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Understanding Behavioral Aspects of Household Spatial Repellent use for Dengue Control in Sri Lanka

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Abstract

Background:
Spatial repellents (SRs) show promise for preventing human infection with vector-borne arboviruses like dengue, transmitted by Aedes aegypti and Ae. albopictus mosquitoes. A recent Peru trial demonstrated a 34.1% decrease in Aedes-borne virus incidence among households protected by an SR compared to those with an identical-looking placebo. Translating epidemiological and entomological efficacy into real-world effectiveness, however, also depends upon social acceptability. This study will investigate the social acceptability of a transfluthrin-based SR among residents of Gampaha District, Sri Lanka.

Methods:
This mostly qualitative study is nested within a double-blinded cluster-randomized controlled trial (cRCT) of SRs. To maintain blinding, the social science team will use a sampling frame drawn by the unblinded data safety monitoring board (DSMB) statistician that includes equal numbers of intervention and control clusters. For each activity, the team will enroll an equal number of participants per cluster, ensuring equal distribution between intervention and control participants without knowing which is which. The study's eight data collection activities include: (1) a retail audit of mosquito control products currently available in Gampaha District; (2) freelisting and (3) ranking to assess perceived efficacy, affordability, and practicality of existing mosquito control products and practices (MCPPs); (4) household-level in-depth interviews (IDIs) to elicit deeper information on MCPPs; (5) a diary card exercise chronicling children's daily activities to determine level of protection afforded by an SR in their household; (6) modified trials of improved practices (TIPs) to observe product installation and solicit participant improvement suggestions; (7) focus group discussions (FGDs) to triangulate other data; and (8) key-informant interviews with individuals who have first-hand knowledge about review, licensing, adoption, procurement, and distribution of new vector control products in Sri Lanka. Study team members will analyze data thematically, employing analytical memos plus inductive and deductive coding.

Discussion:
This study will provide critical data about the social acceptability and perceived efficacy of SRs compared to current MCPPs. It will elucidate participant perspectives on SR benefits, drawbacks, and desired improvements. This will help with future SR promotion and scale-up should the Sri Lanka cRCT confirm efficacy. The study represents a novel opportunity to collect double-blinded longitudinal qualitative data.

Guidelines

Background

An estimated 390 million dengue virus (DENV) infections are recorded each year, with transmission occurring in most tropical and sub-tropical areas (1). Clinical infections can result in undifferentiated fever (viral syndrome), dengue fever, dengue hemorrhagic fever and dengue shock syndrome (2). DENV is transmitted primarily in urban and suburban areas by Aedes aegypti, an indoor, day biting mosquito species, as well as Aedes albopictus, which is adapted to a peri-domestic environment. DENV control has focused largely on vector control, namely larval source management (3), and adult mosquito control during outbreaks and impending outbreaks. However, difficulties in effectively targeting Aedes larvae in small localized habitats including discarded receptacles and water storage containers can limit the impact of this approach (4). Additional prevention tools are urgently needed to reduce human-vector contact and fill gaps in protection.

Spatial repellents (SRs) – designed to protect interior spaces and thus limit human exposure to disease-carrying mosquitoes – represent a promising approach to complement current control efforts. While SRs have been used widely for mosquito bite prevention, their efficacy in reducing Aedes-borne viruses has never been tested rigorously or at large-scale in Asia. To address this gap, a double-blinded cluster randomized placebo-controlled efficacy trial (cRCT) is being carried out in Gampaha District, Sri Lanka (5). This protocol describes a concurrent and complementary social science study. Both the cRCT and the social science protocols are implemented under the Advancing Evidence for the Global Implementation of Spatial Repellents (AEGIS) project. The cRCT is led by the University of Notre Dame (UND) and the National Dengue Control Unit, Ministry of Health (MOH), Sri Lanka with statistical analysis led by the University of Washington and study monitoring provided by FHI Clinical. The cRCT protocol was reviewed and approved by the UND Institutional Review Board (IRB) as well as the Ethics Review Committees (ERCs) of the University of Kelaniya and the World Health Organization (WHO). A brief summary of the cRCT is included here for context.

For the cRCT, clusters of households in Gampaha District were randomly assigned to receive either (a) two transfluthrin-impregnated plastic sheets measuring approximately 21 × 30 cm for every 9 m2 of interior space (intervention) or (b) plastic sheets identical in size and appearance but containing no insecticide (control). The formulation of tranfluthrin is a passive emanator that releases the active ingredient over the course of four weeks without need for electricity or external heat. Clusters were assigned to intervention or control by an unblinded biostatistician affiliated with the cRCT's data safety monitoring board (DSMB) such that neither study participants nor study team members know which clusters are assigned to which study arm.

As noted in the cRCT protocol, "epidemic dengue was first recognized in Colombo, the capital of Sri Lanka, in 1965-1966" (6). Outpatient clinic-based surveillance at Colombo's Lady Ridgeway Hospital for Children (1980-1984) found [that dengue virus (DENV)] accounted for 16% of acute febrile illness, of which 66% were recurrent cases. A 1980-1985 school-based study found a baseline DENV seroprevalence of 50% in Colombo and a 6-month dengue incidence of 15.6%, of which 37% were secondary cases (6). In the early 1980's, severe dengue was rare in Sri Lanka: <10 reported cases were dengue hemorrhagic fever (DHF) (6). However, since 1989, many cases of DHF have been reported from the heavily urbanized western coastal belt of Sri Lanka, which includes Colombo (7), and cases have recently been reported elsewhere in the country." The Sri Lanka Ministry of Health,

National Dengue Control Unit (NDCU) reported 35,924 cases of dengue during calendar year 2021 (8). Dengue transmission in 2022 was considerably higher with 4,527 cases reported in September (compared to 1,370 during 2021) and 60,297 cases from the period January 1 – September 30(8).

In addition to demonstrating product efficacy, it is crucial to understand factors that can influence uptake and use of SRs and how SRs can fit into the DENV prevention landscape. For SRs to become integrated into vector control strategies, dengue control program officials would need to see them as a valuable addition to currently available products. In addition, end-users (families and households) would need to consider SRs both socially acceptable and efficacious. Social science research can shed light on patterns of DENV exposure and factors that may increase or inhibit the operational effectiveness of the product. This social science study will investigate factors that could facilitate or inhibit successful implementation of SRs at large scale. Data will be gathered at the individual, household, community, retail, and national levels with the goal of providing programmatically useful recommendations for procurement, promotion, and distribution of SRs.

The aims of the social science research study are to:

1. Determine what factors are likely to facilitate or inhibit successful large-scale implementation of spatial repellents (SRs) for arbovirus prevention in Sri Lanka;
2. Determine appropriate strategies to reinforce facilitating factors and overcome inhibiting factors related to social acceptability and perceived efficacy of SRs among end-users (i.e., households).

Specific objectives include:

1. Document current availability of mosquito control products for purchase through a retail audit in study sites;
2. Identify perceived efficacy and context for use of mosquito control products and practices;
3. Determine user perceptions regarding susceptibility to dengue virus (DENV) despite existing vector control methods;
4. Document activity and mobility patterns related to potential exposure to dengue-vector Aedes aegypti mosquitos including time spent under protection of the SR product or within range of a placebo product with identical characteristics but no repellent (see trial description under background and rationale below);
5. Determine perceived efficacy and user preferences related to new spatial repellents;
6. Identify key considerations for introduction and implementation of SRs in Sri Lanka.

Discussion

Many public health interventions that work well in theory, or as laboratory prototypes, falter in the real world when they fail to fit the needs or context of the intended end users (18). Conducting social science research on spatial repellents in parallel with epidemiological and entomological efficacy trials will help us better understand the social context and current practices of the intended user population. This, in turn, should increase the likelihood of successful introduction and uptake of SRs should they prove epidemiologically and entomologically efficacious and raise no local or systemic adverse effects in the trial pariticipants. This protocol is designed to shed light on many dimensions of the social context and current practices of Sri Lankans at risk of dengue.

The retail audit will provide data on the current market for mosquito control products from the supply side: what products are available, where they are sold, how much they cost, the market share occupied by different

formulations and presentations, whether there are seasonal trends in sales, and so on. Free-listing and ranking provide complementary demand-side data on what mosquito control products and practices potential SR users currently employ. These activities also highlight when and where people employ current products and practices as well as their perceived efficacy and affordability. If SRs like the one being tested in this trial are eventually offered for retail sale, these data could help guide how best to promote them as an alternative or a complement to existing products.

One potential use case suggests that SRs of this type might never be offered for retail sale but instead purchased and distributed by government disease-control programs or non-governmental aid organizations (9). Examples could include a national dengue control program distributing SRs as part of a rapid outbreak response or a UN agency distributing them in a refugee setting or after a natural disaster, contexts in which large numbers of people become displaced and must be resettled in temporary housing. Even if SRs remain a non-retail intervention, retail audit data will still provide valuable information about other mosquito control products or practices recipients are likely to employ. This knowledge could prove essential to developing health communication campaigns that inform recipients about why SRs are necessary as a complement to or replacement for their existing practices.

Modified trials of improved practices (TIPs) will provide detailed data on the state, durability, and wear-and-tear of SRs as well as user likes, dislikes, concerns, and suggestions for improvement. The observation component of TIPs will track whether the SRs in selected households are present, intact, missing, or damaged. It will provide information on installation method effectiveness and record whether household members have moved any of the installed SRs, covered them with something else (e.g., hung a calendar or picture on top of them) or altered them in any way. In the interview that follows, a research assistant will ask an index household member whether they perceive the SR to be working, whether they have noticed any changes in mosquito density, and their reasons for moving, removing, or altering any of the products if they have done so. RAs will likewise ask participants for product improvement suggestions. Since these (9) are longitudinal data – visits will take place at one week and two, six, twelve, and eighteen months after first installation – TIPs will chronicle any change in user perceptions over time. Although all study team members will remain blinded to study assignment, we will collect TIPs data from an equal number of intervention and control households. At the study's end, once data are unblinded, this will allow us to determine whether participant perceptions coincide with study arm.

In-depth interviews and time-under-protection data will provide a clearer picture of human exposure to potentially infective mosquito bites. This will help delineate where and for what period of time SRs can be expected to provide protection against bites by Ae. aegypti. This might lead to an expanded use case for SRs outside the home or, at the least, identify the need for additional interventions to provide protection in settings where SRs cannot. Focus group discussions planned for the end of data collection will provide an opportunity to build upon and expand insights derived from all the previously described data collection activities.

