

Roll Back Malaria Vector Control Working Group (RBM VCWG)
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Moevenpick Hotel, Rue de Pre Bois 20, 1215 Geneva

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2nd LLIN Priorities Work Stream meeting
14:30-17:30, Wednesday 8th February 2017
Co-leaders: Hannah Koenker & Lucy Paintain

Introduction – Hannah Koenker, Johns Hopkins University Center for Communication Programs

The goal of the LLIN Priorities Work Stream is to maintain high levels of ownership and use of serviceable LLINs in endemic countries through distribution, LLIN durability and next generation nets.

Prioritization for ITN distribution in resource-constrained settings – Melanie Renshaw, the African Leaders Malaria Alliance

Universal coverage with vector control was a top priority for countries applying for GF funding 2014-2016. When funding was allocated, almost 50% (\$1.5 billion) was on vector control, within that most of the funding (\$996 million) was spent on LLIN campaigns and a further \$272 million went to continuous distribution of LLINs. Guidance for countries was to front load resources allowing time later on to fill gaps in funding as required. Countries gave equal prioritization to continuous distribution and campaign distribution needs. Incompletely funded campaigns responded (except in 1 case) by retaining universal coverage as a goal, and to make higher burden geographical areas a priority. In the period 2018-2020 malaria allocation Nigeria, DRC, Tanzania, Kenya, Ethiopia, South Sudan and Niger together have a shortfall of around 75 million LLINs. Additional resource mobilization support will be provided.

Economic, Financial, and Donor costs of continuous distribution channels – Josh Yukich, Tulane University

The scale up in ITN coverage has been hugely successful despite some heterogeneity and a question over the sustainability of coverage. This analysis looked at the cost of providing continuous distribution through case studies of different strategies (school based, ANC/EPI and community-based); review and meta-analysis of existing data; and finally using those outcomes to carry out cost-effective comparisons. In terms of cost drivers, the distribution of costs has not changed much over time as LLINs remain the largest cost for mass or continuous distributions. Country contributions were much higher in continuous distribution systems compared to campaign delivery, around 15-40%. Taking a general view, it seems that continuous distribution costs may not be significantly higher than campaigns. Current information indicates that CD strategies can be effective at delivering nets. The next steps are to determine the additive costs, and what the relative cost-effectiveness of these approaches is in terms of public health impact in varied epidemiological settings.

Continuous Distribution Discussion - All

- It was queried whether areas left without nets in countries' GF prioritisation were low burden. It was responded that the gaps in coverage were in areas of high burden. Therefore, it is between these areas of high burden that prioritisation that decisions had to be made. However, it was emphasised that although prioritisation decisions were made at planning stages, these did not translate to implementation as the gaps in resources had been filled by the time of the campaign.
- The success in filling the funding gaps was not due to luck but down to a lot of hard work from countries and from within the RBM partnerships.
- All countries did prioritise ANC and EPI (infants and pregnant women) before moving onto targeted geographical distribution. There was no examination in the analysis of the added benefit in terms of presence of nets bringing more women into ANC.
- One of the primary obstacles to CD are stock-outs, where not enough nets are allocated to ANC. Distribution through both ANC and EPI are required to make good progress to universal coverage.
- This prioritisation analysis allowed the Global Fund guidance to be reviewed, although it was found that the situation varied so much from country to country that very detailed advice would not be appropriate.
- It was queried whether the costs of next generation nets have been examined. The expectation is that the cost per unit will be higher, so the question is whether the cost-effectiveness is enough to make that worthwhile. This has not really been scrutinised in detail yet, specifically with regards to next generation nets. However, the overall cost estimates are very sensitive to the unit cost of nets when this is varied in sensitivity analyses.
- It was asked whether CD or campaigns was more effective in rolling out nets. Although both approaches have advantages, the big difference between them came from the level of investment from the country which was much higher in CD. The effectiveness was not looked it in this study, other data does suggest that CD is better at sustaining coverage.
- The broader costs/benefits of campaign versus continuous distribution were not considered e.g. the cost to the health system of campaigns diverting resources; broader health system strengthening benefits of integrated delivery of nets through routine services.

LLIN Durability Assessments: What we've learned and what's next? Evidence-based results from 8 countries – Laura Norris, PMI/USAID and Olivier Briet, Swiss TPH

This review by PMI brings together durability monitoring data from 21,000 LLINs across 37 sites in 8 countries. Methodologies were varied, all were prospective rather than retrospective, but both cross-sectional and longitudinal studies were included, as well as differing levels of randomisation in the selection of nets, and different household survey tools, lab and field hole counting and categorisation.

Key findings:

- Net attrition varied widely between countries.
- Net durability was very similar across brands, with high variation within and between countries.
- There were large disparities between lab and field categorisation of holes.
- In terms of bio-efficacy, there were large differences between countries for the same brands.
- The total AI measured by GC or HPLC was again more variable by country rather than by brand. Most came out below target, although this might be due to late sampling.

