



STUDY PROTOCOL

REVISED **Rejoice architecture meets social norms to accelerate vaccination in Nepal: Protocol for a mixed-method quasi-experimental study [version 2; peer review: 1 approved, 2 approved with reservations]**

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Abstract

Background: Each year, 600,000 children under 5 years old die from vaccine-preventable diseases globally. Immunization is an effective way to prevent many diseases, saving two to three million lives per year. The Nepal National Government recommends vaccinations for all children for 11 diseases by 15 months of age. However, only 78% of children between 1-2 years of age have received all recommended vaccines and only 43% receive them at the age-appropriate times for which they are scheduled.

Objectives: This protocol describes the development of an intervention – called “Rejoice Architecture” – that is informed by three theoretical perspectives: choice architecture, the broken windows theory, and the theory of normative social behavior. We also describe a mixed-methods approach to develop the intervention, which will improve the physical and social environments of health facilities in Makwanpur, Nepal. We hypothesize this intervention will improve immunization behaviors and intentions among mothers of children younger than 2 years, pregnant women, and prospective mothers.

Methods: We describe the qualitative formative assessment to understand existing attitudes, norms, and behaviors among caregivers, healthcare workers, and government representatives. The formative assessment will include in-depth interviews, key informant interviews, and focus group discussions. We also describe the overall quasi-experimental study design, used to assess intervention impact.

Impact: This study will contribute to the social and behavioral change communication intervention research by offering a novel strategy for increasing immunization. This study will also illustrate to policymakers

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Any reports and responses or comments on the article can be found at the end of the article.

the value of structural change for health service delivery.

Keywords

social norms, choice architecture, broken windows theory, immunization, study protocol, mixed-methods, quasi-experiment

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REVISED Amendments from Version 1

The new version of this manuscript includes several revisions based on the feedback from peer reviewers. These revisions are summarized below:

- Specified and clarified some areas of confusion in the introduction section, including reports of global immunization data and the summary of the Nepal National Immunization Programme
- Added a footnote to address the controversial use of Broken Windows Theory in United States policing
- Elaborated on the defining features of the study setting and justification for selection as the study area
- Clarification and justification of the study design, including non-random selection of wards and health facilities, 1-km sampling radius, and assignment of in-depth interviews versus focus group discussions
- Justification of sampling mothers 18 years and older
- Clarification of contradicting vaccination rates in quantitative sampling
- Elaboration of consent process by research activity and identification of materials provided to participants
- Elaboration of the intervention design and planned activities in the control and treatment facilities
- Elaboration on the audio recording process
- Added a new section on Data Management describing the process the study team followed to safely collect, store, and share audio files, transcripts, and field notes
- Cited the original creator of [Figure 1](#) (adapted from original)
- Added a new version of [Figure 2](#) which depicts the timeline of activities
- Included the IRB approval numbers
- Updated the corresponding author's email address

Any further responses from the reviewers can be found at the end of the article

Introduction

Communicable diseases constitute a global health threat, with low- and middle-income countries experiencing the greatest burden ([The World Medical Association, 2020](#)). Each year, 1.5 million people die from vaccine-preventable diseases, 600,000 of whom are children under the age of 5 ([Gavi, 2020](#)). Immunization is an effective way to prevent disease and save lives, with two to three million lives saved by vaccines every year ([World Health Organization, 2019](#)). Individuals benefit from immunization through illness prevention, reduced healthcare costs, and greater productivity for themselves and their caregivers ([Gavi, 2020](#); [Njau & Cairns, 2016](#); [Ozawa *et al.*, 2012](#)). Children, who are often at greater risk of morbidity and mortality from communicable disease, experience greater cognitive ability, physical strength, and school performance when they receive vaccines ([Gavi, 2020](#); [Nandi & Shet, 2020](#)). Immunizations also contribute to improved community health through

herd immunity and greater economic stability from long-term cost savings ([Fox *et al.*, 1971](#); [Gavi, 2020](#); [Ozawa *et al.*, 2012](#); [Ozawa *et al.*, 2017](#)).

Currently, nearly 20 million children worldwide younger than one year old have not received the minimum basic vaccines they need to live long, healthy lives; 77% of which represent children living in Gavi-supported countries ([Gavi, 2020](#)). Furthermore, only 17% of children under 1 have received the full dosage recommended by the World Health Organization ([Gavi, 2020](#)). This coverage gap is present in Nepal, where only 78% of children between 1–2 years have received all recommended vaccines ([Ministry of Health Nepal *et al.*, 2017](#)). It is important to note, though, that while the majority of children receive their vaccines by the age of 2, only 43% receive them at the age-appropriate times for which they are scheduled ([Ministry of Health Nepal *et al.*, 2017](#)). Moreover, immunization coverage is highly variable in Nepal, with rates ranging from 65% in some provinces to 93% in others ([Ministry of Health Nepal *et al.*, 2017](#)). Coverage is dependent on the specific vaccine as well, ranging from 73% for the first dose of the Pneumococcal vaccine to 98% for the Bacille Calmette Guerin (BCG) vaccine ([Ministry of Health Nepal *et al.*, 2017](#)). These data demonstrate a critical need to ensure consistent and comprehensive coverage of immunization, including in Nepal.

National Immunization Programme

Since its inception in 1979, Nepal's National Immunization Programme (NIP) has been one of the government's highest priorities, aiming to "reduce child mortality, morbidity and disability associated with vaccine preventable disease" ([Ministry of Health Nepal, 2017, n.p.](#)). The program, which originally offered only BCG and Diphtheria Pertussis Tetanus (DPT) vaccines in three districts, expanded in 1988 to cover all 75 districts in the country and also provide oral polio and measles vaccines ([Department of Health Services, 2018](#)). As of 2020, seven vaccines which protect against 11 vaccine-preventable diseases (Diphtheria, Hepatitis B, Hemophilus Influenza B, Japanese Encephalitis, Measles, Pertussis, Polio, Pneumococcal Disease, Rotavirus, Rubella, Tetanus, and Tuberculosis) are offered ([Ministry of Health and Population Nepal, 2020](#)).

Immunization services are primarily delivered through government networks, such as health facilities, outreach clinics, and mobile clinics, but an upward trend of delivery by private institutions is being observed in urban areas ([Child Health Division, 2011](#)). Vaccines and related logistics are provided free of cost to all health facilities, both public and private, by the government ([Child Health Division, 2011](#); [Department of Health Services, 2018](#)). Many health facilities elect to administer vaccines on one pre-specified day per month, called "Immunization Day." This system helps providers track vaccine uptake in their communities by reaching all children in need of vaccines on the same day, and it also helps parents remember to bring their child for their next immunization.

The NIP played a major role in meeting the fourth target of the Millennium Development Goals to reduce the number of under-five deaths to less than 40 per 1,000 live births

(Ministry of Health and Population Nepal, 2020; National Planning Commission, 2017). The country achieved a number of successes, including being declared polio free in 2014, maintaining elimination status of maternal and neonatal tetanus since 2005, controlling rubella and cognitive rubella syndrome in 2018, and progressing towards the elimination of measles (Department of Health Services, 2018; Ministry of Health and Population Nepal, 2020). More recently, various innovative measures have been taken to declare full immunization in the country. One such initiative, entitled “Reaching Every Child,” was implemented in 2012 and has seen success by providing greater ownership to local political bodies. In total, 56 of 77 districts have declared full immunization; however, 14 districts continue to show dropout rates greater than 10% and 26 districts, including the capital city Kathmandu, have coverage below 80% (Department of Health Services, 2018).

