Final Report

End of Grant Evaluation New Nets Project

Accelerating the adoption of innovative vector control tools by BroadImpact

Development & Business Consulting

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List of Acronyms

20105	2rd Comenstien Indeen Desidual Commu
3GIRS ABR	3 rd Generation Indoor Residual Spray Antibacterial Resistance
ACSM Afl	Advocacy Communication and Social Mobilization
All	Active Ingredient
AMP	Alliance for Malaria Prevention
AMP	Antenatal Care
ANC	American Society of Tropical Medicine and Hygiene
BMGF	Bill and Melinda Gates Foundation
CCM	Country Coordinating Mechanism
CHAI	Clinton Health Access Initiative
COGS	Cost of Goods Sold
COVID-19	Coronavirus Disease
CRSPC	Community/Regional Support Partner Committee
CSE	Civil Society Engagement
CSO	Civil Society Organization
DAC	Development Assistance Committee
DALY	Disability Adjusted Life Year
DCT	Disease Control Technologies
DRC	Democratic Republic of Congo
EIR	Entomological Inoculation Rate
FOB	Free on Board
GDG	Guideline Development Group
HCW	Health Care Worker
121	Innovation to Impact
ICER	Incremental Cost-Effectiveness Ratio
IDA	International Development Association
IG2	Interceptor-G2
IGR	Insect Growth Regulator
IP	Intellectual Property
IRM	Insecticide Resistance Management
IRS	Indoor Residual Spraying
ITN	Insecticide Treated Nets
IVCC	Innovative Vector Control Consortium
KPI	Key Performance Indicators
LLINS	Long-Lasting Insecticidal Nets
LMICs	Low- and Middle-Income Countries
LSHTM	London School of Hygiene and Tropical Medicine
LSTM M&E	Liverpool School of Tropical Medicine Monitoring and Evaluation
MoH	Ministry of Health
Mon	Memorandum of Understanding
MRC	Medical Research Council
NMCP	National Malaria Control Program
NMEP	National Malaria Elimination Program

NNP	New Nets Project
NTI	Net Transition Initiative
OECD	Organisation for Economic Co-operation and Development
PAMCA	Pan-African Mosquito Control Association
PBO	pyrethroid-piperonyl butoxide
PMI	President's Malaria Initiative
PNLP	Programme National de Lutte Contre le Paludisme
PPE	Personal Protective Equipment
PQ	Pre-Qualification
PR	Principal Recipient
PSI	Population Services International
R&D	Research and Development
RBC	Rwanda Biomedical Centre
RCT	Randomized Control Trial
RG	Royal Guard
SBC	Social Behavior Change
SMC	Seasonal Malaria Chemoprevention
SMEP	State Malaria Elimination Program
SOP	Standard Operating Procedure
SR	Sub-Recipient
TA	Technical Assistance
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VC	Vector Control
VCAG	Vector Control Advisory Group
VCP	Vector Control Product
VCWG	Vector Control Working Group
WHO	World Health Organization
WHOPES	World Health Organization Pesticide Evaluation Scheme

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 Co-operation and Development (OECD), Development Assistance Committee (DAC) criteria.¹

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-AI 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.

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-AI 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.

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

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-AI 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 results² showed a 46% reduction in malaria incidence in children 6 months to 10 years of age in the IG2 (chlorfenapyrpyrethroid dual-ALITN) 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,

² Manfred Accrombessi, PhD, Jackie Cook, PhD et al. Efficacy of pyriproxyfen-pyrethroid long-lasting insecticidal nets (LLINs) and chlorfenapyrpyrethroid 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 pyrethroidpyriproxyfen ITNs. This included a strong recommendation for the deployment of pyrethroidchlorfenapyr 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 pyrethroidpyriproxyfen 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 pyrethroidchlorfenapyr ITNs (IG2) over pyrethroid-PBO ITNs, as well as pyrethroid-PBO ITNs over pyrethroidpyriproxyfen 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-AI 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.³
- 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;

³ 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-AI 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 AI 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-AI nets.
- 3. Utilize cost-effectiveness results from the NNP and emerging evidence from NTI for country decisionmaking 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-AI 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 AI nets.
- 2. Explore additional interventions to sustain current dual-AI 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-AI 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-AI 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.

Introduction

1.1 Background

Malaria is one of the leading causes of illness, death, and loss of economic productivity in the world. An estimated 241 million malaria cases occurred globally in 2020, increasing from 227 million cases in 2019. This increase is partly due to the disruption to services associated with the COVID-19 pandemic, as well as other factors including climate change, and conflict. Most malaria cases occurred in sub-Saharan Africa, with six countries accounting for 55% of cases globally; these are Nigeria (27%), the DRC (12%), Uganda (5%), Mozambique (4%), Angola (3.4%) and Burkina Faso (3.4%). These countries also accounted for half of the malaria deaths globally, with malaria deaths increasing by 12% in 2020, also associated with COVID-19 disruptions.⁴

Malaria is preventable with consistent use of insecticide-treated nets (ITNs).⁵ In 2020, in sub-Saharan Africa, 65% of households had at least one ITN, increasing from about 5% compared to the prevalence in 2000. The percentage of households owning at least one ITN for every two people also increased from 1% in 2000 to 34% in 2020. The percentage of the population with access to an ITN within their household also increased from 3% to 50%. In addition to increased access, the use of ITNs has also increased considerably from 2000 to 2020, with the percentage of the population sleeping under an ITN increasing from 2% to 43% for the whole population, and from 3% to 49% for children aged under five years and for pregnant women, who are the most vulnerable subset of the population. These statistics show marked improvements over the last two decades; however, it is important to note that they also show that, even after these gains, only a third of the population in need have access, and less than half of the population uses nets consistently. A review of annual data from 2017 to 2020 also reveals a decline in ITN access and use in sub-Saharan Africa.²

Improvements in prevention and control measures in sub-Saharan Africa remain critical. Vector control has contributed significantly to the progress made against malaria. It is estimated that the use of ITNs accounts for 69% of the malaria cases averted since 2013.⁶ Manufacturers supplied almost 2.3 billion ITNs from 2004–2020 globally (2 billion (86%) to sub-Saharan Africa). In 2020, 229 million ITNs were delivered to malaria-endemic countries, 19.4% were pyrethroid–piperonyl butoxide (PBO) nets (12.4% more than in 2019), and 5.2% were dual active ingredient ITNs (3.6% more than in 2019). About 91% of these ITNs were delivered to countries in sub-Saharan Africa. In response to areas of high malaria burden, about 64% of the ITNs were received in the Democratic Republic of the Congo (33.4 million), Uganda (22.8 million), Nigeria (21.7 million), Cote d'Ivoire (19.8 million), the United Republic of Tanzania (13.1 million), Ghana (12.2 million) and Mozambique (11.4 million); targeting nets where they were needed the most.²

However, the effectiveness of this intervention has been threatened by development of widespread resistance to pyrethroids – the primary insecticide class currently used in ITNs. Resistance was detected in at least one malaria vector in 68% of the sites for which data were collected by the WHO. Monitoring data from 2010 to 2020 reported resistance to other insecticides at lower levels: organochlorines (64% of the sites), carbamates (34% of the sites) and organophosphates (28% of the sites). WHO recommends countries develop and implement national insecticide resistance monitoring and management plans, based on the WHO Framework for a national plan for monitoring and management of insecticide resistance in malaria vectors.² It is also important that endemic countries have access to effective and affordable vector control tools as part of their comprehensive strategy to manage insecticide resistance, potentially including new ITNs that have increased efficacy against pyrethroid-resistant mosquitoes ("dual-AI ITNs"). In 2017, manufacturers were already producing these next-generation ITNs; but purchase volumes remained low, and manufacturers were unable to reach the economies of scale needed for price reductions. At the time, these new tools required additional evidence of their public health value to be considered for a WHO policy recommendation, as well as evidence of their added value in different country operational settings towards

⁴ World malaria report 2021. Geneva: World Health Organization; 2021. Licence:CC BY-NC-SA 3.0 IGO.

⁵ Govella NJ, Okumu FO, Killeen GF. Insecticide-treated nets can reduce malaria transmission by mosquitoes which feed outdoors. Am J Trop Med Hyg. 2010 Mar;82(3):415-9. doi: 10.4269/ajtmh.2010.09-0579. PMID: 20207866; PMCID: PMC2829902.

⁶ Bhatt S, et al. The effect of malaria control on Plasmodium falciparum in Africa between 2000 and 2015. Nature. 2015;526(7572):207-11.

early adoption and scale-up. Unitaid and Global Fund launched an initiative to catalyze the market introduction of next-generation ITNs, through the provision of a time-limited co-payment mechanism, allowing countries to maintain their planned ITN coverage while deploying these more expensive tools. The initiative aimed to generate evidence on efficacy and entomological correlates of dual-AI ITNs; generate and disseminate evidence of effectiveness and cost-effectiveness of dual-AI ITNs; and pilot the implementation of dual-AI ITNs towards operational learning of effective methods for planning and implementation. The resulting project was the New Nets Project (NNP). In 2021, the NNP was further complemented by another Global Fund grant called the Net Transition Initiative (NTI) (2021-2024)⁷, which aimed to address the remaining gaps to early scale-up, including extending co-payment funds through 2024, establishing the systems to normalize the planning for and procurement of dual-AI ITNs within Global Fund, and fill evidence gaps related to durability and net performance - two and three years after deployment.⁸

1.2 Program Description

The New Nets project under the Area for Intervention (AfI) "Accelerating the adoption of innovative vector control tools" is a Unitaid and Global Fund co-investment of 66 million USD towards establishing a sustainable market for a broader set of ITNs and increasing access to dual-AI ITNs through market-shaping interventions. The project was designed to address the following access barriers: inadequate epidemiological evidence on efficacy and entomological effect of next-generation ITNs (specifically dual-AI ITNs) to inform WHO recommendations (innovation and availability barriers); high prices and no data on cost-effectiveness to guide country deployment decisions (affordability barriers); and the absence of a WHO recommendation, and other operational deployment considerations (demand & adoption barriers). *See Theory of Change in Fig 1.3 overleaf.*

The lead grantee was Innovative Vector Control Consortium (IVCC), working in a consortium with Alliance for Malaria Prevention (AMP), Imperial College, Liverpool School of Tropical Medicine (LSTM), London School of Hygiene and Tropical Medicine (LSHTM), PATH, and Population Services International (PSI). IVCC was the lead grantee and was responsible for the overall management of the project. They were also responsible for executing the co-payment and other levers to enable pilots, stimulate market and reduce price. LSHTM was responsible for conducting RCTs to generate evidence to support the VCAG analysis of public health value of dual-AI ITNs. PSI and AMP provided technical assistance to ensure effective implementation of pilots and learning on operational aspects. PATH was responsible for generating evidence of effectiveness and cost-effectiveness during pilots. The Imperial College London Network of Excellence in Malaria and Tulane University also served as technical and research resource partners. In addition to the core implementers, complementary funders like BMGF and MedAccess supported the negotiation of a volume guarantee mechanism with manufacturers, which could accelerate dual-AI ITNs affordability. PMI also supported the strengthening of countries' capacity to use epidemiological, entomological and coverage data to support the optimal deployment of vector control tools through the VectorLink Project.

