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A cluster randomized trial to determine the effectiveness of a novel, digital pendant and voice reminder platform on increasing infant immunization adherence in rural Udaipur, India [☆]

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ABSTRACT

Background: Five hundred thousand children under the age of 5 die from vaccine preventable diseases in India every year. More than just improving coverage, increasing timeliness of immunizations is critical to ensuring infant health in the first year of life. Novel, culturally appropriate community engagement strategies are worth exploring to close the immunization gap. In our study, a digital NFC (Near Field Communication) pendant worn on black thread and voice call reminder system was tested for the effectiveness in improving DTP3 adherence within 2 monthly camps from DTP1 administration.

Method: A cluster randomized controlled trial was conducted in which 96 village health camps were randomized to 3 arms: NFC sticker, NFC pendant, and NFC pendant with voice call reminder in local dialect. Randomization was done across 5 blocks in the Udaipur District serviced by Seva Mandir from August 2015 to April 2016.

Results: In terms of our three primary outcomes related to DTP3 adherence, point estimates show conflicting results. Two outcomes presented adherence in the control. DTP3 completion within two camps after DTP1 showed higher adherence in the Control (Sticker) (74.2%) arm compared to the Pendant (67.2%) and Pendant and Voice arms (69.3%). Likewise, the estimate for DTP3 completion within 180 days of birth in the Control (Sticker) (69.4%) arm was higher than estimates in the Pendant (57.4%) and Pendant and Voice arms (58.7%). However, one outcome displayed higher adherence in the intervention. DTP3 completion within two months from the time of registration was higher in the Pendant (37.7%) and Pendant and Voice arms (38.7%) compared to the Control (Sticker) arm (27.4%). In all primary outcomes, differences in adherence were statistically insignificant both before and after controlling for confounding factors. In terms of secondary outcomes, our results suggest that providing a necklace generated significant community discussion ($H = 8.8796$, $df = 2$, $p = .0118$), had strong satisfaction among users ($\chi^2 = 26.039$, $df = 4$, $p < .0001$), and resulted in increased visibility within families (grandmothers: $\chi^2 = 34.023$, $df = 2$, $p < .0001$, fathers: $\chi^2 = 34.588$, $df = 2$, $p < .0001$).

Conclusion: Neither the NFC necklace nor the necklace with additional voice call reminders in the local dialect directly resulted in an increase in infant immunization timeliness through DTP3, the primary outcome. Still our process outcomes suggest that our culturally symbolic necklace has potential to be an assistive tool in immunization campaigns. Follow-on work will seek to examine whether positive behavior change towards vaccines can be fostered with earlier engagement of this platform beginning in the prenatal stage, under a continuum of care framework.

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1. Introduction

Immunization saves millions of lives against vaccine-preventable diseases (VPDs). However, an estimated 23 million children born every year do not receive proper immunization during their first year of life [1]. Worldwide, 1.5 million children under the age of 5 die from VPDs. An estimated 500,000 of these children die in India [2–4] after having gone non- or partially immunized [3,5–7].

Sociodemographic and geographic disparities pattern the landscape of immunization delivery [6,8]. The rural region of the Udaipur district of Rajasthan has a full immunization coverage rate of only 37.2% and has performed poorly in other key developmental indicators [9–11]. Drivers of under-immunization are multifactorial: supply-side factors, demand-side factors such as vaccine hesitancy, and critically, gaps in data collection contribute to varying degrees. Our novel m-Health platform, known as the Khushi Baby (KB) system, provides a streamlined digital data collection system for frontline health workers that is designed to support community engagement around child immunization. This platform tracks child immunization history using a mobile application and a durable Near Field Communication (NFC)-powered necklace worn by the child, designed to retain its data for years. The Khushi Baby pendant is culturally tailored, as the black thread on which it is strung is commonly believed to ward off evil spirits in the Udaipur community and many tribal regions of India [12,13]. Health workers are equipped with NFC-enabled devices, which contain the KB mobile application. When a child is brought to a given immunization camp, the health worker scans his or her necklace to automatically bring up the child's immunization history on the mobile application. The child's vaccination data is then synced to a cloud-based database when cellular connectivity is available (Supplemental Fig. 1). With the KB cloud-dashboard, health administrators can send automated voice call reminders in the local dialect to the patient's family.

