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Project SALUBONG: Using human-centered design to build vaccine confidence via empathy and narratives in the Philippines

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Title:

Project SALUBONG: Using human-centered design to build vaccine confidence via empathy and narratives in the Philippines

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ABSTRACT

Introduction: Since the onset of a dengue vaccine controversy in late 2017, vaccine confidence has plummeted in the Philippines, leading to a measles and polio outbreak in early 2019. This protocol outlines a human-centered design (HCD) approach to co-create and test an intervention that addresses vaccine hesitancy (VH) via narrative and empathy with and among families and health care workers.

Methods and Analysis: “Salubong” is a Filipino term that means to welcome someone back into one’s life, reinforcing notions of family ties and friendships. We apply this sentiment to vaccines. Following the four phases of HCD, guided by a theoretical framework, and drawing from locally-held understandings of faith and acceptance, we will conduct in-depth interviews (IDIs) and focus group discussions (FGDs) in rural and urban Filipino communities that witnessed dramatic increases in measles cases in recent years. During qualitative engagements with patients, providers and policymakers, we will collect narratives about family and community perceptions of childhood vaccinations, public health systems, and opportunities to restore faith. IDIs and FGDs will continuously inform the development of (and the delivery mechanisms for) story-based interventions. Once developed, we will test our co-created intervention(s) among 600 families and administer a VH questionnaire prior to and immediately following the intervention encounter. We will use the feedback gained through the survey and Kano-style questionnaires to further refine the intervention. Considering the data collection challenges posed by the ongoing COVID-19 pandemic, we have developed workarounds to conduct data collection primarily online. We will use systematic online debriefings to facilitate comprehensive participation of the entire research team.

Ethics and Dissemination: Ethical approval has been granted by the Institutional Review Board of the Research Institute for Tropical Medicine (No. 2019-44) and the ethical commission of Heidelberg University, Faculty of Medicine (S-833/2019), both recognized Ethical Review Committees. Study findings will be disseminated in scientific conferences and published in peer-reviewed journals.

Strengths and Limitations of the Study:

- Project SALUBONG directly responds to calls in the literature for more community-based research on how VH can be addressed and how trust in the public health sector can be bolstered.
- Guided by families and communities, we will co-create an empathic intervention that places the health of children, the concerns of parents, and the needs of HCWs at the center to support trust in vaccines.
- Findings will inform future vaccine confidence efforts and contribute to broader policy discussions regarding VH in the Philippines and globally.
- Due to the COVID-19 pandemic, we have shifted some of our data collection online, and ours will be among the first qualitative studies in this setting to outline opportunities and pitfalls of remote qualitative research.

BACKGROUND

Vaccines are a cost-effective and safe way to prevent millions of deaths annually (1, 2). Although vaccines represent a seminal achievement in terms of mitigating disease, confidence in vaccines has decreased in many countries in recent years (3). This drop in confidence has contributed to stagnation or decreases in immunization rates, which in turn has resulted in outbreaks of previously controlled or eradicated diseases such as measles and polio (4-7).

In 2019, the World Health Organization (WHO) included vaccine hesitancy (VH) - the “delay in acceptance or refusal of vaccines despite availability of vaccination services” (8) - in its list of the top 10 global health threats requiring high-level attention and research (9). Literature that has sought to tease out the causes of VH emphasizes the ‘5Cs’: a lack of confidence (in vaccines and the broader health system), complacency (regarding the severity of vaccine-preventable illness), constraints (psychological, financial or structural barriers), calculation (the degree to which individuals search for information about vaccines), and collective responsibility (a willingness to protect others) (10). More recently, scholars have started to consider the role of trust and unequal power dynamics in undermining vaccine uptake, describing how families have lost trust in the health system and feel that they have no voice in the face of state-mandated decisions or directives about vaccines (11-14).

Effective and efficient solutions to address VH are urgently needed, not only to mitigate the re-emergence of vaccine-preventable diseases (such as polio or measles (6, 15-17)), but also because the development and uptake of an effective vaccine is a cornerstone of controlling the ongoing COVID-19 pandemic (18, 19).

To date there is limited guidance in terms of how to successfully combat VH, most of which stems from high-income settings (20, 21). At the individual level, changing people’s attitudes about vaccines has proven difficult, and successful interventions are limited (22). At the governance level, policymakers in high-income countries (HICs) have considered or enacted laws to punish those who reject vaccines (on non-medical grounds) by denying unvaccinated children admission to elementary schools and public playgrounds, and charging parents substantial fines (23). At the health system level, interventions involving medical professionals have considered how to broach the topic of vaccines in a non-judgmental but affirmative manner, how to listen to parents' vaccine decision-making (24) and how to facilitate vaccination directly through reminders, prompts, or by reducing logistical barriers (22).

More recent studies also highlight opportunities in terms of video-based vaccine promotion (24) and educational messages in the form of graphic pictures and anecdotes (focusing on the consequences of not getting a child vaccinated) (25). Several studies have employed Human-Centered Design (HCD), an approach to co-develop interventions with end-users (26). This methodology has led to the creation of mobile apps, education materials, provider guidelines and the re-design of a health facility, all in the interest of bolstering vaccine uptake (24, 27-31). Results of these HCD studies suggest that the approach supports stronger patient and community engagement (24, 27, 30).

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3 Relatively little attention has been paid to VH and ways to address VH in low- and middle-
4 income countries (LMICs) (14, 21, 24, 25). This is particularly problematic for at least three reasons:
5 1) a majority of the world's vaccine-preventable deaths occur in LMICs (32); 2) immunization
6 structures in LMICs are insufficiently equipped to address VH *in addition to* rolling out national
7 immunization campaigns (and other child health challenges); and 3) in the event of an outbreak of a
8 vaccine-preventable disease, survival rates and containment possibilities are markedly reduced in
9 LMICs where poor structural conditions and extreme poverty can exacerbate pre-existing
10 vulnerabilities (33-35).
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16 The Philippines, an archipelago with a population of more than 105 million, is among the
17 LMICs that are currently experiencing an unprecedented erosion of public trust in childhood
18 vaccinations (36-38). Vaccine confidence fell from 93% of adults “strongly agreeing” to the importance
19 of vaccination in 2015 to 32% in 2018 (36). This is reflected in measles vaccination rates of children
20 under-five, which fell from 88% in 2014 to 55% in 2018 (39). Results from a recent study conducted in
21 two urban communities in Manila, the capital of the Philippines, showed that 31% of parents feel
22 vaccine hesitant and 24% had refused at least one vaccine for their children (40). These sharp declines
23 are associated with a dengue vaccine controversy in 2017 and the ensuing misinformation that eroded
24 faith in vaccine safety (36-38, 41). This erosion led to the country losing its 19-year polio free status,
25 and sparked measles outbreaks across several islands in 2019, with 47,871 cases including 632 deaths
26 (as compared to 2,789 cases and 25 reported deaths in 2018) (39, 41, 42). The Department of Health
27 (DOH) of the Philippines has therefore made it a priority to win back the trust and confidence of the
28 public in vaccination (43). The DOH - in partnership with the WHO and UNICEF - has strengthened
29 routine immunization via the launch of door-to-door immunization campaigns to increase vaccine
30 uptake and to reach unvaccinated children (16, 44). Although recent data has indicated signs of
31 recovery, with the proportion of people agreeing to the importance of vaccines increasing, gains in
32 terms of perceived vaccine safety and effectiveness are insufficient (3). More tailored and innovative
33 initiatives are necessary to regain community trust in vaccines.
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46 **The SALUBONG Intervention**

47 “Salubong”, the moniker for this research, is a Filipino term that means to welcome someone
48 into one's home or life. In the Philippines, the largest predominantly Christian country in Asia, the term
49 Salubong describes a Catholic dramatization of the resurrected Jesus encountering his mother Mary,
50 which is a central part of the Easter week across the Philippines. This encounter, which is not liturgically
51 accounted for, culminates in Jesus – if briefly – reuniting with his mother (45). From this, Salubong has
52 developed into a Filipino tradition that celebrates the beauty of re-connecting with important figures
53 from one's past. The Salubong tradition is commonly observed at international airports throughout the
54 Philippines, where many Filipinos are waiting for their loved ones to return home after having sought
55 employment abroad (the diaspora has fostered an undertone of longing and anticipation in many Filipino
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homes) (46, 47). The homecoming of a loved one is viewed as a special and festive event accompanied with a warm embrace and sumptuous meal.

In using this term as our project moniker, we aim to signal to communities that unwelcoming vaccines into homes or lives is a current dilemma, like many of life's dilemmas, but in unwelcoming there is a progression to re-welcoming. Salubong is intertwined with notions of acceptance, compassion and understanding, and sends the message that we will not rely on an intervention that uses the blunt tool of scientific reason or which excludes population perceptions (particularly as this has proven ineffective in relation to VH (25)). Instead, we will employ HCD (48) to co-develop an intervention together with wary families and communities to encourage them to reconsider their views on childhood vaccinations.

Our central thesis is that by drawing from local narratives, designing, refining, and ultimately testing a story-based intervention that bridges families, policymakers, health care workers (HCWs), community leaders and community health workers (following the terminology in the Philippines, where small administrative communities are termed *Barangays*, termed 'barangay health workers' (BHWs) in the context of this study), we will lay the foundation to build a meaningful campaign that revives faith in vaccines. This foundation will contribute to the sustainable prevention of outbreaks of vaccine-preventable diseases.

Study Objective

The purpose of this study is to understand local perspectives of VH in the Philippines, and to develop and pilot a health promotion intervention to address VH. Following the multiple stages of HCD, we will co-design, develop and iterate a community-based intervention (26). The developed intervention will then be piloted to assess effectiveness and acceptability.

Sub-objectives include:

1. To describe family, policymakers and community perceptions of the public health system and vaccines.
2. To gather narratives regarding childhood vaccination and health facility experiences from families, HCWs, BHWs and community leaders (including real-life dialogue between families who delay and refuse vaccinations).
3. To design and pilot a picture or video-based intervention with families and community leaders, and refine it in cooperation with BHWs.

METHODS AND DESIGN

Theoretical underpinning

We draw on the Theory of Planned Behavior (TPB) (49) to acknowledge how control beliefs (whether to vaccinate and the consequences of this decision), attitudes about vaccinations, and normative beliefs (i.e. notions of social responsibility; subjective norms influenced by social or cultural aspects) shape

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3 the intention to vaccinate and vaccination uptake. Such normative beliefs are of particular relevance in
4 this context, as vaccination uptake has a distinct social responsibility dimension. High vaccination
5 coverage is required to protect those who cannot (yet) get vaccinated, but the possibility of ‘freeloading’
6 exists for those who refuse vaccinations due to the risks for the individual, yet can still benefit from
7 others being vaccinated.
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11 A number of studies have employed the TPB to explain VH, supporting its utility and describing
12 potential starting points for interventions (50-52). A recent meta-analysis suggests that the TPB can
13 explain over 50% of the variance in intention to vaccinate, with attitudes and normative beliefs being
14 stronger predictors than perceived behavioral control (53). A 2017 systematic review of trialed vaccine
15 confidence interventions found few interventions with limited efficacy that aimed at changing
16 individuals’ attitudes or their awareness of social norms, and instead identified interventions aimed at
17 reducing barriers and therefore increasing behavioral control as a more promising pathway (22).
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22 At the core of the current VH crisis in the Philippines is a recent vaccination controversy, which
23 heavily affected the trust in HCWs, the health system, and other vaccination stakeholders (38). We
24 therefore are also informed by the Socio-Ecological Model (SEM) to understand how vaccination
25 attitudes and behaviors are shaped on individual, interpersonal, organizational, community and public
26 policy levels (54). Kumar and colleagues identified factors across all socio-ecological levels to
27 influence influenza vaccine uptake (55), and a number of authors have argued for including multiple
28 socio-ecological levels when considering how to address VH (56, 57). We will draw on the SEM to
29 gain a better understanding of how stakeholders on different levels perceive barriers or facilitators for
30 vaccinations, and how systematic changes or awareness can increase uptake.
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36 Based on these theoretical models, we developed a framework, which guides this project (see
37 **Figure 1**). With the objective to increase the individual parent’s intention to vaccinate their child, we
38 aim at empathetically addressing their attitudes, norms, and perceived behavioral control on an
39 individual level (i.e. the parent receiving the intervention). In developing this intervention, we
40 acknowledge however that factors such as organizational barriers, purveyors of information, or social
41 pressures influence vaccination perception and uptake across several levels of the SEM.
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48 **Study setting**