The project was implemented in 14 countries: Benin, Burkina Faso, Burundi, Cameroon, Côte d'Ivoire, DRC, Ghana, Liberia, Malawi, Mali, Mozambique, Niger, Nigeria and Rwanda, from August 2018 to the end of December 2022. Project countries were classified into three categories: RCT implementation countries, Evaluation Pilot countries and Operational Pilot countries. The RCT was implemented in Benin to provide epidemiological evidence required by the WHO for the determination of the public health value of dual-AI ITNs. This complemented another RCT already ongoing in Tanzania by LSHTM and funded by the UK Research and Innovation Joint Global Health Trials program. These RCTs included both IG2 and RG. The Evaluation Pilot countries where the rollout of dual-AI ITNs was evaluated were Burkina Faso, Mali, Mozambique, Nigeria, and Rwanda. Lastly, the Operational Pilot countries were countries where the dual-AI ITNs were rolled out but not evaluated; these are Côte d'Ivoire, Ghana, Liberia, Malawi, DRC, Cameroon, Niger and Burundi.

 $^{^7\} https://allianceformalariaprevention.com/wp-content/uploads/2021/03/Looking-forward-Expanding-country-access-to-new-ITN-types-beyond-the-New-Nets-Project.pdf$

⁸ https://unitaid.org/call-for-proposal/catalyzing-market-introduction-next-generation-long-lasting-insecticidal-nets-llins/#en

1.3 Theory of Change⁹

Public Health Need Access Barriers	 cases and 445,00 Major gains agains Innovation & Avail Qual listing, prevent Affordability: Lac LLINs) Demand & Adopti 	00 deaths worldwide in 2016 t malaria largely through ITNs (and lesser lability: Weak evidence of efficacy an nting availability of Dual AI LLINs. Ik of data on CE, or an associated polic	extent IRS), are threatened by wide d the need for epidemiological evide cy recommendation, prevents countr cy recommendation, comparative	a at risk of infection particularly in tropic espread mosquito resistance to insect ence creation impede the process for po- ries from procuring these nets at higher cost-effectiveness information (compared	ticides licy recommendation and Pre- prices (compared to standard
Conceptual Pathway Generation Pathway Conceptual Pathway Conceptual Conceptual Pathway Conceptual C	Input NITAID/ Global Fund nding support from WHO am, national unterparts, donors and her implementers se LLIN Funding from ultiple partners (GF,PMI, NICEF) CC and partners pertise in market aping activity.	 Activities RCTs of dual Al nets Pilot implementation in a range of transmission contexts Concurrent entomological work to explore possibility of ento-epi correlates to potentially shorten eval pathway Market shaping activities including co-pay 	 Outputs Evidence for efficacy of Dual AI LLINs created for review by VCAG; Pilot implementations of dual AI nets generate CE info and operational experience to inform implementation guidelines, evidence disseminated. Market intervention levers establish affordability of Dual AI LLINS 	Outcomes Increased access to new generation LLINs Innovation & availability: generate evidence on efficacy & entomological effect Demand & adoption: supportive policy & guidelines Affordability: support activities on price reduction & data on CE 	 Impact Public Health and Economic Impact: ✓ Reduction in morbidity and mortality due to Malaria ✓ Cost saving and efficiencies to Health systems

- National supply systems and HIVIS (out of project control) do not impede ability to integrate new LLINs
- Sufficient competition in the PBO net market continues (i.e. it remains a multi-product market)

⁹ Catalytic Project Plan. The public health need in the ToC represents the context of the project at inception.

2 Purpose & Scope of the Evaluation

2.1 Purpose

The evaluation assessed the relevance, coherence, effectiveness, impact, efficiency, sustainability¹⁰, and lessons learned from the NNP, which was implemented from August 2018 to December 2022. The evaluation focused primarily on the project countries but also assessed the catalytic effect of the project and the scale-up in non-project countries.

2.2 Objectives

Specifically, the evaluation objectives were to:

- 1. Assess the relevance of the NNP towards addressing the emerging pyrethroid resistance and declining ITN coverage. (Relevance)
- o Determine if the expected results and outcomes could have been achieved in the absence of the NNP.
- Assess the need for the number of implementation pilots (on feasibility and cost-effectiveness) conducted.
- $\circ~$ Assess how the design of the NNP and NTI could have been better towards complementarity and efficiency.
- 2. Assess the complementarity and synergy between key stakeholders and other donor investments, including the Global Fund Nets Transition Initiative. (Coherence)
- Assess synergies with other stakeholders in the malaria space (e.g., PMI, national malaria control programs, manufacturers, etc.).
- Assess the quality of engagement of communities and local civil society organizations effectively to support research activities and adoption at country level.
- Assess the effectiveness of the governance structure of the project, including the steering committee and program management at donor level.
- o Assess the benefits of a co-funded effort compared to sole funding.
- Assess the interplay and complementarity of these NNP and NTI and the effectiveness of the interface between them.
- 3. Assess the performance of the New Nets Project against the original Afl objectives, Theory of Change and Pathway to Impact, i.e., the extent to which the investment met the objectives to secure relevant access conditions. (Effectiveness)
- Assess effectiveness of the project across the following key outcomes:
 - Evidence on efficacy, entomological and epidemiological effect.
 - Supportive policy and guidelines.
 - Affordability.
 - Implementation and cost-effectiveness evidence.
 - Demonstration of appropriate delivery models.
- 4. Determine the difference the NNP investments made in accelerating/ enabling equitable access to dual-AI ITNs. (Impact)
- Assess how the project benefited underserved populations (e.g., vulnerable or high-risk populations and how the project ensured these groups have equitable access to the innovation).
- o Determine how the NNP generated any strategic benefits and positive externalities.

¹⁰ Organisation for Economic Co-operation and Development's (OECD) Development Assistance Committee (DAC) standard evaluation criteria

- 5. Determine the status of access and scale-up of dual-AI ITNs in LMICs in 2022-23 using the Unitaid scalability framework, including the extent of the grant's contribution to the progress achieved. (Scalability & Sustainability)
- Construct a retrospective baseline using existing documents and key informant interviews to capture the status of dual-AI ITNs in LMICs at the outset of the investment (2018).
- Assess the degree the New Nets Project contributed to laying the ground for scale-up of dual-AI ITNs (including an assessment of the status of scale-up conditions in 2018 and in 2022-23).
- Determine the extent to which targeted products and approaches have been scaled up and the speed of uptake within project countries and beyond, including the estimated dual-AI ITNs' reach by 2030.
- o Determine how co-funding between Global Fund and Unitaid influenced scale-up of dual-AI ITNs.
- Understand factors that may have contributed towards, or limited, scalability and transition, such as the presence/absence of multiple suppliers in the market, quality issues, and ability to forecast demand, among others.

terviews

2.3 Geographical Scope

Project countries Evaluation site visit countries with country level interviews

The evaluation covered all project countries through global key informant interviews and document reviews. Site visits and country-level interviews were conducted in 4 countries (**Benin, Mozambique, Nigeria and Rwanda**). These focus countries provided a comprehensive picture of the context and all elements of the project as:

- These countries contribute to 34% of malaria cases and 37% of malaria deaths globally.
- The selection also includes a mix of Francophone, Lusophone, and Anglophone countries.
- The selection represents West Africa (Nigeria and Benin), East/Central Africa (Rwanda) and Southern Africa (Mozambique).
- The selection was representative of implementation areas that cover all outputs of the project, e.g., Output 1-RCT generating evidence for efficacy of dual-AI ITNs created and disseminated according to WHO and VCAG requirements, and entomological correlates explored to aid the policy and Pre-Qualification (PQ) process, was implemented in Benin; and Output 2 (Pilot implementations of dual-AI ITNs, and operational learning), Output 3 (Evidence of operational use, effectiveness and costeffectiveness of dual-AI ITNs) and Output 4 (Co-payment and other market intervention levers used to establish affordability of dual-AI ITNs), all implemented in Mozambique, Nigeria and Rwanda.
- Lastly, the selection includes places where BroadImpact has in-country/regional presence and optimized the scope of site visits to the barest minimum, thereby reducing our carbon footprint.

3 Findings

The evaluation results are summarized in Fig 1.0 below. Detailed findings thereafter have been structured by evaluation Criteria and evaluation questions.

Fig 1. DAC Assessment Overview

Criteria	Not achieved	Slightly achieved	Moderately achieved	Largely achieved	Fully achieved	Strength of Evidence
Relevance (Did the intervention do the right things?)						Strong
Coherence (How well did the intervention fit with other interventions?)						Strong
Effectiveness (<i>Did the intervention achieve its objectives</i> ?)						Strong
Efficiency (How well were the resources used?)						Strong
Impact (What difference did the intervention make?)						Medium
Sustainability (Will the benefits last?)						Strong

Supporting documents for strength of evidence: Medium – document review, and key informant interviews. Strong - document review, key informant interviews and secondary data analysis and/or site visits. *See Evidence Framework in Appendix 8.2 Evaluation Approach.*

3.1 Relevance



To what extent did the objectives and design of the project respond to the needs of targeted beneficiaries? Could the expected results and outcomes have been achieved in the absence of the NNP?

Finding 1. The New Nets Project was responsive to the needs of beneficiary countries as well as the global malaria community as it responded to the emergence and spread of pyrethroid resistance, which has stalled progress towards reducing malaria incidence and mortality. It also targeted endemic and high-burden countries in sub-Saharan Africa.

Since 2015, there has been a stall in progress towards reducing malaria incidence and mortality, with a continuous increase in malaria cases and deaths annually. In 2015, there were 210 million cases compared to 241 million in 2020; deaths also increased from 562,114 to 626,909.^{11,12} The decline in progress has been recognized globally, with WHO leading the response towards the development and implementation of new tools to combat malaria.¹³ Improvements in prevention and control measures in sub-Saharan Africa is a priority, with vector control contributing significantly to progress made against malaria. It is estimated that

the use of Long-Lasting Insecticidal Nets (ITNs) accounts for 69% of the malaria cases averted since 2013.¹⁴ The emergence and spread of pyrethroid resistance pose significant risks to the future efficacy and impact of existing ITNs. As a result, it was important to introduce new classes of ITNs with improved efficacy against pyrethroid-resistant mosquitoes. The NNP bridged this gap by deploying the next-generation ITNs.¹⁵ All key informants emphasized the urgency to address the growing resistance to pyrethroids.

"There was high resistance to pyrethroids, and an intervention was needed to make sure we don't lose the gains made in malaria vector control over the last decade." Country respondent

Finding 2. The availability of new products that address the surge in pyrethroid resistance presented an opportunity to support the inclusion of superior products within endemic countries' malaria prevention efforts.

At the start of the project, new classes of ITNs with improved efficacy against pyrethroid-resistant mosquitoes had been developed. Emerging evidence, including early trials and modeling, suggested that these products would provide superior protective efficacy in areas with resistance to pyrethroids as either indoor residual spraying (IRS) or synergists on ITNs, and will increase mosquito mortality and reduce

incidence by 25-55%. These include the pyrethroid insecticide with synergist piperonyl butoxide (pyrethroid-PBO nets) as well as the dual-AI ITNs containing a pyrethroid and a second insecticide. The entomological effect of the dual-AI ITNs was expected to be very similar and potentially superior to that of the pyrethroid-PBO nets, with the added benefit that they will be effective in areas with metabolic resistance, in which the pyrethroid-PBO nets may not be effective. There were, however, gaps in epidemiological evidence that were required to inform policy recommendations. Also, only one dual-AI ITN had achieved WHO prequalification prior to the project,

"By introducing new types of mosquito nets in response to mosquito resistance, and carefully testing their efficacy, we have shown that we can stay ahead of this disease and make a real difference in the lives of those we serve." **Country respondent**

¹¹ World Malaria Report 2015

¹² World Malaria Report 2021. Geneva: World Health Organization; 2021. Licence:CC BY-NC-SA 3.0 IGO.