- Comparing bio-efficacy and AI by brand showed very little correlation at lower doses, although there is better agreement at high doses.
- Questionnaire data showed that damage and destruction was not the main cause of net loss. Other major reasons included movement to another location, or nets that were stolen or sold.
- Nets that have a long survival because they are stored away do not provide any malaria protection, whereas a net that is used frequently, but is then discarded due to damage, has actually provided more malaria protection.

ABCDR Study – Functional survival and methodologies for bio-efficacy testing – Sarah Moore, Swiss TPH and Ifakara Health Institute

The ABCDR study examined 3,420 households in 8 districts in Tanzania to reflect the range of epidemiological settings found in the country. The blinded study is powered to look at attrition, physical degradation, bio-efficacy and chemical content of Olyset, PermaNet 2.0 and NetProtect nets over 3 years. After 3 years, 32% of nets were ‘unserviceable’ by WHO definitions according to proportionate hole index. One net brand (data currently blinded, but should be presented at the end of the year) performed less well, mostly down to the difference in pHl (median pHl double that of the other two brands). Work is currently underway to look at the impact of hole location as well as hole size on mosquito entry. In addition, data is being examined to see at what point householders discard a net because it is ‘too holed’ to use, and whether this corresponds to mosquito penetration. Government universal LLIN distribution has reached 80% of households in the study sites within the past 12 months, but many new nets are being stored rather than used, and the point at which a switch is made to a new net is also being examined. Qualitative work is also ongoing on net care and repair.

Durability Monitoring of LLINs Discussion – All

- The hole size assessment is definitely variable, which is to be expected particularly between lab and field data. But when this is translated into categories (good, damaged and too torn), then nets tend to fall into the same category regardless of who or how the hole assessment has been done.
- It was queried whether any of the sample sizes in the studies included in the PMI review were large enough to look at intra-country variability. Some are big enough, although this has not yet been looked at.
- It was also queried whether it was clear from the PMI review which brand was the best performer in the field. The data was too confounded to make any clear recommendation and it is clear that any such data needs to be collected in each country due to the significant between-country variations in durability of the same net brand.
- The non-use of nets seems to be a huge problem, and deserves greater attention. This has implications for the cost effectiveness.
- It was noted that the target dose for new LLINs is some amount of g/kg or mg/m², +/- 25%, and that these tolerance limits are built into the specifications. ITNs are not expected to retain initial doses of insecticide over their entire lifetime. Therefore, measuring levels of AI in older nets with an expectation that it should be the same as the levels in a new net is not appropriate or useful.
- More detailed information on net size, shape and colour should be gathered and more attention paid to the community preferences in order to increase net usage.

I2I Update – Angus Spiers, Innovation to Impact

An update on Innovation to Impact (I2I) was given. I2I is a process initiated to look at the bottlenecks in getting new vector control products through to getting a WHO recommendation. Three key issues were identified; the disincentives for innovation in the current system; improving efficiency of the evaluation process; and putting in place some quality control process. A number of work streams have helped achieve these goals, including in Good Laboratory Practices (GLP) accreditation, industry engagement, country-level impact and procurement plans. This has led to enhanced or accelerated processes in Vector Control Advisory Group (VCAG) evaluation of new tools, guidance on dossier requirements, Pre-Qualification (PQ) led dossier assessment, and normative guidance from WHO Neglected Tropical Diseases (NTD) and Global Malaria Programme (GMP), as well as new data generation through GLP sites, manufacturing site inspections, post-marketing quality management and collaborative registration with national regulatory authorities.

The road to standardized quality control for LLIN – Stuart Turner, Quality Inspection Unit, UNICEF

Quality assurance (QA) is process driven during manufacturing, whereas quality control (QC) looks at the outcome product of these processes. QA is an assessment of the social aspects (such as pay and conditions, child labour), a factory tour (health and safety, fire safety, environmental issues) and the application of QMS (ISO 9001:2008). The QC checks whether the product meets chemical and mechanical standards, container stuffing, etc. A standard pre-delivery inspection (PDI) process was initially a response to differing results of inspections within UNICEF, but was rolled out to other agencies (including Global Fund, PMI, PSI) and in October 2016 the WHO Vector Control Products Quality Assurance Group agreed to formally move forward with a standard PDI approach. Although the process is standardised, the decision on the outcome of these tests is with the procuring agency. Next steps include adapting new QA processes for new ISO 9001:2015, which are the International Standard covering quality management systems.

Regulatory Processes Discussion – All

- Comment that I2I has helped fill a gap on the manufacturers' side. On the buyer's side, there remains a gap where decision-making is very difficult without data being gathered and assessed in the same way by the same agencies. Who guides country decisions on which PQ approved net to use?
- The new system will not fix the problems associated with transport and storage, as at present there is little data on the problems that occur.
- With next generation nets, informed procurement will need better data than is presently available.

