

# **Executive Summary**

## End of Grant Evaluation New Nets Project

Accelerating the adoption of innovative vector control tools by

BroadImpact

Development & Business Consulting

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### **Executive Summary**

BroadImpact was contracted by Unitaid to conduct the end-of-grant evaluation of the Global Fund and Unitaid co-funded New Nets Project (NNP). The evaluation was conducted between November 2022 and June 2023. It assessed the overall performance of the NNP across the following domains: **relevance, coherence, effectiveness, efficiency, impact, and sustainability,** of the Organisation for Economic Cooperation and Development (OECD), Development Assistance Committee (DAC) criteria.<sup>1</sup>

Global Fund and Unitaid co-invested USD 66 million towards establishing a sustainable market for a broader set of insecticide treated nets (ITNs) and increasing access to a new class of nets through market-shaping interventions. The project was designed to address the following access barriers: (1) inadequate epidemiological evidence on efficacy and entomological effect of next-generation ITNs, specifically dual-Active Ingredient (AI) ITNs (innovation and availability barriers); (2) high prices and no comparative cost-effectiveness data to guide country deployment decisions (affordability barriers); and (3) the absence of a World Health Organization (WHO) recommendation and lack of implementation guidelines (demand & adoption barriers).

The lead grantee was the Innovative Vector Control Consortium (IVCC), working in a consortium with the Alliance for Malaria Prevention (AMP), Liverpool School of Tropical Medicine (LSTM), London School of Hygiene and Tropical Medicine (LSHTM), PATH, and Population Services International (PSI). The Imperial College London Network of Excellence in Malaria, and the Tulane University also served as technical and research resource partners. In addition to the core implementers, partners such as the Bill and Melinda Gates Foundation (BMGF) and MedAccess supported the negotiation of a Volume Guarantee (VG) mechanism with manufacturers to accelerate and improve dual-Al ITN's affordability. The President's Malaria Initiative (PMI) also supported the strengthening of countries' capacity to use epidemiological, entomological, and coverage data, to support the optimal deployment of vector control (VC) tools through its VectorLink Project. The project was implemented in 14 countries: Benin, Burkina Faso, Burundi, Cameroon, Côte d'Ivoire, Democratic Republic of Congo (DRC), Ghana, Liberia, Malawi, Mali, Mozambique, Niger, Nigeria, and Rwanda, from August 2018 to December 2022. Project countries were classified into three categories: A Randomized Control Trial (RCT) Implementation country (Benin), Evaluation Pilot countries (Burkina Faso, Mali, Mozambique, Nigeria, and Rwanda), and the rest were Operational Pilot countries.

The NNP was a relevant and timely response to urgent and emerging needs in the malaria prevention space. At the project's inception, the effectiveness of ITNs was threatened by the development of widespread resistance to pyrethroids (the primary insecticide class currently used in ITNs). This is partly responsible for the stalled progress towards reducing malaria incidence and mortality, especially in endemic and high burden countries in sub-Saharan Africa. A new class of nets (dual-AI ITNs) with the potential to control the surge in pyrethroid resistance had become available. There was a gap in evidence of the public health efficacy, effectiveness and cost-effectiveness of these new nets, to inform WHO recommendations and operational implementation guidance. Also, older ITN classes had faced long product introduction timelines. As a result, an immediate intervention was needed to address these gaps and accelerate access to these newer and potentially more effective ITNs. NNP served as the acceleration catalyst. During the project life, NNP also adapted well to its implementation context; by (1) Leveraging the BMGF/MedAccess-led VG agreement with BASF for its dual-AI ITN (Interceptor G2- IG2). This agreement was a coordinated multipartner investment strategy that was already in progress at project inception; 2) Facilitating the prequalification of Disease Control Technologies' (DCT) dual-Al ITN (Royal Guard-RG); 3) Expanding NNP's planned evaluation pilots to include multiple net types, in response to the evolution of the ITN marketplace; and lastly, 4) Effectively managing a somewhat complex co-payment intervention with multiple manufacturers, donors, procurement agents and country representatives. It is clear that the intervention was urgently needed, and the project's implementation was contextually adapted; however, it is important to note that the donors took a calculated risk, by making a significant investment in deploying ITNs that were not already WHO recommended, though WHO prequalified.