Facilitators and barriers of immunization

Studies in Nepal show that institutional delivery is a prominent facilitator of vaccine uptake (Acharya *et al.*, 2019; Shrestha *et al.*, 2016). Shrestha *et al.* (2016) offer one potential reason for this, stating that the first vaccine (BCG) is often administered immediately after birth, which is more likely to be readily available in a health facility setting than at home. Furthermore, in institutions, new mothers are surrounded by numerous healthcare staff who can share their recommendations for future vaccines (Shrestha *et al.*, 2016).

Multiple studies in Asia and Africa have found a positive association between parental knowledge of immunization and vaccine uptake (Odusanya *et al.*, 2008; Owino *et al.*, 2009; Perry *et al.*, 2020). This can refer to knowledge about the purpose of vaccines, appropriate ages to receive specific vaccines, age at which a child should complete the vaccines, and symptoms of vaccines, among other topics (Odusanya *et al.*, 2008). Some studies show that even in areas of low literacy, parental knowledge is a significant determinant of full immunization (Matsumura *et al.*, 2005; Odusanya *et al.*, 2008). An important aspect of parental knowledge is awareness of the vaccine schedule, which is also strongly correlated with immunization coverage (Owino *et al.*, 2009; Shrestha *et al.*, 2016). In Nepal, full immunization requires seven separate visits over 15 months; it is essential that parents know and remember this schedule in order to bring their children to the facility at the appropriate time (Acharya *et al.*, 2019).

For countries like Nepal that rely on immunization cards to track children’s vaccine records, immunization card retention is a major facilitator of uptake (Acharya *et al.*, 2019; Perry *et al.*, 2020). Perry *et al.* (2020) found that in Bangladesh where, like Nepal, immunization cards are required to receive vaccines, parents are met with anger, shouting, and in some cases a fee when they lose or forget their card. Improving immunization card retention has serious implications for encouraging immunization in Nepal, where the retention rate for immunization cards is only 52% (Acharya *et al.*, 2019).

Barriers to vaccine uptake exist at the individual and health system levels. Several studies suggest an association between

parents’ negative attitudes toward immunization and vaccine incompleteness. Two studies in Nepal point to a fear among parents associated with vaccinating their children, particularly in instances when the child is perceived as being “too ill” to be administered a vaccine (Basel & Shrestha, 2012; Shrestha *et al.*, 2016). Across various countries in Asia and Africa, the most common concern among parents is the potential for side effects and the appropriate response, the fear of which has caused parents to refuse vaccines for their child (Favin *et al.*, 2012; Owino *et al.*, 2009; Perry *et al.*, 2020). To compound the issue, negative attitudes may also be strengthened by competing priorities (Favin *et al.*, 2012; Shrestha *et al.*, 2016; Vonasek *et al.*, 2016). Because immunization can sometimes require long distance travel, followed by long wait times, parents in these circumstances must weigh the benefits of vaccines against the costs of foregoing responsibilities like working, caring for other children, or completing household chores (Favin *et al.*, 2012).

A systematic review of incomplete vaccinations in low- and middle-income countries found that a significant factor for under-vaccination could be explained by health system issues, such as access to services, inadequate health worker knowledge, and vaccine shortage (Rainey *et al.*, 2011). These findings were further established by Favin *et al.* (2012), who found in their review frequent instances of unreliable services (e.g., appointment cancellations, absent providers, lack of supplies) and disrespectful staff (e.g., screaming at mothers, discouraging vaccination). What is less known, and what this project will seek to understand, is the influence of health facilities’ physical infrastructure on vaccine uptake and the underlying conceptual mechanisms that explain this relationship with facility-level factors.

Conceptual framework

This project is informed by ideas from three theoretical frameworks: choice architecture, the broken windows theory,¹ and the theory of normative social behavior. Choice architecture (Thaler & Sunstein, 2008) is based on the idea that human behavior, to some extent, is driven by expediency in decision-making – that people do not want to expend a lot of effort thinking critically about the pros and cons of decisions they need to make. If the decision-making environment is configured in a certain way to promote a particular decision, many will opt for that decision (Thaler *et al.*, 2014). In explaining this theory, the authors write “For reasons of laziness, fear, and distraction, many people will take whatever option requires the least effort, or the path of least resistance” (p. 430). At its most basic level, choice architecture involves two components – options available to the decision-maker, including the number of options from which to make a decision, and the manner in which the options are framed (Johnson *et al.*, 2012).

¹ In the context of this theory, concerns have been raised about its application to policing policies in some parts of the United States. While this demonstrates the misuse of the theory, the theory’s core ideas are nevertheless sound – that a state of neighborhood disrepair communicates broader neglect (see Vedantam *et al.*, 2016). The use of this theory for vaccine promotion in Nepal, to our knowledge, has not been done previously.

The overall idea here is that people’s behaviors can be changed by configuring the environment so that the default choice is in line with the desired behavior. Thus, structurally, if the stairs in a building are the first point of access and taking the elevator requires walking to the back of the building, people are more likely to take the stairs. Applied to the vaccination context, choice architecture principles could be used to immunize an institutionally delivered child by default, but allowing parents to opt out if they so choose (as opposed to making the immunization be the opt-in choice).

While choice architecture focuses on optimal structuring of the environment, the broken windows theory (Wilson & Kelling, 1982) asserts that the condition of disrepair in the environment (e.g., preponderance of broken windows) signals to people that social order is in decay. This further communicates to people that they will not be punished if they, too, engage in behaviors that, literally and metaphorically, break more windows. Hence, the state of broken windows in a community further perpetuates social disorder. In this project, we ask if the reverse is also true in an immunization context: if the physical and social environment in which vaccination is being delivered is improved – from a state of disrepair and disrespect to a state of rejuvenation and respect – will more caregivers come for vaccinations?

One of the mechanisms underlying the broken windows theory is normative influence, the idea that people’s behaviors are driven by their beliefs about what others are doing (called descriptive norms) and pressures they experience to conform (injunctive norms; Cialdini *et al.*, 1990). When people perceive that an environment is in disrepair, they also perceive that others do not care and, by extension, that it would be acceptable for they themselves not to care. In this way, broken windows influence social norms, which in turn affect behavioral choices. The relationship between normative beliefs and behaviors is addressed by the theory of normative social behavior (Rimal & Real, 2005), which posits that social norms affect behaviors

not only directly, but also indirectly when other factors are present. For example, social normative influences are heightened when people have high self-efficacy (Jain & Humienny, 2020; Jang *et al.*, 2013; Johnson, 2011) to enact the behavior and when they perceive that the behavior confers many benefits (Lapinski *et al.*, 2014; Rimal, 2008).