49 The Republic of the Philippines consists of more than 7,000 islands divided into 17 administrative
50 regions (58). This study will be conducted in the Calabarzon region, which has an estimated population
51 of 14 million (of which, 80% accounts for Roman Catholics, and the remainder include Christian
52 denominations and Muslims) including 1.2 million children under age 5; see **Figure 2** (59). Calabarzon
53 experienced a 300% increase in measles cases in 2019 as compared to 2018 (39, 60, 61). The region is
54 middle-income and predominantly consists of agriculture, fishing, manufacturing and high technology
55 industries (62, 63). Calabarzon is composed of five provinces, 20 cities, 123 municipalities and 4,018
56 *Barangays* (“small communities”). The project will be conducted in Dasmariñas City and rural
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3 municipalities of Cavite province, which were purposively selected to reflect both rural and urbanized
4 conditions, and to capture varied socio-demographic factors and health facility related experiences in
5 terms of child health and vaccinations.
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8 9 **Study Population**

10 Our study population will include community leaders (such as the *Barangay* Captains and Councilors
11 on Health), families of young children, policymakers, HCWs (municipal/city health officers, nurses,
12 and midwives), and BHWs (community-based health volunteers who help and assist nurses and
13 midwives in the delivery of essential health care programs (64)). Ethnicity, race, political orientation,
14 religion and class are not criteria for inclusion or exclusion in this study. Respondents will be eligible
15 to participate in the study if they live within Cavite Province and Dasmariñas City. Respondents must
16 be at least 18-years-old or an emancipated minor (who are 15-17 years old but with children under-5)
17 to participate. Incapacitated persons are excluded.
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24 25 **Study Design**

26 Informed by HCD (26), this study employs a mixed methods, exploratory sequential design, drawing
27 on qualitative and then quantitative methods (65). We will first use qualitative methods (IDIs and FGDs)
28 and then quantitative methods (pre-post surveys and Kano questionnaires). **Figure 3** shows the
29 summary of the five study phases (a preparatory phase followed by the four phases of HCD), along with
30 specific objectives and expected corresponding outputs. Within any given phase, iteration and repetition
31 is likely and usually necessary. The ultimate goal of the process is to ensure that the fundamental design
32 of a product or program reflects what users want and works in the setting where they will be using it.
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39 **1. Preparatory phase.**

40 We will conduct IDIs with policymakers (n=15-20) to understand the current challenges for ongoing
41 public health efforts on childhood vaccinations, perceptions of vaccines and the health system. Further,
42 we will also explore how the current COVID-19 pandemic poses challenges and opportunities to health
43 education and vaccination efforts.
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49 **2. Phase 1. Shared Appraising (EMPATHIZE PHASE):**

50 This phase of HCD aims at gathering information about how users frame a childhood vaccination
51 problem, how they situate themselves in relation to the problem (probing on socio-cultural context) and
52 learning which factors would motivate them to address the problem.
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54 **IDIs with parents of children under five:** We will conduct IDIs (n=60) with parents of children under
55 five. In each selected *barangay* in Cavite province and Dasmariñas city, we will purposively select 30
56 parents recommended by a nurse or midwife who will have reviewed vaccination records in order to
57 identify families that have delayed or refused childhood vaccines. Based on IDIs, we will build holistic
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narratives about family perceptions of the public health system and encounters with childhood vaccinations. Participants with particular vaccination or VH experiences will be asked if they are willing to be video-recorded as they tell their personal story related to vaccines. These video-recorded interviews will aid pre-development of the intervention.

IDs with HCWs and community leaders: IDs (n=10) will also be conducted among HCWs (municipal/city health officers, nurses, midwives) and community leaders (specifically the *Barangay* Captain and Councilors for Health) of the selected *barangays* to describe their experiences related to childhood vaccination in their respective community or health facility. Following each interview, the preliminary storyboards developed as a result of the initial IDs (i.e. 10-15 IDs) will be presented to participants. Participants (parents, HCWs) will be asked to conduct a think-aloud exercise while flipping through these storyboards. After each 10-15 IDs, or at the end of each week of data collection, the storyboards will be edited and refined based on participants' comments. These revised storyboards will be included in the following round of IDs for further refinement.

3. Phase 2. Life stories and Uncovering (DEFINE & IDEATE PHASE):

In this phase, end-users will suggest ideas to address the problem in collaboration with a research team.

Records Review: From the selected *barangays*, the research team will seek the help of BHWs to identify potential participants based on childhood vaccination records. We will purposively select 50 potential participants in each selected *barangay* of Cavite province and Dasmariñas City and review their vaccination record through Target Client Lists (TCL) and Individual Treatment Records (ITRs). Each case will be allocated to one of three categories:

1. *Fully Immunized Child (FIC):* Children who complete one dose of BCG, three doses of Oral Polio Vaccine (OPV), three doses of Diphtheria-Pertussis-Tetanus (DPT), three doses of Hepatitis B and 1 dose of Measles Vaccine BEFORE a child's first birthday. These are the children who received their vaccinations within the National Immunization Program (NIP) schedule.
2. *Completely Immunized Child (CIC):* Children who receive one dose of BCG, three doses of OPV, three doses of DPT, three doses of Hepatitis B and one dose of Measles Vaccine AFTER a child's first birthday. These are children who have delays in receiving vaccination based on the recommended NIP schedule.
3. *Refusal to vaccinate:* Children with the remark "refused" in the TCL will be cross-validated with the respective ITR to further review their reasons of refusal.

This process will allow us to initially stratify the participants for FGDs based on their children's vaccination status, preventing contamination and conflict during discussions. Additionally, we will use the records review to confirm delays in children's vaccination schedules, even if these children were later fully immunized.

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3 **Focus Group Discussions:** We will conduct FGDs (n=10-15) with parents, stratified (based on the
4 records review and validation of child vaccination cards) into three groups by their views: 1) in favor,
5 2) delay and 3) refusal of vaccination, to understand how these views evolved or persisted. We will
6 explore the socially held attitudes toward the public health system and vaccines. We will also conduct
7 unstratified FGDs among BHWs of the sampled *barangays* to understand their community and health
8 facility experiences on childhood vaccinations. Results of these FGDs will inform the development of
9 storyboard flip-boards that will be refined in the next phases of the project. To ensure that the design
10 itself of the intervention resonates with the intricate details of Filipino demographic and cultural
11 dynamisms, we collaborate with local animators with years of groundwork experience in developing
12 interventions in the Philippines who will accompany FGDs and graphically record ideas and concepts
13 in real-time, which can be discussed among participants.

22 4. Phase 3. Bridging and Optimizing (PROTOTYPE PHASE):

23 In this phase, prototypes and products are developed and tested in real-world settings with actual users
24 via actual delivery systems.

25 **IDIs with HCWs and BHWs:** The draft intervention, together with data from our FGDs and IDIs will
26 be presented to HCWs (municipal/city health officers, nurses, midwives) and BHWs. We will conduct
27 10 IDIs with HCWs and BHWs to get their perspectives and recommendations regarding additional
28 information that needs to be included or refined, namely related to how, when and by whom the
29 intervention should be delivered. These IDIs will guide the research team in terms of preferred medium
30 (e.g. paper versus video-based presentation) and favorable delivery approach (e.g. spoken text to
31 accompany the intervention, one-on-one vs. group delivery, a stand-alone activity vs. nested in existing
32 outreach, etc.). The result of this phase will allow us to further refine and finalize the intervention, and
33 to determine the “point of contact” for the delivery of the intervention in Phase 4.

42 5. Phase 4. Navigating and Gaining (TESTING PHASE):

43 In this phase, the intervention is introduced to and tested with a larger sample, and large-scale feedback
44 is sought.

45 **Pilot Testing:** We will test the chosen model (intervention + point of contact) in 20-30 *barangays*
46 (divided into urban and rural areas) selected in the previous phases. **Figure 4** shows the detailed design
47 of the pilot phase. The research team will identify and train the BHWs as “champions” of childhood
48 vaccination, an approach that has been critical in the success of several maternal and child health
49 programs in the sub-Saharan Africa (66). These champions will then deliver the intervention in specific
50 “points of contact” (e.g. one-on-one vs. group delivery of the videos; a stand-alone activity vs. nested
51 in existing outreach) as determined in Phase 3. Before and after the BHW delivers the intervention, the
52 study team will administer short surveys. The pre- and post-intervention surveys (based on best
53 practices for measuring VH (8, 67)) will quantify participants’ knowledge, attitudes, and practices
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3 regarding vaccination and VH, and the post-intervention survey will additionally assess any changes in
4 knowledge or attitude. We will revise the survey tool based on outcome from phases one and three.

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6 **Intervention Feedback:** After pilot testing, 200 participants (100 participants randomly sampled from
7 each the urban and rural arms) will be asked a short series of closed-ended questions about features of
8 the intervention and feedback on how the intervention made the user feel based on Kano analysis
9 methodology (attractive vs. essential) (68). After the Kano survey, 25 participants in each area (n=50)
10 will be purposively selected based on critical case sampling and invited to an FGD (n=3-5) to identify
11 comprehension problems and to seek further feedback in smaller groups. Since this study only aims to
12 pilot test the developed intervention, the feedback on the intervention will be useful for further
13 refinement before future trials.
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20 **Patient and Public Involvement**

21 Neither clients nor the public were directly involved in the design, recruitment nor conduct of the study;
22 their only involvement is as research participants. However, following the tenets of HCD, the
23 intervention is co-developed with research participants over the entire course of the study. Participants
24 are not involved in initial recruitment, but those participants completing an IDI may be asked to provide
25 contact details of others who might be interested to participate in the study. Participants are not involved
26 in data analysis or the dissemination of findings. The final results will be shared with policy makers,
27 health programmers, and other stakeholders via roundtable discussion, and in the form of articles
28 published in peer-reviewed journals or policy briefs. Research participants will be given access to the
29 final intervention and be informed through their BHWs and other channels embedded in the community,
30 and have the option to contact study staff for a detailed description of study findings at any time.
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39 **Sample Sizes and Sampling Technique**

40 We will partner with HCWs and BHWs who keep lists of mothers of young children to identify eligible
41 households, particularly families with various experiences or perspectives on vaccines in order to help
42 us capture a range of insights in terms of vaccine attitudes and behaviors.
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45 **Qualitative component:** Purposive sampling will be utilized for the qualitative components of
46 the Pre-phase and Phases 1-3 to gain maximum range of perspectives and depth of information; sample
47 size estimates are guided by saturation estimates and outlined in **Figure 1** (69, 70).
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50 **Quantitative component:** During Phase 4 we will rely on household survey data. The estimated
51 sample size per group (urban and rural arms) is 300, which will result in a total of 600 survey
52 respondents, which offers a binary outcome margin of error of +/- 7% within each group at a 95%
53 confidence level, and a design effect of 1.5. To select the study sites, a multi-stage stratified random
54 sampling frame will be used. The sampling scheme is illustrated in **Figure 5**.
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58 From each selected area in Dasmariñas City and in a rural municipality in Cavite, 10-15
59 *barangays* will be selected purposively: All *barangays* will be ranked from highest to lowest number
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3 of annual births in the most recent report available (preferably 2018-2019) in the Rural Health Unit/City
4 Health Office, and the cumulative sum of the number of births will be computed. We will conduct the
5 survey in those *barangays*, which reported at least 300 births, or in a maximum of 15 *barangays* with
6 the highest number of births, whichever threshold is reached first.
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9 In each of the *barangays* to be surveyed, a list of the mothers with children under one year old
10 will be obtained from the midwife or the BHWs. All mothers listed will be invited to participate in the
11 study. In the event that the number of interviewed mothers is less than 300, the survey will be continued
12 in the next *barangay* on the list.
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16 17 **Data Collection and Data Collector Training**

