

RBM Vector Control Working Group

Optimizing Evidence for Vector Control Interventions Work Stream

Progress on 2012 Work Plan – Christian Lengeler, Swiss TPH, Switzerland

The main areas of work being covered by the Work Stream are:

1. Developing testing guidelines for new VC paradigms:
 - The Work Stream is working closely with (External Scientific Advisory Committee) ESAC3 of IVCC and WHO on issues related to the development of new vector control interventions, including draft testing guidelines.
 - The Work Stream aims to develop with IVCC a similar working relationship to that between the Continuous Distribution Work Stream and the NetWorks Project.
 - New paradigms include: (1) spatial and individual repellents, (2) indoor spatial repellents in Indonesia and (3) attractive toxic sugar baits.
2. Interactions between multiple VC interventions:
 - LLIN-IRS interactions have been investigated in Bioko, Sudan and Tanzania (London School of Hygiene and Tropical Medicine (LSHTM) and The Gambia (Medical Research Center (MRC) and LSHTM)).
 - Other interactions need consideration.
 - A stronger link with modeling is required.
3. Updating and networking on new technologies, including:
 - Plastic sheeting.
 - Durable wall linings.

Discussion

The agricultural sector has decades of experience in new innovation and could provide guidance for the development of new public health interventions. Public sector needs to provide significant investment in innovation as the commercial market alone may not realize the immediate return for investment that may accrue in the long run.

5th Optimizing Evidence for Vector Control Interventions Work Stream Meeting
(Joint meeting with ESAC3)
9.00-12.00, Tuesday 29th January 2013
Auditorium, IFRC, Geneva

Chairs: Christian Lengeler and John Gimnig
Rapporteur: Lucy Tusting

Spatial and individual repellents – Sarah Moore, LSHTM, UK

Spatial repellents are a new paradigm but not a new technology. Repellents might complement LLINs and IRS, which do not protect from all potential exposure to infectious bites. New evidence has been collated with a view to presenting to VCAG, including a meta-analysis using Cochrane methods that shows that spatial repellents had a protective effect against exposure to infectious bites in six studies (OR=0.66, 95% CI 0.44-1.00).

To assess the protective effect of spatial repellents and to gather sufficient evidence for a policy recommendation, repellents will need to be assessed through Phase I, II and III trials. Phase III trials are currently being considered for repellents to examine the community effect (vector survival and abundance) and man-vector contact, however this decision is pending further data from a tropical repellent study by Coosemans and colleagues in Cambodia. Achee and colleagues have also worked on standardised protocols for measuring vector endpoints in a Phase III spatial repellent trial, which must demonstrate an individual and community level reduction in incidence. These correlates must be tested in a range of transmission settings. This work will feed back into endpoints for a Phase II trial (i.e. mode of action, optimum dose of molecule needed, distance that protection extends and where should the molecule be placed). New guidelines from WHOPES have been developed to harmonise testing procedures: 'Guidelines for Efficacy Testing of Spatial Repellents'.

There is an economic benefit to encourage investment in the development of spatial repellents: 45-50 billion mosquito coils are used annually by approximately 2 billion people. A cost comparison of different interventions indicates that costs may be comparable to ITNs, IRS and emanators.

Discussion

- The WHO guidelines on efficacy testing will be a starting point for measuring a reduction in man-vector contact as an outcome. WHOPES is keen to be informed of new developments so it can proactively prepare for the immediate evaluation of new products.
- Antibodies to mosquito saliva could be used as an outcome as a proxy for exposure to bites.
- It will be increasingly necessary to build a suite of outcomes including parity (for measuring vector survival) for testing such interventions, which will provide evidence for an entomological mode of action.

Indoor spatial repellents in Indonesia – Din Syafruddin, Eijkman Institute for Molecular Biology, Indonesia

Methods: A cluster randomised, double-blind, placebo-controlled trial of indoor spatial repellents was conducted in Indonesia to investigate whether spatial repellents can reduce clinical attack rates and entomological outcomes. The primary endpoint was incidence of clinical malaria and the secondary outcome was the human biting rate. The study site is characterised by simple, mud-walled and thatched-roofed housing. Four clusters with a population of 400 people were selected in two villages. Forty five men per sample were administered DHA/pp+PQ to clear infection, followed up and then excluded following re-infection. Two identical coils were placed inside each house. Weekly entomological monitoring of five sentinel houses was conducted per cluster by human landing catch.

Results: 231 participants were screened and 180 enrolled, of which 170 completed radical cure leaving approximately 40 participants per cluster. There was insufficient power to draw conclusions about village level effects. A 61.1% protective efficacy was observed against new parasite infections. There was a significant reduction in the human biting rate in homes with spatial repellents. The primary vector was found to be *An. sundanicus*.

