education against the status quo control as the gold standard.

It is the first of its kind, large-scale randomised trial for an m-health intervention that considers ANM as its key users, and the largest of its kind ever in the Udaipur region to our knowledge. Other related studies have looked at providing ASHAs with mobile applications to improve uptake of essential MCH services in India (Borkum et al. 2015; Prinja et al. 2017) and in redesigning the health card (Usman et al. 2011). The findings here support the literature from other m-health interventions in low- and middle-income countries, particularly around the use of mobile reminders (many of which have been SMS-based to date) to improve immunisation timeliness and coverage, and other health behaviour outcomes (Gibson 2014; Bangure et al. 2015; Chen et al. 2014; LeFevre et al. 2018; Lester et al. 2010; Uddin et al. 2016; Oyo-Ita et al. 2016).

This impact evaluation corroborates findings from many other studies, which outline several key covariates associated with uptake of essential MCH services including SES, distance from health camp, opinions of members of the household; along with qualities of the health worker and local health volunteer, which comprise both demand- and supply-side factors (Vora et al. 2015; Lakew et al. 2015 Banerjee et al. 2010; De and Bhattacharya 2002; Fineberg 2013; WHO 2014; UNICEF 2009; Usman et al. 2010).

4.4 Strengths and limitations of the study

There were several limitations. First the study was unblinded, which makes it difficult to distinguish the success of the real intervention against any placebo intervention. That being said, the underlying mechanisms in the theory of change were investigated to build evidence for or against a causal link between the intervention and outcomes. Another limitation of this study is that the intervention was not rolled out all at once, leading to the possibility of time-based confounding and that the intervention evolved with time. Also, the delay between baseline enrolment and intervention roll-out may have led to selection bias as eligible infants were only considered from February 2017 onwards in treatment subcentres, whereas they were eligible in control subcentres from as early as October 2016. We ultimately did not find evidence to support temporal confounding affecting the main results of the trial. While some may consider the degree of monitoring as playing a confounding role on the impact of the platform, we would instead argue for monitoring as a central component of the complete system. The study strengths include the prioritisation of data quality as an outcome; the nearly 10,000

[9] Alma Sana is a wearable silicon bracelet with punch-out shapes that represent vaccines completed.
[10] Marcus and colleagues (2009) used an RFID (radio frequency identification)-based ankle bracelet for pneumonia tracking in Pakistan for infants coming into a healthcare facility.
[11] Mobile Alliance for Maternal Action (MAMA), and mMitra – ARMANN are two voice-based reminder platforms for MCH for low- and middle-income countries.

interviews conducted with mothers, ANMs, health supervisors and health officials at every level to include quantitative and qualitative feedback; the randomised prospective design to account for measured and unmeasured sources of confounding and to establish causal chronicity of events; the high level of follow-up at endline (88%); the adjustment for potential contaminating interventions such as the Mission Indradhanush door-to-door immunisation scheme; and the corroborations of multiple sources of data for outcomes with highly granular information about intervention uptake, such as duration of voice call listened to by the beneficiary.

4.5 Implications for policy makers

The findings of this impact evaluation demonstrate the highest grade of evidence for the impact of the Khushi Baby system for improving: data retention, data timeliness, data quality, data for action, health behaviour outcomes and health outcomes for infants from poor households in rural settings. Specifically, the data showed Khushi Baby increased immunisation rates by 12 percentage points, decreased MAM rates by 4 percentage points, and improved data completeness and data consistency by nearly 20 percentage points. It also reduced the time needed to acquire data to a median of just under 4 hours, with an average cost of US$4.47 or just about ₹400 per beneficiary per year, and a 4/5 star approval from ANMs.

Khushi Baby is one of several m-health applications for MCH in India. Antara's AAA Platform for ANMs, ASHAs and anganwadi workers is another Android-based tablet app. The Central Ministry of Health and Family Welfare's ANMOL (ANM online) is another, which was tested with over 11,000 ANMs in Andhra Pradesh. Recently, Dimagi announced a partnership with the Ministry of Women and Child Development to scale up ICDS-CAS, a mobile-based data collection app for nearly 100,000 anganwadi workers. The government of Rajasthan along with other states across the country are seeking bulk orders of tablets to empower each frontline health worker. Recently, implementation of a PCTS mobile app by the Rajasthan Ministry of Health and Family Welfare has come across resistance from ANMs who perceive the task as a form of extra data entry. Rajasthan also faced resistance with an earlier attempt to procure and distribute Micromax tablets to bring the mobile app eJanSwasthya to scale. But it had recent success in 2019 in using a version of the system when ASHAs were able to self-procure their own mobile phones without incentives to complete a digital family health survey in two blocks.

In many cases, these applications have been considered for scale-up without a base of evidence to prove stability, acceptability or effectiveness at local level. In other cases, pilot projects have been abandoned after large-scale experimental trials, despite promising results, as was the case with ICT-CCS in Bihar in 2015. Few examples have successfully scaled, such as Gujarat's TeCHO+ app, which combined strong randomised results with state- and central-level political will for scale-up across multiple health worker cadres in the state.

With Digital India, the Smart Cities Mission, Aadhaar and the recent Unified Payment Interface, digitisation will only continue to expand throughout India, even towards the last mile. The question then becomes not whether it is worth replacing existing paper-based systems with a platform, but rather which platform should be considered for scale-up.

Given the significant costs associated with training and replacing an existing system that has for so long worked on paper, assumptions about any digital platform's effectiveness ought to be evaluated thoroughly before crores of investment are spent on tablets, building software and training health workers.

Khushi Baby's unique value proposition begins with rigorous evidence and over four years of experience working and overcoming significant barriers at the last mile. The value centres on the accountability of a decentralized digital health record and the automated dialect-specific voice call for engagement. Most importantly, Khushi Baby's solution is offered as an end-to-end solution, including design, development, deployment, mobilisation, and monitoring and evaluation in an iterative loop.

4.6 Generalizability of findings

The findings of this impact evaluation may be generalized to the full five administrative blocks of Gogunda, Jhadol, Lasadiya, Salumbar and Sarada. The subgroup analysis suggests that the intervention is not partial to groups based on SES, health awareness or distance to health camp. Notably, this evidence has been used to drive the policy of the Udaipur district government and the Khushi Baby system will be scaled to cover these blocks universally by early 2019.

These findings may also be relevant for other areas across India that share cultural beliefs in the black thread, and where populations with similar demographics – living on less than ₹1,000 monthly, with high access to mobile phones, low literacy, low baseline MCH awareness, with predominantly agricultural labour as the primary source of income, within 5 kilometres of a health sessions camp – also reside, with low baseline ANC and full immunisation rates (less than 40%). The findings, however, should not be generalized to other interventions that only capture certain elements of the intervention or which do not cater to the continuous improvement of the solution lifecycle.

Online appendix

https://www.3ieimpact.org/sites/default/files/2020-06/TW10.1078-Online-appendix.pdf

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