Objectives

This protocol seeks to meet three key objectives:

1. Describe the process by which the formative assessment will be conducted to understand existing attitudes, norms, and behaviors relating to immunization.
2. Describe how the results of the formative assessment will be translated to improve the intervention design.
3. Describe the methodology that will be used to evaluate the impact of the intervention on immunization behavior and intentions.

Methods

Study setting

The study is being conducted in three Palikas (equivalent to a municipality) of the Makwanpur District of Nepal: Thaha Municipality, Kailash Rural Municipality and Bakaiya Rural Municipality (see Figure 1). Makwanpur District is one of 77 districts in Nepal with a population of 420,477 (Central Bureau of Statistics, 2014). Makwanpur District was selected as the study area for this project for a number of reasons, including its immunization rate, geographic location, and demographic diversity. As of 2017, the rate of immunization coverage of children under one year in Makwanpur is 76.7%, comparable to Nepal’s overall immunization rate of 73.1% (Ministry of Health Nepal Department of Health Services, 2018). Additionally, Makwanpur has a geographical range which reflects the three regions of Nepal with an altitude of 2,488 meters in the northern parts and 166 meters in the southern parts. The three selected municipalities were chosen to represent Nepal’s



Figure 1. Geographical location of study. Note: This figure was adapted from the original image (NordNordWest, 2019). This image is free to use under the creator’s licensing conditions. Licensing agreement available at <https://creativecommons.org/licenses/by-sa/3.0/de/legalcode>.

three regions of the mountains (Thaha Municipality), hills (Bakaiya Rural Municipality) and terai (lowlands; Kailash Rural Municipality). Additionally, Makwanpur is 76.7%, comparable to Nepal’s overall immunization rate of 73.1% (Ministry of Health Nepal Department of Health Services, 2018). Furthermore, Makwanpur is accessible from Kathmandu, the capital of Nepal, and is large in size (approximately 2,426 km² or 1.6% of the total land area of Nepal; Central Bureau of Statistics, 2014). These geographical features make Makwanpur an ideal candidate setting to maximize feasibility and minimize contamination. Makwanpur also represents much of Nepal’s diverse population, including 78 ethnic groups with various cultures and languages spoken (Central Bureau of Statistics, 2005).

In each of the three Palikas, we selected one ward (the administrative unit below a Palika) as a treatment site, and chose a clinic in the ward based on our desire to maximize geographic diversity across the three Palikas. Treatment facilities were selected purposively based on relative need for immunization and service delivery support and willingness to collaborate, as the intervention design and implementation would require the input and participation of local stakeholders. We considered other designs (including a cluster randomized study) but decided against it for two reasons. First, it would be hard to justify a random sample when the number of units (in this case Palikas) is only six. Second, we were constrained by resources to expand to more than three intervention Palikas.

Given these constraints, it was deemed more useful to choose sites based on specific criteria. For example, for each ward in the treatment arm, we selected another ward and clinic as a control site in that Palika, matched on population characteristics including ethnicity, age distribution, gender ratio, and population size with the treatment ward. Each control facility is located in a separate geographic vicinity from the treatment facility in its Palika to minimize contamination.

Study team

This research is a partnership between Johns Hopkins University (JHU) and Nepal Evaluation and Assessment Team (NEAT), a nongovernment organization in Kathmandu, Nepal. The research team includes university-based researchers with expertise in social norms, social and behavioral change communication interventions, and mixed-methods research in global health contexts.

Research design and intervention

This study is composed of three phases: 1) qualitative formative assessment, 2) intervention implementation, and 3) quantitative impact assessment (see Figure 2). Mixed methods approaches can be useful for producing a more comprehensive picture of the issue at hand and building on initial findings (Denscombe, 2008). For this study, the formative assessment will be used to understand individual and group perspectives of immunization practices in their communities and opinions about their local health facilities. The findings from this assessment will be used

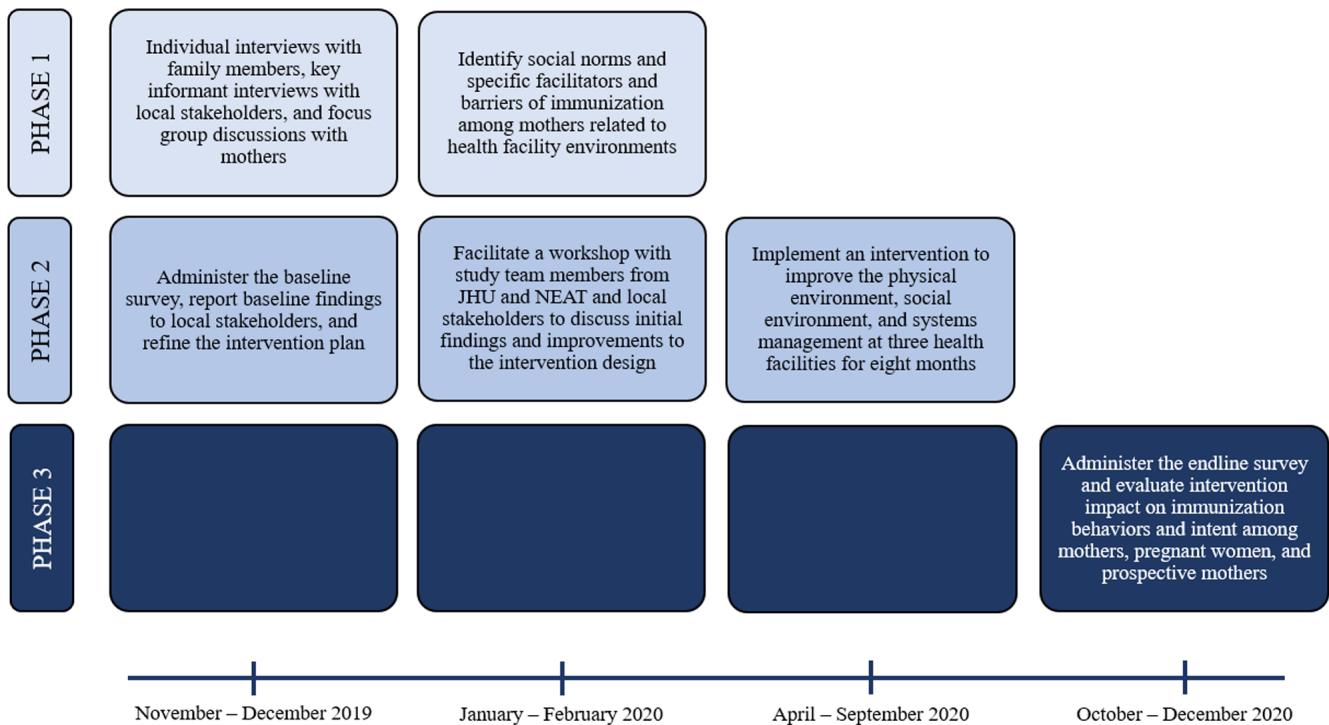


Figure 2. Research study workflow and timeline.

to build on the Rejoice Architecture intervention plan, which will include improvements to the treatment health facilities through three basic components: 1) physical environment and infrastructure, 2) social environment and communication with health staff, and 3) systems management and scheduling. Specific intervention activities in the first component may include painting walls, providing furniture, adding greenery, constructing a covered outdoor waiting area, and displaying educational and entertaining videos on a television screen. For the second component, we may design a client-provider communication checklist and facilitate a workshop on interpersonal communication with clients and caregivers. For the third component, the intervention may involve implementing an appointment reminder system for caregivers and refining the health facility's patient scheduling system. Activities will be refined, expanded upon, or added based on priorities identified in the formative assessment. Health facilities in the control group will receive no intervention components and will provide care as usual. Following the formative assessment, a clustered quasi-experimental survey design will be utilized to determine overall impact of the intervention by comparing outcomes between health facilities which received the intervention and those which did not.