Discussion

Publication of all data (Phase II and III) would allow correlation between different outcomes to be assessed. It would also be valuable to record ARI.

LLIN-IRS interactions: an update on new evidence

Sudan – Hmooda Kafy, National Malaria Control Programme, Sudan

Methods: A trial was conducted in an area of low transmission to assess the additive protective effect of IRS with LLINs. 140 clusters in 4 study areas were randomised to receive either LLINs alone or LLINs with IRS. The size of clusters ranged from 5200 to 7600 with a total of 28000 children aged <10yrs enrolled across all clusters. The primary outcome was incidence of clinical malaria measured by passive and active case detection by community health workers.

Results: Preliminary data suggests no added protective benefit of IRS with high LLIN coverage. The incidence of clinical malaria across all clusters is 38 per 1000 per annum, with no significant difference in the rate between arms (RR 1.09, 95% CI 0.63-1.89).

Bioko –Immo Kleinshmidt, LSHTM, UK

Methods: The added personal protection from nets in the context of short residual IRS and year round transmission was assessed. It was also assessed whether a reduction in mosquito mortality due to a loss of insecticide effect leads to an increased risk of malaria.

Results: It was found that prevalence increases with time since last spray (OR 1.7, 95% CI 1.2-2.5) and sleeping under a net reduces the risk of malaria infection (OR 0.7, 95% CI 0.6-0.9). Mosquito mortality declines with time since last spray. The data suggests that IRS is compromised since residual effects do not last all transmission season and this may explain the benefit of using nets (i.e. there is a greater proportional benefit of LLINs in areas of higher IRS coverage).

The overall conclusion from Bioko and Sudan is that LLINs plus IRS combined have a greater protective effect than one intervention alone if one of the two is compromised, for example where there is inadequate use of nets or where IRS has a short residual effect.

Tanzania – Natasha Protopopoff, LSHTM, UK

Methods: A cluster-randomised controlled trial was conducted in Muleba district, Kagera region, Tanzania, an area of moderate transmission with two transmission seasons. Baseline parasite prevalence was 8.5% in 2011-2012 according to the 2011-2012 Malaria Indicator Survey. The objective was to assess whether IRS with bendiocarb plus LLINs provide added protection against clinical malaria in children aged 6m to 14 yrs compared to LLINs alone. 50 clusters per arm were selected with 80 households per cluster. In the baseline year all arms received IRS and LLINs and in the intervention year, one arm received LLINs alone. The primary clinical outcome was prevalence measured by microscopy and Rapid Diagnostic Test (RDT) and the entomological outcomes were Entomological Inoculation Rate (EIR) and density of adult anophelines, measured by light trap collections. A household questionnaire was also conducted.

Results: LLIN coverage (the proportion of households with at least one net) was 90.8% (95% CI 89-92.3%) post-distribution at baseline in both arms and comparable between control and intervention clusters. In the intervention year, there was little difference between arms in parasite prevalence (OR 0.48, 95%CI 0.18-1.24) however anopheles density was significantly reduced in the intervention arm (OR 0.26, 95%CI 0.15-0.34). The results suggest there may be some additive protective effect of IRS with LLINs, compared with LLINs alone, in areas of moderate net use and high pyrethroid resistance.

SANTE trial, The Gambia – Christian Lengeler Swiss TPH, Switzerland on behalf of Steve Lindsay

Methods: A two-year cluster-randomised controlled trial was conducted in the Upper River Region of The Gambia. 93 villages in 70 clusters were randomly allocated to receive either LLINs alone or LLINs plus DDT IRS (35 clusters per arm). The total study population was 36,611 with a cohort of 7858 children aged 6m-14yrs. The primary outcome was incidence of clinical malaria in children aged 6m-14yrs measured by passive case detection.

Results: Survival analysis indicates no difference in protection against clinical malaria, malaria infection or anaemia between the two arms. WHO bioassays conducted in 2011 indicated 89% mortality to DDT, suggesting low levels of resistance. However a mortality rate of 46% in two villages on the south bank indicated higher levels of resistance in some locations. In conclusion, IRS did not add protective effect under these circumstances.