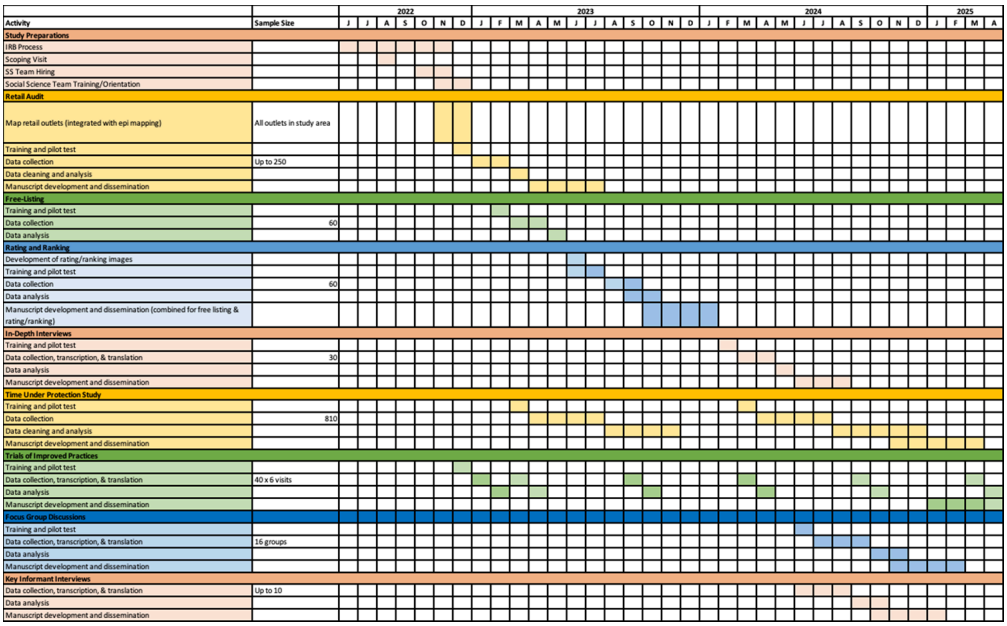
Finally, key-informant interviews with government officials involved in regulation, licensing as well as selection, procurement, and distribution of an appropriate mix of vector-control products for public health use will provide a road map for donors, implementing partners, and government institutions themselves.
The double-blinded design of the parent cluster randomized controlled trial presents a unique opportunity to collect double-blinded longitudinal social science data. Once unblinded at the trial's end, those data will make possible a direct comparison of product acceptability and perceived efficacy in a setting where neither

researchers nor participants knew who was assigned to the intervention and who to the placebo arm of the trial. This should provide a unique opportunity to assess placebo effect or social courtesy bias, often not possible in trials that cannot blinded.

Taken together, these social science data collection activities will provide a solid basis for rapid scale-up should SRs be confirmed as safe and effective against dengue. Conducting the efficacy trial and social science study in tandem means that dengue control programs will already have data essential to ensuring that SRs and the methods used to install them are acceptable to end-users. They will likewise have household level data about existing mosquito control products and practices crucial to promoting SRs as a complement to or replacement for those products and practices.

They will understand the times and spaces where SRs can provide protection and where additional measures may be needed. Finally, they will have critical information from key stakeholders on considerations for introducing a new tool into the vector control landscape. In sum, social science study findings will increase the likelihood that implementation and scale-up begin quickly and proceed effectively once the WHO Vector Control Advisory Group confirms that the SR being tested here is safe and effective for public health purposes. Without such findings, disease control programs might need to devote many additional months or years to researching SR acceptability, perceived efficacy and preferred product form and installation method before they could develop an effective intervention strategy.

Project timeline



List of Abbreviations

	A	B
	AEGIS	Advancing Evidents for the Global Implementation of Spatial Repellents
	BSPH	Bloomberg School of Public Health, Johns Hopkins University, Baltimore, Maryland, USA
	cRCT	Cluster randomized controlled trial
	DENV	Dengue virus
	ERC	Ethics Review Committee
	FGD	Focus group discussion
	FWA	Federal Wide Assurance
	GND	Grama Niladhari Divisions or village officer divisions – the smallest governmental unit in the Sri Lankan government system1
	HHID	Household identification (the household identification number assigned by the parent cRCT
	HSR	Human subjects research
	IDI	In-depth interview
	IRB	Institutional Review Board
	JHU	Johns Hopkins University, Baltimore, Maryland, USA
	KII	Key-informant interview
	PII	Personally identifying information
	SOP	Standard operating procedure(s)
	SR	Spatial repellent

	A	B
	TIPs	Trials of improved practices
	UND	University of Notre Dame, South Bend, Indiana, USA
	WHO	World Health Organization

Declarations

All the authors declare that they have no conflict of interest

Consent for Publication

Informed consent forms for all data collection activities described in this protocol include a statement advising potential study participants that de-identified data may be shared “with other researchers, organizations that donate money for research, government agencies, and journals that publish scientific papers.” Each consent form further explains that data may be shared “through government or other databases/repositories available to other scientists” and “with students who are learning about science, public health and research.” All individuals who consent to participation in the study receive a signed copy of the consent form(s) for the activity (-ies) in which they are participating.

Availability of data and materials

After study completion all de-identified data will be uploaded to CurateND, a data repository hosted by the University of Notre Dame. External researchers may request access to these data through CurateND.

Competing Interests

The authors declare that they have no competing interests.

Authors’ contributions

Steven A. Harvey wrote the social science section of the overall grant proposal and the original three-country protocol on which this study is based, developed or contributed to development of data collection instruments, contributed to adaptation of the protocol for Sri Lanka, and wrote the first draft of the manuscript. Albert Casella led adaptation of the protocol to the Sri Lankan context, conceived of and developed the Time Under Protection component of the study, and reviewed and contributed to the manuscript. Chamini Kanatiwela de Silva provided input on the protocol and the relationship between the social science study and the cRCT and reviewed and contributed to the manuscript. D. S. Anoja F. Dheerasinghe contributed to developing and contextualizing the protocol for dengue and the Sri Lankan context, applied for and obtained ERC approval as a co-investigator, and reviewed and contributed to the manuscript. Prisca Oria helped adapt the protocol to the Sri Lankan context, contributed to development and adaptation of data collection instruments and SOPs, and reviewed and contributed to the manuscript. Samantha W. Tsang contributed to the submission of the protocol for manuscriot. Kaci McCoy contributed to adaptation of the protocol to Sri Lanka and reviewed and contributed to the manuscript. Lucy Hribar Baker contributed to adaptation of the protocol to Sri Lanka and reviewed and contributed

to the manuscript. April Monroe contributed to development of the protocol and reviewed and contributed to the manuscript. Danielle Piccinini Black developed the protocol for the retail audit and reviewed and contributed to the manuscript. John Grieco contributed to identifying social science research questions for the study and reviewed and contributed to the protocol and the manuscript. Nicole Achee contributed to identifying social science research questions for the study and reviewed and contributed to the protocol and the manuscript. Asitha de Silva contributed to development of the protocol and reviewed and contributed to the manuscript. Korelege Hasitha Aravinda Tissera contributed to developing and contextualizing the protocol for dengue and the Sri Lankan context, applied for and obtained ERC approval as PI, and reviewed and contributed to the manuscript.

Troubleshooting

Methods/Design

1 This study will collect data at the individual, household, community, retail, and national levels to better understand the path to successful large-scale implementation of SRs in Sri Lanka. The study includes eight data collection methods:

1. A retail audit of mosquito control products currently available for purchase in the study area,
2. Modified trials of improved practices (TIPs),
3. Free-listing of mosquito control products and practices followed by,
4. Ranking identified products on the dimensions of perceived effectiveness, frequency of use, and likes and dislikes,
5. In-depth interviews (IDIs) with household members to explore products and practices in more detail,
6. Collection of time allocation data to estimate time under protection (TUP),
7. Summary focus group discussions (FGDs) with members of participating households, and
8. Key informant interviews (KIIs) with national stakeholders.

Each activity is described in more detail below.

2 Like the concurrent cRCT, this social science study will take place in three Medical Officer of Health areas within Gampaha District: Kelaniya, Negombo, and Wattala. These areas were selected due to their similar disease ecology and epidemiology, proximity to one another, and ease of access to trial implementers. Gampaha District is urban with a mix of residential and commercial zones. According to the National Dengue Control Unit, in 2022 Colombo District accounted for 22.76% of the DENV case burden country-wide, while Gampaha District accounted for 17.36%. Residential zones span the full wealth spectrum from very poor to wealthy. The district is located on the western coast about 20 km north of Colombo.

3 Figure 1 shows dengue incidence in Gampaha District from 2005 to 2014. The cRCT will enroll a total of 14,430 subjects across 3,900 households and monitor for active disease – labeled the ‘febrile surveillance cohort’. These households will form 30 clusters (15 allocated to SR, 15 allocated to placebo control), each containing ~187 houses. A subset of this cohort, 3,570 (110-120 per cluster) subjects aged ≥4-16 years will also be enrolled for measuring DENV infection based on laboratory-confirmed seroconversion – labeled the ‘longitudinal cohort’. The incidence of dengue in each cohort will be estimated and compared to determine the benefit of using an SR.