¹³ NNP Annual Report 2018

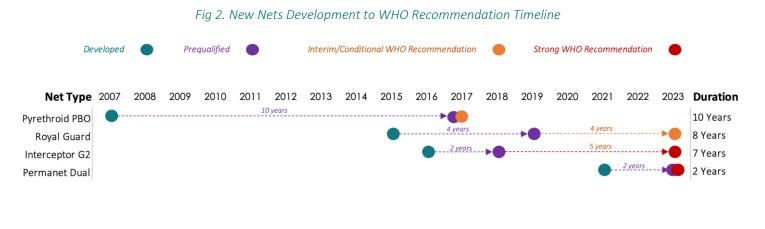
¹⁴ Bhatt S, et al. The effect of malaria control on Plasmodium falciparum in Africa between 2000 and 2015. Nature. 2015;526(7572):207-11.

¹⁵ IVCC. Unitaid Flash Report, New Nets Project. 13 September 2021

so support to prequalify additional manufacturers was urgently needed.¹⁶ Key informants emphasized the need for these new tools with additional AIs to be rolled out quickly in response to resistance.

Finding 3. The product helped to bridge the long product introductory process for ITNs with longitudinal epidemiological trials now required for evaluation. NNP implemented a trial in parallel to market introduction. It also tested an alternate evaluation process comprising experimental hut entomological correlates.

An important criterion for WHO recommendation for ITNs is the use of longitudinal epidemiological trials to demonstrate improved public health value. This increases the length of time towards market introduction. The ability of the project to bridge the long new product introduction timeline by creating a fast-track mechanism to introduce prequalified and potentially superior products within endemic countries' malaria prevention efforts prior to WHO recommendation was the edge of NNP. The results seen here will not have happened in the absence of the NNP. PBO nets, which were an earlier class, are only just reaching the market and have taken more than ten years from their initial development in 2007 to getting prequalified by the WHO Pesticide Evaluation Scheme (WHOPES) and receiving an interim WHO recommendation in 2017. NNP was a necessary and critical catalyst for introducing dual-AI ITNs, reducing the timeline from product availability to WHO recommendation by 2-3 years for Interceptor G2(IG2) and Royal Guard (RG), as seen in Fig 2. below. The project also explored the suitability of entomological data from experimental hut trials as potential correlates for the epidemiological performance of dual-AI ITNs. The results from these can be a game changer for shortening the recommendation timeline and quickening the market introduction of future ITN classes. This will, however, require further consultations and agreement with the WHO. The NTI is also furthering research in this area. Key informants felt that the NNP had provided a precedent, laying the foundation for quicker market introduction and scale-up of new classes of nets and potentially other vector control tools.



Have design and implementation approaches been appropriately adapted/course-corrected to respond to any changes in context?

Finding 4. Sumitomo withdrew its dual-AI ITNs (Olyset Duo) from the market introduction process due to concerns with stability and durability of the product. It was, therefore, not available to be deployed in the project.

The original project plan included the introduction of another product called Olyset Duo from Sumitomo, which was very similar to the RG. The product had been trialed in Burkina Faso through other funding sources with some level of impact demonstrated. However, the manufacturer withdrew the product due to concerns about stability and durability. According to the lead grantee, Sumitomo stated that they could not stabilize the pyriproxyfen in the encapsulation system, hence, could not meet the 20 washes rule recommended by the WHO. The project was, however, still effectively implemented with the other two available products (IG2 and, subsequently, RG).

¹⁶ Catalytic LLIN Project Plan

Finding 5. The project benefited from the BMGF/MedAccess volume guarantee agreement with BASF, which ensured that increased procurement volumes led to higher price reductions. PMI also increased their reference price to align with the exit price creating savings for NNP.

In the second year of the project, negotiations for a volume guarantee with BASF by BMGF and MedAccess were finalized. PMI also increased their reference price to align with the exit price. These changes resulted in significant reductions in price, as the volume of IG2 nets procured increased, as well as increased flexibility of the project budget to support higher volume procurements towards increased project impact. Some of the savings here were reprogrammed to fund additional M&E activities related to other contextual changes (earlier introduction of DCT's Royal Guard and transition of more countries from standard ITNs to PBO nets).¹⁷

Finding 6. The project responded well to the earlier-than-expected evolution of the insecticide-treated nets (ITN) marketplace, with several countries planning to transition from standard ITNs to PBO nets through anticipated support from PMI and the early prequalification of the second dual-AI ITNs: DCT's Royal Guard. With some countries planning to transition from the standard ITNs to PBO nets and a second dual-AI ITN (Royal Guard) becoming prequalified during the project, the project responded by expanding the range of ITN products included in the evaluation pilots towards ensuring a better understanding of the impact of the wider range products that were now available in the market.¹⁸

Finding 7. The implementation of the co-payment intervention was somewhat complex for the project implementers, considering price negotiations with the manufacturers in parallel with the multiple co-payment agreements and MOUs negotiated and signed with procurement partners (USAID/PMI, Chemonics, IDA Foundation, RBC and PSI) and countries.

The project had to juggle negotiations and agreements across many actors, including donors, manufacturers, procurement agents and country governments. Some particularly challenging ones included the initial uncertainty about the protracted BMGF/ MedAccess volume guarantee negotiation with BASF, as it was out of the control of the project. The project implementers negotiated a separate agreement in the interim to cater to the project's needs, pending when the larger negotiation was finalized. There was also the ensuing process to update the preliminary agreement with BASF to reflect the volume guarantee. This was followed by other challenges in specific countries, notably the prolonged negotiations on payment terms between Rwanda Biomedical Centre (RBC) and BASF.¹⁹

Finding 8. NNP clarified duplication in roles and responsibilities of partners, specifically PSI and AMP, with AMP better suited to managing country interactions and delivering technical assistance.

At inception, PSI and Alliance for Malaria Prevention (AMP) had a combined role in providing technical assistance to ensure effective implementation of pilots and learning on operational aspects. There was some confusion about how each partner interacted with countries in delivering technical assistance (TA). This was addressed in the project's second year, with PSI designated a global TA role, and AMP brought on board as a full consortium partner and designated a country TA role.²⁰ Key informants did acknowledge the significant overlap in both partners' roles and indicated that even though PSI was a well-renowned organization with extensive expertise in malaria prevention programs globally, AMP better fulfilled the project's requirements with their expertise supporting countries in planning and execution of net distribution campaigns, and should have been the main partner from inception.

To what extent has the project's design and implementation identified and addressed issues related to gender, social inclusion and equity in line with Unitaid's overall mission to reach the most disadvantaged populations in developing countries using innovative global market-based approaches?

Finding 9. The project did not include any project-specific strategies to address issues related to gender, social inclusion and equity in its design. However, it targeted key and vulnerable populations, a higher

¹⁷ NNP Annual Report 2019

¹⁸ NNP Annual Report 2019

¹⁹ NNP Annual Report 2019

²⁰ NNP Annual Report 2019

proportion of rural populations and the widest coverage possible in project sites, similar to other malaria prevention programs.

Malaria prevention programs have an inherent focus on pregnant women and children under five years of age due to their increased risk for malaria infection and the disproportionate burden of malaria morbidity and mortality. As a result, NNP's impact studies monitored these two categories of beneficiaries. Implementation also included more rural areas than urban areas, as living conditions are poorer and susceptibility to infections is higher in rural areas. AMP's technical guidance for campaigns includes a deliberate targeting of a maximum number of vulnerable populations to be provided with nets. Another dimension of equity during implementation was conducting net distributions through ANC visits to reach pregnant women. Furthermore, the intense community engagement during the COVID-19 context with door-to-door campaigns enabled verification that nets were delivered to the right people. Another consideration during implementation was user preferences related to net texture and color, which influences demand in certain populations; implementers and donors, however, focused on deploying standardized nets to the greatest degree possible. This was to ensure that available funding could provide nets for a larger population in each supported country as net prices increase with changes in these specifications. Implementers found it challenging to articulate how the project deliberately addressed these cross-cutting requirements, as these seemed not to be clearly defined at inception. It will be important for funders to clearly define standards around equity, inclusion, intersectional and people-centered approaches as applicable to different interventions and project types.

Case Study R1. Intentional Market-Shaping vs Natural Market Dynamics

Were the market-shaping strategies employed suitable? How critical were these mechanisms to achieving the results and outcomes of the investment?

A sharp drop in price point

All key informants agreed that the two market-shaping strategies deployed by the project (the volume guarantee and co-payment mechanisms) were timely and urgently needed. The volume guarantee enabled a sharp drop in price point (almost equalizing the price of dual-AI ITNs with PBO nets), followed by the co-payment mechanism, which bridged the price gap between dual-AI ITNs and pyrethroid-only ITNs, resulted in the project achieving its primary market-shaping goal, which was to increase affordability. These results also reduced constraints on the countries' budgets. The price drop happened earlier than expected due to reaching the highest threshold of the volume guarantee a year earlier. This created further savings for the project. The early attainment of the lowest price point in the volume guarantee agreement and the ability to utilize the co-payment mechanism effectively was hinged on strategic partnerships with the Global Fund and PMI, as country demand was increased and maintained through the programmatic procurement commitments of these funders.

Catalytic Market Interventions

Manufacturers described holding out for close to ten years in the introduction of previous products: idle factory capacity, limited cash flow and uncertainty on when their product will gain significant market access. The market-shaping strategies used here allowed the accelerated introduction of the product into the market in a somewhat unnatural but necessary way. The product came to market very quickly and at a sizeable scale, allowing manufacturers to recoup their Research & Development (R&D) investments earlier, eliminating an important incentive for higher pricing. This project had to bypass natural market dynamics to achieve its goals, with the market-shaping interventions automatically guaranteeing a level of demand that equaled supply. The drawback here is that the current price point may be unsustainable, especially as true demand (consumer's willingness to pay in the context of scarce resources) has not been tested.

Could anything have been done differently?

Other market-shaping ideas.

Majority of stakeholders agreed that the approach the project took was appropriate and met the needs of beneficiary countries and the global malaria community in the short term. However, the evolving challenge with malaria resistance has prompted a paradigm shift, with stakeholders becoming more focused on long-term sustainability of new interventions in addition to affordable pricing. For instance, improving net technology; the possibility of producing a longer-lasting net with less insecticides; or utilizing a multi-faceted approach as is used in Antibacterial Resistance (ABR).

More manufacturers

Although many stakeholders mentioned the inclusion of only two manufacturers as a limitation, there was little the project could do about this since there were no other manufacturers with products ready for introduction. The presence of more manufacturers would have improved supply security. Some stakeholders also feel it would have created sufficient competition to reduce prices naturally without the need for a volume guarantee. However, implementers indicate that even though this is true in theory, the market growth due to increasing "copy-cat" products and competition-induced price reductions would potentially lead to quality assurance gaps (given the higher cost of production of dual-AI nets per the COGS analysis). Also, if demands shift dramatically and prices become unsustainable for the original R&D partners, they may leave the market, hence, creating a vacuum in R&D for the next generation of LLINs. The long-term commitment and engagement of R&D partners is a critical element that must also be factored in.