Discussion

- The findings of the four studies above indicate that high coverage with IRS with a longer residual efficacy (and an effective insecticide) could limit the need for adding LLINs. Similarly, high LLIN coverage would limit the impact of adding IRS. Studies that have shown added value of implementing both LLINs and IRS may have done in areas with lower coverage of one or both interventions and the apparent added value may have been due to one intervention compensating for the low coverage of the other.
- The implications of the results for resistance management and GPIRM were discussed. Does adding the second intervention reduce selective pressure? Is there value of IRS as an initial step to knock down transmission and then using LLINs to maintain transmission at a low level? No clear answers are currently available to these questions.
- The application of IRS is often sub-optimal, therefore this needs to be considered in these evaluations and data is required on this. Until recently it was difficult to ascertain the quality

of spraying in the field, but IVCC has developed field tests to assess this. In some ways therefore these trials reflect real-world application rather than perfect implementation (i.e. effectiveness not efficacy).

- It would be valuable to conduct a cost-analysis of the combinations and to consider the operational implication of results, i.e. the incremental benefits of additional interventions combined with a cost-effectiveness analysis.

Update on developments in plastic sheeting and durable wall lining – Richard Allan, MENTOR Initiative, UK

Insecticide treated plastic sheeting (ITPS) is a dual purpose tool providing both shelter and pest control, to reduce dependency on specialized vector control teams and to improve longevity and compliance. There is a considerable literature on this intervention (18 publications), of which two are WHO recommendations relating to the Horn of Africa and to the Indian Ocean tsunami region. A double-blind phase III trial using ITPS was conducted in two refugee camps in Sierra Leone (Largo and Tobanda). This indicated a 62% protective efficacy of ITPS against malaria infection with full protection (inner wall and ceiling). ITPS is highly effective in emergencies and has protected 500,000 people in emergencies to date. A general recommendation from WHO for use by agencies in emergency situations is awaited.

Durable wall lining is another dual purpose tool designed to provide an aesthetic home improvement that screens gaps and windows, kills resting mosquitoes and has a long residual efficacy. Messenger et al conducted a recent meta-analysis in which the bioefficacy of durable linings showed little decline over 12-15 months whereas IRS declined by 6 months with 100% loss by 12 months. Durable linings are highly acceptable to users. In Angola, the first Phase III trial of durable linings has been conducted in six villages in three pairs (Brosseau et al., 2012) and two further large studies are planned this year in Tanzania (of a first generation durable lining) and Liberia (of a second generation durable lining).

Discussion

Membership of VCAG is being finalised. VCAG will soon request data from interventions such as ITPS, to be submitted for proof-of-principle. WHOPES will then establish product standards for efficacy and safety.

Toxic sugar baits – Gunter Mueller, The Hebrew University of Jerusalem, Israel

Methods for detecting sugar in mosquitoes and for assessing the attractiveness of sugar compared to humans and chickens were described. Work is ongoing in Mali to assess the relative preference of *An. gambiae* to different sugar sources. Recently published studies have assessed how early *An. gambiae* is feeding on sugar in the field, whether sugar feeding influenced by the environment, whether there is a difference in sugar feeding between indoor and outdoor feeding mosquitoes and the rate of detectable and digestion of sugar meals over time. Preliminary results indicate that the importance of sugar feeding for *An. gambiae* has been underestimated. Attractive Toxic Sugar Baits (ATSB) use baits prepared from fermented fruit with added stabilisers and oral toxin. A study was conducted in northern Mali in a small village surrounded by 80 ASB stations (50% with sugar bait, 50% with control). The ASB attracted 7.82 times more females than the control.

Discussion

- There is no growth of bacteria or fungi in the ATSB due to preservative, nor does palatability change over time.
- Concern over non-target insects (such as bees) was voiced, however analysis of a range of insect species caught through human landing catch and spray catch indicates that very few were poisoned by the ATSB. Ant protection can be added using grease and large insects can be screened out with netting.

Draft testing procedures for combination nets – Hilary Ranson, LSTM, UK

An additional set of standards is required to evaluate combination nets. Combination nets are those that contain pyrethroids plus a second active ingredient. Only two are currently on the market (Sumitomo Olyset Plus®; Vestergaard Permanet 3.0®). Methods for testing claims of superiority are required. For example, how can it be established that one LLIN is more effective against pyrethroid resistance mosquitoes and reducing selection for resistance in the population than another?

To assess whether a LLIN is more effective against pyrethroid resistance mosquitoes, standard methodology would be appropriate for Phase I trials, although the resistant strain to be tested needs careful definition. Phase II (experimental hut) trials would need to be conducted in areas known to be resistant to the specific pyrethroid used in the net (i.e. the study should proceed only if a cone bioassay indicates resistance is compromising conventional LLINs). The effects of synergists and secondary insecticides must also be determined prior to the trial. A Phase III trial would need to demonstrate that the combination net significantly reduces the number of blood fed mosquitoes collected resting in and exiting houses, compared to a conventional LLIN, and that this effect is sustained for the lifespan of the net.