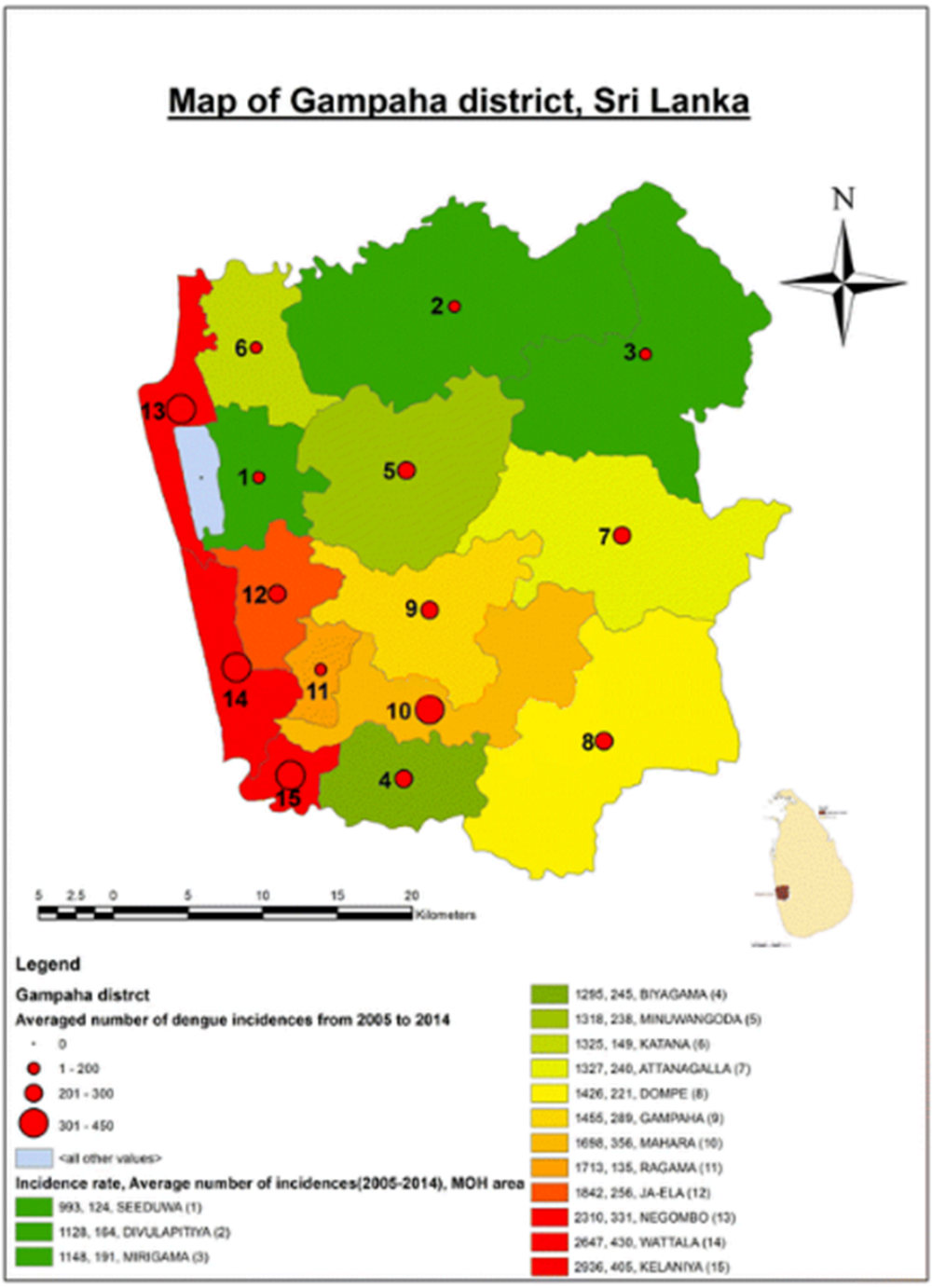


Figure 1: Dengue cases in Gampaha District 2005-2014

Sampling

4 Table 1 lists each data collection activity planned in the study, as well as the total anticipated sample size and unit of analysis (i.e., individual, household, retail outlet, etc.)

associated with each activity. Table 1 also specifies which recruitment scripts, consent forms, and data collection instruments will be used in each activity.

Table 1: Research Activities and Sample Sizes.

	A	B	C	D	E	F
	Data collection activity	**Total sample size**	**Data collection level**	**Recruitment script**	**Consent Form (CF)** **Assent Form (AF)** **Parent Permission Form (PP)**	**Data Collection Instrument**
	1. Retail audit	Up to 250	Retail outlet	G	CF-G	G1 & G2
	2. Modified Trials of Improved Practices (TIPs)	40	Household	D	CF-D	D
	3. Free-listing	60	Individual	A-C	CF-AB	A
	4. Ranking	60	Individual	A-C	CF-AB	B
	5. Household in-depth interviews (IDIs)	30	Individual	A-C	CF-C	C
	6. Time under protection study	Up to 810 (27 adults in each cluster)	Individual	E	CF-E	E
	7. Focus group discussions (FGDs)	16 groups of ≤ 10 participants / group (≤ 160 participants)	Group	F	AF-F & CF-F & PP-F	F

	A	B	C	D	E	F
	8. Key informant interviews with national stakeholders (KIIs)	Up to 10	Individual	H	CF-H	H
	Total participants	**Up to 1,420**				

5 Including preparation, baseline data collection, data collection after installation of SRs, and analysis and write-up, the study duration should be approximately 34 months. The preparatory phase, including development of the protocol and study instruments and submission for ethics review began in June 2022. Final dissemination is currently scheduled to be completed by April of 2025. Appendix A contains an approximate timeline over which we expect to complete the study. Specific activities are described in detail immediately below.

6 **A note on sampling method and study design**:
Like the parent cRCT to which it is linked, this study is double-blinded: Neither study team members nor participants will know until after all data collection is complete which participants were assigned to the intervention arm and which to the control (placebo) arm. Nevertheless, to achieve the specific aims and objectives described above, a roughly 50-50 split between intervention- and control-arm participants is needed for many of the included data collection activities. Since the parent study is randomized by cluster, the first step in sampling for each activity in this study will be to have the unblinded data safety monitoring board statistician select an equal number of intervention and control clusters as a sampling frame. The social science study team will then select an equal number of individuals or households from each cluster for each study activity based upon the specific selection criteria for that activity. This procedure will allow the study team to achieve an equal balance between intervention and control participants without knowing which participants are assigned to which arm.

Data collection activities: Retail Audit

7 Before introducing a spatial repellent as a new mosquito control product in the selected study sites, it will be helpful to have a comprehensive understanding of the current mosquito control landscape. Determining what mosquito control products the target population is currently using, the channels through which they are obtaining these

products, and in what contexts they are using them, is important for new product introduction.

8 There are many assumptions in these settings that people are using a variety of mosquito control products to meet their lifestyles, preferences, and needs; the retail audit will provide information on the extent to which people obtain such products in the retail sector. If the retail sector turns out to be an important source of mosquito control products, the audit will help to determine what products consumers are acquiring from the commercial market and by extension what they are using, and in what quantities.

9 This data will be used to triangulate findings about mosquito control product use at the household-level. It will also provide an idea of potential competition for spatial repellent uptake and continued use. Ultimately, understanding what mosquito control products our target population purchases, in what quantity, with what frequency, and at what price will inform product positioning as well as offer ideas for dissemination and messaging.

10 The audit will begin by listing all retail outlets in the study area that potentially sell mosquito control products with simultaneous identification of outlets that stock or have stocked mosquito control products. For each retail outlet captured in the listing, the study team will take note of the GPS coordinates, shop name (or name of retailer if the shop is not named), type of shop, and if they currently stock or previously stocked mosquito control products. As they are enumerated, retail outlets will be categorized by type.

11 The types of retail outlets stocking and selling mosquito control products may differ—in some contexts it may be large chain stores in urban or peri-urban areas to rural kiosks that serve and carry a limited range of basic necessities such as matches, soap, toilet paper, single-serving soft-drinks and biscuits, and small-denomination mobile phone air-time cards. In between these opposite poles would be pharmacies, drug shops, small family-owned grocery stores, community markets, and other outlets that vary by location.

12 From that overall listing, a subset of retail outlets that currently stock and previously stocked mosquito control products will be sampled for semi-structured interviews. Retail outlet categories will inform a stratified random sampling approach that ensures inclusion of the entire range of retail outlets that stock and previously stocked mosquito control products operating in a given site. Up to 50 retail outlets in each category will be sampled, up to a total of 250 retail outlets, based on the total number of outlets identified in the study area.

13 Prior to data collection at each study site, the semi-structured interview guide will be pilot tested in a small number of retail outlets not selected as part of the study sample and adapted as necessary to include the types of outlets and types, brands, and quantities of available mosquito control products.

14 Data collectors will visit the sampled retail outlets and determine eligibility using the recruitment script. If the participant meets the eligibility criteria, and expresses willingness to participate, then they will be asked to sign a consent form before the interview is initiated. A semi-structured interview guide will be administered by data collectors to store owners or managers of the sampled retail outlets.

15 The interviews will last between 00:30:00 and 00:45:00 each. Descriptive analysis will be carried out including calculation of the proportion of retail outlets stocking mosquito control products and the types of spatial repellents and other mosquito control products by retail outlet category. Analysis will also be informed by Oria, et al., 2020 (9).

Data collection activities: Modified Trials of Improved Practices (TIPs)

16 Upon distribution of the SR in each study site, a modified Trials of Improved Practices (TIPs) approach will be employed to assess perceived efficacy and social acceptability of the product and to solicit participant input on strategies to make product installation, use, and replacement more convenient and more likely to be accepted by the population at large.

17 **TIPs traditionally and in this study**
TIPs are a form of participatory research used to test and refine health interventions on a small scale based on community input. The study team typically recruits a small number of households and develops a close relationship with members of these households through multiple visits over an extended period of time (10,11). As a result of the rapport developed between the research team and participating households, household members come to act as advisors on the pros and cons of the intervention being tested and provide suggestions to make the intervention more effective, more practical, and therefore more attractive to the target population. A sample size of 15-20 households per study site is typical when using TIPs (10). We refer to the approach to be used in this study as “modified TIPs” because TIPs were originally designed to test the feasibility of promoting health interventions requiring human behavior change. For example, Leontsini and colleagues used TIPs in the Dominican Republic to negotiate improved water storage practices that would eliminate *Aedes aegypti* larval breeding sites and thereby reduce dengue transmission (12).

18 Practices tested included covering water barrels with mesh to prevent mosquito oviposition, teaching household members how to recognize *Aedes aegypti* eggs and larva, and cleaning water containers regularly with a bleach solution to kill eggs and larva. In this study, the cRCT team is introducing a new product rather than a new set of behaviors. Modified TIPs will ask participating households for input on questions such as where and how to hang the SR, how to install it so that it does not interrupt daily household routines or raise concerns about safety, what information household

members need to use the product effectively, preferences about product appearance (shape, color, graphics, size, smell), as well as product acceptability and other issues that arise over the course of testing.