In the event of delays due to COVID-19, the study team will prioritize the health and safety of the communities, health facility staff, and study team. The research team will maintain constant communication with Palika leaders via e-mail and video conferencing to assess the local impact of COVID-19 on each community, stay up-to-date on local safety guidelines, and determine when it is safe to resume research activities. If necessary, the research team will request a project extension to ensure all phases of the study are complete when it is safe to do so. When the study team may resume activities, they will follow safety procedures outlined by JHU, Makwanpur District, and each Palika.

Qualitative methods

The formative assessment will be used to understand the attitudes of and behaviors toward immunization within each community and show how mothers, other community members, and community leaders perceive the environment of their local

health facilities. This assessment will also aid us in identifying mothers' priorities for making the health facilities' environments more welcoming to patients and caregivers.

Study design

We plan to collect qualitative data from five of the six study sites, excluding one control site, as the study team anticipates saturation in the data. Data will be collected primarily from treatment sites to ensure the needs of the treatment sites are identified for the intervention design. Qualitative data will include approximately 10 in-depth interviews, 13 key informant interviews, and eight focus group discussions. Interviews will be used to explore and identify individuals' views, experiences, and motivations related to providing or seeking immunization services from both supply and demand sides. In comparison, focus group discussions will be used to understand the collective attitudes, beliefs, and behaviors of our target population, mothers of young children, to establish community norms and generate ideas to refine the intervention. Refer to [Table 1](#) for our target breakdown of qualitative data by treatment and control sites. It is important to note that due to travel restrictions to prevent spread of COVID-19, actual numbers may vary.

Furthermore, we will match the interviewer and interviewee by gender when possible to strengthen rapport and help the participant feel more at ease. Researchers will conduct all assessments in Nepali, the local language, and collect audio recordings, permitting consent.

Participants

We will conduct in-depth interviews with fathers and grandmothers of children under the age of 2. We will conduct key informant interviews with Female Community Health Volunteers (FCHVs); health workers, with priority given to workers in a leadership role (i.e. Health In-Charge, Immunization Program Manager, etc.); and representatives of the local government (i.e. Ward Chair, chair of the Health Facility Operation Management Committee, etc.). Focus group discussions will consist of mothers of children under 2 years of age. All participants will be at least 18 years or older and live within the catchment area (measured by a one-kilometer radius) of

Table 1. Breakdown of qualitative data collection by treatment and control facilities.

Participant	Session Type	# Sessions (Control)	# Sessions (Treatment)	Total
Mothers	FGD	2	6	8
Fathers	IDI	2	3	5
Grandmothers	IDI	2	3	5
Health worker	KII	1	3	4
Government representative	KII	2	3	5
FCHV	KII	1	3	4

a study health facility or work for, oversee, or volunteer at a study health facility. We recognize that there are mothers younger than 18 years old in this region. Given that marriage of a girl who is below the age of 18 is considered child marriage in Nepal (Nepal Law Commission, 2011), including mothers younger than 18 in the study would require another layer of confidentiality and protection that the study team was unprepared to provide, which is why we limited the sample to those older than 18. This, of course, reduces our study generalizability.

Sampling

FCHVs will provide assistance in identifying eligible participants for the interviews. They maintain an updated list of community members served by their health facilities, including families with newborn children and record of the child's immunization status. Using these lists, FCHVs will identify homes with potential participants for us to contact and recruit. For two of the eight focus groups, we will only recruit individuals from marginalized communities based on their caste to broaden our scope and gain a more comprehensive image of the community and their array of experiences. Each discussion group will consist of five to nine participants. For In-depth interviews, potential participants will be excluded if any member of their family has participated in one of our interviews or focus groups. Participants of the key informant interviews will be identified through discussions with community leadership.

Instruments

We have prepared the qualitative instruments using influence from the theory of normative social behavior (Rimal & Real, 2005) and choice architecture (Thaler *et al.*, 2014). Interview and focus group instruments also include concepts from the literature on facilitators and barriers of immunization (Acharya *et al.*, 2019; Shrestha *et al.*, 2016) and adapted survey questions regarding clinic infrastructure from the Rapid Assessment Tool (Scholz *et al.*, 2015) and the Site Assessment for Maternal and Newborn Health Programs (JHPIEGO, 2004). The instruments were adapted for local use based on feedback from the Nepali team on cultural considerations including language, phrasing, and use of probes. The tools will undergo pre-testing and will be revised to ensure smooth flow of questions, avoid confusing technical terms and jargon, and assure appropriate phrasing to avoid misunderstanding or offense.

Topics covered in each interview and focus group will vary based on the instrument in use as well as flow of the conversation. All qualitative instruments include questions regarding facilitators, barriers, and social norms of immunization. The focus group guide will also cover the physical and social characteristics that mothers desire in an ideal health facility, a description of their current health facility, and typical communication between caregivers and health care providers. The in-depth interview guide will cover the family's personal experiences with vaccination, family involvement in child health and decision-making, and aspirations for the child's education and career. The key informant interview guide will include items regarding immunization coverage in the ward, typical communication between caregivers and health care providers, a physical description of the

local health facility, opinions of their workload, and feasibility of the proposed intervention.

Each of these instruments will aim to reveal the facilitators of and barriers to immunization uptake across various socio-ecological levels. For instance, the in-depth interviews with fathers and grandmothers will address the household-level factors while the focus group discussions with mothers will get at the interpersonal and community levels. Additionally, the key-informant interviews will address the systems level variables at play.

Interview guides are available as *Extended data* (Paul, 2020).

Quantitative methods

Whereas the qualitative component of the research helps inform the intervention design and the quantitative instrument, the quantitative component's primary use is in tabulating the impact of the intervention in as rigorous a manner as possible.

Study design

We will use a clustered quasi-experimental design with panel data to measure the impact of the intervention on immunization behaviors, intent to vaccinate, and uptake of other health services. Participants from each of the six study sites will complete a baseline survey preceding intervention implementation and an end-line survey approximately eight months later. Data collectors will read questions aloud to participants and then record responses on a handheld tablet. Surveys are available as *Extended data* (Paul, 2020).

In addition, the physical conditions of the health facilities and immunization centers will be assessed using checklists at baseline. These checklists will be used to corroborate subjective reports from interviews, focus group discussions, and surveys and assist with identifying needed resources to include in the intervention design. Our data collectors will visit each health facility and the surrounding immunization centers on the designated "Immunization Day" to complete the checklists.