Did any of the approaches limit or de-incentivize (unintentionally) other potential suppliers or innovators in this space?

Manufacturers are highly incentivized and motivated.

All manufacturers interviewed felt that these market-shaping approaches were ideal for the introduction of urgently needed public health commodities and technologies. They attributed the successes of the project largely to these interventions. Those who benefited from the market-shaping interventions are motivated to keep investing in similar innovations, and those who were not involved are optimistic and hope to leverage similar opportunities in the future. None of the approaches de-incentivized any of the innovators in the space.

What lessons can be gleaned from this experience to inform future investments by Unitaid or by other funders?

Sustaining the price point

Many stakeholders described the challenge with co-payment mechanisms as their potential to distort the market. The price point enabled by the co-payment needs to be sustainable for both the manufacturers and the market. The current price point seems sustainable to the manufacturers involved in the project but not to new manufacturers and to beneficiaries. Other manufacturers have concerns about recouping their R&D costs, alternate sources of chlorfenapyr resulting in a different cost base and the time and assurances needed to scale their commodity to the level required for the current price point to be reasonable. Beneficiary countries simply do not have the funds to cover the co-payment amount when NTI ends, as ITNs are largely donor-funded in these countries, and most of these funding pots have not increased. There are increasing concerns that when the NTI ends, a gap will be created, and there will be difficulties transitioning the current coverage levels of dual-AI ITNs to normal market conditions. Although affordability was achieved during NNP and NTI, future challenges with affordability may arise when the co-payment/top-ups end, with huge implications for countries with high levels of pyrethroid resistance.

Heavy tilt to supply than demand side strategies.

Some stakeholders described these market shaping strategies as concentrated more on the supply than demand side. The engagement of country governments and other private sector actors in market shaping was said to be limited. This is linked to the earlier remark about not testing "willingness to pay" and as a result not having a good understanding of how much these dual-AI ITNs are valued. The absence of a WHO recommendation at the time of implementation was the limiting factor towards engaging countries to make commitments towards increased prices. Also, private sector engagement to support affordability, may have been premature during NNP, but with the co-payment transitioned to the NTI, there is still an opportunity for Global Fund and its PRs to explore the private sector engagement piece towards serving as a stop gap for the co-payment/top-up deficit post project, as a contribution to sustainability. In addition, with the WHO recommendation now available, the barrier to these engagements no longer exists.

The increasing need for local manufacturers and the feasibility of local manufacturing

The project relied on the only two available manufacturers during the project life. However, the COVID-19 pandemic significantly disrupted production and supply systems, especially shipping. These challenges are discussed extensively in *Section 3.3 Effectiveness*. Identifying mechanisms to mitigate supply chain disruptions is becoming increasingly important. Though not feasible in the timeline of the project, local manufacture within project countries or regions has been highlighted by several key informants as one such mechanism. However, the local production of ITNs is a difficult business case to establish for many reasons, including the absence of manufacturers of raw materials, especially large-scale polyester-producing companies in Africa. This means that even if an ITN factory is established, raw materials will need to be imported from Asia (China and Thailand). Also, the cost of energy is high, and electricity can be unreliable, which significantly impacts the cost of production. Other less critical considerations are transferring the AI-binding technology and guaranteeing health and safety standards. Significant capital investment will be required to address these factors leading to further price pressure for already more expensive nets. Manufacturers indicate that the most challenging factor is the absence of large polyester producers in Africa and that if this can be overcome, the other challenges can more easily be tackled.

3.2 Coherence



To what degree does the work undertaken by the project fit with other interventions within targeted countries, sectors, or institutions?

Finding 1. The NNP was internally coherent, comprising a broad range of partners with complementary competencies required for different elements of the project.

The large consortium and technical partners were essential to recorded achievements. Each partner had a specific role and contribution. While the Global Fund and Unitaid provided the overall global oversight and the necessary finances needed to fund this project, the IVCC as lead partner, had a co-payment and negotiation role and galvanized the contribution of the other partners. PATH

supported with pilots' data collection and, in collaboration with Tulane, undertook a cost-effectiveness study. PSI and AMP provided country support on procurement and data collection. LSHTM executed the country trials and entomological correlates of epidemiology. Imperial College supported with the trials and impact modeling. The consortium was well constituted, and each of the partner organizations (and their highly skilled staff) effectively played their roles. The role of PSI became redundant early on and did not add distinct value outside of brokering the AMP as earlier described.

How well does the intervention align with priorities/needs identified by partners/the global disease response?

Finding 2. The NNP was externally coherent as it aligned almost seamlessly with other external stakeholders' needs and collaborated effectively by leveraging ongoing complementary initiatives to meet shared objectives: The NNP formed other important partnerships with BMGF, PMI and a host of other partners. Pre-NNP contract signing, IVCC and Global Fund conducted early stakeholder engagement visits

in Burkina Faso, meeting with the NMCP, Global Fund Principal Recipient (PRs) and PMI in preparation for the first co-payment to procure IG2, especially facilitating the signing of the Memorandum of Understanding (MoU) with NMCP, prior to the arrival of the NNP team responsible for the pilot design (PATH, PSI and LSTM). These engagements were funded by BMGF through a supplemental grant. This BMGF grant also supported the enhancement of entomological and behavioral elements of the Tanzania RCT to complement the upcoming Benin RCT plans. The volume guarantee negotiations by BMGF/MedAccess with BASF, already discussed earlier, were also based on a Cost of Goods Sold (COGS) study conducted by KPMG in collaboration with the BMGF's Deal Team.^{21,22} Other donors (PMI and AMF) also leveraged the volume guarantee agreement. PMI supported the strengthening of countries' capacity to use epidemiological, entomological, and coverage data to support the optimal deployment of vector control tools through its VectorLink Project. NNP was critical as a special purpose vehicle, as it brought together a wide range of actors to achieve its objectives and theirs. It is doubtful that the objectives of the project would have been achieved without this magnitude of multi-level engagement, partnership, and collaboration. Key informants, including donors and wider global stakeholders, described the NNP as well aligned to their priorities and that it served as an enabler to achieve their own objectives.

²¹ NNP Annual Report 2018

²² NNP Annual Report 2019

"The diversity and scope of the team/expertise was excellent, both organizations and the people involved." Global respondent

"The project did not only align

with our priorities, but it was sort

of critical for us achieving our

own priorities."

Global respondent

22

How well did the project maximize alignment/coherence and synergies with government, in-country stakeholders, and CSOs during planning, implementation, and assessment to promote adoption and scale up? To what extent was the project consistent with national vector control strategies?

Finding 3. The NNP was designed to be implemented through the existing country structures by having National Malaria Control Programs as lead implementer in most project countries. This enabled the project to be completely integrated into country health systems: The NNP was adapted to fit into the integrated vector management strategy in participating countries. The program relied on the existing country structures, such as the national/ state malaria programs' net distribution systems. To a large extent, there were no disruptions to the usual country-level strategies and integrated vector management approaches. The various levels of oversight at global, national, and state further enhanced programming and engagement among partners.²³ Also, the Global Fund procurement processes were retained and led by the existing

country structures as was the norm.²⁴ All relevant players in the malaria vector control landscape in countries were involved and had distinct contributions tailored to their organizational capacity.²⁵ This approach is critical to institutional sustainability. Key informants at country level (especially NMCPs) reported not just being actively involved but leading the initiative in their countries as part of their programs.

"The leadership from NMEP was good, in terms of their coordination and collaboration with various partners." Country respondent

Finding 4. The project had somewhat limited direct engagement with CSOs by design, with expectations to utilize already existing CSE activities of its implementing partners; however, it implemented largely comprehensive CSE activities around its research activities: As the project worked through national malaria programs, Global Fund Principal Recipients (PRs) and PMI implementers, there was no expectation that it would engage Civil Society directly and as such no specific CSE activities were included in the grant agreement. There were, however, a number of CSE interactions related to community sensitization prior to the commencement of research activities. These interactions took place with a wide range of community actors, including community leaders/village chiefs, community health workers, and district health staff.²⁶ These engagements were sufficient in scope and intensity to achieve their desired objectives. This is discussed in more detail in *Section 3.3 Effectiveness (Demand and Adoption)*.

What is the level of interplay and complementarity of the NNP and NTI, and the effectiveness of the interface between them?

Finding 5. The follow-on strategic initiative to the NNP, Global Fund's \$50 million Nets Transition Initiative was complementary and well aligned with NNP. Its design allowed it to overlap without duplications, fill in additional evidence gaps, as well as support transitioning of the dual-AI ITNs into standard implementation processes: The timing of Global Fund grant cycles resulted in a follow-on project that was initiated in the middle of the NNP. The follow-on project was critical to ensure sustenance in procurement of dual-AI ITNs under Global Fund's Strategic Initiatives, pending the WHO recommendation that would enable donors to fund dual-AI ITNs as part of their standard procurement processes. This mid-term introduction could have created challenges with duplication of project activities; however, the NTI was well coordinated with NNP by design, ensuring that NNP frontloaded its co-payments into 2020 and 2021, allowing the NTI's copayment mechanism to cover 2022 and 2023, as well as supporting transitioning of the dual-AI ITNs into standard Global Fund procurement processes.²⁷ The research agenda of NTI is also informed by emerging gaps during NNP that will enable the transition and sustainability of the intervention. NNP's evidence generation goal was to generate the evidence required to ascertain the public health impact of the dual-AI ITNs toward the WHO policy recommendation. NTI's evidence generation goal is evidence to inform prioritization and decision-making between effective vector control tools, especially for national decisionmakers. The steering committee of NNP has also been transitioned over to the NTI, enabling seamless continuity in the scale-up and institutionalization of dual-AI ITNs.

²³ Unitaid Flash Report, IVCC, September 2021

 $^{^{\}rm 24}$ The Global Fund: Evolution of NNP Partnerships and transition to the NTI

²⁵ WHO, Geneva. World Malaria Report 2022

²⁶ NNP Annual Report 2019

²⁷ NNP Annual Report 2020

Case Study C1. Co-funding vs Sole funding

What synergies did the partnership model between Unitaid and the Global Fund create at global and country levels, and what are the lessons from this experience?

The partnership between Global Fund and Unitaid created the greatest synergies at the global level, pulling together the most important actors in the space, including policymakers, donors, implementers, coalitions, researchers, and manufacturers. These relationships also influenced the synergies for delivery and coordination within project countries, with key stakeholders largely aligned on the expectations for dual-AI ITNs deployment.

Benefits

1. Leveraging each other's technical expertise: Unitaid's innovation and market shaping expertise and Global Fund's disease management and scale up capacity.

2. Increased funding levels, with both donors contributing 50% of the funding and jointly sharing the risk.

3. Increased access to information that may have been difficult to obtain, with better sharing across both organizations.

4. Clear linkage and commitment between innovation partner and scale-up partner from inception, reducing scale-up concerns throughout project life and increasing the ease of leveraging Global Fund's programmatic support to countries.

5. Increased focus on the public health problem (pyrethroid resistance and the need to deploy new nets) by the global community.

6. Increased influence amongst stakeholders, with the partnership galvanizing a wider variety of interested stakeholders, seemingly making the project everyone's business.

7. The high-level coordination between both funders and other donors cascaded to the implementation level (country level), eliminating the tensions often experienced when donors working in the same space have differing priorities.

What worked well

1. Having one funder (Unitaid) serve as a sole administrator allowed seamless program management/coordination with implementers.