19 **Recruitment of TIPS participants**

In TIPs, participating households are typically selected purposively rather than randomly from within a defined population because participation requires an extended commitment to the study and repeated contact with the study team – a burden not all households are willing to accept. However, since the SR efficacy trial on which this study is dependent will be double-blinded and randomized by cluster, the study team will ask the unblinded data safety monitoring board (DSMB) statistician to draw a random sample of 40 households overall; 20 in intervention clusters and 20 in control clusters.

20 As noted in the background and rationale section of this study plan, all households in intervention clusters will receive the SR product while households in the control clusters will receive a placebo product identical to the SR product in appearance but lacking the active ingredient. The statistician's assistance should enable the social science team to purposively recruit at least 15 households per study arm, although we will not know which households are assigned to which arm until after the cRCT is over.

21 Once the DSMB statistician provides the random sample, the local research partner and community leaders will help recruit 15 households from each cluster in which the head of household or his/her designee over 18 years of age is willing to commit to TIPs participation. Participants will be purposively selected to include males and females to better understand any differences in experience with or use of the SR product.

22 **TIPs procedures**

A study team member will make a total of 6 visits to each TIPs household according to the following schedule:

1. one week after initial installation to capture initial reactions to the product and any immediate suggestions for change;
2. two months after initial installation where participating households will have experienced two 30-day cycles of product installation and use and may have medium-term perceptions about product efficacy and use; and then at 6, 12, 18 and 24 months after initial installation to capture the perceptions and suggestions of households that have experienced the product over time.

22.1 With consent of the head of household or their designee, interviews may be audio-recorded. Each visit will last roughly 01:00:00 to 01:30:00. Visits will include, observing and recording the number and condition of installed products, photographs of the product, surrounding environment, and participants if they consent. Participants may participate in TIPs without consenting to having photographs taken.

22.2 Each round of TIPs data will be analyzed thematically using a combination of deductive codes drawn from the research questions and interview guide and inductive codes developed from the notes themselves to account for new themes that emerge during conversations between researchers and participants. Computer-aided qualitative software may be used to assist with data management and organization. Regular discussions between team members from the University of Kelaniya and Johns Hopkins University (JHU) will ensure integration of local perspectives and accurate interpretation of participant comments. To avoid unintentional unblinding, any analyses conducted prior to the end of the cRCT will require agreement between the study PI, Co-Is, and cRCT partners. Any sharing of results prior to official unblinding of the cRCT will be aggregate and not presented by cluster.

Data collection activities: Free-listing of currently used SRs and other mosquito control products and behaviors

23 Free-listing is a structured qualitative method in which participants are asked to name all the items they know that belong to a particular category. This participant-generated list provides the basis for further inquiry about the items such as when, where, why, how and by whom these items are used. Constructing and inquiring further about a participant-generated list of mosquito control products and behaviors will help us understand perceptions of existing prevention measures and the potential and strategies for introducing new ones. However, there may be products identified in the retail audit (described above) that do not appear in the consumer-generated list. In this case, we will add in any such products before moving on to additional exploration of the items.

24 As described by Weller and Romney, a sample size of 20-30 participants is typically sufficient for free-listing within a relatively homogeneous setting (e.g., housing structure, dengue endemicity, socioeconomic status, etc.) such as any of the 3 proposed study settings (13). Thus, we will sample 20-30 participants from study households in each study arm (intervention and control) of the SR efficacy trial, for a total of up to 60 participants. A study team member will ask each participant to list all the methods they use to prevent mosquito bites. Participation involves one approximately 00:30:00 visit and may be audio-recorded if consent is provided.

25 Free-listing data for SRs and other mosquito control products will be analyzed for salience according to the method described by Smith (14). Typically, analyses of this type result in a relatively small number of items (<15) mentioned by a majority of participants and a much larger number of items mentioned by only one or two participants. With consent of the participant, the free-listing discussion may be audio-recorded to accurately capture what participants said about the items they listed. For further analysis and data collection (see ranking below), it is then typical to use only those items mentioned by the majority of participants.

Data collection activities: Ranking of free-list items

26 Free-list data are necessary to generate a set of items that people in a particular setting see as related to a specific category (e.g., mosquito control). The lists themselves, however, do not provide information about several key questions related to reasons why people choose the specific products they use. For instance, lists alone cannot reveal which products or behaviors people see as most efficacious or most affordable and the contexts in which people would use them. To answer these questions, we will ask a new set of participants to rank a subset of the products generated by the free-listing activity according to several criteria.

27 For the ranking exercise, we will include mosquito prevention products and behaviors mentioned by a majority of free-list participants. If too few items are mentioned by a majority during free-listing, a different cutoff will be established to generate approximately 6-10 items for further exploration. To the participant-generated product list, we will add any items from the retail audit deemed to be important but not mentioned during free-listing. Similar to free-listing, this activity will require a sample of 20-30 individuals per site, a total of 60 (13).

28 To collect the ranking data, a study team member will present the new participants with either photographs or drawings of the selected items or behaviors. The photographs or drawings will be presented in a different random order to each participant. Each participant will then be asked to choose the product they consider most effective and the one they consider least effective. Each participant will then be asked to rank the others in order. However, perceived effectiveness is not always a good predictor of what people actually use. Thus, the same participants will be asked to rank the products a second time, based on which product they use most, which product they use least, and order the others in between. Both rankings will be recorded on a data collection form created for this purpose. Once the rankings are complete, the interviewer will choose the product or behavior the participant ranked as most effective and ask about what the participant sees as the strengths and weaknesses of the product, in what conditions they would use it or, if they would not use it, why.

29 The interviewer will then ask if there are conditions in which the participant would use other products or behaviors they ranked as less effective and why. Then the interviewer will ask similar questions about the products the participant identified as ones s/he is most likely to use. Finally, the interviewer will ask what the participant likes or dislikes about the products and behaviors they have identified as most and least effective and those they use most and least frequently. Asking about likes and dislikes for each item would exhaust the patience of most participants, but because different participants select different products as their first choice, it is typically possible to collect information about each product over 20-30 interviews per site.

30 Participation involves one visit of approximately 90 minutes and may be audio-recorded if consent is provided. If the participant consents to be photographed during the ranking

exercise, photographs may be taken to illustrate how the data collection method works when reporting results in presentations, papers, or for educational purposes. However, consent for photographs is not required as a condition of participating in the ranking exercise: A participant who meets other inclusion criteria may consent to participate in the ranking exercise but withhold consent for photography.

31 Ranking data will be analyzed by aggregating perceived efficacy and frequency of use. Interviewee comments about why they see certain products as more or less efficacious, more or less useful, and what products they would use in what contexts will be analyzed using a qualitative coding scheme developed for that purpose.

Data collection activities: In-depth interviews on mosquito control products and practices, mobility, and activity patterns

32 In-depth interviews (IDIs) will be carried out to determine household perceptions about mosquito control products and daily routines. In-depth interviews will follow a semi-structured guide framed around key areas of interest. These will include household decision making around mosquito control, current mosquito prevention methods, barriers and facilitators to use of existing products, daily routines and activity and mobility patterns related to potential DENV exposure. The IDI will include a technique called journey mapping, which will include creating a visual representation of key events and actions that comprise the participants' daily routine. IDIs will take place at the participant's home or another convenient location of his or her choosing.

33 Most IDI participants will be interviewed once. Occasionally, if a participant is particularly informative or a follow-up interview would be useful to clarify something the participant said in an initial interview, he or she may be asked to participate in a second interview of no more than 90 minutes. Based on past experience, this is likely to occur with a maximum of 4-5 participants out of the total sample.

34 Since there is no way to identify in advance which participants will be invited to participate in a second interview, all participants will be asked to consent to a possible second interview during the intitial consent process. At the end of each interview, the interviewer will ask the participant if they are willing to be contacted again should the interviewer have additional questions after reviewing their notes from the first interview. Alternatively, if both interviewer and participant agree at the end of the first interview that they have more to discuss, the interviewer may schedule a second interview immediately for a time convenient to the participant.

35 Topics to be addressed in a second interview will vary by interviewer, participant, and first interview topics, so it is not possible to design a fixed interview guide in advance. This is consistent with standard qualitative research practice in which follow-up questions are not pre-scripted but based upon a participant's answers to previous questions.

36 Data will be collected until saturation is reached on the key topics of interest, up to 30 IDIs. IDI participants will be purposively selected to include males and females from among the free-listing or ranking participants to better understand any unique experiences or associated gender norms that could impact dengue prevention practices. IDIs will be audio-recorded and transcribed on an ongoing basis. Study team members will debrief following each interview to identify emergent themes for follow-up.

37 IDIs will be analyzed thematically through an interactive process, beginning during data collection. Deductive codes will be developed based on the questions in the interview guide. Inductive codes will be added as necessary to account for themes in the data not anticipated during study design. Computer-aided qualitative software may be used to assist with data management and organization. Regular discussions between team members from the University of Kelaniya and JHU will ensure integration of local perspectives and accurate interpretation of participant comments. To avoid unintentional unblinding, any analyses conducted prior to the end of the cRCT will follow the restrictions described for TIPs in subsection 2(c) above.

Data collection activities: Time under protection and activity/mobility patterns

38 Understanding daily routines and activities, as well as travel patterns can provide important information about how much time residents of the study district spend protected or unprotected by the SR product or placebo. They can likewise provide important information about the types of activities that could create gaps in protection and increase risk of DENV infection.

39 JHU may help develop a set of questions related to mobility and time under protection to be incorporated into monthly household surveys routinely conducted by the epidemiological and entomological cRCT teams during SR product replacement. Respondents to these questions will be parents of school-age children.

40 To control for recall bias, complementary information on time spent under protection will be collected using diary cards to track movement and activities of school-age children in real time throughout the day (15). A sample of mothers or other caregivers of children 4-16 years of age enrolled in the cRCT longitudinal panel will be recruited to complete one diary card per day on one child in the household for 7 consecutive days, a span recommended by Mehl, et al., 2014 (16). Parents will be prompted to complete entries onto the card throughout the day: once in the morning hours, once in the afternoon, and once in the evening. To account for seasonality of DENV transmission as well as potential changes in human behavior, data collection will occur at the start of the May-August transmission season through the fall, when DENV transmission rates are considerably lower.