Participants

Eligible participants include mothers of children younger than two years, pregnant women, and prospective mothers. Prospective mothers are defined as women of reproductive age (18–30 years) who are not currently pregnant and do not have a child two years or younger, but express interest in having a child in the future. All participants must be 18 years or older and live within a one-kilometer radius of the health facility being studied. Potential participants will be excluded if they or a member of their family participated in any of the qualitative assessments.

Sampling

Like the qualitative methods, FCHVs from each ward will assist in identifying women in the community who fit the eligibility requirements. With their list of names and locations, data collectors will randomly select houses for recruitment. The target sample size is $n = 950$ (treatment = 475, control = 475) with

an anticipated attrition rate of 20%. This was determined by assuming an increase in vaccination rates from 83% (2019 estimate) to 93% (envisioned), an alpha level of 0.05 and power of 80%, and data collection from 6 clusters. To estimate the vaccination rate in Makwanpur in 2019, we assumed an increase of approximately 6% from 2017, when the data were last reported, based on antigen coverage trends from 2014 to 2017 (Ministry of Health Nepal Department of Health Services, 2018). We estimate an intraclass correlation of 0.01, making the required sample size 380 in the treatment and 380 in the control groups. However, because this is a panel design, we envision an attrition rate of 20%, which brings our sample size at baseline to 950. We will sample four cohorts of women with children younger than one year, women with children between 1–2 years, women who are pregnant at baseline, and prospective mothers. We anticipate greatest availability of women in the first two cohorts, and the least availability of pregnant women, which we expect will create variation in our sample sizes between cohorts. For the complete anticipated sampling breakdown, see Table 2.

Instruments

Baseline and end-line surveys will measure primary outcomes of immunization behavior and intent to immunize future children. A secondary outcome of general service utilization will also be measured. To assess influencing variables, surveys will measure vaccine knowledge, vaccine attitudes and beliefs, self-efficacy, information sources, and perceived social norms regarding immunization. To understand participants' experiences and perceptions of their health facilities, surveys will measure quality of communication with providers, past experiences with pregnancy and delivery, and perceptions of their facility's physical environment. Lastly, the surveys will measure concepts relating to the individual, including their demographics, common methods of communication, interspousal relationships (if married), and mental health. End-line surveys will include all items from the baseline surveys plus an additional section to measure exposure to the intervention.

Surveys will vary slightly depending on the participant's classification. For instance, mothers of children younger than 2 will receive a survey which includes questions about their immunization behaviors. Conversely, pregnant women and prospective mothers will receive a similar survey that, instead, includes

questions about their intentions to immunize their future children and, for some items, requests they answer as if they currently have a child younger than 2. All other survey items will be identical for participants, regardless of their classification.

The Health Facility Checklist will measure the quality of the interior physical environment, exterior physical environment, consultation room, storage and supplies, and accessibility of health facilities. Immunization centers are significantly smaller than health facilities and are only used once per month to provide vaccines. Therefore, the Immunization Center Checklist has been modified to measure the same concepts with only the relevant items. Both checklists use items adapted from the Rapid Assessment Tool (Scholz *et al.*, 2015) and the Site Assessment for Inpatient Postpartum Care (JHPIEGO, 2004).

Outcomes

Immunization behavior and intent. Items measuring immunization behavior and intent are adapted from the Nepal Woman Questionnaire from the 2016 Demographic and Health Survey (DHS) and reflect either the degree to which participants have followed the National Immunization Schedule of Nepal (for mothers) or their intent to follow the schedule in the future (for pregnant women and prospective mothers; Ministry of Health and Population, 2020; Ministry of Health Nepal *et al.*, 2017).

General service use. Items measuring health service utilization will address how often the participant has visited their health facility in the last three months for common health issues including family planning, pregnancy checkups, Tuberculosis treatment, diarrhea treatment, pneumonia treatment, and child sick visits.

Data collection

Training

An in-person training will be held in Kathmandu, Nepal for all data collectors to prepare for the qualitative and baseline assessments. The Principal Investigator will conduct the training alongside research staff from the data collection agency. The training will be held for five days with an objective to prepare the researchers for qualitative and quantitative data collection. Training topics will include key concepts of the study like child health and immunization, techniques for probing in interviews and facilitating focus group discussions, and ethical research conduct.

Following researcher training, we will pretest all instruments and research methods in one ward in Makwanpur that is not part of the actual study. During pretesting, supervisors will observe and provide feedback on research techniques.

Instrument development

All instruments were designed through an iterative process in which team members from the U.S. and Nepal collaborated to provide feedback and make revisions. Each instrument underwent multiple rounds of revisions until all team members concluded the items appropriately reflected the study's objectives, well-developed theory and literature, and cultural

Table 2. Breakdown of quantitative data collection by treatment and control facilities.

Participant	Control	Treatment	Total
Women with children <1 year	150	150	300
Women with children 1–2 years	150	150	300
Pregnant women	50	50	100
Prospective mothers	125	125	250
Total	475	475	950

context. Each instrument was translated from English to Nepali by a team member to ensure that questions would be understandable to participants without compromising construct validity.

All instruments will undergo a final round of revisions during the pre-testing phase during which time we will assess the instruments for flow, cultural appropriateness, and use of technical terms and jargon. Data collectors will provide feedback from their experiences which will be incorporated into final revisions for the instruments.

Consent process

Prior to collection of any data, participants will be read aloud and provided an information sheet detailing the purpose of the study, expected duration of participation, types of questions they may be asked, and their options to decline to participate or quit at any time. For interview and survey participants, consent will be obtained immediately following recruitment at the individual's home or place of work in a private space. Data collection will then immediately follow. For focus group discussions, written consent will be obtained individually at the location of data collection. When each participant arrives at the pre-determined location (shared during recruitment), the facilitator will pull them aside to a private spot, review the information and consent form, and obtain consent. The focus group discussion will not begin until individual consent has been provided by all in attendance. Consent will be received with a written signature. All participants will receive an un-signed copy of the information and consent form. Informed consent materials are available as *Extended data* (Paul, 2020).

Data analysis

Qualitative

As data are being collected, researchers will use an audio recording device and will document field notes using a handheld tablet to capture the overall picture of the interview or focus group. In their field notes, they will note their perceptions of the participant's attitude and willingness to engage, as well as the surroundings, interruptions, or other notable characteristics of the session. Following data collection, team members will transcribe the audio recordings and translate them from Nepali to English. Researchers will omit any personally identifiable information shared in interviews and focus groups in the transcripts.

Following Braun & Clarke's (2006) guidelines, we will adopt an iterative, thematic analysis approach to analyze the in-depth interviews, key informant interviews, and focus group discussions to uncover prominent themes. This approach will allow us to thematize both the supply-side (e.g., clinic environments, providers' communication patterns) and demand-side (e.g., attitudes, physical access, etc.) facilitators and barriers of immunization behaviors (Braun & Clarke, 2006).

Researchers with experience in qualitative analysis will independently read through transcripts to gain familiarity with the data and develop an initial codebook. The team will then code

transcripts independently, using QSR International's NVivo software, meeting regularly to revise the codebook as themes emerge. Codes will be added both deductively, based on our research question, and inductively as new trends appear. Team members will each be paired with another teammate, rotating on a weekly schedule, to compare codes, discuss discrepancies, and reach consensus. All transcripts will be coded by at least two team members. We will determine prominent themes by comparing codes across the in-depth interviews, key informant interviews, and focus group discussions; running word queries; and creating visual conceptual maps to link patterns.

