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Understanding behavioral, market and practical factors affecting the potential of household spatial repellent use for malaria control in western Kenya: study protocol

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Abstract

Background

Vector control strategies, namely mass distribution of insecticide-treated nets and indoor residual spraying, have contributed to declines in malaria morbidity and mortality. Despite these gains, malaria kills over half a million people each year. Complementary tools are needed to close existing gaps in protection. Spatial repellents are products designed to release vapor-phase active chemicals into the air to prevent malaria-causing mosquitoes from entering an enclosed space, interrupting host detection and/or human blood-feeding thereby supplementing existing vector control strategies by providing a malaria prevention alternative in contexts where current methods are less effective. For spatial repellents to be successful at scale, it is important to understand factors that can influence acceptance and uptake of the product, considerations for procurement and implementation, and how spatial repellents will fit into the broader malaria prevention landscape. To meet this objective, we are conducting social science research following the protocol presented here.

Methods

The social science study is set in Busia County in western Kenya. It includes a retail audit to identify mosquito control products available in the local market, free-listing and ranking of mosquito control products and practices used by residents, observations of nighttime activities and sleeping patterns, trials of improved practices to better understand participant experiences with and perceptions of spatial repellents over time, and key informant interviews with national-level stakeholders.

Discussion

Social science findings will complement data from a concurrent cluster-randomized placebo-controlled trial in the same location. Trial data will contribute to a determination by the World Health Organization Vector Control Advisory Group on spatial repellents as a new product category for vector control. If the spatial repellent product is effective, it may be deployed in malaria endemic areas to complement other vector control interventions. Social science study results will inform programmatically useful recommendations for spatial repellents procurement, promotion, and distribution in Kenya and beyond.

Guidelines

Background:

Malaria, a parasitic disease transmitted by the female Anopheles mosquito, is responsible for over half a million deaths and 249 million cases each year **(1)**. Insecticide-treated nets (ITNs) and indoor residual spraying (IRS) represent the two core vector control interventions recommended by the World Health Organization (WHO) for wide-scale implementation among populations at risk of malaria **(2)**. Between 2000 and 2019, global malaria incidence decreased from 82 to 57 per 1,000 people at risk, and deaths from 897,000 to 568,000, before both increased in 2020 due to disruption to services during the COVID-19 pandemic **(1)**. ITNs, which provide a physical barrier of protection and kill mosquitoes that come into contact with them, were responsible for an estimated two-thirds of the reduction in malaria infections between 2000 and 2015 **(3)**.

Despite these gains, there are limitations to the protection these tools can provide. ITNs, for example, are primarily designed to protect people while indoors and sleeping, limiting their protection during times when people are awake and local malaria mosquitoes are biting. This issue can be compounded by shifts in vector biting behavior from a nighttime indoor pattern to earlier evening and outdoor patterns **(4)** as well as growing levels of insecticide resistance in malaria vectors **(5)**.

Complementary malaria prevention tools are urgently needed to address these challenges and fill remaining gaps in protection. Spatial repellents (SRs), products designed to protect an enclosed space and thereby limit human exposure to disease-carrying mosquitoes, could supplement ITNs and IRS by providing a malaria prevention alternative in contexts where these methods are less effective **(6)**. This social science study is designed to complement a concurrent double-blinded cluster-randomized placebo-controlled trial (cRCT) testing the efficacy of an SR in western Kenya, where high levels of malaria transmission persist in the context of wide-scale coverage of ITNs **(7, 8)**. Both the cRCT **(9)** and the social science protocols are implemented under the Advancing Evidence for the Global Implementation of Spatial Repellents (AEGIS) project **(10)**. The cRCT is evaluating the efficacy of the Mosquito Shield™, an SR that incorporates transfluthrin on a plastic sheet, on malaria-related outcomes in Busia County **(9)**.

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 malaria prevention landscape. Social science research can shed light on patterns of malaria exposure and factors that may increase or inhibit the operational effectiveness of the product. Social science endpoints will be gathered alongside the trial to better understand factors that could influence the success of implementing SRs. This will include capturing perceptions of the SR product, measuring activity patterns and time spent under the protection of the SR product, documenting availability and use of other mosquito control products, identifying opportunities to optimize distribution pathways, and developing key social and behavior change considerations.