41 Once consent is secured, a study team member will provide diary cards to each enrolled mother or other caregiver and provide step-by-step instructions for completing them. The study team member will then send text reminders at appropriate times during the

day to prompt participating mothers or caregivers to make an entry on the card. The exact time intervals during which the parent or caregiver will record observations will be determined using entomological data to be collected at or shortly after the launch of the cRCT (17). No photographs will be taken during this study activity.

42 After seven days, the study team member will collect the diary cards, upload the data to a secure server, and store the physical cards in a locked, secure place. If a household is not responsive or not available to return the cards, the member will retry at a later time. If social science study team members are unable to retrieve the cards after 3 attempts, they will ask epidemiological and entomological cRCT team members to retrieve them during SR replacement.

43 Sample size was calculated using a 95% confidence interval and a 5% margin of error, and the assumption that children spend 35% of their time under protection. Up to 27 households in each cluster from the cRCT panel will be randomly selected through consultation with the cRCT external biostatistician to ensure the intervention/control balance, as each cluster's study assignment will be unknown to the study team. This approach will yield up to 810 participants.

44 Responses from the study will be compiled and categorized according to date/time of response and question number. In each cluster, the team will calculate the number of hours a participant spent under protection or at risk during potential biting hours over the previous week as well as the median hours spent under protection or at risk in the cluster. The team will also document and count the instances in which certain activities (e.g., walking to school; playing football) were reported, and calculate the median time spent conducting each of the reported activities during potential biting hours. The study team will only use complete data (i.e., from participants who completed each scheduled diary entry for the entire week). Analysis will be disaggregated by sex and will include:

- Calculation of hours spent under protection or at risk during potential biting hours;
- Identification of common activities during times at risk and participation rates;
- Movement patterns within or outside the cluster.

45 To avoid unintentional unblinding, any analyses conducted prior to the end of the cRCT will follow the restrictions described for TIPs in subsection 2(c) above.

Data collection activities: Focus Group Discussions

46 Focus group discussions (FGDs) will be carried out at the end of the study to triangulate and build upon topics that emerge through earlier study methods. The FGDs will cover activity and mobility patterns and perceptions of the SR product and allow for new themes to emerge. FGDs will allow for interaction and discussion across participants and a better understanding of social norms and experiences related to SR product use and other mosquito control measures.

47 FGDs will be carried out until saturation is reached across the key topics of interest. Based on past experience, this may include up to 16 FGDs: four FGDs per cluster in each of four clusters. Two of the selected clusters will be intervention and two will be control, producing a total of eight FGDs in intervention clusters and eight in control clusters.

48 Participants will be purposively selected to include representation from the following categories: local leaders, community members, caregivers of children under 11 years old, and youth ages 12-16 who participated in the cRCT cohort. Focus groups will include an average of 8 people (minimum of 6, maximum of 10), for a total of up to 160 participants. It is anticipated that four of the 16 FGDs will be comprised of youth ages 12-16 years.

49 FGDs will include roughly even numbers of male and female participants to ensure a balance of perspectives across genders. FGDs will take place at an appropriate venue within selected clusters. A trained FGD moderator will lead the sessions in the local languages and a separate note-taker will record verbal and non-verbal information throughout the discussion. The moderator will follow a semi-structured discussion guide, developed around key topics of interest. Each FGD and mapping activity will last approximately 01:30:00 to 02:30:00 .

50 With participant consent, FGDs will be audio recorded. Recordings will be transcribed verbatim in the local language, where non-verbal cues will also be taken into account in the transcriptions, then translated to English. If participants consent, photographs may be taken of the mapping activity described in the FGD discussion guide to illustrate the data collection method when reporting results in presentations, papers, or for educational purposes. Consent for photographs is not required as a condition of participating in the FGD. If some members of the group consent to be photographed and others do not, the study team will limit any photographs to those who have consented.

51 Data will be analyzed iteratively, beginning during data collection through weekly reviews of data and emerging themes. Following data collection, a preliminary codebook will be developed deductively based on discussion guides and research aims and inductively through review of transcripts and field notes. For ease of storage, indexing, and retrieval, transcripts and field notes will be uploaded into ATLAS.ti, a qualitative data analysis software program. All transcripts will be coded in ATLAS.ti, using the final codebook, and will be analyzed by theme. To avoid unintentional unblinding, any analyses conduc¬ted prior to the end of the cRCT will follow the restrictions described for TIPs in subsection 2(c) above.

Data collection activities: Key Informant Interviews with National Level Stakeholders

52 To determine stakeholder perspectives on the adoption and integration of new vector control products such as SRs into the global public health arena, key informant interviews will be conducted with national stakeholders. The purpose of these interviews is to collect information from people who have first-hand knowledge about review,

licensing, adoption, and distribution of vector control products. This will provide insight into potential problems and recommended solutions for getting a new vector control tool into the national public health landscape.

53 Prior to the interviews, a desk review will be undertaken to identify the appropriate stakeholders and to tailor the discussion guide. The desk review will include examining available vector control strategies and procurement policies. Key informant interviews will be carried out with up to 10 stakeholders from the Ministry of Health, National Dengue Control Unit, and other key vector control stakeholders. Interviews are expected to last no more than 90 minutes. With consent of the key informant, interviews will be audio recorded, and interviewers will take notes using a semi-structured template. Notes will be stored electronically and analyzed by theme.

Community engagement

54 Although staff for the cRCT and staff for the social science study will operate separately, cRCT staff will inform participants upon enrollment that the study contains a social science component and that data collectors from the social science study may contact them and invite them to participate in one or more activities relevant to the social science study. The cRCT protocol includes mechanisms to develop and maintain partnerships with local communities ahead of the start of the AEGIS project and throughout its duration in Sri Lanka. These mechanisms include:

1. Community meetings held at the local Ministry of Health clinics where study staff will present the study and have discussions with the community.
2. Study staff will attend the established local Community Advisory Board and opinion leaders meetings; i.e., women groups and men groups (or equivalent) where information sheets will be read and handed to potential participants.
3. Study staff will be granted opportunities to explain the study and have discussions with meeting participants.

55 In addition to these activities carried out by the cRCT team, the social science team will pilot-test all instruments with community members prior to the start of data collection.

56 The complementary social science activities study described here are separate from the cRCT; no JHU staff will be involved in the cRCT. Thus, though associated with a clinical trial, this study does not itself meet the US National Institutes of Health definition of a clinical trial. Staff in both this study and the concurrent SR efficacy trial will be blinded to the intervention status of participants in the SR efficacy trial. The cRCT study team will explain to all participating households that the product is experimental, its efficacy is unknown, and half of all households will receive a placebo with no active ingredient; therefore, the cRCT team will instruct all study households to continue taking whatever vector control measures they already take and not to change their behaviors as a result of participating in the study. When the social science team recruits and consents

households, study staff will reinforce this message that has been previously communicated by the cRCT team.

Participants: Inclusion and Exclusion Criteria

57 Table 2 lists inclusion and exclusion criteria and Table 3 describes the recruitment process for each data collection activity. Study staff will recruit potential participants using the ERC/IRB-approved recruitment script associated with that activity. A member of the study team will determine eligibility based on a potential participant's answers to the questions on the respective recruitment script. If the study team member determines that the potential participant meets all elibility criteria, the study team member will ask if the potential participant is interested in learning more about the study. If the potential participant expresses interest, the study team member will procede with the informed consent process immediately or, if the potential participant prefers, will leave the informed consent form with the potential participant to review and arrange to procede with the consent process at a later date convenient to the potential participant. Recruitment scripts, consent forms, and data collection instruments are all available as supplemental file XX. For activities involving child participants, parent consent forms and child assent forms are also available. All recruitment and consent forms and data collection instruments are available in Sinhala, Tamil, and English thus enabling potential participants to select the language with which they are most comfortable.

Table 2. **Participant inclusion and exclusion criteria.**

	A	B	C
	Data collection activity	**Inclusion criteria**	**Exclusion criteria**
	1. Retail Audit	Individuals age 18 or above who work in a retail outlet within the study area i.e., store owner, manager, salesperson or attendant.	Individuals who are under age 18 or who do not work in a retail outlet within the study area.
	2. TIPs	Individuals age 18 or above who reside in the study area and are competent to offer informed consent; approximately 50% of participants should be male and approximately 50% female.	Individuals who are under age 18 and/or reside outside the study area or who are not competent to provide informed consent.
	3. Free-listing	Individuals age 18 or above who reside in the study area and are competent to offer informed consent; approximately 50% of participants should be male	Individuals who are under age 18 and/or reside outside the study area or who are not competent to provide informed consent.
	4. Ranking		

	A	B	C
		and approximately 50%	
	5. Household IDIs	Individuals age 18 or above who reside in the study area, who have provided detailed answers to the free-listing or ranking exercises and are competent to offer informed consent.	Individuals who are under age 18 and/or reside outside the study sites and/or provided limited information during free-listing or ranking or who are not competent to provide informed consent.
	6. Time under protection study	Individuals in households who are enrolled in SR efficacy trial. Child of participant is enrolled in either primary or secondary school. Child is aged between 4 and 16 years. Approximately 50% of children should be male and 50% female.	Individuals who reside in households not enrolled in SR efficacy trial; children are not aged between 4 and 16 years; children are not currently enrolled in primary or secondary school.
	7. FGDs	Individuals who reside in the study area and are part of the category of interest. For youth ages 12-16, the youth must be able to provide assent and a caregiver must be able to provide consent.	Individuals who reside outside of the study area or who are not competent to provide informed consent. For youth ages 12-16, if the youth is unable to provide assent or a is unable to provide consent.
	8. KIIs	Decision-makers for national programs that would be involved in procurement or implementation of SRs (e.g., head of National Dengue Control Program; head of pesticide licensing agency) in Sri Lanka.	Anyone not in a position to make decisions about procurement or implementation of vector control products in Sri Lanka.

Note: While several data collection activities involve taking photographs of some participants and/or their surroundings, photographs will only be taken with the expressed written consent of the participant. Withholding consent to be photographed or allow one's surroundings to be photographed will not be an exclusion criterion for any study activity.