18 Before the onset of data collection, we will contact Department of Health (DOH) officials (national,
19 regional and provincial offices) to explain study objectives and procedures, and to discuss and resolve
20 any concerns regarding data collection. We will also seek their permission and support to conduct the
21 project in the selected primary health care facilities. Official communications explaining the nature,
22 study objectives and procedures will be sent to local government executives and community leaders.
23 Spot maps of the community, if available, will be requested from the Rural Health Units or community
24 health centers. The spot maps will be used to locate prospective families in communities. Courtesy calls
25 to local officials and leaders will be made to seek their support to conduct the project in their respective
26 localities.
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33 The research team will conduct the qualitative interviews, FGDs and quantitative surveys with
34 the assistance of field interviewers (FIs) in either English or Filipino, depending on the preference of
35 the participant. FIs will be fluent in English and Filipino with bachelor's level education in nursing,
36 midwifery or social sciences. FIs will be trained for five days to collect the data with instruments and
37 online platforms for data collection for this study. Training topics will include modules on VH,
38 interviewing and/or surveying techniques, research ethics, software resources, Kano analysis and
39 qualitative and quantitative methods.
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46 **Data Collection in times of Covid-19**

47 All IDIs and FGDs were initially planned to be conducted in-person. However, the ongoing pandemic
48 and measures taken to curb infection rates pose unique challenges to conducting research. Considering
49 the time-sensitive nature of this project, we have developed new operating procedures for conducting
50 online data collection, to ensure minimal risk for participants and the research team concerning COVID-
51 19, and in compliance with the recommendations by the European Medicines Agency (71) and the
52 Philippines Inter-Agency Task Force (IATF) (72). This includes informed consent processes and the
53 engagement of research team members who are unable to travel to the study site. Until the situation
54 changes, only strictly necessary visits will be performed at sites.
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Remote recruitment and consenting: We will contact prospective participants via email or a phone call to briefly introduce the study aims and invite them to participate. After this initial phone call or email, we will set an appointment for the comprehensive discussion of the study and to answer questions. An information sheet (including study aims, procedures, and expected risks and benefits) and consent forms will be sent to potential respondents in advance via email or courier. If participants agree to enroll in the study, we will ask them to sign the consent form during a recorded Skype or Zoom video call, and to take a picture while holding the signed consent form. The signed consent forms will be returned to the study team as scanned or photographed copy, or per courier (as preferred by the participant; courier costs will be covered by the study team). Participants will receive duplicate copies with the signature of the interviewer per courier.

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Focus Group Discussions: At the time of writing (October 2020), we continue to hope that by the beginning of 2021, when we plan to conduct FGDs, small group discussions in person with appropriate distance will be possible. However, we will conduct remote FGDs if necessary, to ensure the safety of participants and research team. In this case, we will draw on the assistance of local stakeholders (HCWs, BHWs etc.) to orient participants on group discussions via a web-based platform.

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Systematic Debriefings: As a number of research team members are not be able to travel to the study site due to Covid-19 travel restrictions, we will employ remote systematic debriefings (73) to discuss and triangulate findings, to amend interview guides and to refine lines of inquiry.

33 34 35 **DATA PROTECTION AND ANALYSIS**

36 37 **Data quality checks and cleaning process**

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Most of the data in the project will be primary and collected by the research team. Interviews will be audio-recorded using digital or online audio-recorders. All recorded information will be transcribed verbatim and translated into English. For all qualitative data, the research team collecting and analyzing the qualitative data will be directly responsible for quality checks of audio recordings, interview notes and qualitative transcripts. Random checks of transcripts will be conducted to support quality.

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All quantitative data will be entered into a customized Microsoft Access data entry system with a built-in validation program. The data management unit (DMU) of the Research Institute for Tropical Medicine (RITM)'s Department of Epidemiology and Biostatistics (DEBS) will be responsible for quality checks. DMU staff will reach out to the SALUBONG team in the event of questions or data inconsistencies.

52 53 54 **Data storage and protection**

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Both primary and secondary data (quantitative and qualitative) collected by the research team will be stored according to German and Philippine regulations. At the point of data collection, unique codes will be assigned to all participants. A master sheet linking the code with identifying information (including a name and, when feasible, contact information) will be kept in a secure (locked/password

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3 protected) location that is accessible to the investigators. Only the research coordinator will have access
4 to and manage this master sheet - across quantitative and qualitative data. The master sheet will facilitate
5 the process of revoking information should a respondent decide (at a later point) that they wish to have
6 their data removed from the study. Further, audiotaped interviews will also be stored in
7 locked/password-protected computers controlled by the research coordinator. All data will be accessible
8 only to those within the research team, but can be made available to others upon reasonable request
9 after approval from ethical review boards.
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16 **Data analysis**

17 While the work is divided into phases, the ultimate aim of this study is to analyze and apply findings
18 continuously across phases to address the overall study objective. The PIs and Co-Is will be directly
19 responsible for the triangulation of findings across data sources and the development of an integrated
20 interpretative analysis.
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25 **Qualitative analysis**

26 The qualitative component of this study will be analyzed based on constructivist grounded theory as
27 outlined by Charmaz (74). The application of this approach will help us generate theories on why
28 parents would or would not agree to childhood vaccinations, and it will allow us to investigate the
29 constructions and underlying processes of parents' perceptions, so that informed and relevant
30 approaches can be applied to help resolve highly salient concerns. NVivo Pro 12 (QSR International
31 Pty Ltd. Version 12, 2018) will support qualitative analysis.
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38 **Quantitative Analysis**

39 The quantitative component of this study will be analyzed using descriptive and inferential approaches,
40 facilitated by Stata statistical software (*Stata Statistical Software: Release 13*. College Station, TX:
41 StataCorp LP). The effect of the intervention on the knowledge, attitude and practices scores will be
42 analyzed using *t*-test inferential statistics. Knowledge and practices scores will be calculated using a
43 point marking system, (1 point for each correct and 0 for each false answer or no answer). Further, we
44 will calculate whether knowledge has increased in total (i.e. the total points in the suggested approach
45 are higher pre- versus post-intervention) and in which particular domain knowledge has increased. Items
46 on attitudes (Likert scale) will be analyzed using descriptive statistics. Additionally, the Likert scale
47 will be analyzed inferentially by coding answers from 1 (strongly disagree) to 5 (strongly agree) and
48 drawing on parametrical (paired *t*-test) or non-parametrical (*Wilcoxon signed rank test*) approaches,
49 depending on sample characteristics.
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57 Kano-style questions place user ratings of product or service features on a two-dimensional
58 scale (38). One dimension is satisfaction, which can range from frustration to delight. The other is
59 functionality, which ranges from not functional to highly effective. Hence, Kano analysis of post-
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3 intervention survey responses to Kano-style questions will be used to prioritize resource allocation in
4 improving the intervention functionality, with the intention of causally affecting customers' satisfaction
5 (38). The results will then be used for the revision or re-development of intervention features for future,
6 large-scale testing.
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10 **DISCUSSION**

11 Although vaccination uptake and VH are central parts of the current public health and global health
12 discourses, few interventions have proven efficacious in sustainably increasing vaccine confidence. In
13 this study protocol, we explain how we will work with clients, providers and policymakers to develop
14 a narrative-based intervention to increase vaccine confidence in the Philippines. Guided by the tenets
15 of HCD, we will co-develop and iterate this intervention to address the needs and expectations of those
16 it is developed to support.
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22 HCD is a promising new approach in the development of global health interventions (48). In our
23 application of this methodology we will move beyond the way it currently is often applied and extend
24 the understanding of 'clients' (following terminology from HCD field understood here as the end-users
25 of the intervention) to those involved across several levels including: parents who are deciding whether
26 to vaccinate their children (clients in the sense of 'target population'), HCWS and BHWs who interact
27 with parents (clients in the sense of those who will – or will not – incorporate the intervention into their
28 service delivery) and policymakers and key vaccination stakeholders whose decisions and policies
29 shape the vaccination landscape (clients in the sense of those who decide the implementation of large
30 scale interventions).
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36 We also expand the existing body of literature on HCD-based vaccine confidence interventions by
37 drawing on a theoretical framework to inform our sampling and design procedures and using well-
38 established behavior change theories to guide data collection activities. This for example includes
39 identifying topics to be probed for in IDIs (e.g. perceived behavioral control about getting a child
40 vaccinated), but also those topics with a clearly social dimension to be focused on in FGDs (e.g. social
41 responsibility of vaccinations). We therefore do not employ a purely inductive approach for conducting
42 qualitative research, as is common in global health qualitative research and HCD approaches, but allow
43 for the existing literature and established theories to guide our approach.
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49 Previous studies demonstrate that decision-making surrounding vaccine is complex, and that those
50 who provide vaccine-related information are in a unique position to sway or break vaccine acceptance
51 (75, 76). A high general trust in the health authorities and providers that decide what vaccines to
52 introduce is a deciding factor in vaccine uptake (77). However, trust and source credibility plays a
53 pivotal role not only in direct communication between healthcare providers and their clients, but also
54 across all levels: Health-related controversies have been shown to disrupt the trust healthcare providers
55 have in political agents, or implementing government institutions have in those who make the respective
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3 policies (38). Our inclusion of stakeholders from all levels in the design process will support our ability
4 to identify pathways to rebuild both confidence in vaccines and trust in the general system.
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6 The Dengvaxia-controversy in the Philippines highlights the pace and reach of misinformation
7 regarding the effectiveness and safety of a vaccine, causing a drop in general vaccine confidence and
8 rolling back decades of immunization work (36, 38). Dayrit and colleagues (38) stated that the
9 communication gaps among the health authorities themselves, as well as a lack of transparency,
10 proliferation of non-scientific speakers in the mainstream media, and distorted messages in social media
11 played a key role in the panic felt among Filipino families. The Dengvaxia controversy was exacerbated
12 by an exceptionally rapid spread of (mis)information via social media channels (36, 38). In the broader
13 context of vaccination, factually false or misleading information shared in online forums or via social
14 media, often in the form of short quotes or emotionalized images, is considered a central contributor to
15 anti-vaccination narratives (78). In many cases, countering these narratives is challenging as it requires
16 longer and complex explanations of vaccination risks and benefits, which are not as easily spread
17 through social media (79, 80). We are taking this into consideration while developing our narrative-
18 based intervention in part or entirely in a form that can be easily relayed (e.g. as a short video or even
19 a GIF). With vaccine confidence or uptake interventions delivered via social media showing promising
20 results (81, 82), we explicitly include this notion in our HCD-based discussion of promising delivery
21 strategies.
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23 The Dengvaxia controversy has been repeatedly linked to the steep decline in vaccination rates
24 and vaccine confidence in the Philippines (3, 36). However, to the best of our knowledge, there so far
25 has not been any qualitative exploration of how this case has shaped narratives about vaccines, health
26 programming and the health system in general. Furthermore, there has been remarkably little research
27 highlighting Philippine perspectives on how to move forward after the controversy. The SALUBONG
28 project will thus provide robust, culturally-attuned data that can inform future programs and policies to
29 rebuild trust and confidence in relation to vaccines (22, 83, 84).
30

31 Finally, similar to many research projects, the ongoing COVID-19 pandemic has forced us to
32 reconsider the way we collect data to ensure the safety of our participants and study team. We have
33 developed new approaches to remotely undertake this study. In close cooperation with the ethical
34 review boards evaluating this project, we have developed protocols to ensure that recruitment, consent
35 and rapport building are supported despite the remote nature of data collection. We hope that the
36 procedures outlined in this protocol will spark a discourse on how to conduct ethical and trustworthy
37 research during a pandemic, and that our experiences will allow us to further develop and validate
38 methodological approaches.
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40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 **DECLARATIONS** 58 59 60