Study objectives:

- **General Objective**

The overall objectives of this social science study include:

1. Determine what factors are likely to facilitate or inhibit successful global health implementation of spatial repellents (SRs) at scale in Kenya;
2. Determine appropriate strategies to reinforce facilitating factors and overcome inhibiting factors related to social acceptability and perceived efficacy of SRs among end-users (households).

- **Specific Objectives**

Specific objectives include:

1. Document the types and quantity of mosquito control products available in retail outlets within the study area prior to distribution of the SR product;
2. Characterize perceptions of malaria susceptibility and context for use of mosquito control products and practices within the study area prior to distribution of the SR;
3. Measure nighttime activities and sleeping patterns related to exposure to malaria and prevention gaps within the study area through observations across seasons;
4. Determine perceived efficacy and user preferences for a new spatial repellent in study area through in-depth follow-up with a subset of SR trial participants;
5. Identify considerations for introduction and implementation of SRs in Kenya through engagement with key stakeholders at the national level after the SR product has been distributed and prior to the completion of the two-year study.

Consent for publication

Not applicable

Availability of data and materials

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.

Competing interests

The authors declare that they have no competing interests.

Troubleshooting

Study site

1 The social science study will be carried out in the same study area as the concurrent SR efficacy trial **(9)** in Busia County, north-west of Kisumu City. Approximately 750,000 people reside in Busia County, primarily comprising Luo, Luhya, and Teso ethnic groups. This study will be conducted in two sub-counties in Busia County, Teso North and Teso South, which are predominantly Teso-speaking communities. The area experiences year-round malaria transmission, with an estimated average of 2-4 malaria infections per person per year with peaks in transmission corresponding with the long rains in March through June and short rains in October and November **(11)**.

Study design

2 This is an exploratory study using primarily qualitative methods, so it is not designed to test any specific hypotheses. Findings will be descriptive in nature. The qualitative methods rely principally on purposive rather than random sampling and sample sizes are determined based on application of standard qualitative sampling practices **(12-14)** rather than calculating a sample size using a specific formula as would be the case for a quantitative study meant to test a hypothesis.

3 The social science study design is informed by a social-ecological model **(15)**. This theoretical framework recognizes that factors at multiple levels will influence the success of SR introduction and uptake. In Kenya, data will be collected across the individual/household, community, retail, and national levels to better understand the path to successful large-scale implementation of SR products. This data will contribute to the larger body of evidence required for successful introduction of SRs into the global public health landscape.

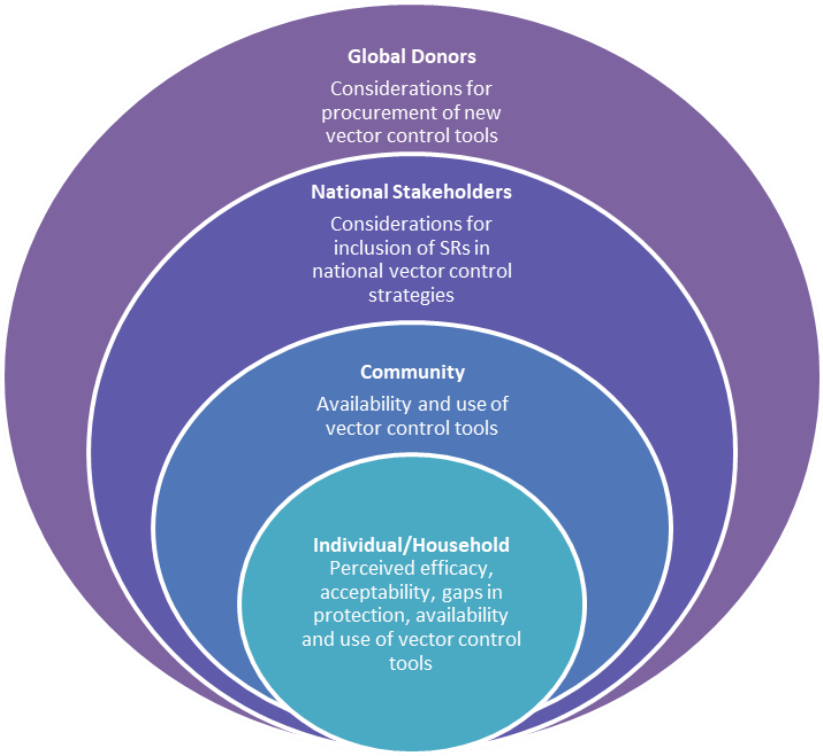

Figure 1. *Socio Ecological model for Introduction of SRs into Global Public Health Landscape*