58 **Table 3. Participant recruitment process for study activities.**

	A	B
	Data collection activity	**Recruitment process**
	1. Retail Audit	Data collectors will visit the sampled retail outlets and determine eligibility using the recruitment script. If the participant meets the eligibility criteria and expresses willingness to participate, then they will be asked to sign a consent form before the interview is initiated. A

	A	B
		field worker representing the University of Kelaniya will recruit participants as described in activities 1 and 2 above, however it is anticipated no recruitment script will be needed since we believe the IRB/ERC will classify this activity as non-HSR.
	2. TIPs	The study team will ask the unblinded DSMB statistician to draw a random sample of 40 households overall: 20 from intervention clusters and 20 from control clusters. The social science team will not know which households are assigned to which arm until after the main study is over. Once the statistician provides the random sample, the field workers representing the University of Kelaniya and community leaders will help recruit 15 households from each cluster (see Section III – Study Design; A (5) – Modified Trials of Improved Practices above for more detail).
	3. Free-listing	For both free-listing and ranking exercises, households will be identified using simple random sampling from a population census created during the SR efficacy trial baseline period. A field worker representing the Clinical Trials Unit, Faculty of Medicine, University of Kelaniya (i.e., University of Kelaniya) will visit the household of each selected individual, ask to speak to him or her, and explain the study using the recruitment script. If the participant is interested in learning more about the study, the field worker will explain the study procedures using the recruitment script and initiate the consent process.
	4. Ranking	
	5. Household IDIs	Household IDI participants will be selected purposively from free-listing and ranking participants. A field worker representing the University of Kelaniya will recruit participants as described in activities 1 and 2 above. Participants who accept to participate will provide consent specifically for this activity.
	6. Time under protection study	Households will be identified using stratified random sampling from a list of households within each cluster. Then, a field worker representing the University of Kelaniya will visit the household and screen for eligibility. If the prospective participant (head of household or other adult that is a parent of an eligible child) is interested, then the field worker will explain the study and conduct consent procedures. If the prospective participant is interested and consents, then the field worker will initiate study procedures.
	7. FGDs	FGD participants will be identified purposively from selected clusters. A field worker representing the University of Kelaniya will visit the household of each selected individual, ask to speak to him or her, and explain the study using the recruitment script. If the participant is interested in learning more about the study, the field worker will explain the study procedures using the recruitment script. If the participant is interested in participating, the field worker will provide the date and time for the FGD.

	A	B
		Parental permission will be sought from the parent/guardian before approaching a child for assent.
	8. KIIs	National stakeholders from the Ministry of Health and partners will be identified by the local PI. A field worker from the University of Kelaniya will recruit participants as described in activities 1 and 2 above; however, it is anticipated no recruitment script will be needed since we anticipate the IRB/ERC will classify this activity as non-HSR.

Participants: Recruitment and Informed Consent

59 Since this social science study is focused on factors affecting social acceptance of SRs for dengue control, participants for study activities 4-7 will be recruited from among housheolds already enrolled in the parent cRCT. Activities 1-3 (retail audit, free-listing, and ranking) and 8 (key-informant interviews) do not require direct experience with SRs, so participants need not be already enrolled in the parent cRCT. Recruitment for all activities will be based on recruitment scripts approved by the three IRBs and included as supplemental file XX. As stipulated by the local and WHO Ethical Review Committees, written consent will be obtained from all participants, with the exception of national stakeholders who will provide oral consent for the KIIs. Participants who are unable to sign will be able to use a thumbprint. Witnesses will be required for participants who are not able to read and/or sign the consent form.

60 To recruit participants under 18 years of age, a study team member will will first approach the child's parent or caregiver, explain the study, and request the parent or caregiver's written consent for the child to participate. If the parent or caregiver consents to their child's participation, the study team member will then explain the study to the child and request assent. The youth and caregiver will both have an opportunity to ask questions. If the youth chooses to assent, they will provide written assent by signing or marking the child assent form.

61 All consent forms have been translated into both Sinhala and Tamil. Table 4 lists the consent form letter (A-H) and the location at which the study staff will request consent from potential study participants for each study activity.

Table 4. Consent forms and consent discussion locations by study activity.

	A	B	C
	Data collection activity	**Consent form**	**Location of consent discussions**
	1. Retail audit	G	Consent discussions will take place in retail outlets at a time convenient to the

	A	B	C
			potential participant.
	2. Trials of Improved Practices (TIPs)	D	Consent discussions for all these activities will occur at the potential participant's home.
	3. Free-listing	AB	
	4. Ranking	AB	
	5. Time under protection study	E	
	6. Household in-depth interviews	C	
	7. Focus group discussions	F	Consent and assent discussions will occur in a private setting at the FGD venue. Form F includes the adult consent form, the adult assent form for youth participants under 18, and the youth assent form
	8. Key informant interviews with national stakeholders	H	Consent discussions will take place at the potential participant's office or another location of the potential participant's choice.

Participants: Descriptions of contacts between the study team and study participants

62 For the retail audit, most participants will be contacted one time for a screening interview to determine whether their retail outlet currently sells mosquito control products or has sold such products in the previous six months.

63 01:30:00 That screening interview will take approximately five minutes. We expect to identify roughly 2,500 retail outlets within the Grama Niladhari Divisions (GNDs) included in the parent cRCT.[1] A subset of approximately 250 of these outlets will be selected for participation in the second phase of the activity which will involve a second interview of approximately 01:30:00 . This means a maximum of two visits and a total of 95 minutes contact time for retail audit participants.

Note

[1]Grama Niladhari Divisions are the Sri Lankan government's most local division. The country is divided into nine provinces, these are further divided into 25 districts. Each district is divided into Divisional Secretary's Divisions which are then further divided into GNDs.

64 TIPs involves the greatest number of study contacts, six altogether, each lasting roughly 01:00:00 to 01:30:00 . The first visit is scheduled to occur one week after the first SR product is installed, the second visit two months after first installation, then at six, 12, 18, and 24 months. This translates to a total possible contact time of 540 minutes (09:00:00) but since all but the first visit are distributed over an interval of several months, the total number of visits should represent a minimal burden for participants.

65 The time under protection study will involve two in-person visits, one at the beginning of the 7-day period, one at the end, each lasting approximately 00:45:00 . In addition, a study team member will text a short message service (SMS) prompt to each participant once each morning and once each evening, reminding them to complete the diary card for the child whose activities they are tracking. Thus total contact time for this activity will be 01:30:00 face-to-face plus 14 instant messages.

66 Free-listing interviews will involve a single visit of approximately 00:30:00 . For most participants, ranking, IDIs, and KIIs will each involve a single interview of approximately 01:30:00 . While participation in one of these activities does not explicitly exclude a person from participating in another, the samples will be drawn from different population groups, so the likelihood of overlap is minimal.

67 The large majority of participants will participate in a single interview. As noted in the activity descriptions above, the study team may invite an IDI or KII participant to participate in a second interview if there are outstanding questions from the first or if both the interviewer and participant agree during the first interview that a second would be helpful. For those participants, total study contact time will be a maximum of 03:00:00 . Based on past experience, we expect this to happen in fewer than 10 cases. Focus group discussions are scheduled to last a maximum of 150 minutes (02:30:00), though most will be shorter. FGD participants will participate in only one group, so their maximum study contact time will be 02:30:00 .

Results dissemination: Expected Application of Study Results

68 As with the affiliated cRCT, results from this study will guide the Ministry of Health in their selection of dengue control strategies. In particular, social science study results will help the Ministry of Health determine the most effective strategies for promoting, installing, and encouraging adherence to appropriate use of SRs in households. Results may also help manufacturers of SRs better understand what characteristics will make such products attractive to end-users. The results of the study will also be analyzed and published in scientific, peer-reviewed journals and may be presented in the form of oral or poster presentations at national or international scientific meetings. To maintain participant anonymity and confidentiality, only de-identified data stripped of any personal identifying information will be presented.

Results dissemination: Dissemination of Study Results to Policymakers, Participant Communities and Participants

69 Dissemination of study results to policy-makers will take place through group or individual meetings where the investigators and/or members of the study team will present study results and distribute leaflets or fliers summarizing key findings. Dissemination to community members and participants will utilize a variety of community-based channels including local newspapers, local radio stations, bulletin boards, and posters. We will also use community-based activities, such as health fairs, concerts, and parades, and community mobilization efforts on prevention of vector-borne disease organized by civil society leaders.

Data Custody, Management, Security, and Confidentiality: Management of personally identifiable information (PII)

70 Data sources will include study participants themselves and, in the case of participants under 18 years of age, a parent, guardian, or legally authorized representative. No medical records or secondary sources will be used as data. Table 5 lists participant privacy issues associated with each form of data collection.

Table 5. Participant privacy issues for study activities.

	A	B
	Data collection activity	**Privacy issues**
	1. Retail Audit	Participation in the retail audit will not involve discussion of sensitive or possibly stigmatizing issues. There are no known risks associated with participation.

	A	B
	2. TIPs	Participation in TIPs will not involve discussion of sensitive or possibly stigmatizing issues. There are no known risks associated with participation.
	3. Free-listing	Neither free-listing of methods for preventing mosquito bites nor ranking of these will involve discussion of sensitive or possibly stigmatizing information. There are no known risks associated with these activities.
	4. Ranking	
	5. Household IDIs	Participation in IDIs will not involve discussion of sensitive or possibly stigmatizing issues. There are no known risks associated with participation.
	6. Time under protection study	Participation in the time use study will not involve disclosure and is unlikely to involve stigmatizing information.
	7. FGDs	Participation in FGDs will not involve discussion of sensitive or possibly stigmatizing issues. There are no known risks associated with participation.
	8. KIIs	Participation in KIIs will not involve discussion of sensitive or possibly stigmatizing issues. There are no known risks associated with participation.

71 Table 6 lists the personally identifying information (PII) that will be collected during recruitment and/or serve as study data. Both data and PII in electronic format will be stored on JHU OneDrive, a password protected platform approved by the JHU Bloomberg School of Public Health IRB as a secure storage site for human subjects research data and PII. PII will be stored separately from data and linked by an alphanumeric study identification number kept in a password-protected file.

Table 6: Personally Identifiable Information (PII) during recruitment and as a part of data collection.