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11 contributed to and edited the protocol paper. KB participated in the design and writing of the qualitative
12 components and edited the protocol paper. MA, JLG, VE, JL, TAB, MPD, JRG and NDC participated
13 setting up local implementation systems including development of standard operating procedures for
14 online data collection and edited the protocol paper. MT advised on the quantitative study design,
15 sample size calculation, local study implementation and edited the protocol paper. MA advised on the
16 HCD process and edited the protocol paper. RC advised on the quantitative study design, sample size
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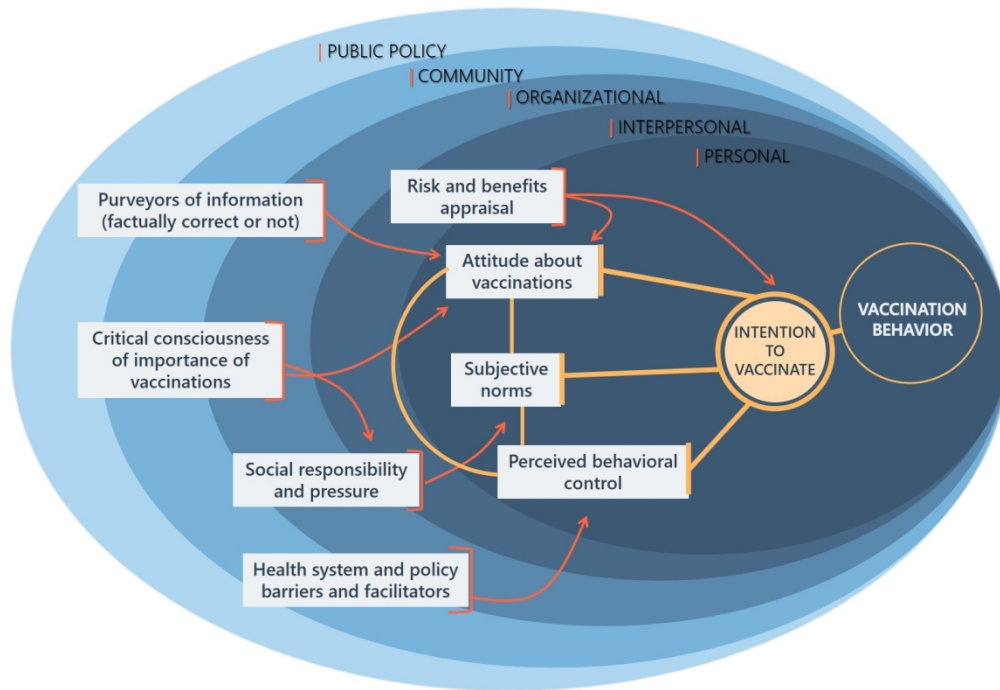


Figure 1. Preliminary conceptualization of different influences on vaccination behavior and VH to ground intervention development.

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Figure 2. Location of Calabarzon Region included in the Project SALUBONG in the Philippines, 2020-2021. Map credits: a) Map of the Philippines showing the location of Calabarzon region; and, b) Political map of Calabarzon, courtesy of www.wikipedia.com (CC BY-SA3.0 and CC BY 2.5, respectively)

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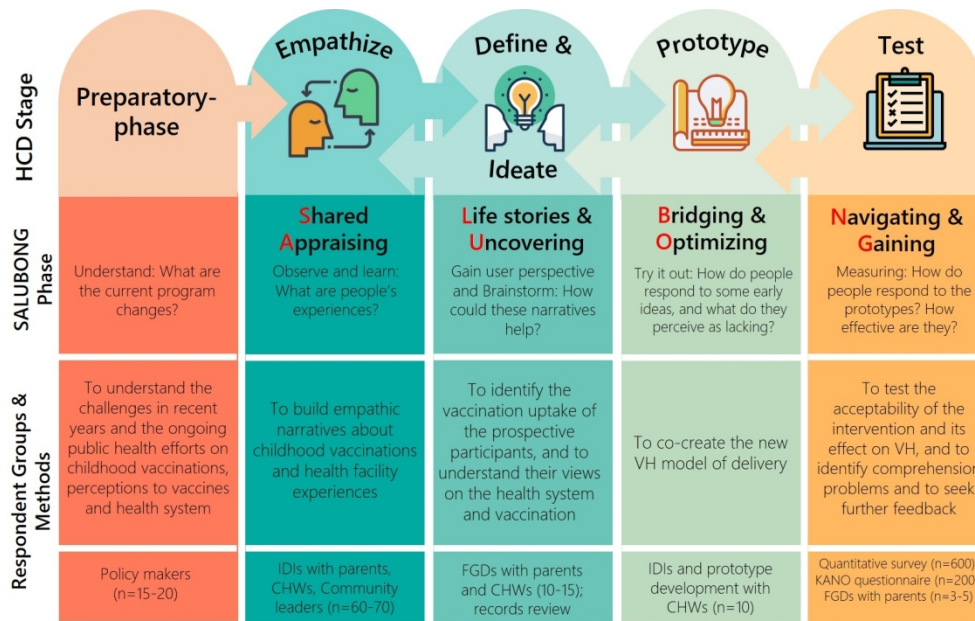


Figure 3. Summary of the Project SALUBONG guided by the human-centered design, 2020-2021. Icon credits: all icons made by Freepik (<http://www.freepik.com>) courtesy of www.flaticon.com.

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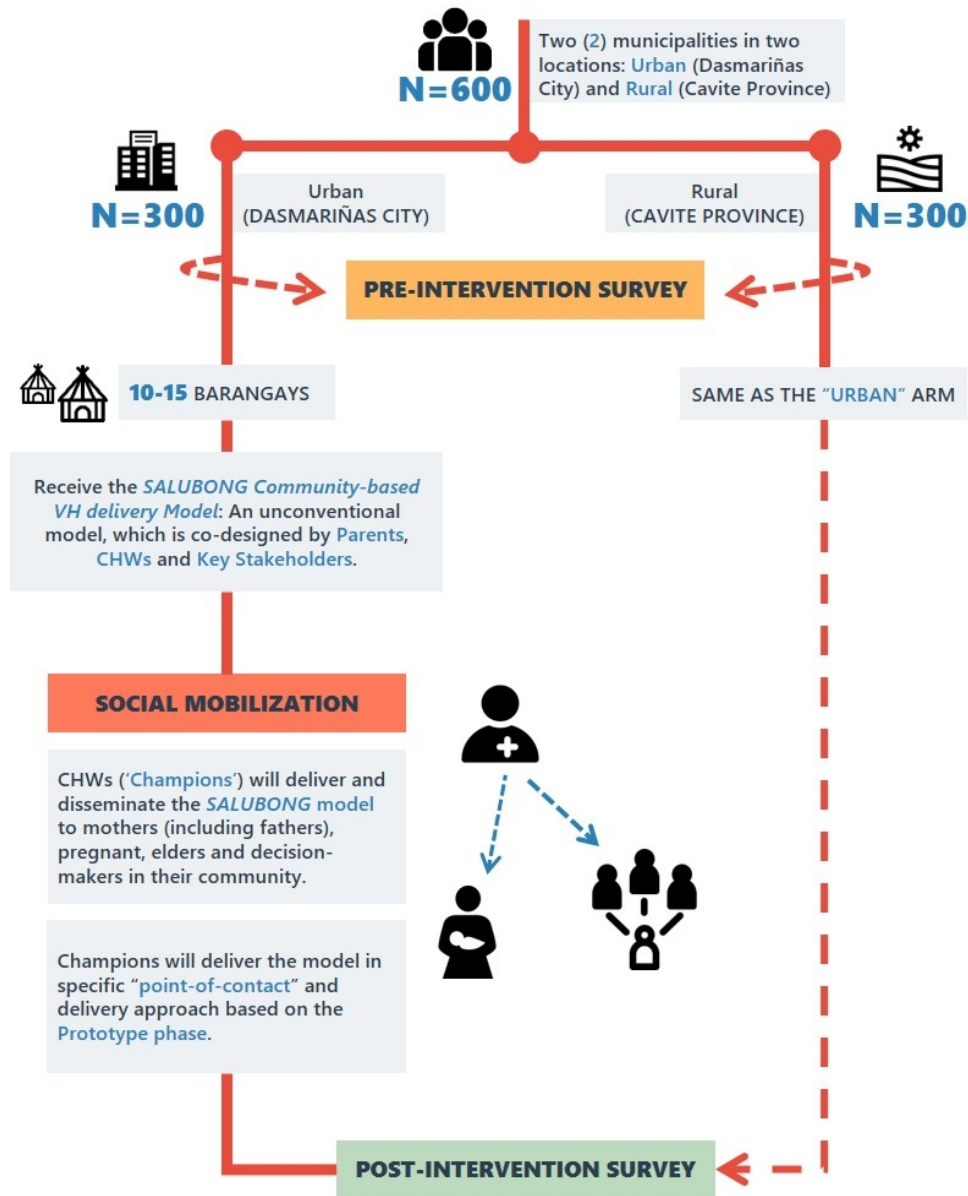


Figure 4. Study Design of Phase 4: "Navigating and Gaining". Icon credits: all icons made by Freepik (<http://www.freepik.com>) courtesy of www.flaticon.com.

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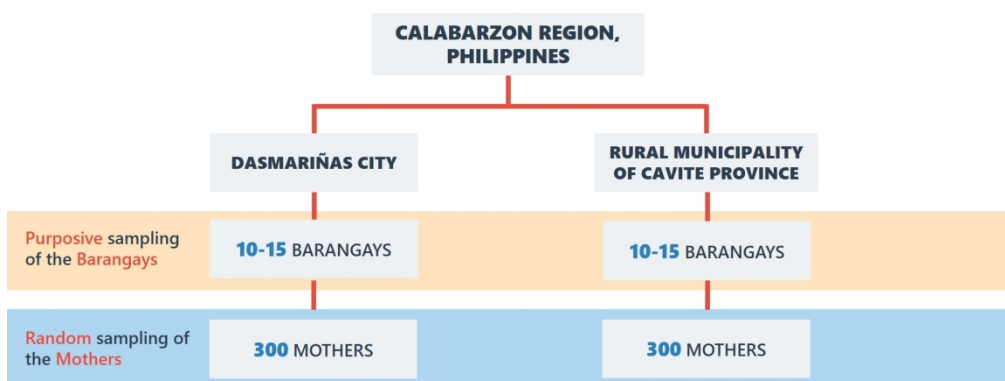


Figure 5. Schematic diagram of the sampling design of Phase 4.

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HEIDELBERG UNIVERSITY HOSPITAL

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06 November 2020

ADRIAN ALDCROFT

Editor, BMJ Open

Dear Mr. Aldcroft,

On behalf of my co-authors and I, please see enclosed our protocol paper entitled: "Project SALUBONG: Using human-centered design to build vaccine confidence via empathy and narratives in the Philippines" for your consideration in *BMJ Open*

Since the onset of a dengue vaccine controversy in late 2017, vaccine confidence has plummeted in the Philippines, leading to a measles and polio outbreak in early 2019. This protocol outlines a human-centered design approach to co-create and test an intervention that addresses vaccine hesitancy via narrative and empathy with and among families and health care workers.

We are confirming that this study is ongoing, and have not completed participant recruitment. Further, this paper is original, has not been submitted for review in other journals, and has been approved by all authors. We remain available to answer any questions you may have.