4 Methods will include a retail audit to identify malaria prevention tools available in the local market, free-listing and ranking of malaria prevention products, in-depth interviews, observations of nighttime activities and sleeping patterns, trials of improved practices (TIPs) to better understand participant experiences with and perceptions of SRs over time, and key informant interviews (KIIs) with national-level stakeholders **(Table 1)**.

	A	B	C	D	E
	Data collection activity	**Total sample size***	**Data collection level**	**Inclusion Criteria**	**Exclusion Criteria**
	1. Free-listing	60	Individual	Individuals aged 18 or above who reside in the study areas and are competent to offer informed consent	Individuals under aged 18 and/or reside outside the study area or who are not competent to provide informed consent

	A	B	C	D	E
	2. Ranking	60	Individual		
	3. In-depth interviews	30	Individual		
	4. Structured spot-check observation	144 heads of household will be recruited (up to 864 household members will be observed)	Household	Households within the study area with head of household or representative 18 years or older and competent to provide informed consent	Households outside of the study area or without a representative aged 18 or over able to provide informed consent on behalf of the household
	5. Semi-structured observation	72 heads of household will be recruited (up to 432 household members will be observed)	Household	Households within the study area with head of household or representative 18 years or older and competent to provide informed consent	Households outside of the study area or without a representative aged 18 or over able to provide informed consent on behalf of the household
	6. Community observation	12	Community	Individuals aged 18 years or above who reside in the study areas and are competent to provide informed consent	Individuals under 18 years and/or reside outside the study area or who are not competent to provide informed consent
	7. Trials of improved practices	40	Household	Individuals aged 18 and above and who reside in one of the study sites in a household participating in the SR trial and are competent to offer informed consent	Individuals under aged 18 or residing outside the area or who are not competent to provide informed consent
	8. Retail audit	Up to 250	Retail outlet	Individuals aged 18 or above who work in a retail outlet within the study area	Individuals under aged 18 or who do not work in a retail outlet within the study areas

	A	B	C	D	E
	9. Key informant interviews	Up to 10	National stakeholder	Decision-makers for national programs that would be involved in procurement or implementation of SRs	Anyone not in a position to make decisions about procurement or implementation of vector control products in Kenya

Table 1: Data collection activities

5 Social science data collection involving cRCT participants will be evenly split across the SR intervention and control arms. However, since both this study and the parent cRCT are double-blinded, the social science study team cannot know study arm assignment at the time of recruitment. To maintain blinding, the 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 or households per cluster, ensuring equal distribution between arms without needing to know study arm assignment.

6 In addition to individual and contextual factors, it is important to consider how gender norms may influence access to or use of the product and opportunities to address any gender-related barriers to uptake. Gender can vary across settings and over time and can have a significant impact on a range of health behaviors and outcomes **(16)**. Gender norms can impact all aspects of malaria prevention, including access to and use of prevention measures, household decision-making, as well as patterns of malaria exposure **(17)**. Gender will be considered and reported on across social science research activities.

Activities under the specific objectives

7 **Free-listing of currently used SRs and other mosquito control products and practices:**

7.1 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 they 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 below) 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.

7.2 For both free-listing and ranking exercises, participants will be identified using simple random sampling from a population census created during the SR efficacy trial baseline period. A field worker from KEMRI, trained by KEMRI in research ethics and qualitative research methods, 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 and begin the consent process.