Quantitative

The primary objective of the quantitative analysis is to determine whether the Rejoice Architecture intervention results in greater vaccination uptake (or intentions for vaccination) among mothers (or prospective mothers) in the treatment, compared to the control, arm. Hierarchical linear regressions (HLM) will be used to test the primary hypothesis that vaccination rates (number of newborns vaccinated divided by total live births within a catchment area) in the treatment group will be significantly greater (goal is 10 percent) than that in the control group. This analysis will take into account the clustered nature of data within each of the six catchment areas (three in treatment and three in control areas).

Data management

Qualitative interviews and focus group discussions will be recorded on audio recording devices and field notes will be documented on a handheld tablet. Survey responses will also be recorded on a handheld tablet. Audio recording devices and handheld tablets will be stored securely in a locked cabinet or room, accessible only by NEAT researchers, until the data can be uploaded to a computer. Audio recordings, field notes, and survey responses will be uploaded to password protected, encrypted laptops owned by NEAT and shared with the study team using a secure JHU SharePoint account with a built-in encrypted backup solution. Transcription and translation of audio recordings will be completed on NEAT computers and shared with the study team through SharePoint. The original audio recordings will then be destroyed.

Limitations

This study may be limited in several ways. For instance, the study sites were selected purposively and are in one of 77 districts in Nepal; therefore, generalizability could be limited. Findings may also be limited to rural settings among certain ethnic groups in Makwanpur and may vary among other geographic or ethnic contexts.

Considering the current COVID-19 pandemic, intervention implementation may be delayed, and data will likely reflect the pandemic's effects on facility closures, attitudes toward help-seeking, and health-related behaviors. However, both treatment and control facilities will be exposed to the virus and Nepal's national response, and so no significant differences due to COVID-19 are expected between groups.

Contribution to the field

Currently in phase 2 of the study, we have collected baseline data and modified the Rejoice Architecture intervention design, and will implement the intervention when COVID-19 travel restrictions are lifted. We expect this project will make incremental, though important contributions to the global efforts in increasing immunization and reducing child mortality. The iterative and multi-phase procedure will allow for constant adaptation of the intervention, driven by a deepened understanding of individual and contextual factors that will be achieved through community-based participation at every phase. This theory-driven approach will offer a novel connection between community-level theory and individual behavior, bridged by changes in social norms. More specifically, this study will test the pathway between physical infrastructure, mothers' behavior and child immunization, and will therefore provide direction for future research aiming to address immunization uptake and other service use in LMICs.

Ethics and dissemination

The Institutional Review Boards with Johns Hopkins University (no. 9951) and the Nepal Health Research Council (no. 860/2019) approved this study. All participants will

provide written consent before data collection. Findings from this study will be disseminated in participating Palikas and wards in Makwanpur, at international research conferences, and through peer-reviewed journals.

Data availability

Underlying data

No underlying data are associated with this article.

Extended data

Open Science Framework: Rejoice Architecture Meets Social Norms to Accelerate Vaccination in Nepal: Protocol for a Mixed-Method Quasi-Experimental Study. <https://doi.org/10.17605/OSF.IO/JYBK4> (Paul, 2020).

This project contains the following extended data:

- Interview and focus group guides
- Baseline survey instruments
- Consent forms

Extended data are available under the terms of the [Creative Commons Zero "No rights reserved" data waiver](#) (CC0 1.0 Public domain dedication).

References

- Acharya K, Lacoul M, Bietsch K: **Factors Affecting Vaccination Coverage and Retention of Vaccination Cards in Nepal**. DHS Further Analysis Reports No. 121. Rockville, Maryland, USA: ICF. 2019.
[Reference Source](#)
- Basel PL, Shrestha IB: **Factors associated with dropout between Bacille Calmette Guerin (BCG) and measles vaccination in a village development committee of a district**. *J Nepal Health Res Counc*. 2012; **10**(21): 147–151.
[PubMed Abstract](#)
- Braun V, Clarke V: **Using thematic analysis in psychology**. *Qual Res Psychol*. 2006; **3**(2): 77–101.
[Publisher Full Text](#)
- Central Bureau of Statistics: **District profile of Makwanpur district**. Government of Nepal National Planning Commission. 2005.
[Reference Source](#)
- Central Bureau of Statistics: **National population and housing census 2011: General and social characteristics tables**. Government of Nepal National Planning Commission Secretariat. 2014.
[Reference Source](#)
- Child Health Division: **National immunization program: Reaching every child, Comprehensive multi-year plan 2068-2072**. Government of Nepal. 2011.
[Reference Source](#)
- Cialdini RB, Reno RR, Kallgren CA: **A focus theory of normative conduct: Recycling the concept of norms to reduce littering in public places**. *J Pers Soc Psychol*. 1990; **58**(6): 1015–1026.
[Publisher Full Text](#)
- Denscombe M: **Communities of practice: A research paradigm for the mixed methods approach**. *J Mix Method Res*. 2008; **2**(3): 270–283.
[Publisher Full Text](#)
- Department of Health Services: **Annual report 2074-75**. Government of Nepal. 2018.
[Reference Source](#)
- Favin M, Steinglass R, Fields R, et al.: **Why children are not vaccinated: A review of the grey literature**. *Int Health*. 2012; **4**(4): 229–238.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Fox JP, Elveback L, Scott W, et al.: **Herd immunity: basic concept and relevance to public health immunization practices**. *Am J Epidemiol*. 1971; **94**(3): 179–189.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Gavi: **Facts and figures: Statistics measuring our impact on global immunization**. 2020.
[Reference Source](#)
- Jain P, Humienny R: **Normative influences on the role of prescription medicine misuse among college students in the United States**. *Health Commun*. 2020; **35**(3): 331–340.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Jang SA, Rimal RN, Cho N: **Normative influences and alcohol consumption: The role of drinking refusal self-efficacy**. *Health Commun*. 2013; **28**(5): 443–451.
[PubMed Abstract](#) | [Publisher Full Text](#)
- JHPIEGO: **Site assessment tool for inpatient postpartum care basic information. Part A: Equipment and supplies**. In A. Blouse, P. Gomez, & B. Kinzie (Eds.), *Site assessment and strengthening for maternal and newborn health programs*. JHPIEGO. 2004; 1–6.
- Johnson KF: **The influence of school connectedness and academic self efficacy on self-reported norm related pro-social behavior**. Doctoral dissertation. Pennsylvania State University. 2011.
[Reference Source](#)
- Johnson E, Shu SB, Dellaert BGC, et al.: **Beyond nudges: Tools of a choice architecture**. *Market Lett*. 2012; **23**: 487–504.
[Publisher Full Text](#)
- Lapinski MK, Anderson J, Shugart A, et al.: **Social influence in child care centers: A test of the theory of normative social behavior**. *Health Commun*. 2014; **29**(3): 219–232.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Matsumura T, Nakayama T, Okamoto S, et al.: **Measles vaccine coverage and factors related to uncompleted vaccination among 18-month-old and 36-month-old children in Kyoto, Japan**. *BMC Public Health*. 2005; **5**(1): 59.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Ministry of Health and Population Nepal: **National immunization programme**. Government of Nepal. 2020.
[Reference Source](#)
- Ministry of Health Nepal: **Nepal Health Sector Strategy Implementation Plan 2016-2021**. Government of Nepal. 2017.
[Reference Source](#)
- Ministry of Health Nepal Department of Health Services: **Annual Report 2016-17**. 2018.
[Reference Source](#)

Ministry of Health Nepal, New ERA, & ICF: **Nepal Demographic and Health Survey 2016**. 2017.