 $<sup>^{1}\,\</sup>underline{\text{https://www.oecd.org/dac/evaluation/daccriteria for evaluating development assistance.htm}}$ 

The NNP achieved a high level of internal and external coherence. It was internally coherent, with its broad range of implementers who had complementary competencies, that were required for different elements of the project. The consortium was well constituted and each of the partner organizations effectively played their roles. The project was also externally coherent as it was designed to collaborate with key external stakeholders and to be implemented through the existing country structures and mechanisms. The NNP established productive partnerships with BMGF and PMI as earlier described. It also aligned well with participating countries' national and sub-national malaria programs, as it was designed to fit into their integrated vector management strategies. The project successfully leveraged already existing Civil Society Engagement (CSE) activities led by National Malaria Control Programs (NMCPs) during their campaigns, and implemented largely comprehensive CSE activities specifically focused around its research activities. The follow-on project to the NNP, the Global Fund's Nets Transition Initiative (NTI), was also complementary and well aligned with NNP. Its design allowed it to overlap without duplication, filling in additional evidence gaps, as well as supporting the transition of the dual-AI ITNs into standard Global Fund procurement and implementation processes.

The project effectively addressed the target access conditions towards innovation and availability, affordability, demand and adoption of dual-AI ITNs. NNP increased the market share of these nets from 0% to 10-11% annually during the project life and 13% in the final project year, over double its intended 5% target, enabling both project and non-project countries access to dual-AI ITNs. Specific achievements towards addressing the target access barriers are as follows:

- The NNP effectively addressed the innovation and availability barrier, by creating and disseminating evidence on the efficacy of dual-Al ITNs, and data exploring entomological and epidemiological outcomes that met the WHO and Vector Control Advisory Group (VCAG) requirements. This evidence informed the March 2023 consolidated WHO guidelines for malaria. The Benin-RCT results<sup>2</sup> showed a 46% reduction in malaria incidence in children 6 months to 10 years of age in the IG2 (chlorfenapyrpyrethroid dual-Al ITN) arm over 2 years, compared to standard nets, much higher than the project's estimated target of 30%. The RG (pyriproxyfen-pyrethroid dual-AI ITN) arm of the study showed a nonsignificant reduction in incidence. IG2 also showed a significant reduction in odds of malaria prevalence (52% at 6 months and 39% at 18 months). RG did not achieve significantly better results than pyrethroidonly nets, alongside other durability concerns. This may be indicative of difficulties with producing stable and durable pyriproxyfen-containing nets, as was also seen with the Olyset Duo ITNs (studied by other organizations outside NNP). Although IG2 outperformed other net types against pyrethroid-resistant mosquitoes, wash resistance tests, as well as on durability studies at 12 and 24-months, there are still questions on the physical integrity and bio-efficacy of all ITNs in their third year of use. Net durability is an important and cross-cutting issue that needs broad systemic solutions, including a review of how quality is assessed, how nets are made, and what durability claims can be made.
- In addressing the availability barrier, the project made dual- AI ITNs commercially available in many Lowand Middle-Income Countries (LMICs), with both manufacturers' (BASF and DCT) production levels scaled up and maximized through the life of the project. IG2 is now registered in 26 countries and RG in 5 countries, and these countries represent over 70% of the global malaria burden. All respondents confirmed that this would not have been possible without the intervention of Unitaid and Global Fund through this project.
- The project also effectively addressed the affordability barrier by implementing its market-shaping strategy, comprising the co-payment mechanism and leveraging the BMGF/MedAccess-led VG agreement. The volume guarantee reduced the price point of dual-AI ITNs by almost half, and the co-payment mechanism bridged the remaining price gap with standard nets during the life of the project. It is important to note that the VG would not have been possible without the presence of NNP, as a vehicle to allow massive, consolidated procurement of nets funded by different donors, prior to WHO guideline release. Through the NNP, 21 countries have procured dual-AI ITNs: 14 NNP countries and 7 non-project countries (Senegal, Guinea, Uganda, Equatorial Guinea (Bioko Island), Kenya, Sierra Leone,

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<sup>&</sup>lt;sup>2</sup> Manfred Accrombessi, PhD, Jackie Cook, PhD et al. Efficacy of pyriproxyfen-pyrethroid long-lasting insecticidal nets (LLINs) and chlorfenapyr-pyrethroid LLINs compared with pyrethroid-only LLINs for malaria control in Benin: a cluster-randomised, superiority trial. Published: January 24, 2023. DOI: https://doi.org/10.1016/S0140-6736(22)02319-4