Yours sincerely,

SHANNON A. MCMAHON, PHD

Olympia Morata Assistant Professor at the HIGH, Heidelberg University
Associate at the School of Public Health, John Hopkins University

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BMJ Open

How can Human-Centered Design build a story-based video intervention that addresses vaccine hesitancy and bolsters vaccine confidence in the Philippines? A mixed-methods protocol for project SALUBONG

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Title:

How can Human-Centered Design build a story-based video intervention that addresses vaccine hesitancy and bolsters vaccine confidence in the Philippines? A mixed-methods protocol for project SALUBONG

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ABSTRACT

Introduction: Since the onset of a dengue vaccine controversy in late 2017, vaccine confidence has plummeted in the Philippines, leading to measles and polio outbreaks in early 2019. This protocol outlines a human-centered design (HCD) approach to co-create and test an intervention that addresses vaccine hesitancy (VH) via narrative and empathy with and among families and health care workers.

Methods and Analysis: “Salubong” is a Filipino term that means to welcome someone back into one’s life, reinforcing notions of family ties and friendships. We apply this sentiment to vaccines. Following the phases of HCD, guided by a theoretical framework, and drawing from locally-held understandings of faith and acceptance, we will conduct in-depth interviews (IDIs) and focus group discussions (FGDs) in rural and urban Filipino communities that witnessed dramatic increases in measles cases in recent years. During qualitative engagements with caretakers, providers, and policymakers, we will collect narratives about family and community perceptions of childhood vaccinations, public health systems, and opportunities to restore faith. IDIs and FGDs will continuously inform the development of (and delivery mechanisms for) story-based interventions. Once developed, we will test our co-created intervention(s) among 800 caretakers and administer a VH questionnaire prior to and immediately following the intervention encounter. We will use the feedback gained through the survey and Kano-style questionnaires to further refine the intervention. Considering the data collection challenges posed by the ongoing COVID-19 pandemic, we have developed workarounds to conduct data collection primarily online. We will use systematic online debriefings to facilitate comprehensive participation of the full research team.

Ethics and Dissemination: Ethical approval has been granted by the Institutional Review Board of the Research Institute for Tropical Medicine (No. 2019-44) and ethical commission of Heidelberg University, Faculty of Medicine (S-833/2019). Study findings will be disseminated in scientific conferences and published in peer-reviewed journals.

Strengths and Limitations of the Study:

- Project SALUBONG directly responds to calls in the literature for more community-based research on how VH can be addressed and how trust in the public health sector can be bolstered.
- Guided by families and communities, we will co-create an empathic intervention that places the health of children, the concerns of parents, and the needs of HCWs at the center to support trust in vaccines.
- Findings will inform future vaccine confidence efforts and contribute to broader policy discussions regarding VH in the Philippines and globally.
- Due to the COVID-19 pandemic, we have shifted some of our data collection online, and our study will be among the first in this setting to outline opportunities and pitfalls of remote qualitative research.

BACKGROUND

Vaccines are a cost-effective and safe way to prevent millions of deaths annually (1, 2). Although vaccines represent a seminal achievement in terms of mitigating disease, confidence in vaccines has decreased in many countries in recent years (3). This drop in confidence has contributed to stagnation or decreases in immunization rates, which in turn has resulted in outbreaks of previously controlled or domestically eliminated diseases such as measles and polio (4-7).

In 2019, the World Health Organization included vaccine hesitancy (VH) – the “delay in acceptance or refusal of vaccines despite availability of vaccination services” (8) – in its list of the top 10 global health threats requiring high-level attention and research (9). Literature that has sought to tease out the causes of VH emphasizes the ‘5Cs’: complacency (regarding the severity of vaccine-preventable illness), constraints (psychological, financial or structural barriers), a lack of confidence (in vaccines and the broader health system), calculation (the degree to which individuals search for information about vaccines), and collective responsibility (a willingness to protect others) (10). More recently, scholars have started to consider the role of trust and unequal power dynamics in undermining vaccine uptake, describing how families have lost trust in the health system and feel that they have no voice in the face of state-mandated decisions or directives about vaccines (11-14).

Effective and efficient solutions to address VH are urgently needed, not only to mitigate the re-emergence of vaccine-preventable diseases (such as polio or measles (6, 15-17)), but also because the development and uptake of an effective vaccine is a cornerstone of controlling the ongoing COVID-19 pandemic (18, 19).

To date there is limited guidance in terms of how to successfully combat VH, most of which stems from high-income settings (20, 21). At the individual level, changing people’s attitudes about vaccines has proven difficult, and successful interventions are limited (22). At the governance level, policymakers in high-income countries have considered or enacted laws to limit access rights and to punish those who reject vaccines (on non-medical grounds) by denying unvaccinated children admission to elementary schools and public playgrounds, and charging parents substantial fines (23). At the health system level, interventions involving medical professionals have considered how to broach the topic of vaccines in a non-judgmental but affirmative manner, how to listen to parents' vaccine decision-making (24), and how to facilitate vaccination directly through reminders, prompts, or by reducing logistical barriers (22).

More recent studies also highlight opportunities in terms of video-based vaccine promotion (24) and educational messages in the form of graphic pictures and anecdotes (focusing on the consequences of not getting a child vaccinated) (25). Several studies have employed Human-Centered Design (HCD), an approach to co-develop interventions with end-users (26). This methodology has led to the creation of mobile apps, education materials, provider guidelines, and the re-design of a health facility, all in the interest of bolstering vaccine uptake (24, 27-31). Results of these HCD studies suggest that the approach supports stronger patient and community engagement (24, 27, 30).

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3 Relatively little attention has been paid to VH and ways to address VH in low- and middle-
4 income countries (LMICs) (14, 21, 24, 25). This is particularly problematic for at least three reasons:
5 1) a majority of the world's vaccine-preventable deaths occur in LMICs (32); 2) public health and
6 immunization structures in LMICs are insufficiently equipped to address VH while rolling out national
7 immunization campaigns and fielding other child health challenges; and 3) in the event of an outbreak
8 of a vaccine-preventable disease, survival rates and containment possibilities are markedly reduced in
9 LMICs where poor structural conditions and extreme poverty can exacerbate pre-existing
10 vulnerabilities (33-35).

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16 The Philippines, an archipelago with a population of more than 105 million, is among the
17 LMICs that are currently experiencing an unprecedented erosion of public trust in childhood
18 vaccinations (36-38). Vaccine confidence fell from 93% of adults "strongly agreeing" to the importance
19 of vaccination in 2015 to 32% in 2018 (36). This is reflected in measles vaccination rates of children
20 under-five, which fell from 88% in 2014 to 55% in 2018 (39). Results from a small 2019 study
21 conducted in two urban communities in Manila, the capital of the Philippines, found that 36% of
22 responding parents had hesitated to give at least one vaccine and/or refused at least one vaccine for their
23 children (40). These sharp declines are associated with a dengue vaccine controversy in 2017 and the
24 ensuing misinformation that eroded faith in vaccine safety (36-38, 41). This erosion led to the country
25 losing its 19-year polio-free status, and sparked measles outbreaks across several islands in 2019, with
26 47,871 cases including 632 deaths (as compared to 2,789 cases and 25 reported deaths in 2018) (39, 41,
27 42). The Department of Health (DOH) of the Philippines has therefore made it a priority to win back
28 the trust and confidence of the public in vaccination (43). The DOH - in partnership with the World
29 Health Organization and UNICEF - has strengthened routine immunization via the launch of door-to-
30 door immunization campaigns to increase vaccine uptake and to reach unvaccinated children (16, 44).
31 Although recent data has indicated signs of possible recovery, with the proportion of people agreeing
32 to the importance of vaccines increasing, gains in terms of perceived vaccine safety and effectiveness
33 are less substantial (3). More tailored and innovative initiatives are necessary to regain community trust
34 in vaccines.

45 46 47 **The SALUBONG Intervention**

48 "Salubong", the moniker for this research, is a Filipino term that means to welcome someone into one's
49 home or life. In the Philippines, the largest predominantly Christian country in Asia, the term Salubong
50 describes a Catholic dramatization of the resurrected Jesus encountering his mother Mary, which is a
51 central part of the Easter week across the Philippines. This encounter, which is not liturgically accounted
52 for, culminates in Jesus – if briefly – reuniting with his mother (45). From this, Salubong has developed
53 into a Filipino tradition that celebrates the beauty of re-connecting with important figures from one's
54 past. The Salubong tradition is commonly observed at international airports throughout the Philippines,
55 where many Filipinos are waiting for their loved ones to return home after having sought employment
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3 abroad (the diaspora has fostered an undertone of longing and anticipation in many Filipino homes) (46,
4 47). The homecoming of a loved one is viewed as a special and festive event accompanied with a warm
5 embrace and sumptuous meal.
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8 In using this term as our project moniker, we aim to signal to communities that unwelcoming
9 vaccines into homes or lives is a current dilemma, like many of life's dilemmas, but in unwelcoming
10 there is a progression to re-welcoming. Salubong is intertwined with notions of acceptance, compassion
11 and understanding, and sends the message that we will not rely on an intervention that uses the blunt
12 tool of scientific reason or which excludes population perceptions (particularly as this has proven
13 ineffective in relation to VH (25)). Instead, we will employ HCD (48) to co-develop an intervention
14 together with wary families and communities to encourage them to reconsider their views on childhood
15 vaccinations.
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20 Our central thesis is that by drawing from local narratives, designing, refining, and ultimately
21 testing a story-based intervention that bridges caretakers (e.g., parents, other family members, legal
22 guardians), policymakers, health care workers (HCWs), community leaders, and community health
23 workers (following the terminology in the Philippines, where small administrative communities are
24 termed *barangays*, termed 'barangay health workers' (BHWs) in the context of this study), we will lay
25 the foundation to build a meaningful campaign that revives faith in vaccines. This foundation will
26 contribute to the sustainable prevention of outbreaks of vaccine-preventable diseases.
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33 **Study Objective**

34 The purpose of this study is to understand local perspectives of VH in the Philippines, and to develop
35 and pilot a health promotion intervention to address VH. Following the multiple stages of HCD, we
36 will co-design, develop, and iterate a community-based intervention (26). The developed intervention
37 will then be piloted to assess effectiveness and acceptability.
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41 Sub-objectives include:

- 42 1. To describe caretakers, policymakers, and community perceptions of the public health system
43 and vaccines.
- 44 2. To gather narratives regarding childhood vaccination and health facility experiences from
45 caretakers, HCWs, BHWs, and community leaders (including real-life dialogue between
46 families who delay and refuse vaccinations).
- 47 3. To design, pilot, refine, and assess the immediate impact of a picture or video-based
48 intervention with caretakers and community stakeholders.
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55 **METHODS AND DESIGN**

56 **Theoretical underpinning**

57 We draw on the Theory of Planned Behavior (TPB) (49) to acknowledge how control beliefs (whether
58 to vaccinate and the consequences of this decision), attitudes about vaccinations, and normative beliefs
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3 (i.e. notions of social responsibility; subjective norms influenced by social or cultural aspects) shape
4 the intention to vaccinate and vaccination uptake. Such normative beliefs are of particular relevance in
5 this context, as vaccination uptake has a distinct social responsibility dimension. High vaccination
6 coverage is required to protect those who cannot (yet) get vaccinated, but the possibility of ‘freeloading’
7 exists for those who refuse vaccinations due to the risks for the individual, yet can still benefit from
8 others being vaccinated.
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12 A number of studies have employed the TPB to explain VH, supporting its utility and describing
13 potential starting points for interventions (50-52). A recent meta-analysis suggests that the TPB can
14 explain over 50% of the variance in intention to vaccinate, with attitudes and normative beliefs being
15 stronger predictors than perceived behavioral control (53). A 2017 systematic review of trialed vaccine
16 confidence interventions found few interventions with limited efficacy that aimed at changing
17 individuals’ attitudes or their awareness of social norms, and instead identified interventions aimed at
18 reducing barriers and therefore increasing behavioral control as a more promising pathway (22).
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24 At the core of the current VH crisis in the Philippines is a recent vaccination controversy, which
25 heavily affected the trust in HCWs, the health system, and other vaccination stakeholders (38). We
26 therefore are also informed by the Social Ecological Model (SEM) to understand how vaccination
27 attitudes and behaviors are shaped on individual, interpersonal, organizational, community and public
28 policy levels (54). Kumar and colleagues identified factors across all socio-ecological levels that affect
29 influenza vaccine uptake (55), and a number of authors have argued for including multiple socio-
30 ecological levels when considering how to address VH (56, 57). We will draw on the SEM to gain a
31 better understanding of how stakeholders on different levels perceive barriers or facilitators for
32 vaccinations, and how systematic changes or awareness can increase uptake.
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38 Based on these theoretical models, we developed a framework which guides this project (see
39 **Figure 1**). With the objective to increase individual caretakers’ intention to vaccinate their child, we
40 aim at empathetically addressing their attitudes, norms, and perceived behavioral control on an
41 individual level (i.e., the caretaker receiving the intervention). In developing this intervention, we
42 however acknowledge that factors such as organizational barriers, purveyors of information, or social
43 pressures influence vaccination perception and uptake across several levels of the SEM.
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49 **Study setting**