[Reference Source](#)

Nandi A, Shet A: **Why vaccines matter: Understanding the broader health, economic, and child development benefits of routine vaccination**. *Hum Vaccin Immunother*. 2020; 1–5.

[PubMed Abstract](#) | [Publisher Full Text](#)

National Planning Commission: **Nepal's sustainable development goals, baseline report**. Government of Nepal. 2017.

[Reference Source](#)

Nepal Law Commission: **Nepal marriage bill 2011**. Government of Nepal. 2011.

[Reference Source](#)

Njau JD, Cairns LK: **A literature review on the economic benefits of vaccines in low and middle income countries: Evaluating progress in the era of 'a decade of vaccines' initiative**. *Vaccine Reports*. 2016; 6: 62–76. Scopus.

[Publisher Full Text](#)

NordNordWest: **Makwanpur District in Nepal 2015**. 2019.

[Reference Source](#)

Odusanya OO, Alufohai EF, Meurice FP, et al.: **Determinants of vaccination coverage in rural Nigeria**. *BMC Public Health*. 2008; 8(1): 381.

[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)

Owino LO, Irimu G, Olenja J, et al.: **Factors influencing immunisation coverage in Mathare Valley, Nairobi**. *East Afr Med J*. 2009; 86(7): 323–329.

[PubMed Abstract](#) | [Publisher Full Text](#)

Ozawa S, Clark S, Portnoy A, et al.: **Estimated economic impact of vaccinations in 73 low- and middle-income countries, 2001–2020**. *Bull World Health Organ*. 2017; 95(9): 629–638.

[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)

Ozawa S, Mirelman A, Stack ML, et al.: **Cost-effectiveness and economic benefits of vaccines in low- and middle-income countries: A systematic review**. *Vaccine*. 2012; 31(1): 96–108.

[PubMed Abstract](#) | [Publisher Full Text](#)

Paul A: **Rejoice Architecture Meets Social Norms to Accelerate Vaccination in Nepal: Protocol for a Mixed-Method Quasi-Experimental Study**. 2020. <http://www.doi.org/10.17605/OSF.IO/JYBK4>

Perry H, Nurani S, Quaiyum M, et al.: **Barriers to immunization among women and children living in slums of zone 3 of Dhaka City, Bangladesh: A qualitative assessment**. *icddr, b Knowledge for Global Lifesaving Solutions*. 2020.

[Reference Source](#)

Rainey JJ, Watkins M, Ryman TK, et al.: **Reasons related to non-vaccination**

and under-vaccination of children in low and middle income countries: Findings from a systematic review of the published literature, 1999 – 2009. *Vaccine*. 2011; 29(46): 8215–8221.

[PubMed Abstract](#) | [Publisher Full Text](#)

Rimal RN: **Modeling the relationship between descriptive norms and behaviors: A test and extension of the theory of normative social behavior (TNSB)**. *Health Commun*. 2008; 23(2): 103–116.

[PubMed Abstract](#) | [Publisher Full Text](#)

Rimal RN, Real K: **How behaviors are influenced by perceived norms: A test of the theory of normative social behavior**. *Communication Research*. 2005; 32(3): 389–414.

[Publisher Full Text](#)

Scholz S, Ngoli B, Flessa S: **Rapid assessment of infrastructure of primary health care facilities – a relevant instrument for health care systems management**. *BMC Health Serv Res*. 2015; 15: 183.

[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)

Shrestha S, Shrestha M, Wagle RR: **Predictors of incompletion of immunization among children residing in the slums of Kathmandu valley, Nepal: A case-control study**. *BMC Public Health*. 2016; 16(1): 970.

[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)

Thaler RH, Sunstein CR: **Nudge: Improving decisions about health, wealth, and happiness**. New Haven: Yale University Press. 2008.

[Reference Source](#)

Thaler RH, Sunstein CR, Balz JP: **Choice architecture**. In Shafir E (Ed.), *The behavior foundations of public policy*. Princeton University Press. 2014; 428–439.

[Publisher Full Text](#)

Vedantam S, Benderev C, Boyle T, et al.: **How A theory of crime and policing was born, and went terribly wrong**. NPR. 2016.

[Reference Source](#)

Vonasek BJ, Bajunirwe F, Jacobson LE, et al.: **Do maternal knowledge and attitudes towards childhood immunizations in rural Uganda correlate with complete childhood vaccination?** *PLoS One*. 2016; 11(2): e0150131.

[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)

The World Medical Association: **Communicable diseases: Diseases transmitted by bacteria and viruses**. 2020.

[Reference Source](#)

Wilson JQ, Kelling GL: **Broken windows**. *Atlantic Monthly*. 1982; 29–36.

[Reference Source](#)

World Health Organization: **Immunization coverage: Key facts**. 2019.

[Reference Source](#)

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Robert A. Bednarczyk 

Rollins School of Public Health, Emory University, Atlanta, GA, USA

This protocol describes the Rejoice Architecture intervention, designed to improve childhood vaccination in Makwanpur, Nepal. This mixed-methods study aims to utilize three theories - choice architecture, broken windows, and normative social behavior - to guide development, implementation, and evaluation of the intervention.

There are some clarifications needed to help this manuscript:

1. In the second paragraph of the introduction, please indicate which ages are under evaluation when describing 20 million children who are not appropriately vaccinated. Additionally, what percentage of the global childhood population does this represent (either in total or in LMIC)?
2. In the first paragraph under "National Immunization Programme", please spell out rotavirus rather than saying "rota". Additionally, the language here is difficult to follow because in some cases it seems like a disease is presented and in some cases the specific vaccine is presented. Please edit for clarity (e.g. "vaccines against seven additional diseases...").
3. I am a bit concerned about the use of Broken Windows theory, as there have been some studies that have shown that this is a flawed theory, specifically as it relates to crime in the US. Has this been used to guide interventions (vaccine-related or in other settings) in Nepal?
4. In the Methods, you refer to the geographic location of Makwanpur as maximizing "external validity" but given differences across Nepal, as indicated by highlighting the Terai and mountain regions, I am unclear by what you are referring to. This is especially of concern when, in the limitations, you reference generalizability issues given the location of the intervention.
5. Can you reference the population of Makwanpur, both in terms of numbers and breakdown

of other characteristics relative to the general Nepal population, to help address some of these generalizability issues.

6. Why are you doing IDI for fathers/grandmothers and FGD for mothers?

7. In the sampling section of the Quantitative Methods, you describe sample size estimation with a starting point of 83% vaccinated, but this contradicts the 77% referenced in the first paragraph of the Methods.