- and Papua New Guinea), with over 37 million dual-AI ITNs procured through the life of the project via the co-payment mechanism, exceeding the 35 million life of project target.
- It also addressed the demand and adoption barriers by providing evidence of the public health impact of dual-AI ITNs, leading to WHO recommendations for both pyrethroid-chlorfenapyr and pyrethroid-pyriproxyfen ITNs. This included a strong recommendation for the deployment of pyrethroid-chlorfenapyr ITNs (IG2) instead of pyrethroid-only nets to prevent malaria in adults and children in areas with pyrethroid resistance; a conditional recommendation for the deployment of pyrethroid-pyriproxyfen ITNs (RG) instead of pyrethroid-only ITNs, to prevent malaria in adults and children in areas with pyrethroid resistance; as well as conditional recommendations for the deployment of pyrethroid-chlorfenapyr ITNs (IG2) over pyrethroid-PBO ITNs, as well as pyrethroid-PBO ITNs over pyrethroid-pyriproxyfen ITNs (RG).
- A review of preliminary anthropological findings on barriers, facilitators and patterns of ITN access and use revealed that human behavior did not differ significantly across districts within evaluation pilot countries with different net types. The key barriers and patterns observed are not unique to dual-Al ITNs, instead they emphasize some general limitations of ITNs within different country contexts. With respect to access, respondents were split on whether they received enough bed nets; they also reported inequity in net allocation and distribution processes in Burkina Faso, Mozambique and Nigeria, including less access for those living in remote locations, some nepotism in the distribution processes, and perceptions of inflated household sizes. Also, in all four countries, the recommendation to share nets between two people did not align with family sleeping arrangements and family compositions (especially the gap in considerations for adolescent girls who often have their own separate sleeping arrangements). Bed net use was viewed as very important and as the most common malaria prevention method in all countries; respondents in Rwanda and Burkina Faso reported more consistent net use than those in Nigeria and Mozambique. Barriers to net use are similar in all countries: primarily seasonal differences with higher net use in rainy/cold season compared to dry/hot season due to increased heat. During hot seasons, sleeping under an ITN has been associated with reduced airflow and increased heat, which causes discomfort, thereby reducing the acceptability of ITNs.<sup>3</sup>
- The project also piloted dual-AI ITNs in selected countries, generating cost-effectiveness data alongside the pilots and developing implementation guidelines on effective methods for planning and implementation of multi-product campaigns that include dual-AI ITNs. The consortium partners: PATH and Tulane University conducted cost-effectiveness studies comparing next-generation nets to pyrethroid-only nets using net pricing at the time of procurement for effectiveness pilot countries with the additional manufacturer co-payment and excluding cost savings to the health system. Results are \$0.50-\$1.62 per additional case averted for PBO nets in Burkina Faso and Mozambique, \$1.43 per additional case averted for Royal Guard® in Northern Mozambique, and \$0.98-\$5.30 per additional case averted for Interceptor®G2 in Northern and Western Mozambique, Burkina Faso and Rwanda. It should be noted that net pricing is dynamic, and as of April 2023, point estimates for costs per additional case averted, excluding cost savings to the health system, using the most up-to-date price information available are \$0.66-\$3.56 for Interceptor G2, \$0.84 for Royal Guard, and \$1.33-\$4.34 for PBO nets when Nigeria is excluded. Excluding Nigeria, all next-generation nets provide cost savings if you allow for savings on treatment costs. Incidence data analysis in Nigeria was confounded by migration, suboptimal reporting, inconsistent data quality, and inconsistent use of the public health sector, which significantly reduced the reliability of cost-effectiveness estimates.

#### The NNP was enabled by:

- The familiarity of the intervention as beneficiary countries already had experience implementing mass ITN campaigns;
- The substantial level of funding contributed by both donors, in a traditionally underfunded disease area;
- The BMGF/ MedAccess-led volume guarantee agreement;
- Harnessing the purchasing power of Global Fund, PMI and other donors;
- Local data availability in implementing countries;

<sup>&</sup>lt;sup>3</sup> Pulford, J., Hetzel, M.W., Bryant, M. et al. Reported reasons for not using a mosquito net when one is available: a review of the published literature. Malar J 10, 83 (2011). https://doi.org/10.1186/1475-2875-10-83

- The expertise and pre-existing relationships of IVCC and the selected consortium members with national malaria control programs, manufacturing partners and other global stakeholders; as well as
- The active involvement of the co-funders, who contributed their technical and market-shaping expertise and provided a partnership model that galvanized a wider array of stakeholders, and improved coordination and alignment in priorities from global to country level.