	A	B	C
	PII to be collected or accessed	**During recruitment**	**During data collection**
	Name, signature, initials or other identifiable code	X	X
	Geographic identifier (address, GPS location, etc.)	X	X
	Dates (birth, death, clinical service, discharge, etc.)	X	X
	Contact information (phone number, email address, etc.)	X	X

	A	B	C
	Audio recordings		X
	Full-face photographic images		X

72 Transcriptions and translations from IDIs, TIPs, and FGDs will not include names or other PII. Because the study will need to be able to recontact households participating in TIPs, the study team will retain a codebook linking PII for TIPs households to household ID (HHID) numbers retained in the data. This codebook containing the PII and the link to the HHID will be destroyed once TIPs analysis is complete. The codebook linking PII to household ID information will be stored on JHU OneDrive. Only the social science project coordinator and the overall social science PI will have access to the complete codebook for all data collection activities. Data will only be shared in aggregate form, and will be double-checked to insure that all PII has been removed prior to sharing Identifiable data, including audio-recordings, will be destroyed at the close of the project.

Data Custody, Management, Security, and Confidentiality: Photographic data

73 The sole exception to the management of PII described above will be photographic data. Photographic data is often essential to illustrate both research methods and research results. Comparing photographs taken at different sites and times can often illustrate a range of variation – for instance, in different installation methods for spatial repellents or in the different ways participants organize and classify mosquito control products. Photographs provide scientific audiences with visual and spatial information that helps convey contextual information in a way that words alone cannot.

74 In this study, photographs will be taken only with the express written consent of the participant. As specified in the study consent forms, participants may choose to consent (or not) to three different levels of photographs: (1) those in which humans do not appear at all (i.e., of a wall, household, or surrounding area), (2) those which include human images but with facial features omitted or obscured sufficiently to prevent personal identification, or (3) those that include full facial features. However, consent for photographs is not a condition for participation in any research activity: Participants may refuse to allow photographs but still participate in all other aspects of the activity. Photographs will exclude house numbers, street names, and other features that might permit identification of a particular site and thus a person affiliated with that site.

75 Photographic metadata will be handled according to cybersecurity guidelines developed by the University of Michigan (https://safecomputing.umich.edu/privacy/consider-metadata): Photos will be stored in PNG rather than JPEG format and will be stripped of any metadata related to geocoding or location. Like all other data, photographs will be stored on JHU OneDrive. Both the cRCT and the social science protocols are

implemented under the Advancing Evidence for the Global Implementation of Spatial Repellents (AEGIS) project (5).Any photos to be transmitted electronically for presentations or use in manuscripts or other forms of communication accessible to those outside the research team will be checked a second time before being transmitted to ensure that all metadata have been removed.

76 Photos will likewise be re-checked to confirm deletion of metadata before being uploaded to any digital data repository. Non-photographic data will similarly be checked a second time to ensure all PII have been deleted prior to being uploaded to a digital data repository. The data and supporting information will be made available following completion of data analysis and will be archived and remain open access in the public domain, distributed under the terms of the Creative Commons Attribution (CC-BY) License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Data Custody, Management, Security, and Confidentiality: Data collection formats

77 Data will be collected in a variety of formats including hard copy (paper-based forms), digital (tablet computer using CommCare software, a web-based digital app), audio recording, and digital photography. Table 7 describes data management processes from collection until deletion. This table includes details for each activity regarding responsible persons/roles, the level of access team members will have to the data, the level of data anonymity, risk mitigation strategies, and data ownership.

78 **Table 7: Description of Data Management Procedures.**

	A	B	C	D	E
	Activity	**Data collection**	**Data storage**	**Data analysis**	**Data deletion**
	Retail Audit	An external market research firm with experience in conducting retail audits will collect this data. The social science team in Sri Lanka will oversee data collection, in collaboration with the U.S.-based PI and Co-Is. Prior to data collection, the social science team will conduct a research ethics training with the market research firm. The training will be aligned	Retail audit data will be submitted to the social science study team having already been de-identified by the market research firm.	Analysis will be conducted by members of the social science team in collaboration with the market research firm.	Retail audit data will be maintained by the social science team until the end of the AEGIS project, which is currently planned for 2024.

	A	B	C	D	E
		with the Human Subjects Research Ethics Field Training Guide developed by the JHU BSPH IRB.			
	TIPs	Social science data collection team will collect this data. The study team will retain a codebook linking PII for TIPs households to household ID (HHID) numbers retained in the data.	TIPs data and the codebook will be stored on a secure server only accessible to study team members and the social science data collection team. The codebook linking PII for TIPs households will be stored in a separate folder from the TIPs data.	TIPs data analysis will utilize qualitative thematic coding. Since TIPs data address perceived efficacy, any interim analysis will be aggregated across all clusters. Excluding cluster assignment will minimize the risk of unintentionally unblinding the study. Stratifying by cluster will occur only after conclusion and intentional unblinding of the cRCT.	Interview recordings will be deleted at the end of the AEGIS project, which is currently planned for 2024.
	Free-listing	Data will be collected on a paper form. With participant consent, sessions will be audio-recorded. Recordings will not be transcribed, but will serve as a memory aid for data collectors as they write up their field notes. Since free-listing and ranking participants will be contacted only	Data will be uploaded to a secure server by the data collector. Only study team members will have access to the data at this time. Data collected on paper will be MS Word for later analysis. Audio data will be stored in a separate folder on a secure server. Both data types	Social science study team members will analyze numerical data using an MS Excel-based application. Textual data (explana-tions of choices and rankings) will remain in MS Word and will be	Deidentified data will be archived in CurateND, a data repository hosted by UND. Audio recordings will be destroyed once data analysis is complete.

	A	B	C	D	E
	Ranking	one time by the study, no personally-identifying information (PII) will be collected.	will be identified and linked by a unique study ID number that will not contain any PII.	analyzed manually. Free-listing results will inform the ranking activity. Free-listing and ranking data collection instruments do not ask about the SR.	

	A	B	C	D	E
	Household IDIs	With participant consent, IDIs will be audio recorded. Interviewers will also take notes during the interviews. Both audio recordings and raw field notes will be assigned a unique study ID number and uploaded to a secure server immediately following the interview. Audio recordings and raw field notes will be identified ONLY with the unique study ID number. The interviewer will attempt to limit the amount of PII recorded during the interview and any such PII that appears on the audio recording will be anonymized during transcription and translation.	Recordings and raw field notes will be assigned a unique study ID number. This study ID number will be linked to PII through a password-protected codebook that contains only the study ID number and the PII and is accessible only to the social science data coordinator, and overall social science study PI. After transcription and translation, data will be uploaded to a secure server that is password-protected and only accessible to the study team. Transcripts will not include names or other identifying information. Recordings will be stored in a location separate from transcripts.	Prior to analysis, data will be anonymized. Social science study team members will conduct analysis. Interview transcripts and translations will be identified only by study ID number, not by any PII. IDIs focus on mosquito control products and practices in existence prior to installation of the SR. Since they do not touch on the topic of the SR, there is no risk on unintentional unblinding in any of these activities.	Interview recordings will be deleted at the end of the AEGIS project, which is currently planned for 2024.

	A	B	C	D	E
	Time under protection study	Diary cards will be printed on paper. Parent or caregiver participants will complete one diary card per day for 7 consecutive days by checking appropriate boxes on the paper form. Participants will be prompted to complete entries onto the card throughout the day: once in the morning hours, once in the afternoon, and once in the evening.A social science data collector will retrieve the diary cards at the end of the 7-day period. Diary cards will use the household and participant ID numbers assigned by the cRCT to the participating family.	Social science study team members will be returned completed diary cards to the office. Data from the cards will be entered onto an electronic form stored on a secure server. The physical cards will be stored in a locked file cabinet until analysis. The cRCT household and participant ID number will be the only link between the diary card and the parent and child PII.	Data management during analysis will follow the same process as IDIs described above.	Physical diary cards will be deleted at the end of the AEGIS project and after all data from these cards have been successfully uploaded to CurateND.
	FGDs	With participant consent, FGDs will be audio recorded. Facilitators (members of the social science data collection team) will take notes during the FGD. Both audio recordings and raw notes will be assigned a unique ID number and uploaded to a secure server immediately after the FGD. Audio recordings and raw field notes	Data management during storage will follow the same process as IDIs described above.	Data management during analysis will follow the same process as IDIs described above.	Interview recordings will be deleted at the end of the AEGIS project, which is currently planned for 2024.

	A	B	C	D	E
		will be identified ONLY with the unique study ID number. The facilitator will try to limit the amount of PII recorded during the FGD and any such PII that appears on the audio recording will be anonymized during transcription and translation.			
	KIIs	Social science data collection team will collect this data. Data collection will occur on password-protected electronic devices.	Data management during storage will follow the same process as IDIs described above.	Data management during analysis will be similar to IDI analysis described above.	Interview recordings will be deleted at the end of the AEGIS project, currently planned for 2024.
	Data ownership and sharing	Data are owned jointly and non-exclusively by the Principal Investigators and the collaborating institutions. To the extent possible, key publications during the study and within the first two years the study concludes will be developed based on consensus between the overall social science principal investigator, the country principal investigator, and the overall AEGIS principal investigator. However, should achieving consensus prove impossible, the overall social science PI will have decision-making authority regarding preparation and submission of study-related publications. Beyond 24 months from the conclusion of the study, de-identified data will be uploaded to CurateND, a data repository hosted by the University of Notre Dame. External researchers may request access to these data through CurateND.			

Risks of study participation

79 There are no known physical risks associated with participation in this social science study. Since the study does not involve any use of medication, any medical or surgical procedures, or collection of any biological samples, there is no physical risk of an adverse event occurring for one of those reasons. Topics covered in free-listing, ranking, IDIs, TIPs, and FGDs are of limited sensitivity and should not pose any risk to participants. Nevertheless, to minimize the possibility of breach of confidentiality or

anonymity, all consent procedures and data collection activities will be conducted in a private location to minimize distractions and ensure the comfort of the participant.

80 As part of the consent process, study staff will inform participants that there is always a slight risk of a breach of anonymity or confidentiality, despite systems in place to protect data security. Full-face photographs or photos in which a participant could otherwise be identified will be used only if the participant consents explicity in writing as part of the informed consent process. There is a checkbox in the consent form that allows participants to choose if and how photos are taken and used.