7.3 In structured methods such as free-listing and ranking, there is no mathematical or statistical formula for calculating the sample size needed to determine an outcome based on a hypothesized effect size and Type I error rate (alpha level) equivalent to sample size formulas used in quantitative research. The cognitive anthropologists who developed these methods have typically relied on empirical experience that demonstrates how many interviews were needed before additional interviews stopped producing new information **(18, 19)**. Using empirical data, cognitive anthropologists developed a formal mathematical model estimating the number of informants (sample size) needed "to classify a desired proportion of questions with a specified confidence level when average cultural competence is known" **(20)**. This model suggests that by interviewing informants with an average cultural competence of 0.9 (on a scale of 0.0-1.0), a researcher will be able to accurately infer the culturally "correct" answers to 95 percent of questions related to a given topic at a 99% level of confidence by interviewing as few as four informants (Ibid.). Cultural competence includes skills to listen, observe, evaluate, analyze, interpret and relate in order to successfully engage with differences **(21)**. Unfortunately, average cultural competence of informants is rarely known a priori. As a result, researchers using these methods have typically made the much more conservative estimate of 0.5 average cultural competence. At this level, the model predicts that 29 informants will be needed to achieve the same level of accuracy. By convention, researchers have thus adopted the practice of proposing sample sizes of 20-30 participants belonging to any relatively homogeneous cultural group when collecting structured qualitative data.

7.4 More recently, many of the anthropologists involved in developing structured methods have re-examined their original conclusions through a systematic review of 28 datasets that employed these methods in a wide variety of contexts over the intervening 30+ years **(22)**. Samples in the datasets ranged from 20 to 99 interviews. The review finds that in almost all cases, the lists produced generated a relatively small number of items mentioned by a significant portion of the sample (≥ 20%) and a long tail of items

mentioned by two or fewer interviewees. Building models based upon the existing data, the authors demonstrate that the sample size needed to identify all items in a given category depends on the number of items in and the cohesiveness of the category, both of which are very difficult to predict prior to data collection. However, identifying all items in a particular category would often require sample sizes of 100 or more while identifying all culturally relevant items (defined by the authors as items mentioned by ≥ 20% of participants) is sometimes possible with a sample as small as 10. However, the sample size required to identify all the culturally relevant items in a particular category also depends on the average number of items per list which, in turn, depends on the skill with which interviewers probe for additional items. Given the number and complexity of factors – including factors impossible to identify prior to data collection – they cannot offer a set sample size formula. Instead, they suggest applying the following principles in determining sample size:

Note

In general, probing and prompting during an interview seems to matter more than the number of interviews... If the goal is to get a few widely held ideas, a small sample size will suffice. If the goal is to explore a larger range of ideas, a larger sample size or extensive probing is needed. Sample sizes of one to two dozen interviews should be sufficient with exhaustive probing (listing interviews), especially in a coherent domain. (Ibid., p. 15)

7.5 This is the logic upon which we have concluded that a sufficient sample for purposes of this study should be 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. Participants will include roughly even numbers of males and females.

7.6 Free-listing data for SRs and other mosquito control products and practices will be analyzed for salience according to the method described by Smith **(23)**. 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. For further analysis and data collection (see ranking below), it is then typical to use only those items mentioned by the majority of participants.

8 **Ranking of free-list items:**

8.1 Free-list data is necessary to generate a set or group 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 mentioned on the lists according to several criteria. 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 arm, a total of 60 **(18, 20, 22)**.

8.2 To collect the ranking data, study team members 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 actual 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 sheet 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. 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.

8.3 Ranking data will be analyzed by aggregating perceived efficacy and frequency of use. Interviewee comments about why participants 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.

9 **In-depth interviews on ITNs, IRS, and spatial repellents:**

9.1 In-depth interviews (IDIs) will be carried out to determine household perceptions about where ITNs and IRS cannot provide protection and where a spatial repellent might serve as an effective alternative. 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, and barriers and facilitators to use of existing products, and activity and sleeping patterns during times when malaria vectors are biting. In-depth interviews will also explore how gender norms may influence access to and use of prevention tools and night time activity patterns.

9.2 Data will be collected until saturation is reached on the key topics of interest, up to 30 IDIs. This sample size is based on modelling by Guest, et al about the number of in-depth interviews necessary to achieve thematic saturation **(24)**. IDI participants will be purposively selected to include roughly even numbers of male and female participants from free listing and ranking activity participants. 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. 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. Based on past experience, this is likely to occur with a maximum of 4-5 participants out of the total sample. IDIs will be analyzed thematically through an interactive process, beginning during data collection.