#### The NNP encountered several challenges, including:

- Its donors facing initial challenges aligning with WHO, as the project represented a deviation from the sequence of product introduction; however, in the face of a global public health threat (Insecticide resistance), extraordinary measures were urgently needed.
- Quality assurance gaps in Burkina Faso, Malawi, and Rwanda;
- Early gaps in BASF's (IG2 manufacturer) production capacity;
- Several effectiveness pilot research obstacles; and
- The coronavirus disease (COVID-19) pandemic.

Although, the project successfully addressed all challenges, multiple delays were nevertheless incurred, which impacted efficiency.

Impact modeling estimates of dual-AI ITNs across NNP countries, by Imperial College (NNP Consortium Partner), reveal that NNP copaid IG2 nets, NTI and PMI procurements averted an estimated 13 million malaria cases and 24,614 deaths. These were expected to result in \$29m in financial savings to the health system. Five-year modeling projections also estimate an additional 38 million malaria cases and 73,091 deaths averted compared with standard pyrethroid nets, resulting in financial savings of \$99m based on the current global forecast for dual-AI nets from the Clinton Health Access Initiative (CHAI) Global Malaria Commodities Forecast project on the Roll Back Malaria (RBM) site. In addition to the public health and economic impact, beneficiary countries also experienced strategic benefits and positive externalities, these include:

- Increased understanding of how to manage multi-product campaigns in the different country contexts;
- Expanded capacity of local research institutions;
- Increased collaboration and multi-sector alliances including regulators, implementers and government
  at country level; an increased understanding of the interdependence of these actors, as well as
  improved ways of working together for future products, beyond nets; and
- Accelerated the use of routine surveillance data (both epidemiological and entomological data) to help guide evidence-based decision-making at country level in terms of determining the appropriate mix of vector control measures for implementation areas.

The project was moderately time-efficient, meeting major milestones and deliverables on time including volume and price targets which were achieved one year ahead of schedule, despite some setbacks and implementation delays during the COVID-19 pandemic. Through the life of the project, there were varied implementation delays related to manufacturer capacity constraints, protracted contract negotiations, a health workers' strike, disagreement on procurement terms, failed quality inspections, differing net specifications, rejected dual-AI ITNs and COVID-19, amongst others. These setbacks were all effectively resolved towards completion of all project deliverables within the project timeline. The NNP was largely cost-efficient, improving its absorptive capacity annually, expending 99% of its budget by December 2022. NNP's annual budget consumption increased in tandem with the scale-up of project activities and the project team proactively adjusted and realigned budgets each year, rolling over unspent funds. The NNP also created internal efficiencies and leveraged external resources towards significant cost savings of about 9%, mostly related to its market-shaping interventions. The savings were reprogrammed towards expanding procurement of nets and implementing additional Monitoring & Evaluation (M&E) activities.

Lastly, the project has created an enabling global environment with critical evidence now available and a WHO recommendation in place. With respect to country readiness, the use of the pilot countries' NMCP as lead implementer means they already have the experience to run multi-product campaigns that include dual-Al ITNs, with a collection of implementation manuals supported by the Alliance for Malaria Prevention

(AMP). Dual-AI ITNs have also been registered in 10 project countries and 16 additional non-project countries, with procurement waivers received in several other countries who accept prequalified products without registration. The intervention was introduced at scale by NNP, so the scale-up process already began during pilot implementation, and most countries plan to maintain or increase their coverage levels of dual-AI ITNs. Most operational elements of the intervention are already inherently transitioned to NMCPs, except the co-payment which was transitioned to the NTI during the life of the project and will remain in place until December 2024. Co-payment was also phased out with PMI supported country programs. How the co-payment gap is transitioned after the NTI remains a critical question for the sustainability of the current price point, as countries will need to prioritize amongst malaria treatment and prevention commodities within their largely static funding pots, with small increases and decreases across countries. Also, NTI applied a co-payment that was linked with 2019 pricing for standard LLINs rather than the updated reference pricing, to limit funding gaps in the short term as countries transitioned from standard to dual-AI nets. However, this approach will lead to a more significant adjustment than had the co-payment been pegged to annual adjustments in the GF reference pricing.