2. Regular meetings and updates with both donors present. This demonstrated a high level of synergy and enabled productive decision-making, facilitating progress across different elements of the project.

3. The different implementation styles with Unitaid implementing through consortia of expert organizations and Global Fund supporting countries directly worked well to achieve the different project objectives.

Challenges

There were no notable challenges in the partnership arrangement. Generally, having multiple donors increases the complexity of implementation, but the sole administrator approach seems to have eliminated these complexities.

Recommendations

Majority of key informants applauded the approach and hope to see similar collaborations in the future. Recommendations to guide future utilization of this approach mostly reiterate elements of this partnership that worked. These include:

1. Employing this type of partnership with product/technology types that are relatively proven, with related global policies already in place, and within a context where demand for an improved product is already very high.

2. Designate one funder as the sole administrator and ensure there is strong alignment around each funder's goals and expectations.

3. Ensure adequate avenues for communication and coordination between both co-funders, as well as with implementers.

4. Leverage each funder's wider connections and relationships.

5. Ensure ongoing knowledge-sharing and transparency between funders on other elements of their work that could be leveraged for the success of the project in focus.

3.3 Effectiveness

Criteria	Not achieved	Slightly achieved	Moderately achieved	Largely achieved	Fully achieved	Strength of Evidence
Effectiveness (Did the intervention achieve its objectives?)						Strong

Innovation & Availability

To what extent has the project contributed to the increased availability of dual-AI ITNs that are commercially available for rapid introduction in LMICs?

Finding 1. The project successfully created and disseminated evidence on the efficacy of dual-AI ITNs and data exploring entomological correlates that met WHO and VCAG requirements to inform policy recommendation processes. It also generated anthropological evidence through its effectiveness pilots. NNP conducted all planned research within the West Africa trial (Benin RCT) towards informing WHO requirements, with results published in the January 2023 Lancet.²⁸ The trial comprised three arms: IG2, Royal Guard and Interceptor LN (Standard ITN). The local vectors in trial locations were *Anopheles gambiae and Anopheles coluzzi*. The key outcomes of interest were malaria case incidence in children 6 months to 10 years, malaria infection prevalence in the population measured at 6 and 18-months post-distribution, and entomological inoculation rate (EIR) and anopheles density. The larger NNP evidence-generation agenda is detailed in *Table 1* below.

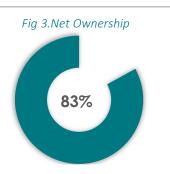
Table 1. NNP Evidence Generation Agenda

Epidemiology	Durability Monitoring	Entomology	Anthropology
Measure impact of new nets and standard ITNs, and if feasible, PBO ITNs, through observational studies	Estimating survivorship, attrition, physical integrity and	Understanding the transmission landscape in each setting.	Examine barriers, facilitators, and patterns of ITN access and use.
comparing trends in: Malaria prevalence in community surveys Malaria prevalence in antenatal care Malaria case incidence	insecticidal content throughout the study time period.	Evaluate the impact of new nets and standard ITNs, and if feasible, PBO ITNs, on vector population density, behavior, infection and resistance status.	Measure time spent under an ITN and correlate use patterns with vector behaviors to explore transmission risks and understand the limitations of ITN interventions.

Culled from IVCC NNP Overview Presentation, November 2022

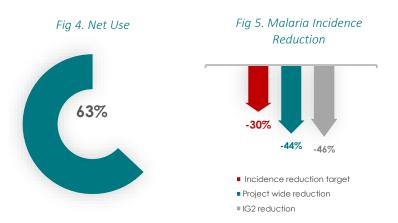
Epidemiology

Finding 1.1. The trial reported 83% of households owning ITNs as per allocation in dual-AI settings and control settings (in the trial) and 63% of people sleeping under the allocated net the night before the 18-month prevalence survey, higher than the 60% target. Most importantly, the IG2 (chlorfenapyr-pyrethroid) ITN arm resulted in a 46% reduction in malaria incidence in children 6 months to 10 years compared to standard ITN arm, a much higher incidence reduction than the project's estimated target of 30%. The RG (pyriproxyfen-pyrethroid) arm of the study showed a non-significant reduction in

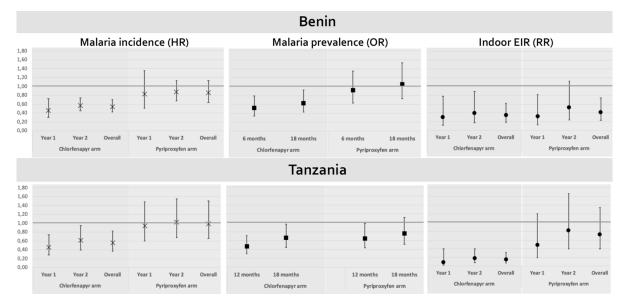


²⁸ Manfred Accrombessi, PhD, Jackie Cook, PhD et al. Efficacy of pyriproxyfen-pyrethroid long-lasting insecticidal nets (LLINs) and chlorfenapyrpyrethroid LLINs compared with pyrethroid-only LLINs for malaria control in Benin: a cluster-randomised, superiority trial. Published: January 24, 2023. DOI: https://doi.org/10.1016/S0140-6736(22)02319-4

incidence compared to standard nets. These results were very similar to the Tanzania RCT funded by UK Medical Research Council (MRC), Wellcome and BMGF.²⁹ See *Fig.6* and *Table.2* below for additional result summaries. The studies concluded that mass distributions of new net types, especially IG2 and PBO nets, are more effective in controlling malaria than standard pyrethroid-only ITNs in moderate to high transmission areas with pyrethroid-resistant vectors.^{30,31}







Reference: NNP Overview Presentation, November 2022



Other Results	Interceptor G2 vs Standard ITN	Royal Guard vs Standard ITN
Reduction in Malaria prevalence	 ✓ 52% reduction at 6 months ✓ 39% reduction at 18 months 	X Reduction not statistically significant.
Reduction in Malaria transmission for Indoor EIR	✓ Significant reduction	✓ Significant reduction
Reduction in Malaria transmission for Outdoor EIR	✓ Significant reduction	X No significant reduction
Wash resistance- Entomological Impact (performance against	✓ Significant reduction	✓ Significant reduction

²⁹ Jacklin F Mosha*, et al Effectiveness and cost-effectiveness against malaria of three types of dual-active-ingredient long-lasting insecticidal nets (LLINs) compared with pyrethroid-only LLINs in Tanzania: a four-arm, cluster-randomised trial. 2022. DOI:https://doi.org/10.1016/S0140-6736(21)02499-5

³⁰ Annual Report 2021

 $^{^{\}rm 31}$ IVCC NNP Overview at Evaluation Kick-off Meeting, November 2022

Other Results	Interceptor G2 vs Standard ITN	Royal Guard vs Standard ITN
pyrethroid-resistant mosquitoes, compared to Interceptor LN)		
Durability (Mortality reduction in 12 and 24-month field-aged nets)	 ✓ IG2 was superior to all ITN types ✓ Median survival = 2.2yrs 	 RG was inferior to IG2 but showed similar performance to a pyrethroid only net. The sterilizing effect of RG was lost at 12 months. It dropped from 86% to 29% at 12 months, Median survival = 1.7yrs

Further, there is emerging evidence that suggests potential resistance to chlorfenapyr in some field sites.³² WHO bottle assays by PMI revealed that chlorfenapyr has produced less than 98% mortality in these field sites. This is the threshold for suspected resistance.³³ According to implementers, there seem to be two separate phenomena affecting results in chlorfenapyr susceptibility tests and results from exposure to IG2 nets in huts, both of which appear to be related to differences in mosquito populations and acting on a fine geographical scale. There are, however, further studies in progress to better explain these findings.

Finding 1.2. DCT's Royal Guard, which includes an insect growth regulator pyriproxyfen as one of the active ingredients and other similar products, seemed problematic and was unable to achieve better results than pyrethroid-only nets, alongside other durability concerns.

The Benin RCT results revealed that RG did not show superior efficacy compared to standard ITNs with respect to reducing malaria incidence and prevalence. The study also reported a drop in the impact of pyriproxyfen on mosquito reproduction from 86% to 29% at 12 months, indicating low durability. At project inception, there seemed to have already been lesser confidence in the product. Many stakeholders, including manufacturers, researchers, policymakers and implementers, described the mechanism of action of Insect Growth Regulators (IGRs) as not well understood and accepted in the global malaria community. In an attempt to understand the poorer performance of the net, key informants described manufacturing challenges faced by Sumitomo on the Olyset Duo, ultimately leading to the withdrawal of the product from the market. Others made reference to cost-saving measures by DCT with size reductions, shrinking of the polyethylene net, and low preference for the polyethylene fabric, compared to the polyester fabric of IG2 and IG. This resulted in earlier reductions in RG net usage and may have contributed to the lower efficacy seen.

Durability Monitoring

Finding 1.3. The experimental hut trials examining wash resistance showed superiority of both dual-AI ITNs to standard ITNs; however, the durability of ITNs was significantly higher for IG2 than the other ITNs.

Interceptor G2 and Royal Guard outperformed Interceptor LN against pyrethroid-resistant mosquitoes with respect to wash resistance. However, data on 12-month and 24-month field-aged nets showed significantly higher mortality from field-collected IG2 nets than the other net types. Implementers have postulated that the lower durability of these polyethylene-based nets (RG and PBO) could be responsible for the difference in effect as compared to IG2. A similar study in Tanzania also postulated that poor textile and active ingredient durability in the Piperonyl Butoxide and pyriproxyfen in ITNs might have contributed to their relative lack of effectiveness compared with standard ITNs.³⁴ The Tanzania study also showed chlorfenapyr ITNs provided significantly better protection than pyrethroid-only ITNs after two years. There are, however, still questions on the physical integrity and bio-efficacy of all ITNs (including dual-AI ITNs) up to three years or more of use. Durability monitoring was also conducted in pilot countries with similar results.

³² Semi Annual Report 2022

³³ https://pubmed.ncbi.nlm.nih.gov/33298071/

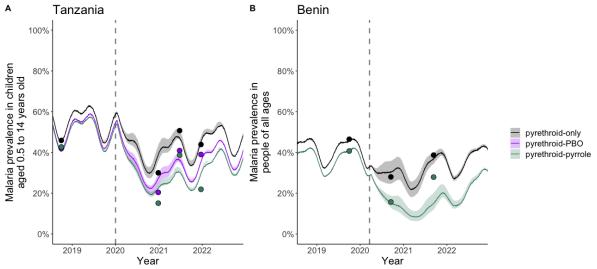
³⁴ Jacklin F Mosha*, et al Effectiveness and cost-effectiveness against malaria of three types of dual-active-ingredient long-lasting insecticidal nets (LLINs) compared with pyrethroid-only LLINs in Tanzania: a four-arm, cluster-randomised trial. 2022. DOI:https://doi.org/10.1016/S0140-6736(21)02499-5

Entomology Outcomes

Finding 1.4 The entomological study findings were not available at the time of this evaluation; however, provisional analysis using entomological data from a similar project as well as the results of a systematic review published in 2022, indicate that using hut study data can reliably predict epidemiological trial results for IRS, standard ITNs, and PBO ITNs.