81 To minimize these risks, all participants will be informed during the consent/assent process that their participation is voluntary and that they can withdraw at any time without consequence. All data collected will be stored on password-protected devices only accessible by study team members. No full-face photos or photos in which a participant could otherwise be identified will be taken without the participant's explicit written informed consent. Any names, locations, or other potentially identifying information about the participant will be removed and not included in a caption of the photo. Since this is a low-risk study, we cannot quantify an expected number or frequency of adverse events. In past studies of this type conducted by this study team, no participant has reported any adverse or severe adverse event.

Study burden on participants

82 The social science study consists of multiple activities at the individual or household level, however consent for each activity is separate. It is likely that different households will be selected for different methods and in each case, the participant has the right to decide whether and how much to participate. As described above, most data collection activities involve a single visit or participation in a single activity. For TIPs, participation involves six 60 to 90-minute visits over the course of a two-year period.

COVID risk mitigation

83 The study team will follow local government guidelines, which may change over time. All staff will be instructed to stay home from work if they have a fever or other symptoms of illness. Symptom screening of participants will be conducted by staff calling participants prior to visiting. If any participant in the household has a fever, social science study staff will follow government guidelines in force at that time to decide whether to proceed with or postpone the visit. Depending on activity and feasibility, some data collection may be done over the phone. Otherwise, the visit will be rescheduled.

Direct personal and social benefits of study participation

84 There are no direct benefits to participants of the social science research study; however, results from this study will provide valuable information on SRs that can inform

improved DENV prevention in Sri Lanka and beyond.

Payment or token of appreciation

85 As approved by the University of Kelaniya Ethics Review Committee, parents or caregivers who participate in the time under protection study will receive LKR 3,600 (the equivalent to approximately $10 USD at the time this protocol was written) as a token of appreciation for their participation over the 7-day period of the activity.

86 All FGD participants will receive LKR 2,500 (the equivalent of approximately US $6.94 at the time this protocol was written) to cover the cost of any transportation they might use to reach the FGD site. Light refreshments will also be provided. Key informant and in-depth interviews will be held at a location convenient to the participant (e.g., their home or office) and so will not require additional travel.

Study Management: Oversight Plan

87 Like the cRCT to which it is linked, the social science study is based at the Clinical Trials Unit, Faculty of Medicine, University of Kelaniya ("U Kelaniya"). The U Kelaniya Ethics Review Committee (ERC) took primary responsibility for reviewing the scientific and ethical justification for the study. The research plan, recruitment scripts, informed consent forms, and data collection instruments originally submitted to WHO/ERC in September 2022 are those reviewed and approved by the U Kelaniya ERC. In addition to U Kelaniya, study collaborators include the National Dengue Control Unit and RemediumOne in Sri Lanka and Johns Hopkins University and the University of Notre Dame in the United States.

88 The social science study was conceived of and designed collaboratively by investigators affiliated jointly with the Clinical Trials Unit, Faculty of Medicine, University of Kelaniya and the Epidemiology Unit and National Dengue Control Unit of the Ministry of Health, Sri Lanka (Dr. Korelege Hasitha Aravinda Tissera, Dr. D. S. Anoja F. Dheerasinghe) and Johns Hopkins University Bloomberg School of Public Health (Dr. Steven Harvey) with oversight by Dr. John Grieco, (University of Notre Dame), the Principal Investigator for the cRCT. Figure 2 illustrates the relationship between the different collaborators and their roles in implementing the social science study.

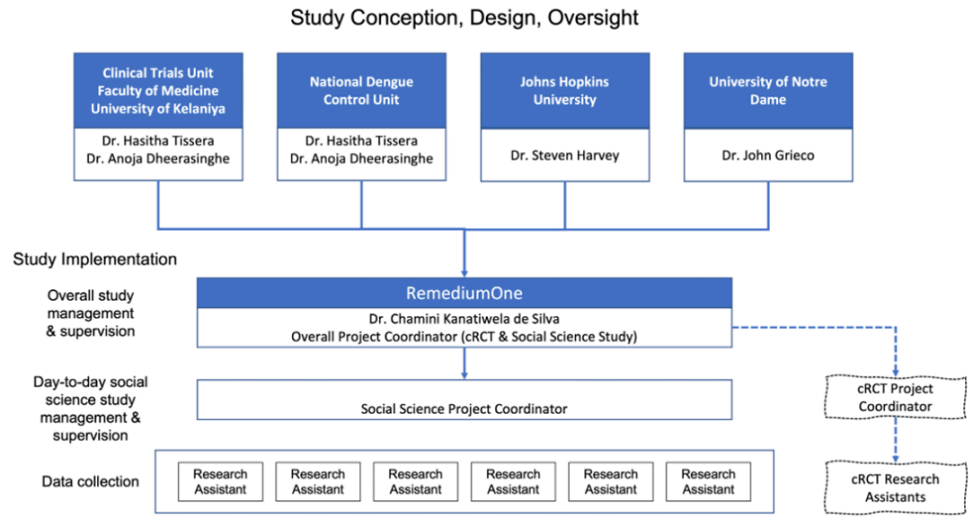


Figure 2: Social Science Study Organization and Management

89 The PI, Dr. Harvey will oversee the study from Baltimore, Maryland. Dr. Harvey will oversee training activities and will make supervisory visits throughout the data collection period. Dr. Tisseria, local PI, and co-Investigator Dr. Anoja will oversee the study in Sri Lanka. Co-investigator Mr. Albert Casella will supervise implementation of the retail audit with support from Mrs. Danielle Piccinini Black and will provide support to study activities.

Study Management: Qualifications of study personnel?

90 Dr. Harvey is a faculty member of the Johns Hopkins Bloomberg School of Public Health in the Department of International Health and has 25 years' experience leading human behavioral research studies in Africa, Latin America, and South Asia. Dr. Tisseria is the site PI and a Senior Medical Epidemiologist with the Sri Lanka Ministry of Health. He has experience working in dengue prevention and control in Sri Lanka since 2002; he began work with the Sri Lanka Ministry of Health as a Regional Epidemiologist in Eastern Province in 1998. A medical doctor since 2000, Dr. Anoja has worked with public health institutions, including Sri Lanka's anti-malaria campaign, since 2004. She has been a board-certified Medical Specialist in public health since 2015 and joined the National Dengue Control Unit, where she is now a Senior Consultant, in 2017. Mrs. Piccinini Black has expertise in market-based research and serves as adjunct faculty at the Johns Hopkins Carey School of Business. Mr. Casella has 10 years' experience supporting social science research in low- and middle-income settings.

91 The Clinical Trials Unit (CTU) at the University of Kelaniya Faculty of Medicine in Ragama, Sri Lanka, and the Sri Lanka Ministry of Health have contracted with RemediumOne (Pvt) Ltd., to implement the current study. RemediumOne is an ISO-

certified medical and public health research firm established in 2009 and affiliated with the CTU. Over its 14-year history, RemediumOne has conducted 35 clinical trials or other types of public health research in collaboration with the Sri Lankan Ministry of Health, private industry, and both Sri Lankan and international academic institutions. RemediumOne will also be implementing day-to-day activities for the parent cRCT previously approved by the U Kelaniya ERC and the WHO/ERC ("Spatial Repellent Products for Control of Aedes-borne Diseases in Gampaha District, Sri Lanka," ERC.0003619 v9.1 Approved 14 February 2022). While RemediumOne will manage day-to-day activities of both studies, each will be managed by different staff members. There will be no overlap between the two in terms of implementation, data collection or data management. More information about RemediumOne and its research experience is available on the **RemediumOne website**.

Study Management: Human subjects research (HSR) ethics training for non-professional study personnel

92 Dr. Harvey and Mr. Casella will work with RemediumOne to train local data collectors using the BSPH Ethics Field Training Guide.

Study Management: PI site visits, supervision over consent and data collection, communication plan for PI and study team

93 The PI, Dr. Harvey, and co-investigator Mr. Casella will meet with the Sri Lanka data collection team weekly via Zoom and will travel to Sri Lanka periodically to lead trainings and supervise data collection. During weekly Zoom meetings with the Sri Lankan social science team, Dr. Harvey and Mr. Casella will discuss activities completed during the previous week and planned for the following week including consent, enrollment, and data collection. Discussions will include review of and feedback on all study activities to ensure that the local team is complying with the study protocol. Timing of visits to Sri Lanka will be scheduled to coincide with the launch of new data collection activities but will also include review of ongoing activities.

Study Management: Protocol compliance and recordkeeping

94 The study team will develop and implement standard operating procedures (SOPs) for protocol compliance including informed consent, each data collection activity, and the data management, storage, and security procedures discussed elsewhere in this study plan. SOPs will also be developed for securely storing consent forms and for following IRB regulatory and institutional requirements including preparation and submission of study progress and continuing review reports. All these topics will be included as part of the agenda for weekly team meetings and for field visits by the JHU PI and co-

investigators. Project Manager Dr. Chamini Kanatiwela de Silva, will provide day-to-day oversight for this study and for the cRCT to which it is linked. Dr. Harvey and co-investigator Mr. Casella will make supervisory visits throughout data collection to ensure procedures are being followed appropriately. Dr. Harvey and Mr. Casella will also meet with Dr. Chamini and with the social science project coordinator weekly by phone or on a web-based meeting app to monitor study implementation including protocol compliance.

Study Management: Reporting unanticipated problems/adverse events

95 Data collectors will report any unanticipated events or problems to the Project Manager, who will report them to the local IRB, local PIs Drs. Tisseria and Anoja, and PI Dr. Harvey within 72 hours. Dr. Harvey will be responsible for notifying the JHU IRB. If a data collector suspects child abuse within a study household, that data collector will report it immediately to the Project Manager. The Project Manager will report it to the study PIs, the Sri Lanka National Child Protection Authority, and the police.

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This project is made possible thanks to Unitaid's funding and support. Unitaid saves lives by making new health products available and affordable for people in low- and middle-income countries. Unitaid works with partners to identify innovative treatments, tests and tools, help tackle the market barriers that are holding them back, and get them to the people who need them most – fast. Since it was created in 2006, Unitaid has unlocked access to more than 100 groundbreaking health products to help address the world's greatest health challenges, including HIV, TB, and malaria; women's and children's health; and pandemic prevention, preparedness and response. Every year, these products benefit more than 170 million people. Unitaid is a hosted partnership of the World Health Organization.