There are also other external factors that threaten the current price including inadequate competition for chlorfenapyr-pyrethroid nets, the increase in the cost of petroleum (polyester/polyethylene), the need for upcoming manufacturers who have not benefitted from the market-shaping interventions to recoup their research and development costs, as well as different cost bases due to different chlorfenapyr sources. The current supply base is inadequate; however, BASF is currently scaling production of IG2 to 50 million nets per year through factories in China and Thailand, and new manufacturers are expected to enter the market in the next few years, starting with Vestergaard's PermaNet Dual which achieved WHO prequalification in March 2023. Further, there is emerging evidence that suggests potential resistance to chlorfenapyr in some field sites, with WHO bottle assays supported by PMI revealing less than 98% mortality (the threshold for suspected resistance). There are, however, further studies in progress to better explain these findings. Irrespective of the final results of these investigations, sustainability will eventually be threatened by resistance as these new nets are scaled. As a result, there is a continued need for product development to advance other new Al alternatives to sustain this intervention.

Recommendations from this evaluation for different stakeholder groups include:

#### To National Malaria Control Programs and Ministries of Health:

- 1. Messaging and communication on ITNs should emphasize the benefits of all net types to prevent reduced uptake of standard nets that are still effective in many areas in implementation countries.
- 2. Given limited resources, national net campaigns should prioritize the most effective (expensive) nets for the most vulnerable populations within high-burden communities, in addition to other prioritization criteria for dual-Al nets.
- 3. Utilize cost-effectiveness results from the NNP and emerging evidence from NTI for country decision-making towards prioritizing dual-AI ITNs.
- 4. Before scale-up of chlorfenapyr-pyrethroid ITNs, resistance management strategies should be well defined to preserve their effectiveness, including plans to closely monitor the development of resistance.
- 5. Continue early forecasting and order placement, as well as aligning the arrival of different products to be deployed in multi-product campaigns.

#### To Global Fund, Unitaid, other Donors & Global Policy Makers, the evaluation recommends:

- 1. Support expansion of the supplier base to ensure adequacy of supply to meet the expected increase in demand for dual-Al ITNs by facilitating the prequalification of at least two more products, conducting regular demand forecasts to justify early scale-up for new manufacturers, as well as deploying similar market levers (VG, buy-down, co-pay) to support manufacturers working on novel Al nets.
- 2. Explore additional interventions to sustain current dual-Al ITNs price point and address potential affordability barriers by considering another stop gap to phase out the co-payment price difference and incentivizing co-investment from private sector to expand coverage of dual-Al ITNs and reduce the

- burden on public funding or cover some costs of expansion of other proven interventions like IRS so that donors can focus more on ITNs without an overall reduction in coverage and impact.
- 3. Explore more sustainable options and methods for ITN development and management, with an increased focus on quality and durability, as well as to reduce the climate footprint of nets "cradle to grave." These may include exploring new net technology with the possibility of producing longer-lasting nets with less insecticides; using recycled fabrics and more environmentally friendly innovations (materials, packaging); harmonizing quality control systems across manufacturers and countries, as well as addressing user-driven durability issues (repurposing, discomfort, inconvenience, perceived lack of effectiveness, etc.), through user research, product improvement and improved communication.
- 4. Optimize the use of chlorfenapyr-pyrethroid ITNs and other vector control tools by mitigating chlorfenapyr resistance through introduction of new Als, and generating additional evidence to facilitate a multi-product malaria prevention approach (including combining standard nets distribution with IRS).
- 5. Strengthen program design and explore additional focus areas for future interventions: especially redefining the role of PBO nets (with dual-Al nets rapidly gaining market share against it), exploring more demand-side/ down-stream market-shaping interventions, increasing focus on social and behavioral science in product development, strengthening community engagement throughout project life, and developing/adopting a program framework and standards around equity, inclusion, intersectional and people-centered approaches, as applicable to different interventions and project types to guide implementers and align expectations.

### **About BroadImpact**

BroadImpact is an international development and business consulting firm whose vision is to see equitable, high-quality, and self-sustaining health and social protection systems in Africa. We hope to achieve this through the provision of technical support to deliver innovative systems strengthening solutions, including robust monitoring systems and rigorous evaluations for public and private sector institutions in Africa.

Our expertise spans: strategic planning; monitoring, evaluation and learning services; organizational development; capacity building; and quality improvement services. Our suite of monitoring and evaluation services, includes M&E frameworks and systems design, program evaluations, strategic reviews, M&E capacity building activities, and the development of digital solutions.

BroadImpact is registered in Nigeria, Zambia and the UAE, and has a footprint in 23 countries in Africa and Asia.

Contact us at:

info@broadImpact.org | www.broadImpact.org 5a Matandani Close, Rhodes Park, Lusaka | BLUE HILLS, Plot 538, Natasha Akpoti Street, Abuja | Exchange Tower, Business Bay, Dubai