The analyses here indicate that "mosquito data collected in experimental hut trials can be used to parameterize mechanistic models for *Plasmodium falciparum* malaria and may be a reliable tool to predict the epidemiological efficacy of quick-acting, neuro-acting ITNs and IRS." The results suggest that using this framework, instead of clinical endpoints from epidemiological trials, can predict the effect of certain types of ITNs and IRS and can serve as an evidence base for decision-making on policy and scale-up of these interventions.³⁵ The graphs presented below (*Fig.7*) are provisional model predictions of the Benin and Tanzania RCTs and do not include real-world durability data. They are based on entomological data collected from hut trials under the BMGF-funded ESSENTIALS project. The dots are the trial data points that align well with the predicted prevalence trends. The model seems to fit better the Benin RCT outcomes than the Tanzania RCT outcomes.





Anthropology

Anthropological findings are discussed later in this section. Finding 11 under *Demand and Adoption*.

To what extent has the availability of better products increased for the target groups/region? Have the products supported through the project been registered for commercial use in relevant project countries, or are plans in place for their registration after project closure?

Finding 2. The project increased availability of dual-AI ITNs through registration in 26 LMICs, including 10 project countries and 16 additional non-project countries.

At project inception, only IG2 was prequalified. Subsequently, the project facilitated Royal Guard's introduction after its pre-qualification in 2019. Both manufacturers' production levels were scaled up and maximized through the life of the project.³⁶ IG2 is now registered in 26

"Yes, the project has helped to fast-track registration ahead of requests in any country. It is often an uphill task engaging countries one by one to get products registered. " Manufacturer

 ³⁵ Sherrard-Smith E, Ngufor C, Sanou A, Guelbeogo MW, N'Guessan R, Elobolobo E, Saute F, Varela K, Chaccour CJ, Zulliger R, Wagman J, Robertson ML, Rowland M, Donnelly MJ, Gonahasa S, Staedke SG, Kolaczinski J, Churcher TS. Inferring the epidemiological benefit of indoor vector control interventions against malaria from mosquito data. Nat Commun. 2022 Jul 5;13(1):3862. doi: 10.1038/s41467-022-30700-1. PMID: 35790746; PMCID: PMC9256631. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9256631/
 ³⁶ Annual Report 2021

countries and RG in 5 countries. These registered countries already account for over 70% of the global malaria burden. Additional country registrations are also being sought throughout sub-Saharan Africa for IG2, with eight registration processes currently ongoing. There are a few countries where registration was challenging; however, these were due to internal country factors unrelated to the products and project. All key informants attribute the coverage of the new nets in sub-Saharan Africa to the project and indicate that in the absence of the project, these products will have had similarly slow traction as the PBO nets.

"The project's efforts have not only improved the availability of better products but have also helped to save lives and improve health outcomes in areas with high rates of malaria in the country." **Country respondent**

Has the project contributed to eliminating intellectual property barriers (if they exist) or ensuring that such barriers are not created, which may prevent equitable access to a product?

All respondents mentioned that there were no prohibitive IP rights, especially on the active ingredients, since these are already widely used in multiple sectors beyond public health. BASF is open to licensing the chemistry (for chlorfenapyr) out to other manufacturers to improve the global production capacity of dual-Al ITNs (on the condition that these manufacturers meet the required health and safety measures). They also have a general sense of commitment to public health, indicating that it would be counter-productive to have patents that hinder the manufacturing of products that could improve public health outcomes. However, Vestergaard was unable to access chlorfenapyr from BASF and had to work with another chlorfenapyr supplier to be prequalified, indicating that there may be a need to address this gap for new innovators.

Affordability

To what degree has the project contributed to making dual-AI ITNs available at lower prices that are affordable for governments and other donors?

Findings 3. The NNP contributed significantly to making dual-AI ITNs available at lower prices in project and non-project countries through its two market-shaping strategies: the co-payment mechanism and leveraging the BMGF/MedAccess-led volume guarantee negotiation with BASF.

Dual-AI ITNs were more expensive, with prices more than double that of standard ITNs. Without price reductions and information on cost-effectiveness in different settings, adoption of these tools was expected to be slower, even in the presence of a policy recommendation.

The most critical market-shaping strategy utilized by the NNP was the volume guarantee agreement. This led to reduced Free on Board (FOB) prices of these dual-AI ITNs to less than \$3 by the third year of the project, a year ahead of the estimated timeline. Through NNP, manufacturer production levels were maximized through the life of the project, and the end-of-project pricing targets were met and are similar to PBO nets, although slightly higher. The volume guarantee was also applied retroactively to purchases made by IVCC under the negotiated pricing in 2019 through a credit note from BASF. The resulting savings of \$2,785,000 enabled the project further expand procurement quantities and other reprogramming needs. BMGF/MedAccess would not have been able to negotiate the agreement without the presence



of NNP as a vehicle to allow massive, consolidated procurement of nets funded by different donors prior to

WHO guideline release. Key informants from these organizations affirm that the NNP was the single most important factor in the volume guarantee negotiation process. This indicates that, to some extent, the VG could have been negotiated directly by NNP implementers, especially as the negotiation fee by other actors was factored into the price of the nets.

The co-payment mechanism was established to be a time-limited system used in conjunction with the volume guarantee prior to WHO policy recommendation, and it led to further price reductions for countries. It enabled the countries to only pay the Global Fund pyrethroid-only reference price (i.e., the 2018 PPM reference pricing for standard ITNs), with the difference between the floor/reference price and the negotiated price (co-payment amount) covered by the project. Further, RG was introduced earlier than

anticipated, and as such, the project also negotiated a similar price point as IG2's lowest price point (under \$3 for the 180x190x150 net). These market-shaping interventions are very attractive to manufacturers and are incentivizing, as they create stability and predictability, which are important to maintaining manufacturer commitment and prices.

"The volume guarantee agreement negotiations brought the prices to the barest minimum, with manufacturers having single-digit margins, which is very rare." Consortium Member

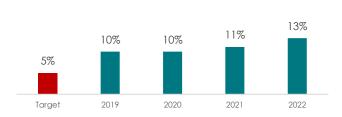
Finding 4. The project maximized its market-shaping price points by leveraging other donors. This included a favorable pricing agreement with PMI, with IVCC signing an MOU with United States Agency for International Development (USAID) and implementing a co-payment agreement with their procurement agent (Chemonics), as well as the Against Malaria Foundation (AMF) also procuring dual-AI ITNs at NNP prices.

The project negotiated and implemented a co-payment agreement with PMI's procurement agent (Chemonics), in which PMI procured IG2 and RG nets at the project exit price for a standard IG2. The similarity between the exit price and the PBO net prices enabled this collaboration with PMI already transitioning from procuring standard ITNs to PBO nets. The savings to NNPs co-payment budget also enabled additional budget to procure more nets.³⁷ The project also partnered with AMF, a United-Kingdom-based charity that provides long-lasting insecticidal nets to populations at high risk of malaria, primarily in Africa. AMF accessed NNP pricing for Royal Guard nets and procured for DRC and Uganda without co-payment. These partnerships also contributed to increasing access to dual-AI ITNs within and beyond the projects geographical scope.³⁸ Country respondents reported gaps in national funding pots to cater to ITNs in general and the current affordability of all nets, including dual-AI ITNs being heavily dependent on donor funding.

Finding 5. The project increased the market share of dual-AI ITNs from 0% to 10-11% annually during the project life and up to 13% in the final year. This is over double the intended 5% target, as it enabled both project and non-project countries to access dual-AI ITNs.

Through the NNP, 21 countries have procured dual-AI ITNs, 14 pilot countries and 7 non-project countries (Senegal, Guinea, Uganda, Equatorial Guinea (Bioko Island), Kenya, Sierra Leone, and Papua New Guinea). 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. IG2 nets were purchased in 21 countries (14 NNP, 7 non-NNP), and RG nets were purchased in 5 countries (3 NNP, 2 non-NNP).

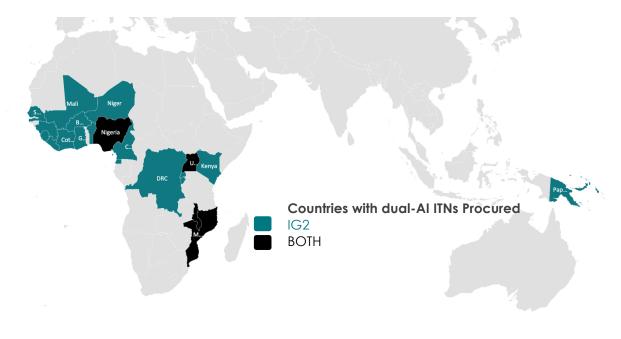
Fig 9. Market share (%) of dual-AI ITNs during project life



³⁷ Annual Report 2019

³⁸ Annual Report 2020

Procurement status of dual-AI ITNs



Demand and Adoption

What progress did the project make in facilitating increased demand and uptake for scale-up of cost-effective dual-AI ITNs within target countries and beyond? How effectively have implementers partnered with/engaged and supported communities and civil society organizations to support research activities, increase demand, political support and financial commitments?

Finding 6. Demand pre-dated the project, with countries experiencing an increasing spread of resistance and a stall in progress towards malaria prevention, as well as an urgent desire for more effective vector control tools.

All key informants (at global and country levels) described the urgency for innovation and additional vector control tools due to emerging resistance. They reported that NMCPs in many countries in sub-Saharan Africa were already having extensive discussions on how to address the spread of resistance and were focused on improving their Insecticide Resistance Management (IRM) plans. The project was, therefore, timely as it was an immediate response to increasing demand for intervention to curb the effect of resistance.

Finding 7. WHO policy recommendations were issued for both pyrethroid-chlorfenapyr ITNs and pyrethroidpyriproxyfen nets in March 2023, with a strong recommendation for the deployment of pyrethroidchlorfenapyr ITNs instead of pyrethroid-only nets and a conditional recommendation for the deployment of pyrethroid-chlorfenapyr ITNs instead of pyrethroid-PBO nets, as well as a conditional recommendation for the deployment of pyrethroid-pyriproxyfen nets instead of pyrethroid-only nets to prevent malaria in adults and children in areas with pyrethroid resistance.³⁹

A key precursor to introducing and scaling these new-generation ITNs is the presence of a WHO policy recommendation. The project generated sufficient evidence of the public health value of the dual-AI ITNs deployed, which informed the recommendation.

For pyrethroid-chlorfenapyr ITNs, WHO issued:

• A strong recommendation for their deployment instead of pyrethroid-only nets to prevent malaria in adults and children in areas with pyrethroid resistance. This is based on the increased killing effect against pyrethroid-resistant malaria vectors, thus its greater impact against malaria.

³⁹ WHO Guidelines for malaria, 14 March 2023. Geneva: World Health Organization; 2023 (WHO/UCN/GMP/ 2023.01). License: CC BY-NC-SA 3.0 IGO.

A conditional recommendation for their deployment instead of pyrethroid-PBO nets to prevent malaria in adults and children in areas with pyrethroid resistance. The conditionality of this recommendation is based on the balance of desirable and undesirable effects favoring pyrethroid-chlorfenapyr nets and the evidence base being drawn from only one trial in Africa.

For pyrethroid-pyriproxyfen ITNs, WHO issued:

- A conditional recommendation for their deployment instead of pyrethroid-only nets to prevent malaria in adults and children in areas with pyrethroid resistance. The conditionality is based on concerns around the poor cost-effectiveness of pyrethroid-pyriproxyfen nets compared to pyrethroid-only nets, which may negatively impact coverage and equity.
- A conditional recommendation against their deployment instead of pyrethroid-PBO nets. The conditionality is based on the balance of effects favoring pyrethroid-PBO nets and that, based on current cost and efficacy data, pyrethroid-PBO nets are more cost-effective.⁴⁰

Finding 8. NNP effectively distributed dual-AI ITNs in project countries, with 94-100% of the lowest-level ITN storage facilities receiving the correct ITN type. Beneficiaries are also using these similarly to the standard nets.