10 **Nighttime observations:**

Nighttime human activity will be examined to better understand when and where people risk malaria exposure. This will include structured and semi-structured household observations and community-level observations of nighttime activities occurring away from home.

10.1 **Structured household spot-check observations**

- Structured household observations will be conducted in the same households where mosquito collections are being carried out as part of the SR efficacy trial. Observations will be carried out once during baseline and quarterly thereafter for a total of nine rounds of observations over two years. The study team will use simple random sampling with replacement to select 24 households per study arm (48 total), at three time points during the study. The same households will participate in both

mosquito collection and nighttime observation during each round of data collection for up to nine visits per household.

- This protocol was first developed and approved by the IRB prior to the start of the 2019 COVID pandemic. The original plan was to have study team members carry out the structured household observations. COVID made that impossible since having someone from outside of the household spend an entire night in a participant's home would be unsafe for both the observer and the household members. As a result, the research team has decided to modify our methods by recruiting only someone from within the household to conduct the structured household observations.
- Observers will be selected from among 4 household members who will have been previously identified and trained to participate in the entomology component of the larger Spatial Repellent project. All candidates for the entomology component of the trial must be 18 or older, literate, agree to participate voluntarily, and receive approval to participate from the head of household. For each household selected for the structured observations, we will select an observer from among the 4 entomology volunteers based on performance during training and pilot testing. This will include level of participation and ability to carry out observations accurately and completely.
- Household members will be involved in only the structured form of observations, which involve recording a small set of highly structured responses on the location of household members over a 5-minute interval once per hour. To more accurately reflect the nature of these observations, we will refer to them from this point forward as spot check observations. Training will include hands-on instruction and practice carrying out the structured spot-check observations. During training and pilot testing the study team will provide detailed feedback to ensure trainees are following study procedures and to address any issues that arise during the process. The training will also include a module on human subjects' research using an adapted version of the training approved by the local IRB, the KEMRI Scientific Ethics Review Unit (SERU). Household members selected as observers will receive an honorarium of Ksh. 1,000 (approximately US $10.00 at the time of writing the protocol) per day of observation in recognition of their time and effort. This is the same daily amount that our local collaborator, the Kenya Medical Research Institute (KEMRI) will pay entomology participants and the same amount customarily paid to community members who volunteer to help with data collection of any type in any local study.
- To ensure quality during data collection, a study team member will make in-person visits to check on each observer throughout the night. To ensure sufficient supervision, observations will only be carried out in a small number of households each night. To protect both the household member conducting the observation and the study team member from COVID transmission, in-person visits will occur in the open air with both parties wearing masks to be provided by the study. Tablets will be programmed to notify household observers when it is time to carry out the hourly spot check. The tablet will record the time at which each spot check is entered. Finally, all electronic data submitted by household observers will be reviewed by the

study team within 48 hours of completing the observation to identify any data entry errors or other anomalies.