50 The Republic of the Philippines consists of more than 7,000 islands divided into 17 administrative
51 regions (58). This study will be conducted in the Calabarzon region, which has an estimated population
52 of 14 million (with approximately 80% being of Roman Catholic faith, and the remaining 20%
53 predominantly belonging to Christian and Muslim denominations), including 1.2 million children
54 under-five (see **Figure 2**) (59). Calabarzon experienced a 300% increase in measles cases in 2019 as
55 compared to 2018 (39, 60, 61). The region is middle-income and predominantly consists of agriculture,
56 fishing, manufacturing and high technology industries (62, 63). Calabarzon is composed of five
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3 provinces, 20 cities, 123 municipalities and 4,018 *barangays* (“small communities”). The project will
4 be conducted in Dasmariñas City and rural municipalities of Cavite province, which were purposively
5 selected to reflect both rural and urbanized conditions, and to capture varied socio-demographic factors
6 and health facility related experiences in terms of child health and vaccinations.
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10 11 **Study Population**

12 Our study population will include community leaders (such as the *barangay* captains and councilors on
13 health), caretakers of young children, policymakers, HCWs (municipal/city health officers, nurses, and
14 midwives), and BHWs (community-based health volunteers who help and assist nurses and midwives
15 in the delivery of essential health care programs (64)). Ethnicity, race, political orientation, religion and
16 class are not criteria for inclusion or exclusion in this study. Caretakers, HCWs, BHWs and community
17 leaders will be eligible to participate in the study if they live within Cavite Province and Dasmariñas
18 City. Participants must be at least 18-years-old or an emancipated minor (who are 15-17 years old but
19 with children under-five) to participate. Incapacitated persons are excluded.
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26 27 **Study Design**

28 Informed by HCD (26), this study employs a mixed methods, exploratory sequential design, drawing
29 on qualitative and then quantitative methods (65). We will first use qualitative methods (IDIs and FGDs)
30 and then quantitative methods (pre-post surveys and Kano questionnaires). **Figure 3** shows the
31 summary of the five study phases (a preparatory phase followed by the four phases of HCD), along with
32 specific objectives and expected corresponding outputs. Within any given phase, iteration and repetition
33 will typically be necessary. The ultimate goal of the process is to ensure that the fundamental design of
34 a product or program reflects what users want and works in the setting where they will be using it. Data
35 collection for this study will occur from September 2020 through August 2021.
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42 43 **Sample Sizes and Sampling Technique**

44 We will partner with HCWs and BHWs who keep lists of caretakers of young children to identify
45 eligible households, particularly families with various experiences or perspectives on vaccines in order
46 to help us capture a range of insights in terms of vaccine attitudes and behaviors.
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50 **Qualitative component:** Purposive sampling will be utilized for the qualitative components of the Pre-
51 phase and Phases 1-3 to gain a maximum range of perspectives and depth of information; sample size
52 estimates are guided by saturation estimates and outlined in **Figure 3** (66, 67). To select the study sites,
53 initially, all municipalities of Cavite province and Districts in Dasmariñas City will be listed. We will
54 select one municipality in Cavite Province and one district in Dasmariñas City with the lowest Expanded
55 Program on Immunization coverage for the period of 2018-2019; this approach maximizes the
56 probability of finding caretakers who delay or refuse childhood vaccinations. For each selected
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3 municipality and district, one to two *barangays* with the highest number of children under-five will then
4 be purposively selected.
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8 ***Quantitative component:*** During Phase 4 we will rely on household survey data. The estimated sample
9 size per group (intervention and control arms in both rural and urban areas) is 200, which will result in
10 a total of 800 survey responses sought. This will allow us to detect a difference of 15% in the binary
11 outcome between intervention and control groups in each area with an 85% response rate, 5% type I
12 error rate, and 20% type II error rate. To select the study sites, a multi-stage stratified random sampling
13 frame will be used. The sampling scheme is illustrated in **Figure 4**.
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17 The four *barangays* (two from Dasmariñas City and two from a rural municipality in Cavite)
18 will be purposively selected based on the number of annual births in the most recent report available
19 (preferably 2018-2019) in the Rural Health Unit/City Health Office. We will select the two *barangays*
20 with the highest number of births in their respective region and randomly assign study arms.
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24 In each of the selected *barangays*, a list of caretakers with children under-five will be obtained
25 from the midwife or the BHWs. All caretakers listed will be invited to participate in the study. In the
26 event that the number of interviewed caretakers does not reach the envisioned sample size of 200 per
27 area and study arm, we will continue sampling in the *barangay* with the next most births in the area in
28 the matter described above.
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33 **Data Collection Preparation and Data Collector Training**

34 Before the onset of data collection, we will communicate with Department of Health (DOH) officials
35 (national, regional and provincial offices) to explain study objectives and procedures, and discuss and
36 resolve any concerns regarding data collection. We will also seek their permission and support to
37 conduct the project in the selected primary health care facilities. Official communication explaining the
38 nature, study objectives, and procedures will be sent to local government executives and community
39 leaders. Spot maps of the community, if available, will be requested from the Rural Health Units or
40 community health centers. The spot maps will be used to locate prospective families in communities.
41 Courtesy calls to local officials and leaders will be made to seek their support to conduct the project in
42 their respective localities. All required formal endorsements (i.e., memorandums of agreement) will
43 have been granted prior to data collection.
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50 The research team will conduct IDIs, FGDs, and quantitative surveys with the assistance of
51 field interviewers in either English or Filipino, depending on the preference of the participant.
52 Interviewers will be fluent in English and Filipino with bachelor's level education in nursing, midwifery
53 or social sciences. Interviewers will be trained for five days to collect the data with instruments and
54 online platforms for data collection for this study. Training topics will include modules on VH,
55 interviewing and/or surveying techniques, research ethics, software resources, Kano analysis and
56 qualitative and quantitative methods.
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Data Collection

Data collection will be conducted in five phases: One preparatory phase to develop an understanding for the current situation with regards to vaccination policies and challenges, including but not limited to the ongoing COVID-19 pandemic, and the four phases of HCD.

Preparatory Phase

We will conduct IDIs with policymakers (n=15-20) to understand the current challenges for ongoing public health efforts on childhood vaccinations, perceptions of vaccines, and the health system. We will also explore how the current COVID-19 pandemic poses challenges and opportunities to health education and vaccination efforts.

Phase 1. Shared Appraising (EMPATHIZE PHASE):

This phase of HCD aims at gathering information about how users frame a childhood vaccination problem, how they situate themselves in relation to the problem (probing on socio-cultural context) and learning which factors would motivate them to address the problem.

IDIs with caretakers of children under-five: We will conduct IDIs (n=60) with caretakers of children under-five. In each selected *barangay* in Cavite province and Dasmariñas city, we will purposively select 30 caretakers recommended by a nurse or midwife who will have reviewed vaccination records in order to identify families that have delayed or refused childhood vaccines. Based on these IDIs, we will build holistic narratives about family perceptions of the public health system and encounters with childhood vaccinations. Participants with particular vaccination or VH experiences will be asked if they are willing to be video-recorded as they tell their personal story related to vaccines. These video-recorded interviews will aid pre-development of the intervention.

IDIs with HCWs and community leaders: IDIs (n=10) will also be conducted among HCWs (municipal/city health officers, nurses, midwives) and community leaders (specifically the *barangay* captain and councilors for health) of the selected *barangays* to describe their experiences related to childhood vaccination in their respective community or health facility.

Refinement of intervention storyboards: Following each interview, the preliminary storyboards developed as a result of the initial IDIs (i.e., 10-15 IDIs) will be presented to participants. Participants (caretakers, HCWs) will be asked to conduct a think-aloud exercise while flipping through these storyboards. After each 10-15 IDIs, or at the end of each week of data collection, the storyboards will be edited and refined based on participants' comments. These revised storyboards will be included in the following round of IDIs for further refinement.

Phase 2. Life stories and Uncovering (DEFINE & IDEATE PHASE):

In this phase, end-users will suggest ideas to address the problem in collaboration with a research team.

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3 **Records Review**: From the selected *barangays*, the research team will seek the help of BHWs to identify
4 potential participants based on childhood vaccination records. We will purposively select 50 potential
5 participants in each selected *barangay* of Cavite province and Dasmariñas City and review their
6 vaccination record through Target Client Lists and Individual Treatment Records. Each case will be
7 allocated to one of three categories:
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- 11 1. *Fully Immunized Child*: Children who complete one dose of BCG, three doses of Oral Polio
12 Vaccine (OPV), three doses of Diphtheria-Pertussis-Tetanus (DPT), three doses of Hepatitis
13 B and one dose of Measles Vaccine BEFORE a child's first birthday. These are the children
14 who received their vaccinations within the National Immunization Program schedule.
15
- 16 2. *Completely Immunized Child*: Children who receive one dose of BCG, three doses of OPV,
17 three doses of DPT, three doses of Hepatitis B and one dose of Measles Vaccine AFTER a
18 child's first birthday. These are children who have delays in receiving vaccination based on
19 the recommended National Immunization Program schedule.
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- 21 3. *Refusal to vaccinate*: Children with the remark "refused" in the Target Client Lists will be
22 cross-validated with the respective Individual Treatment Records to further review their
23 reasons of refusal.
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29 This process will allow us to initially stratify the participants for FGDs based on their children's
30 vaccination status, preventing contamination and conflict during discussions. Additionally, we will use
31 the records review to confirm delays in children's vaccination schedules, even if these children were
32 later fully immunized.
33

34 **Focus Group Discussions**: We will conduct FGDs (n=10-15) with caretakers, stratified (based on the
35 records review and validation of child vaccination cards) into three groups: 1) in favor, 2) delay and 3)
36 refusal of vaccination, to understand how these views evolved or persisted. We will explore the socially
37 held attitudes toward the public health system and vaccines. We will also conduct unstratified FGDs
38 among BHWs of the sampled *barangays* to understand their community and health facility experiences
39 with childhood vaccinations. Results of these FGDs will inform the development of storyboard flip-
40 boards that will be refined in the next phases of the project. To ensure that the design itself of the
41 intervention resonates with the intricate details of Filipino demographic and cultural dynamisms, we
42 will collaborate with local animators with years of groundwork experience in developing interventions
43 in the Philippines who will accompany FGDs and graphically record ideas and concepts in real-time,
44 which can be discussed among participants.
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53 ***Phase 3. Bridging and Optimizing (PROTOTYPE PHASE):***

54 In this phase, prototypes and products will be developed and tested in real-world settings with actual
55 users via actual delivery systems.
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57 **IDIs with HCWs and BHWs**: The draft intervention, together with data from our FGDs and IDIs will
58 be presented to HCWs and BHWs. We will conduct 10 IDIs with HCWs and BHWs to get their
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3 perspectives and recommendations regarding additional information that needs to be included or
4 refined, namely related to how, when, and by whom the intervention should be delivered. These IDIs
5 will guide the research team in terms of preferred medium (e.g. paper versus video-based presentation)
6 and favorable delivery approach (e.g. spoken text to accompany the intervention, one-on-one vs. group
7 delivery, a stand-alone activity vs. nested in existing outreach, etc.). The result of this phase will allow
8 us to further refine and finalize the intervention, and to determine the “point of contact” for the delivery
9 of the intervention in Phase 4.
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15 16 ***Phase 4. Navigating and Gaining (TESTING PHASE):***