Pilot distribution of dual-AI ITNs took place in 12 of the 13 project countries. The only outstanding country is DRC, whose campaign had to be postponed to mid-2023 due to in-country logistical arrangements. The demand and uptake has also expanded to include 7 non-project countries, as discussed under Section 3.3 Effectiveness: Affordability. Process evaluation reports and distribution data from pilot countries showed that 94-100% of lowest-level ITN storage facilities received the correct ITN type, higher than the targeted 90%. The difference in percentage use of any given net between pilot and comparator areas was largely

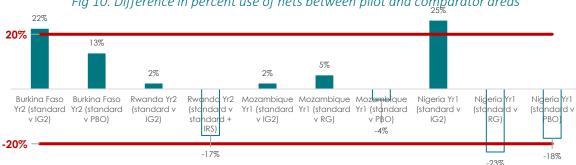


Fig 10. Difference in percent use of nets between pilot and comparator areas

similar across countries and commodities and this difference was close to or within the 20% estimated range of difference in percentage use per project target. See Fig.10 below. Country-level respondents reported effective distribution of nets (especially targeting high-incidence locations with pyrethroid resistance) during net campaigns in their respective countries.

Finding 9. Implementation guidelines on effective methods for planning and implementation of PBO and dual-AI ITNs were generated and disseminated through NNPs' implementation pilots. AMP's toolkits were updated with pilot operational learnings, and several guidance documents were produced, including:

- Guidance on managing waste generated during mass insecticide-treated net (ITN) distribution campaigns in the COVID-19 context (2020)
- Training for implementation of ITN mass distribution campaigns (2021) .
- Planning and operational recommendations for multi-product ITN campaigns (2021)
- Messages on hanging of new types of insecticide-treated nets (ITNs) (2021)
- Planning for Transition of Insecticide Treated Net (ITN) Types through Routine and Community Channels Post Multi-product Campaign (2022)
- Standard Operating Procedures: Management of More than One Net Type for Campaign, Routine, and Community Channels during Storage and Transport (2022)

⁴⁰ Implementers report that the cost that WHO used here to compare pyrethroid- pyriproxyfen ITNs and PBO nets was significantly more than the current price of Royal Guard net.

- ITN Distribution Guidance During COVID-19 (2020)
- Rumor Management Around COVID-19 Communication in Communities (2020)

Finding 10. Although community and civil society engagement was primarily through national malaria programs, Global Fund PRs and PMI implementers, the project implemented a sizeable level of engagement as part of the AMP planning and in support of research activities.

As earlier described under *Section 3.2 Coherence*, the project's CSO and community engagement were expected to be implemented through existing mechanisms by country implementers (national malaria programs, Global Fund PRs, and PMI implementers). Activities varied across countries; however, a key theme across countries was the sensitization of community leaders, which became a prerequisite for successful net distribution and monitoring. The

"The ACSM unit of the SMEP had used existing strategies to sensitize the communities on the importance of using nets." **Country respondent**

Benin RCT engaged community leaders (district mayors, ward leaders and village leaders) prior to each research activity; mid-media (town criers) and mass media (radio shows) were used for awareness creation on distribution. Also, health facilities, through ANC and vaccination visits, supported awareness creation through interpersonal communication. These initiatives increased community acceptance, as seen with net usage proportions. The evaluation/evidence pilot countries also engaged a range of community stakeholders, orienting them on study objectives the procedures; these included village leaders, health facility staff and community health workers. In some countries, local community radio programming was utilized. The engagements facilitated introduction of study staff to communities, enabled the identification and selection of households, increased awareness and acceptance of the study activities. These engagements also served as avenues to provide relevant information to communities on COVID-19 preventive measures.⁴¹

Finding 11. 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-AI ITNs; instead, they emphasize some general limitations of ITNs in general, within different country contexts. Evidence here was only available for the Evaluation Pilot countries (Burkina Faso, Mozambique, Nigeria and Rwanda).^{42,43}

- Access in all countries is through mass campaigns, with door-to-door distributions introduced as an adaptation to the constraints of the COVID-19 pandemic. ANC and immunization visits are also common distribution methods. Qualitative interview respondents were split on whether they received enough bed nets. They also reported challenges accessing nets if people are away from home during registration or distribution. Respondents also report inequity in net allocation and distribution processes in Burkina Faso, Mozambique and Nigeria.
- Bed net use was viewed as very important, and as the most common malaria prevention method in all countries, with many prevention methods used in all countries. Awareness of the effectiveness of nets at preventing malaria transmission is a key motivating factor for use in these countries. Respondents in all 3 districts in Rwanda reported using nets at night throughout the year, and due to vulnerability to malaria, special attention to pregnant women, the elderly and young children was reported when there were few nets compared to sleeping spaces. Interim project reports revealed inconsistent net use in Nigeria, with use generally delayed from when distribution happens, and seasonal variation in use patterns.⁴⁴ In Burkina Faso, many respondents reported using nets every day and throughout the year in both the dry and rainy seasons. However, some reported not using nets when sleeping outside or during the dry season. In Mozambique, there were mixed responses on net use, with some respondents describing using their nets every day, sometimes in spite of tears, and others describing irregular or seasonal net use based on perceptions of malaria risk and relative nuisance of heat, mosquitoes, and other pests.

⁴¹ Annual Report 2020

⁴² New Nets Project interim results, Preliminary evidence from the pilot evaluations August 2022.

⁴³ New Nets Project Human Behavior Results January 2023 Draft.

⁴⁴ Annual Report 2022

• 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 and community perception that malaria is more common in the rainy season. Other less common reasons are traveling/having visitors in Nigeria and irritation from ITN chemicals (often remedied by washing or airing out a new net before use) in Rwanda, Burkina Faso and Mozambique. Many respondents in Mozambique also described outdoor use and a preference for taller and wider nets that could be used while standing or sitting. Respondents in Rwanda also preferred conical-shaped nets because they were said to be easier to hang and use. Another barrier mentioned across all countries was inadequate numbers of nets.

Finding 12. The intervention is expected to be cost-effective, with similar studies demonstrating costeffectiveness compared to standard ITNs. The intervention is expected to be cost-effective as a similar study in Tanzania reported that chlorfenapyr-pyrethroid ITNs are cost-effective, costing only US\$19 (95% uncertainty interval 1-105) more to public providers or \$28 (11-120) more to donors per Disability Adjusted Life Year (DALY) averted over a 2-year period compared with pyrethroid-only ITNs and saving costs from societal and household perspectives.⁴⁵ The consortium partners, PATH and Tulane University, also estimated the cost and cost-effectiveness through data on product price, delivery and deployment costs and effectiveness based on incidence rates. The cost-effectiveness studies covered the six evaluation pilot countries. Cost-effectiveness point estimates comparing next-generation nets to pyrethroid-only nets using net pricing at the time of procurement for effectiveness pilot countries with the additional manufacturer copayment, and excluding cost savings to the health system, 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.

In addition, practical factors the project considered to achieve value for money included: Working directly with NMCPs as country implementers; integration of the intervention within existing national NMCP campaigns; the co-funding, co-governed model, reducing the risk of both donors; and the project with its volume guarantee, enabled manufacturers to recoup a significant proportion of their R&D costs.

⁴⁵ Jacklin F Mosha^{*}, et al Effectiveness and cost-effectiveness against malaria of three types of dual-active-ingredient long-lasting insecticidal nets (LLINs) compared with pyrethroid-only LLINs in Tanzania: a four-arm, cluster-randomised trial. 2022. DOI:https://doi.org/10.1016/S0140-6736(21)02499-5

Case Study E1. Understanding Countries' Decision-Making on Dual-AI ITNs Deployment

To what extent, in a context of limited resources, did country decision-making prioritize deployment of dual-AI ITNs? What was the rationale behind the selected approach and level of deployment of dual-AI ITNs?

Evolution in rationale for deploying dual-AI ITNs pre- and post-project.

Recent decisions around deployment of dual-AI ITNs were tied to the NNP and, subsequently, the NTI project. These projects facilitated the introduction of these new nets at similar price points as standard nets, and as a result, countries basically focused on replacing other nets with dual-AI ITNs in locations experiencing pyrethroid resistance. However, post-project, the rationale for deployment has expanded beyond just data on resistance to assessing available funding pots, reviewing the effectiveness of pilot results, and considering the price difference between new nets and previous net types (standard ITNs and PBO).

How was effective coverage determined?

Effective coverage vs coverage of dual-AI ITNs

Majority of stakeholders felt that there are still questions around what effective coverage means in each country context, indicating a need for more rigorous data collection and analysis than available through routine systems. Implementers framed dual-AI ITN coverage in countries around increased access to and utilization of new nets (not necessarily effective coverage), as measured by household surveys. Other key informants reported improved use of local routine data, including data on resistance in project countries during macro and micro-planning, as the main process for ensuring effective distribution and coverage of dual-AI ITNs.

What are the drivers for dual-AI adoption (e.g., price, ease of implementation, increased effectiveness, etc.)? Which is the predominant driver among these, if any?

Available funding and price trump all other adoption drivers.

There is general consensus amongst all stakeholders at global and country levels that the main factors influencing the adoption of dual-AI ITNs are case burden, resistance profiles, effectiveness of dual-AI ITNs, the presence of a WHO recommendation, funding pots, price/affordability of dual-AI ITNs, and quality of nets/perceptions of quality. Most respondents report several of these factors working together to influence adoption. Effectiveness was an important factor mentioned. However, in many countries, PBO nets performed very well, so countries are still interested in the product, especially since it also comes at a slightly lower price point than dual-AI ITNs. Also, the marginal price difference between PBO and dual-AI ITNs can still translate to millions due to the volumes of nets required in countries. The combination of available funding and the price of dual-AI ITNs are said to be the most critical drivers, especially as countries get weaned off the NTI top-up that replaced the NNP co-payment. Countries' ability and willingness to pay the full price of the nets when the top-up ceases to exist has not been tested, and there are expectations that new nets will compete with other evolving malaria interventions, such as revised SMC guidelines and malaria vaccines for the same largely static funding pots that most countries have.

See country-specific perspectives in Section 7. Country Case Studies

What were the main factors influencing the achievement or non-achievement of the intended outputs or overall outcomes?