- The household spot-check observation form will be pilot tested and refined prior to the start of data collection. After a household agrees to participate, a study team member will administer a pre-observation survey. Using the previously validated spot-check observations form, the selected household member/spot-check observer, will spend 5 minutes of each hour between 5 p.m. and 7 a.m. to record the location and activities of all household members. Information will be recorded about when household members are indoors, outdoors, or away from home, under a bed net, and types of activities carried out throughout the night.
- Structured household observation data will be recorded electronically using tablets configured with programmed questionnaires and observation forms. The data will be uploaded daily to a secure server configured with Secure Socket Layer (SSL) with encryption. Appropriate logical constraints (skip patterns) will be applied to each question to ensure data quality. In addition, for household observations, time stamps will be fixed to prevent later entry of missed observations. Supervisors will review data for quality daily and provide feedback to the data collection team.
- Structured household observation data will provide information on time spent under the protection of a bed net and time spent under the protection of an SR. Human behavioural data will be combined with mosquito biting patterns to estimate human exposure to malaria vector bites across intervention and control arms. Exposure to malaria vectors will be estimated by weighting the mean indoor and outdoor biting rates throughout the mosquito collection period by the proportion of humans that are observed to be indoors or outdoors at each time period, taking into consideration when participants are under a bed net using the methods described by Monroe et. al. **(25)**.
- Direct observation creates the potential for reactivity, also known as the Hawthorne Effect, a phenomenon in which participants alter their normal behavior in response to the presence of an observer **(26)**. To reduce the threat of reactivity in this work, observations will be carried out by a household member who will be trained and supervised by the study team. Other work on this topic suggests that reactivity is often unrelated to the behavior of interest and decreases over time **(27, 28)**. Semi-structured household observations
- When COVID conditions permit and the Kenyan government issues guidelines permitting it, study team members will complement the structured household spot-check observations with a smaller number of more detailed semi-structured observations. Semi-structured observations will be carried out in 72 different households in clusters where structured observations will be taking place. The semi-structured observations will collect the same information as the structured observations but will include an additional paper-based form to collect qualitative information on nighttime activities and sleeping patterns continuously throughout the night. Semi-structured observations were successfully carried out previously by a research team in northern Ghana **(29)**. The semi-structured observations will provide

rich detail of nighttime activities and sleeping patterns, and the context in which they occur, that cannot be obtained through more structured methods.

- For households that consent, structured and semi-structured household observations will include taking photos of the environment and nighttime activities. Photos will provide detailed information on the context of the nighttime activities and environment that may not be captured through other data collection methods and will be useful in presenting research findings to those unfamiliar with the context. Prior to household observations, the observer will fill out a brief pre-observation survey, which includes information on housing characteristics and a register of household members to be observed. Because data is being collected for individual household members results can be disaggregated to better understand trends across age and sex in the intervention and placebo communities. This includes exploring time spent outdoors while malaria mosquitoes are active, use of ITNs, and time spent away from home by age and sex.

10.2 **Semi-structured community observations**

In addition to household observations, semi-structured community observations will be carried out to better understand activities occurring away from home and outside of the protection of SR products. Observations will include hourly recordings of routine activities and special events occurring within selected clusters, but outside of the peri-domestic space i.e. inside and directly outside of homes. Up to 3 observations will be carried out at different times of year in each of the 12 clusters (and surrounding areas), where structured and semi-structured household observations are being carried out (maximum total: 36 observations). Examples of routine community activities that may be observed include buying and selling at local shops, income-generating activities such as brickmaking, fishing, and distilling alcohol, and entertainment activities such as watching television at local gathering places. Examples of special events that may be observed include holiday celebrations, weddings, funerals, and religious events **(30)**. Documenting events like these through community observation is an important part of assessing exposure to potentially infectious mosquito bites and the extent to which a spatial repellent could provide effective protection. Community activities and events will be identified with the help of local leaders in the selected communities.

11 **Modified Trials of Improved Practices:**

11.1 Upon distribution of the spatial repellent 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. 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 **(31, 32)**. 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.

11.2 We refer to the approach to be used in this study as “modified TIPs” because TIPs was 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 **(33)**. 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.

11.3 In this study we are introducing a new product rather than a new set of behaviors. Modified TIPs will ask participating households for input about 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) and other issues that arise over the course of testing. As described above, the study team will ask the unblinded DSMB statistician to draw a purposive sample of 30 households. The statistician’s assistance will assure that the sample consists of 15 intervention and 15 control households, though the social science team will not know which households are assigned to which arm until after the main study is over. The sample will include males and females and questions asked during TIPs interviews will explore how gender may impact experiences with and perceptions of the SR product.

11.4 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. Participants will therefore be selected with help from the local research partner and community leaders. A study team member will make a total of 6 visits to each TIPs household according to the following schedule: (1) one week after installation to capture initial reactions to the product and any immediate suggestions for change; (2) two months after 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 to capture the perceptions and suggestions of households that have experienced the product over time. Each round of TIPs data will be analyzed thematically using a qualitative coding scheme developed for that purpose.

12 **Retail Audit:**

12.1 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. There are many assumptions in these settings that people are using a variety of mosquito control products to meet their lifestyles 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. 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.