17 In this phase, the intervention will be introduced to and tested with a larger sample, and large-scale
18 feedback will be sought.
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20 ***Pilot Testing:*** We will test the developed intervention versus a control intervention (a standard health
21 education, unrelated to vaccines or VH) in four *barangays* (divided into urban and rural areas) in the
22 same municipality and district selected in the previous phases. **Figure 4** shows the detailed design of
23 the pilot phase. Before and after the delivery of the intervention, the research team will administer short
24 surveys. The pre- and post-intervention surveys (based on best practices for measuring VH (8, 68)) will
25 quantify participants’ knowledge, attitudes, and practices regarding vaccination and VH, and the post-
26 intervention survey will additionally assess any changes in knowledge or attitude. We will also collect
27 participants’ socio-demographic characteristics (i.e., *barangay* of residence, caretakers’ age, sex, civil
28 status, occupation, number of children and education level) and vaccination status of children to allow
29 for further analyses and the identification of potential sampling biases. We will store contact data with
30 an intention to reach out to families in future intervals to determine whether vaccination completion
31 rates differed between intervention and control groups. We will revise the survey tool based on
32 outcomes from phases one and three.
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40 ***Intervention Feedback:*** After pilot testing, a subset of 200 participants (100 participants randomly
41 sampled from each the urban and rural intervention arms) will be asked a short series of closed-ended
42 questions about features of the intervention and feedback on how the intervention made the user feel
43 based on Kano analysis methodology (attractive vs. essential) (69). After the Kano survey, 10-15
44 participants in each area (n=50) will be purposively selected based on critical case sampling and invited
45 to IDIs to identify comprehension problems and to seek further feedback in smaller groups. Since this
46 study only aims to pilot test the developed intervention, the feedback on the intervention will be useful
47 for further refinement before future trials.
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55 **Patient and Public Involvement**

56 Neither clients nor the public were directly involved in the design, recruitment, or conduct of the study;
57 their only involvement is as research participants. However, following the tenets of HCD, the
58 intervention is co-developed with research participants over the entire course of the study. Participants
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3 are not involved in initial recruitment, but those participants completing an IDI may be asked to provide
4 contact details of others who might be interested to participate in the study. Participants are not involved
5 in data analysis or the dissemination of findings. The final results will be shared with policymakers,
6 health programmers, and other stakeholders via roundtable discussion, and in the form of articles
7 published in peer-reviewed journals or policy briefs. Research participants will be given access to the
8 final intervention and be informed through their BHWs and other channels embedded in the community,
9 and have the option to contact study staff for a detailed description of study findings at any time.
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16 **Data Collection in times of COVID-19**

17 All IDIs and FGDs were initially planned to be conducted in-person. However, the ongoing pandemic
18 and measures taken to curb infection rates pose unique challenges to conducting research. Considering
19 the time-sensitive nature of this project, we have developed new operating procedures for conducting
20 online data collection, to ensure minimal risk for participants and the research team concerning COVID-
21 19, and in compliance with the recommendations by the European Medicines Agency (70) and the
22 Philippines Inter-Agency Task Force (IATF) (71). This includes informed consent processes and the
23 engagement of research team members who are unable to travel to the study site. Until the situation
24 changes, only strictly necessary visits will be performed at sites.
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30 **Remote recruitment and consenting:** We will contact prospective participants via email or a phone call
31 to briefly introduce the study aims and invite them to participate. After this initial phone call or email,
32 we will set an appointment for the comprehensive discussion of the study and to answer questions. An
33 information sheet (including study aims, procedures, and expected risks and benefits) and consent forms
34 will be sent to potential participants in advance via email or courier. If participants agree to enroll in
35 the study, we will ask them to sign the consent form during a recorded Skype or Zoom video call, and
36 to take a picture while holding the signed consent form. The signed consent forms will be returned to
37 the research team as scanned or photographed copy, or per courier (as preferred by the participant;
38 courier costs will be covered by the research team). Participants will receive duplicate copies with the
39 signature of the interviewer per courier.
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46 **Focus Group Discussions:** At the time of writing (October 2020), we continue to hope that by the
47 beginning of 2021, when we plan to conduct FGDs, small group discussions in person with appropriate
48 distance will be possible. However, we will conduct remote FGDs if necessary to ensure the safety of
49 participants and research team. In this case, we will draw on the assistance of local stakeholders (HCWs,
50 BHWs etc.) to orient participants on group discussions via a web-based platform.
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54 **Intervention pilot-testing:** If necessary, amid the pandemic and associated lockdowns, the intervention
55 (VH and control) and surveys (pre and post) will not be delivered in person but instead via an online
56 platform of the participant's choosing. During the presentation of the intervention, there will be no
57 interaction between the researchers and participants to prevent any sort of biases or contamination of
58 the results. We will similarly administer the quantitative survey via an online platform. All online
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processes will be pilot tested prior to the implementation to assess feasibility and operational challenges. If feasible, the survey will be in a self-administered format (i.e., interviewers will send the survey link and participants will input their answers in the online form). However, if deemed not feasible, the research team will switch to an interviewer-assisted survey format (i.e., interviewers will read the questions to the participants and are responsible in inputting the answers in an online form).

Systematic Debriefings: As a number of research team members will not be able to travel to the study site due to COVID-19 travel restrictions, we will employ remote systematic debriefings (72) to discuss and triangulate findings, to amend interview guides and to refine lines of inquiry. The weekly debriefings will also allow us to continuously assess, discuss, and refine study tools, data collection procedures, and emerging issues in data collection as a means to ensure fidelity to the tenets of high-quality interviewing. Additionally, in light of the timely relevance of vaccination research in the context of the ongoing pandemic, we will use these debriefings to discuss emerging topics and potential probing approaches with regards to adult and COVID-19 vaccination and continuously refine data collection tools accordingly.

DATA PROTECTION AND ANALYSIS

Data quality checks and cleaning process

Most of the data in the project will be primary and collected by the research team. Interviews will be audio-recorded using digital or online audio-recorders. All recorded information will be transcribed verbatim and translated into English. For all qualitative data, the research team collecting and analyzing the qualitative data will be directly responsible for quality checks of audio recordings, interview notes and qualitative transcripts. Random checks of transcripts will be conducted to ensure quality.

All quantitative data will be entered into a customized Microsoft Access data entry system with a built-in validation program. The data management unit (DMU) of the Research Institute for Tropical Medicine's Department of Epidemiology and Biostatistics will be responsible for quality checks. DMU staff will reach out to the SALUBONG team in the event of questions or data inconsistencies.

Data storage and protection

All data collected by the research team will be stored according to Germany and Philippines regulations. At the point of data collection, unique codes will be assigned to all participants. A master sheet linking the code with identifying information (including a name and, when feasible, contact information) will be kept in a secure (locked/password-protected) location that is accessible to the investigators. Only the research coordinator will have access to and manage this master sheet. The master sheet will facilitate the process of revoking information should a participant decide (at a later point) that they wish to have their data removed from the study. Further, audiotaped interviews will also be stored in locked/password-protected computers controlled by the research coordinator. All data will be accessible

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3 only to those within the research team, but can be made available to others upon reasonable request
4 after approval from ethical review boards.
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8 **Data analysis**

9 While the work is divided into phases, the ultimate aim of this study is to analyze and apply findings
10 continuously across phases to address the overall study objective. The Principal Investigators and Co-
11 Investigators will be directly responsible for the triangulation of findings across data sources and the
12 development of an integrated interpretative analysis.
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15 **Qualitative analysis:** The qualitative component of this study will be analyzed based on constructivist
16 grounded theory as outlined by Charmaz (73). The application of this approach will help us generate
17 theories on why caretakers would or would not agree to childhood vaccinations, and it will allow us to
18 investigate the constructions and underlying processes of caretakers' perceptions, so that informed and
19 relevant approaches can be applied to help resolve highly salient concerns. NVivo Pro 12 (QSR
20 International Pty Ltd. Version 12, 2018) will support qualitative analysis.
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23 **Quantitative Analysis:** The quantitative component of this study will be analyzed using descriptive and
24 inferential approaches. Earlier phases of the study will identify relevant dimensions of knowledge and
25 attitudes to assess in the survey; at its most basic, the analysis will assess binary improvement (1) versus
26 no improvement (0) across those dimensions comparing after and before intervention exposure.
27 Additional analyses will describe and compare the rates of generally favorable versus unfavorable
28 attitudes toward vaccination. Exploratory analyses will seek to uncover sociodemographic variables
29 related to pre-intervention response patterns as well as post-intervention change patterns.
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32 Kano-style questions place user ratings of product or service features on a two-dimensional
33 scale (69). One dimension is satisfaction, which can range from frustration to delight. The other is
34 functionality, which ranges from not functional to highly effective (69). Hence, Kano analysis of post-
35 intervention survey responses to Kano-style questions will be used to prioritize resource allocation in
36 improving the intervention functionality, with the intention of causally affecting customers' satisfaction.
37 The results will then be used for the revision or re-development of intervention features for future, large-
38 scale testing.
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49 **Ethics and Dissemination**

50 Ethical approval has been granted by the Institutional Review Board of the Research Institute for
51 Tropical Medicine (No. 2019-44) and the ethical commission of Heidelberg University, Faculty of
52 Medicine (S-833/2019), both recognized Ethical Review Committees. The investigators will
53 consistently respect the principles of ethical research on human subjects described in the Declaration of
54 Helsinki. Written informed consent will be obtained from all eligible participants before data collection
55 begins and after the participants have been fully informed about the study. Study findings will be
56 disseminated in scientific conferences and published in peer-reviewed journals, as well as via policy
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3 briefs and roundtable discussions. We will adhere to specific reporting guidelines for all publications
4 as applicable, such as the Standards for Reporting Qualitative Research (SRQR) or the Consolidated
5 Criteria for Reporting Qualitative Studies (COREQ).
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9 **DISCUSSION**

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11 Although vaccination uptake and VH are central parts of the current public health and global health
12 discourses, few interventions have proven efficacious in sustainably increasing vaccine confidence. In
13 this study protocol, we explain how we will work with clients, providers, and policymakers to develop
14 a narrative-based intervention to increase vaccine confidence in the Philippines. Guided by the tenets
15 of HCD we will co-develop and iterate this intervention to address the needs and expectations of those
16 it is developed to support.
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20 HCD is a promising new approach in the development of global health interventions (48). In
21 our application of this methodology we will move beyond the way it currently is often applied and
22 extend the understanding of ‘clients’ (following terminology from HCD field understood here as the
23 end-users of the intervention) to those involved across several levels including: caretakers who are
24 deciding whether to vaccinate their children (clients in the sense of ‘target population’), HCWS and
25 BHWs who interact with caretakers (clients in the sense of those who will – or will not – incorporate
26 the intervention into their service delivery), and policymakers and key vaccination stakeholders whose
27 decisions and policies shape the vaccination landscape (clients in the sense of those who decide the
28 implementation of large scale interventions).
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35 We also expand the existing body of literature on HCD-based vaccine confidence interventions
36 by drawing on a theoretical framework to inform our sampling and design procedures and using well-
37 established behavior change theories to guide data collection activities. This for example includes
38 identifying topics to be probed for in IDIs (e.g., perceived behavioral control about getting a child
39 vaccinated), but also those topics with a clearly social dimension to be focused on in FGDs (e.g., social
40 responsibility of vaccinations). We therefore do not employ a purely inductive approach for conducting
41 qualitative research, as is common in global health qualitative research and HCD approaches, but allow
42 for the existing literature and established theories to guide our approach.
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48 Previous studies demonstrate that decision-making surrounding vaccine is complex, and that
49 those who provide vaccine-related information are in a unique position to sway or break vaccine
50 acceptance (74, 75). A high general trust in the health authorities and providers that decide what
51 vaccines to introduce is a deciding factor in vaccine uptake (76). However, trust and source credibility
52 play a pivotal role not only in direct communication between healthcare providers and their clients, but
53 also across all levels: Health-related controversies have been shown to disrupt the trust healthcare
54 providers have in political agents, or implementing government institutions have in those who make the
55 respective policies (38). Our inclusion of stakeholders from all levels in the design process will support
56 our ability to identify pathways to rebuild both confidence in vaccines and trust in the general system.
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3 The Dengvaxia controversy in the Philippines highlights the pace and reach of misinformation
4 regarding the effectiveness and safety of a vaccine, causing a drop in general vaccine confidence and
5 rolling back decades of immunization work (36, 38). Dayrit and colleagues (38) stated that the
6 communication gaps among the health authorities themselves, as well as a lack of transparency,
7 proliferation of non-scientific speakers in the mainstream media, and distorted messages in social media
8 played a key role in the panic felt among Filipino families. The Dengvaxia controversy was exacerbated
9 by an exceptionally rapid spread of (mis)information via social media channels (36, 38). In the broader
10 context of vaccination, factually false or misleading information shared in online forums or via social
11 media, often in the form of short quotes or emotionalized images, is considered a central contributor to
12 anti-vaccination narratives (77). In many cases, countering these narratives is challenging as it requires
13 longer and complex explanations of vaccination risks and benefits, which are not as easily spread
14 through social media (78, 79). We are taking this into consideration while developing our narrative-
15 based intervention in part or entirely in a form that can be easily relayed (e.g., as a short video or even
16 a GIF). With vaccine confidence or uptake interventions delivered via social media showing promising
17 results (80, 81), we explicitly include this notion in our HCD-based discussion of promising delivery
18 strategies.