The intended outcomes of this intervention were to increase process efficiencies in the data collection chain and to improve health behavior outcomes around immunization timeliness. To date, few studies have rigorously evaluated mobile Health (m-Health) innovations for vaccination record keeping, including the usage of mobile phone image capture for secondary immunization data collection and the use of NFC technology for global public health in general [14,15]. While new technologies are being developed to address maternal and child health tracking in resource-limited settings, these innovations need to be rigorously evaluated for effectiveness in the field – where real world implementation constraints and cultural norms play a large role. The current study seeks to systematically evaluate the Khushi Baby system's adoptability by mothers and the system's potential to drive behavior change around immunization timeliness with the primary objective of increasing DTP3 adherence in the first 180 days after childbirth [2,4].

2. The present study

This study seeks to quantitatively examine the primary outcome of timely DTP3 adherence amongst all 3 study arms and 3 key secondary outcomes of the Khushi Baby cluster Randomized Controlled Trial (cRCT). Secondary outcomes will be based on group comparisons of mothers' survey responses that are indicative of whether the necklace is visible, discussed, and accepted by users. Two data collection tools were compared in this study: the NFC sticker and the NFC necklace worn by the child.

3. Materials and methods

The current study examines whether or not the KB intervention improves timely health seeking behavior towards infant vaccination among mothers in rural Udaipur. While many health benchmarks and evaluations utilize primary outcome measures of DTP3 or full immunization coverage [16,17], timeliness is increasingly being recognized as standard [16,18–20]. Infants in the research cohort were tracked from the onset of registration into the KB system. In this first camp visit, the child receives the first DTP shot, meaning that two additional DTP shots would be required to complete the series. In this study, the primary endpoint was receipt of 3 DTP shots before 180 days after birth, as per WHO standards [4]. Secondary timeliness outcomes were also considered to account for standards set by the Indian Academy of Pediatrics (receipt of 3 DTP shots by two months after receipt of DTP1 at registration, spaced by 1 month), and to account for camp cancellations which were not in the control of the beneficiary (receipt of DTP2 and DTP3 in the two consecutive camps from the time of registration) [21]. Due to limitations of the trial scope, outcome measures of adherence through measles could not be considered in this study. A focus on early vaccines, however, was considered relevant due to increased mortality in early stages of infancy.

Randomization for this 3-arm cRCT was conducted on the immunization camp level, which has a catchment area of up to multiple hamlets from multiple villages. Ninety-six camps were randomized evenly to 3 arms (Fig. 1). Patients enrolled in the study's catchment area received their immunizations at vaccination camps held by Seva Mandir, a local NGO that is well established in the Udaipur community. Baseline DTP3 coverage rate in Seva Mandir camps was determined with a 30 cluster, population-based probability sample survey conducted before the trial began. An endline coverage evaluation was not performed due to budget constraints.

3.1. Inclusion and exclusion criteria

The target population for this study included those living in rural regions of Udaipur, Rajasthan, India. Descriptive statistics of the study population can be found in Table 2. All mothers with an infant less than 6 months old in this population were assessed for potential inclusion. Mothers are self-identified residents within 1 of the villages associated with the immunization camp. The following exclusion criteria was utilized: infants who already received 1 or more DTP doses, mothers and infants intending to move from the area in the next 6 months, and mothers without mobile phone access were excluded from the Pendant with Voice Call arm (P+V). All mothers who finished the DTP1-3 series and took the exit survey (Supplemental Table 1) were included in the analyses regardless of timeliness of vaccination (camps are held once monthly and the DTP series is meant to be completed within two camps of receiving the first DTP shot).

3.2. Study design and randomization

Control Arm: Near Field Communication (NFC) stickers were placed on the existing immunization card. These stickers serve as a digital record of the child's immunization while retaining the paper card that the mother currently uses. The sticker can be updated via our app and allows for consistent methodology of immunization data collection. **Pendant Only:** the immunization record was digitally stored on a pendant with black thread, worn by the child. Unlike the sticker, the pendant is visible, wearable, and culturally significant. **Pendant + Voice Call Reminders:** children received the pendant as described above and mothers received

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