12.2 The audit will begin by listing all retail outlets in the study area with simultaneous identification of outlets that stock or have stocked mosquito control products. This process will be included as part of the mapping exercise carried out under the SR efficacy trial. For each retail outlet captured in the census, 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. 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 (an East African example would be Megastores such as Nakumatt, Uchumi, or Shoprite) 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.

12.3 From that overall census, a subset of retail outlets that currently stock or 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 sell 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.

12.4 Prior to data collection at each study site, the guide will be pilot tested in a small number of retail outlets not selected as part of the study sample. The guide will then be adapted as necessary to include the types of outlets and types, brands, and quantities of available mosquito control products. 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 survey is initiated. A semi-structured interview guide will be administered by data collectors to store owners or managers of the sampled retail outlets. As part of the interviews, data collectors will ask permission to take photos of the mosquito control products found in each outlet. The interviews will last between 30 and 45 minutes each. Descriptive analysis will be carried out including frequency and proportion of retail outlets stocking mosquito control products and the types of spatial repellents and other mosquito control products by retail outlet category.

13 **Key Informant Interviews with National Level Stakeholders:**

13.1 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 in Kenya. This will provide insight into the nature of potential problems and potential solutions for getting a new vector control tool into the global public health sphere. Where possible, male and female stakeholders will be included.

13.2 Prior to beginning KIIs, 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 national level stakeholders from the Ministry of Health, National Malaria Control Program, Pest Control Products Board, and partners. This sample is based upon our estimation of the total number of MOH officials likely to have information about the decision-making processes involved in adopting a new vector-

control product. Key informant interview notes will be recorded in a semi-structured template and audio-recorded. Notes will be stored electronically and analyzed by theme.

Data management and analysis

14 Data from the retail audit and structured household observations will be collected on tablets. Electronic devices will be used that allow a detailed programming of skip patterns and internal controls to ensure that all necessary data is collected and consistent. Depending on local conditions data from each data collector will be uploaded daily to the web-based database, maintained by study team members. From the digital data entry devices, the data from household observations and pre-observation surveys will be transferred via a secure Internet connection to the central data base (e.g. MS Excel), which will be kept on a non-mobile device and will be encrypted, and password protected. Once data collection for each assessment round has been completed and data verified, the data sets will be transferred to R or Stata Statistical software package for further consistency checks and preparation for analysis. Qualitative data from semi-structured household observations and community observations will be analyzed thematically.

15 IDI, TIPs, and KII transcripts and audio files will be stored on a password-protected computer. Transcripts will not include names or other personal identifying information of participants. Qualitative data will be analyzed thematically through an interactive process, beginning during data collection **(34)**. 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 KEMRI and JHU will ensure integration of local perspectives and accurate interpretation of participant comments.

16 Free-listing data for SRs and other mosquito control products will be analyzed for salience according to the method described by Smith **(35)**. 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 mentioned by only one or two participants. For further analysis and data collection (see ranking below), it is then typical to use only those items mentioned by the majority of participants. Ranking data will be analyzed by aggregating perceived efficacy and frequency of use. Interviewee comments about why participants 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.

Discussion

17 Data collected through the social science study will complement epidemiological and entomological data collected from the efficacy trial in western Kenya. The efficacy trial data will contribute to a WHO Vector Control Advisory Group (VCAG) determination about the public health value of spatial repellents for malaria prevention **(10)**. If VCAG determines that spatial repellents are of public health value for malaria prevention, SRs will become a new class of vector control products. As one dimension of its evaluation, VCAG will review user acceptability data collected as part of the social science study. SRs could then be deployed in malaria endemic areas to complement other vector control interventions. Results from the social science study will provide critical information on how to effectively scale-up SRs and promote high levels of use.

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Authors' contributions:

SAH conceived the study and led the proposal and protocol development. AM conceptualized and drafted significant portions of the protocol. EO and GO contributed to study design and proposal development. DPB designed the retail audit. SAH, AM, GO, EO, JIO, SE, DPB and PAO trained the data collectors. JPG (PI) and NLA (Scientific Director) are leading the AEGIS project and providing guidance and feedback throughout the study. All authors read and approved the final manuscript.

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