To assess the effect of a LLIN in reducing selection for resistance in the population, studies must determine LC50 before and after net use. Such studies could be conducted in a biosphere, but ultimately large-scale community trials would be needed.

Discussion

- There was some discussion of how to define the threshold level of where a conventional net is compromised. It is necessary to know the strength of resistance within a population and to find an operationally significant cut-off.
- Careful definitions are required, for example synergists should not be classified as an active ingredient. A definition of resistance management is also needed; does management entail reducing resistance, slowing it or maintaining at a given level?
- Comparison products for the trials described above must ideally have the same type of pyrethroid. If such a product does not exist there is no operational benefit in creating an artificial product comparison, therefore it is necessary to be pragmatic and to use a similar product as a comparison.
- Guidelines for new testing methods are important because it is difficult to compare data from individual studies when different methodologies are required.

Initiative for new vector control interventions from the Bill and Melinda Gates Foundation (BMGF)
– Kate Aultman, BMGF, USA

There are three objectives in the BMGF portfolio:

1. To extend and maintain the life of LNs and IRS through resistance management and new active ingredients.
2. To develop transformational new tools to enable malaria eradication.
3. To support the creation of an enabling environment for innovation.

The critical path for the development of new tools includes: (1) early lab studies to define the overall concept, (2) small-scale proof-of principle studies, (3) final prototype design, (4) confirmation and quantification of efficacy (multi-site; single, common core protocol), (5) product reach and essential characteristics. BMGF would also like to consider the engineering approach to evaluation (i.e. making trials as slim as possible whilst remaining robust). VECNet is a new online tool with various resources including maps of different vectors and their suitability for different interventions due to exo- and endophily.

Discussion – All

The discussion focused on (1) how the VCWG and WHO can productively work together and (2) overlap between the Work Streams. It will be difficult to eliminate all overlap however it is the responsibility of Work Stream leaders to communicate and reduce this as far as possible.

It was discussed how the VCWG can interact with the WHO new committees. WHO appreciates the interaction between the VCWG, VCAG and VCTEG. WHOPES also welcomes the drafting of guidelines by academia.

- The role of VCAG is to assess new tools and paradigms in all vector-borne disease. It will not address implementation issues at the country level. The VCWG should support the generation of new evidence, which will then be assessed by VCAG.
- Where proof of principle has been established, it is the role of VCTEG to examine implementation issues and related policy recommendations. The VCWG should identify gaps and make recommendations to VCTEG. Potential overlap between VCWG and VCTEG will require careful consideration and the VCWG should avoid the policy and normative functions of WHO, however overall the VCWG likely to speed up the process of approving new interventions for malaria control that will be considered by the VCAG and VCTEG.
- The overall remit of the VCWG is advocacy, communication and resource mobilisation. The VCWG can provide a forum for new ideas and can help widely communicate discussions being held at VCAG and VCTEG. It should also support the development and evaluation of new interventions. The strong links between the VCWG and ministries of health can help countries with implementation.

Actions and 2013 Work Plan

1. Reinforce communication with Work Stream members.
2. Hold a meeting on combined LLINs and IRS.
3. Circulate draft documentation on LLINs and IRS for input.

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Agenda		
8:30-9:00	Coffee and tea	
	Poster viewing	
9.00-9.10	Welcome and overview	Christian Lengeler
		John Gimnig
9.10-9.25	<i>New paradigm 1:</i> spatial and individual repellents (10 min overview and 5 min discussion)	Sarah Moore
9.25-9.40	<i>New paradigm 2:</i> Indoor spatial repellents in Indonesia (10 min overview and 5 min discussion)	Din Syafruddin
9.40-10.20	LLIN-IRS interactions – an update of recent evidence (10')	Immo Kleinschmidt
	- Sudan and Bioko	Mark Rowland
	- Tanzania	Steve Lindsay
	- Gambia	
	(3x7 min presentation, 7 min discussion)	
10.20-10.30	Brief update on developments in plastic sheeting and durable wall lining	Richard Allan
	(5 min overview and 5 min discussion)	
10.30-10.50	<i>New paradigm 3:</i> toxic sugar baits (10 min overview and 10 min discussion)	Günter Müller
10.50-11.10	Draft testing procedures for resistant mosquitoes (10 min overview and 10 min discussion)	Hilary Ranson
11.10-11.30	Initiative for new VC interventions from the BMGF (10 min overview and 10 min discussion)	Kate Aultman
11.30-12.00	Work plan for 2013, including interactions with IVCC	All
	Closing	Christian Lengeler John Gimnig
12:00-13:00	Lunch	
	Poster viewing	