8. In the analysis of the qualitative methods, you talk about recordings, but don't directly discuss how this recording will be done, how files will be stored, etc.

9. A figure describing the timeline for the project, to clarify the evaluation period, timing of surveys, etc. would be helpful.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Infectious disease epidemiology, vaccine acceptance, global health

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 24 March 2021

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Nimesh Poudyal 

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Ondari D. Mogeni 

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The article describes a well-designed study protocol to develop an intervention termed "Rejoice Architecture" within the conceptual framework of choice architecture, broken windows theory, and theory of normative social behavior and evaluate the impact of the intervention on immunization behavior and intentions through mixed-method quasi-experimental study. The rationale on the need for developing such an intervention and approach for evaluation of the impact is well laid-down by the authors and the study objectives are also clearly described in the protocol. It is clear that the study aims to understand the challenges of immunization uptake and measuring the impact of intervention instituted.

The overall design of the study is replicable, but it would be good if the authors are able to describe the study setting further elaborating the population demographics and in particular under 2 years and how this compares to the rest of the country, the size of Makwanpur district, and what is the mortality per 1000 live births, in order to put the vaccine coverage of 76.7% into perspective. Additionally, it may be good to add a justification for the selection of that particular study area and describing the selection criteria used. Furthermore, of the units to be included in the study, some will be categorized into "treatment group" and "control group". Providing more details on what qualifies a unit to be termed "control group" and providing specific activities/intervention planned in each group will help understand the study design more clearly for its replication. One 'control group' is ultimately excluded during the intervention stage of the study and it is not clear what role this excluded group serves.

It may also be good to consider including a section on data management. The study design in the article mentions the use of handheld tablets, but it does not provide any detail on how the data will be managed throughout the study period, where it will be warehoused, how data safety and security will be ensured, who will be able to access the data? Is there an egalitarian approach given this is a collaboration?

One must be 18 years and over to be eligible to participate in the study. Given the challenges faced by mothers who are less than 18 years old in accessing immunization services, not including them during the formative assessment may lead to a bias on the designing of the intervention. A few articles seem to suggest teenage motherhood is prevalent in the area as well as in the country:

1. <https://kathmandupost.com/national/2018/02/15/teenage-pregnancy-rife-in-makwanpur>
2. <http://www.bibalex.org/Search4Dev/files/428878/455706.pdf>

It is not clear in the consenting process whether it will be done individually or collectively in the case of focus group discussion. And will each participant sign an informed consent form? Will a signed copy be extended to them?

It is mentioned that the respective IRBs have approved the study. It will be helpful to include the IRB approval number from respective IRBs for future reference.

It is great that part of the dissemination process includes engagements of the participating Palikas. Will this be done at the community level or at the official level? Though it is mentioned that the results may not be generalized, it may be good to provide this feedback to stakeholders such as government officials to consider the study at a larger scale more so if the results are positive and given the overall goal is to increase immunization coverage.

There is mention of COVID-19 and its impact. What may be the mitigation measures if travel is not possible?

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Vaccinology, Infectious Disease, Epidemiology

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 22 March 2021

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Ann M. Weber 

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This is a well-written manuscript of an ambitious study to improve childhood immunization rates in Nepal. Overall, the protocol is clear and easy to follow. The introduction very nicely lays out the importance of the issue, the local context, and the facilitators and barriers to increased uptake. The open source links to the qualitative interview guides and surveys are particularly appreciated and very helpful. My major comments are for 1) consideration of addressing the normative behavior aspects of the issue in more depth, 2) recommendations to describe plans for the intervention itself in more detail, and 3) improved clarity for the justification of some of the study design decisions.

Major comments:

1. The inclusion of fathers and grandmothers is an important component of the qualitative research and understanding normative influences around the barriers to immunization of children. It might be helpful to readers to briefly explain the reasoning behind their inclusion. Importantly, transforming social norms is difficult, but possible. It requires engaging stakeholders at multiple levels (including fathers, grandparents, village leaders) and across multiple domains (of families, communities, and institutions) in the intervention. It would be helpful to understand how various stakeholders are involved in the intervention itself as well as in the quantitative aspect of the study, if at all. For example, are fathers and grandmothers engaged as part of the intervention? Will they be interviewed or surveyed after the program implementation to assess change in their beliefs, knowledge or attitudes? If no to both questions, I would recommend that the researchers consider opportunities to include them throughout the study process.

2. As a reader, I would appreciate more detail on the plans for the intervention itself (in addition to the question above about fathers and grandparents) that address some of the barriers raised in the introduction. For example, will health workers be trained to address barriers related to how families are treated in the clinics (assuming this issue if raised in the qualitative portion)? The implementation of an appointment reminder system seems to be a key element to addressing the essential enabler that: "parents know and remember this schedule in order to bring their children to the facility at the appropriate time." How might such an appointment system be implemented, for example, with text messages to moms? Does it require an electronic records system to be implemented in the clinics? How does the intervention address the issue of loss of immunization cards?

3. There are some elements of the study design that aren't clearly justified or motivated for the reader. For example:

- The justification of non-random selection of wards and clinics within wards is unclear and I would encourage the researchers to consider the possibility of performing a cluster randomized study. The researchers state that they want to "maximize geographic diversity across the three Palikas." However, this might be accomplished with stratified sampling. Athey and Imbens recommend "researchers to stratify the population into small strata and then randomize within the strata and adjust the standard errors to capture the gains from the stratification" and furthermore "that one should always stratify as much as possible, up to the point that each stratum contains at least two treated and two control units." (Athey and Imbens, 2017¹).
- Is limiting the participants to a 1 km radius of a study health facility for ease of access for the research? If so, are the researchers concerned that they might be overlooking an important barrier to immunization uptake due to the time cost of travel in terms of generalizability to participants living further away? How are they trying to address this concern?
- Why are mothers only part of focus groups and not planned for any in-depth interviews? It might be useful to ask mothers in-depth questions about the people in her life that influence her behavior and the same questions about household dynamics that are asked of fathers and grandmothers.

- The checklist evaluation of the intervention implementation may miss opportunities to better understand implementation challenges. It might be valuable to have more quantitative data to understand implementation or process issues not picked up by the checklist in the event that the program is not as effective as hoped. For example, will any of the key health workers be surveyed before and after the intervention? How will the appointment system be evaluated?

Minor comments:

- Methods - Second paragraph – “For each ward in the treatment arm, we selected another ward and clinic as a *treatment* site in that Palika, matched on population characteristics with the treatment ward.” Did the authors mean to write “...we selected another ward and clinic as a *control* site in that Palika...”? Also, what are the population characteristics that they will match on?
- Qualitative - What is the rationale for excluding one control site from the collection of qualitative data?
- Quantitative - The ICC of 0.01 seems very small. How was this value determined?
- Will administrative data be available on overall vaccination rates in the communities?
- A 20% attrition rate after 8 months seems high. Why do the researchers think that there will be so much attrition? Is there any action that could be ethically included in the study to minimize attrition?

References

1. Athey S, Imbens G: The Econometrics of Randomized Experiments a. **1**: 73-140 [Publisher Full Text](#)

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Child health and development; program impact evaluations in low- and middle-income countries; gender inequality and norms; health disparities.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.