Work Plan and Next Steps – Hannah Koenker and Lucy Paintain

1. Host conference calls to keep updated on ongoing work.
2. Look at net use by season – so surveys in December can be scaled to predict net use in July – challenged as an activity for this work stream.
3. How do we take net use into account when assessing net durability?
4. Every country should collect its own durability data.
5. Provide a platform for information exchange – what data are missing, who can provide the data or the networks.
6. Next generation nets & PQ process transitions: help prioritise and focus attention on key issues.
7. Look at scenarios of continuing universal net coverage with next generation nets. What are some of the likely scenarios for need for new products identify the likely funding gaps and how they could be bridged.

8. Better comparison between brands could help stimulate competition on pricing and would help decision makers in charge of net procurement.

Session 2: Feedback from the work stream meeting and discussions

The goal of this work stream is to maintain high levels of ownership and use of serviceable LLINs in endemic countries by focusing on (i) distribution approaches, (ii) LLIN durability and (iii) next generation nets. The presentations were summarised and the questions that were discussed were highlighted.

- Ongoing Questions from Previous Years
 - The impact of net preference on ITN use? In SSA there appears to be no programmatic effect of preferences on use, which has implications for procurement.
Discussion
Net preferences are not being accommodated. Can the work stream find a small piece of work on ways of facilitating between manufacturers and consumers? A paper will be presented at VCTEG, and also submitted for peer-review and publication.
 - The cost/value of sustaining ITN access over time vs. dropping between repeated campaigns. Much discussion around distribution decisions. How are existing nets in houses taken into account in successive campaigns when households may accumulate nets, storing new ones for later use?
 - What is the impact of location of net holes on overall durability; impact of durability on ITN retention and use (or vice versa), and what drives household decisions to switch to a new net?
 - Deployment of next-generation nets – monitoring and evaluation requirements.
 - Insecticide resistance is a common issue across work streams, but it is everyone's challenge.
- LLIN Distribution
 - Implications of net cost for continuous distribution – how many NGN would be needed in various scenarios? How many needed for wholesale replacement? How many for targeting/mosaic?
 - If richer quintiles have low malaria risk and are buying untreated nets, is that a bad thing? Do we need to reach them with free ITNs?
 - If countries increase continuous distribution between campaigns to maintain coverage, then at successive campaigns, there will be more existing nets. Are these accounted for? Ignored? New ITNs stored by households until they are needed? Implications of storage for ITN durability/bio-efficacy? Move to fully continuous strategy?
- Communication
 - There is a need for working group to focus on key issues during and after pre-qualification transition process.
 - Will LLIN durability monitoring and post-spray monitoring feed into post-marketing surveillance and PQ process? If so, how?
 - All LLINs used to be the same, but this is changing. There is a need for clarity on which are most appropriate in different settings.
Discussion
It was suggested that additional swatches from the roof of LLINs be taken when

conducting bio-efficacy analyses and chemical content testing, as this is more relevant to mosquito exposure to the nets.

It was queried whether low net durability countries correlate with areas where nets are lost at a higher rate.

- Targets and Target Setting
 - Reaching 80% of households with 1 ITN for 2 people is 'unreachable', 62% seems to be max immediately after a strong universal coverage campaign. So should target be lowered and to what level?
 - How to measure community effect.
 - Look for places where LLIN access is low – how has transmission been impacted?
 - Seasonal ITN use in Senegal 2014-2015 – use of nets amongst those with access was lower in dry season, but very high by late rainy season.
 - What is the impact of reduced use in the low transmission season, if any?

Discussion

The 80% figure is from modelling, and country programmes who do not reach this level should know it is probably not a disaster. It may be that imperfect coverage is what is protecting nets from more widespread insecticide resistance.

- MERG question for VCWG
 - Dipping and retreating dropped from standard Malaria Indicator Survey questionnaire, so there is now no difference between ITN and LLIN. MERG is proposing to drop LLIN category, so only reporting on ITN and other.
 - Brand data will still be collected to allow additional analysis.

Discussion

Support for "LLINs" as this acronym is already known. Support for ITNs as this is a more flexible name and is closer to the description of the product and future products. Consensus with "ITNs".

Suggested that the question about source might as well be dropped as responses are not useful. Response to maintain the question but ensure that response options are standardized to be useful across countries. Request to add a question to pregnant women section specifically whether they received a net during their pregnancy. That question should be useful for distinguishing between nets from public and private sector.

Action Plan

- Conduit for issues arising and being flagged for action/research by partners.
- Report back to partnership on progress.
- Small(ish) doable actions in the next 12 months.
- HK and LP will transform discussion into a Work Plan.