19
20 The Dengvaxia controversy has been repeatedly linked to the steep decline in vaccination rates
21 and vaccine confidence in the Philippines (3, 36). However, to the best of our knowledge, there so far
22 has not been any qualitative exploration of how this case has shaped narratives about vaccines, health
23 programming and the health system in general. Furthermore, there has been remarkably little research
24 highlighting Filipino perspectives on how to move forward after the controversy. The SALUBONG
25 project will thus provide robust, culturally-attuned data that can inform future programs and policies to
26 rebuild trust and confidence in relation to vaccines (22, 82, 83).

27
28 Finally, similar to many research projects, the ongoing COVID-19 pandemic has forced us to
29 reconsider the way we collect data to ensure the safety of our participants and research team. We have
30 developed new approaches to remotely undertake this study. In close cooperation with the ethical
31 review boards evaluating this project, we have developed protocols to ensure that recruitment, consent
32 and rapport building are supported despite the remote nature of data collection. We hope that the
33 procedures outlined in this protocol will spark a discourse on how to conduct ethical and trustworthy
34 research during a pandemic, and that our experiences will allow us to further develop and validate
35 methodological approaches.

36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 **FIGURE LEGENDS**

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57 **Figure 1.** Preliminary conceptualization of different influences on vaccination behavior and VH to
58 ground intervention development.
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3 **Figure 2.** Location of Cavite, Calabarzon Region included in the Project SALUBONG in the
4 Philippines. Map credits: courtesy of www.mapchart.net
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8 **Figure 3.** Summary of the Project SALUBONG guided by the human-centered design. Icon credits: all
9 icons made by Freepik (<http://www.freepick.com>) courtesy of www.flaticon.com
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13 **Figure 4.** Study design of Phase 4: “Navigating and Gaining”. Icon credits: all icons made by Freepik
14 (<http://www.freepick.com>) courtesy of www.flaticon.com
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17 **DECLARATIONS**

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20
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23 to Meghan Obermeyer for her inspiring global health stories, which sparked the idea of this project.
24
25

26
27 **Contributors:** MDR participated in all aspects of the study design, set up of local study implementation
28 systems and led the writing of the protocol. JW oversaw the Heidelberg ethics approval process,
29 contributed to and edited the protocol paper. KB participated in the design and writing of the qualitative
30 components and edited the protocol paper. MA, JLG, VE, JL, TAB, MPD, JRG and NDC participated
31 setting up local implementation systems including development of standard operating procedures for
32 online data collection and edited the protocol paper. MT advised on the quantitative study design,
33 sample size calculation, local study implementation and edited the protocol paper. MA advised on the
34 HCD process and edited the protocol paper. RC advised on the quantitative study design, sample size
35 calculation and edited protocol paper. SM supervised all aspects of the study design, the writing and
36 editing of the protocol paper. All authors have read and approved the final version of the manuscript.
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47 Generic License has already been assigned to the Author Accepted Manuscript version that might arise
48 from this submission. The funders do not have competing interests and did not play a role in the
49 preparation of this protocol paper.
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56 the authors and does not necessarily represent the views of any funder.
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60 **Availability of data and materials:** Not applicable.

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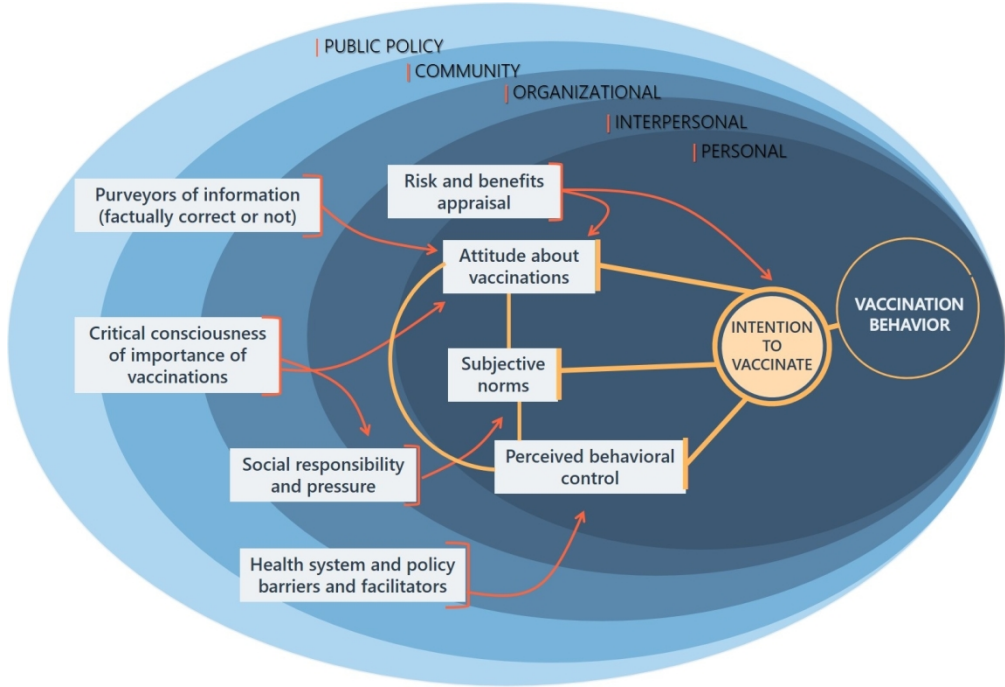


Figure 1. Preliminary conceptualization of different influences on vaccination behavior and VH to ground intervention development.

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Figure 2. Location of Cavite, Calabarzon Region included in the Project SALUBONG in the Philippines. Map credits: courtesy of www.mapchart.net

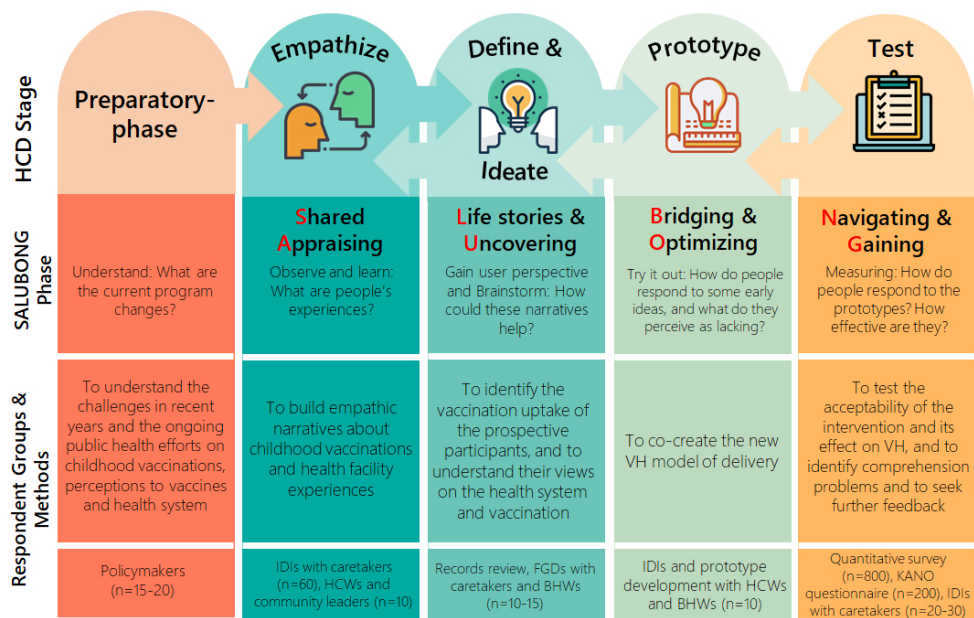


Figure 3. Summary of the Project SALUBONG guided by the human-centered design. Icon credits: all icons made by Freepik (<http://www.freepik.com>) courtesy of www.flaticon.com

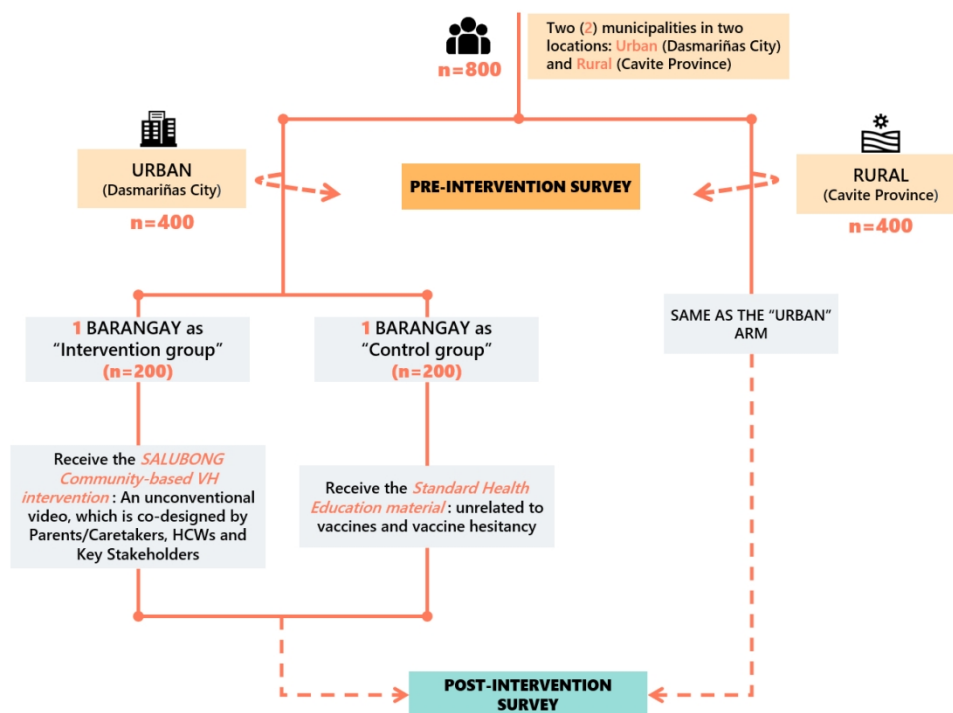


Figure 4. Study Design of Phase 4: "Navigating and Gaining". Icon credits: all icons made by Freepik (<http://www.freepik.com>) courtesy of www.flaticon.com.