Enablers

- 1) Familiarity of the intervention: The familiarity of the beneficiaries with ITNs and mass distribution campaigns was a good enabler. It eased the introduction of dual-AI ITNs as communities were introduced to a better version of something they already use, and in countries that were silent on the differences in the net types, it was just a new net to replace their existing one.
- 2) Availability of funding for this initiative: Implementers described the limited funding and increasingly shrinking donor funding towards Malaria interventions, indicating that the availability and the size of funds from Unitaid and Global Fund was timely and a major enabler that influenced the achievement of the outcomes on the project.
- **3)** Leveraging the volume guarantee agreement in partnership with BMGF: Most stakeholders felt the volume guarantee (supported by MedAccess and BMGF) was a crucial element for the project, with NNP serving as a consolidation platform enabling procurers access dual-AI ITNs at lower prices.
- 4) Harnessing the purchasing power of Global Fund, PMI, UNICEF and AMF: The project leveraged the key funders of ITNs, who supported dual-AI ITN procurements for project and non-project countries.
- 5) **Implementation countries' ownership and leadership:** The involvement of countries as implementing partners through their NMCPs was an enabler for adoption, integration, and sustainability of the intervention in project countries. IVCC had established strong relationships with national malaria programs during its previous Unitaid/GF-funded NgenIRS project, which created a foundation for the effective partnerships it had with project countries under NNP.
- 6) Local data availability for informed decision-making: Although the quality of data varied across countries, implementers reported improved use of local data for country decision-making around campaigns. All site visit countries reiterated this factor, indicating the use of incidence and resistance data in their forecasting and planning processes.
- 7) Consistent communication and coordination through the project life: Key informants, including implementers, funders and the wider stakeholder community, described a somewhat elaborate and comprehensive communication plan that involved meetings at various levels, among co-funders, among implementers and consortium members and the steering committee, with very frequent touch points that enabled effective decision making and information sharing throughout the life of the project.
- 8) Expertise of IVCC, the selected consortium and pre-existing relationships with wider stakeholders: All respondents emphasized the quality of the multi-disciplinary implementation consortium, their complementary expertise, and commitment to a common goal, as one of the most important enabling factors for the success of the project. Also, the implementers were very familiar with the global malaria community and easily leveraged on existing relationships at global and country levels, achieving very early alignment with a wide base of key stakeholders. Lastly, the close collaborative relationship between IVCC and manufacturing partners, with ongoing reviews of demand, production levels and product registration, also enabled the project.
- **9)** Active involvement of the co-funders (high-level advocacy and joint problem-solving): The co-funders (GF and Unitaid) were actively involved in the project through relevant coordination meetings where they participated in joint problem-solving. They also supported high-level advocacy to other wider global stakeholders. The level of involvement was said to show intentionality among these funders to reduce the malaria burden globally.

Challenges

- 1) Funders faced early challenges in aligning with WHO, as the project represented a deviation from the sequence of product introduction: In the face of a global public health threat (Insecticide Resistance), extraordinary measures were urgently needed, and as a result, Global Fund and Unitaid took a calculated institutional and reputational risk to deviate from WHO's standard process for product introduction. This involved implementing several elements of the introduction process in parallel (Conducting both efficacy and effectiveness studies with implementation pilots at the same time) instead of sequentially. The risk was evidence-based, with both dual-AI ITNs already WHO prequalified and early trial efficacy data available. Many key informants discussed the initial challenges with gaining WHO's support and alignment on the objectives of the project. This was eventually resolved through advocacy by the wider stakeholder community, who emphasized the sense of urgency to introduce these products in the light of growing pyrethroid resistance.
- 2) Quality Assurance Gaps in Burkina Faso, Malawi, and Rwanda: The project experienced a number of Quality Control issues; some were identified prior to shipping, others on post-delivery inspection. These challenges were effectively addressed in time and did not affect project implementation.
 - IG2 orders for Burkina Faso failed a flammability test during the pre-shipment quality assurance process. This was reported to be due to conducting the tests too early in a shorter timeline than required for the curing process. On re-testing after full curing, the results were then deemed within acceptable parameters.
 - In Malawi, five lots of IG2 nets (1.8M) were rejected on post-delivery inspection because the fabric weight and bursting strength were below product specifications provided by BASF (though within WHO specifications). Subsequent re-testing found that 1.5 million of these nets met quality standards. However, the country decided to replace the nets with 1.8M Royal Guard nets (a less-effective net) in mid-2022 and significantly delayed the distribution campaign. These have also resulted in losses to the manufacturer.
 - In Rwanda, both IG2 and PBO nets failed in-country quality inspections and had to be re-inspected, with BASF financially responsible for the reinspection, repair, and repackaging. After this process, there were still 70,000 nets of the 1.2 million which were rejected or to be re-inspected due to insufficient funding. The project reported that similar inspection failures occurred with standard ITNs from other manufacturers, leading to discussions about Rwandan standards being more rigorous than international standards (higher than typical Global Fund and PMI procurements). However, it was also clear that a certain percentage of the nets were not within the agreed size specification and had other damage or manufacturing defects. Subsequently, BASF also provided a credit note for the 70,000 nets that were rejected by Rwanda.
 - Lastly, there were also reports that Royal Guard nets were shrinking in height in Tanzania, Benin, and Mozambique, due to cost-saving measures regarding the material used in production by DCT. These may have contributed to the lower efficacy seen with these nets, as they affected net use.
- 3) Early Gaps in BASF production capacity, exacerbated by COVID-19-related challenges leading to delays in receipt of nets in most countries: Dual-AI ITNs already have longer lead times than other net types (PBO and pyrethroid-only), requiring 12 more months, and with the project scaling up its orders rapidly from a single supplier (BASF) in the first two years, there was an inevitable backlog of orders. The production capacity at BASF was inadequate to cater to the initial surge in orders. This created delays in delivery but was promptly addressed by BASF scaling up production in Thailand, as well as supporting countries and procurers to prioritize and phase orders. These delays were further increased by the effect of COVID-19 on factories and supply chains. The delays also resulted in desynchronized ITN arrival for multi-product campaigns under NNP, which led to financial and planning implications, wasted resources, time inefficiencies, and postponement of other activities.
- 4) Increased waste management burden due to individual packaging of IG2 nets: Mass ITN campaigns typically generate waste, primarily plastic waste contaminated with insecticides. The packaging of ITNs

can either be in individual bags for each ITN or in baling material (outer wrapping, plastic straps, and bands), which bundles multiple LLINs into compacted bales of up to 200 ITNs per bundle. In some cases, both individual bags and baling material are used. IG2 nets were individually packaged as BASF's interpretation of international shipping requirements dictated this. Otherwise, they may have been classified as "hazardous", thereby increasing the level of bureaucracy, costs and lead times. Although this prevented the earlier challenges, it created extra waste management requirements. The project developed additional guidance focused on waste to address this issue. Individual packaging is not recommended for mass campaigns in order to limit the waste disposal burden. However, for routine distribution at health centers or other locations further away from beneficiaries' homes and to prevent the risk of damage during transport, individual packaging may be more ideal.^{46,47}

- 5) Managing somewhat cumbersome co-payment processes: Key informants applauded the efforts of IVCC to manage the seemingly cumbersome co-payment processes with many different actors, including donors, procurement agents, manufacturers, and country NMCPs playing a role. Reports from the supplier end were that the process went on relatively seamlessly, with IVCC navigating unexpected bottlenecks in the process. Complexities included dealing with more donors, procurement agents and countries than originally anticipated, negotiation of a separate interim VG agreement with BASF prior to the BMGF/MedAcess facilitated one, subsequently updating agreements with BASF, in addition to navigating other related country-specific challenges, mostly related to payment terms between countries and BASF. A few respondents suggested that the co-payment could have been handled directly by Global Fund as is currently being done on NTI, making it more efficient and less expensive. However, with several donors and procurement agents involved, having a third-party institution manage the process was critical for NNP. It would also have been out of scope for Global Fund to play this role.
- 6) Managing rumors and misconceptions in countries: Implementers reported experiencing challenges with product acceptance and use; related to rumors and misconceptions that spread due to context inappropriate labelling and packaging, COVID-19 affiliation, and other internal country-generated beliefs. This created the need to closely manage the messaging around the new nets and dispel myths at the community level. NMCPs, through their social behavior change (SBC) partners, led efforts to dispel rumors and misconceptions by following the guidance provided by AMP, including the development of rumor management plans, especially clear post-distribution messaging around new nets.
- 7) Effectiveness pilot research obstacles (clashing SMC activities In Burkina Faso & Nigeria, HCW strike in BF, Rwanda implementation delays): The effectiveness pilots experienced very few challenges; these were also addressed timely with the project adapting adequately to accommodate these events.
 - The project experienced early challenges in selecting comparable districts in which to implement effective pilots. Despite identifying similar locations, data still showed significant differences, which were somewhat addressed through modeling. In Burkina Faso & Nigeria, SMC activities were implemented by the NMCPs in the NNP pilot locations. This will skew the findings of the studies with a higher impact estimate than would have been obtained by the nets. This has been addressed through modeling estimates of the impact of nets and SMC on prevalence.
 - In Burkina Faso, there was also a healthcare worker strike that limited access to pilot study data, especially from routine sources.
 - In Nigeria, there were also some disruptions related to the "ENDSARS" protest, with surveys implemented at night for the safety of surveyors.
 - In Rwanda, there were delays in starting research activities, mostly due to the limited experience of specific staff assigned at RBC and the University of Rwanda, in planning for and conducting large cross-sectional surveys.
 - In Rwanda, the RBC timeline for their nets campaign in the second year was earlier than the project plan. The early net campaign resulted in not having comparable Year 2 prevalence data.

⁴⁶ Guidance on managing waste generated during mass insecticide-treated net (ITN) distribution campaigns in the COVID-19 context V1. December 2020

https://allianceformal aria prevention.com/wp-content/uploads/2021/02/Waste-Management-EN.pdf

⁴⁷ https://continuousdistribution.org/wp-content/uploads/2022/02/USAID-Recommendations-LLIN-Packaging.pdf

- 8) Communication and coordination gaps: Although the efficiency of communication was mostly recognized as an enabler, some respondents described critical gaps in communications across different actors and at country level. These include limited coordination and communication across research actors with some duplication in research efforts. Also, during the project start-up phase, there were often many different actors at the country level, with inadequate communication provided to country-level stakeholders on the different roles and responsibilities each actor played and how they would work with NMCPs. However, this was flagged at the steering committee and resolved early on.
- 9) COVID-19 significantly impacted the availability of dual-AI ITNs: The impact of the Covid-19 pandemic on dual-AI ITNs availability included:
 - The interruption in the supply chains of raw materials such as plastics, technical grade active ingredients and other chemical components. For Malawi orders in 2021, BASF had to source nets from a different supplier leading to quality control issues related to fabric weight, bursting strength, and flammability, which resulted in the rejection of 1.8 million IG2 nets, as earlier discussed.
 - There was a temporary shutdown in production up till March 2020 (3 months) due to lockdowns and movement restrictions in China and Thailand. This increased the lead time from manufacture through quality assurance to shipping and delivery. Manufacturers were only able to return to full production capacity and maximize their warehouse capacity by June 2020.
 - There was also direct impact on the shipping and clearance process, with protracted delays at ports and restricted movement of customs officials. This was also exacerbated by a global shortage of shipping containers and cargo space, increasing shipping timelines by a few weeks. Further, the supply and demand imbalance for shipping contributed to significant increases in the cost of freight, challenging Global Fund/IDA and PMI/Chemonics procurement processes. In addition, manufacturer warehouses became full, and the backlogs at ports slowed down the place of production at times during the project.
 - The reinspection process of nets supplied to Rwanda that failed initial quality control inspections were also further delayed by the effects of the pandemic, as restricted movements and allowable gathering sizes reduced the manpower for inspection, repair, and packaging. The cost of inspection also increased with the need to accommodate COVID-19 preventive measures such as personal protective equipment (PPE), sanitizers, additional vehicles to transport staff in smaller numbers, etc.)
 - Program implementation was also delayed as lockdowns shifted the timing of campaigns and research activities. There was a temporary suspension of fieldwork and data collection from March until June 2020 in all countries, and interruptions in 2021 in a few countries due to new waves of the pandemic. These implementation delays and interruptions were reported not to have any marked effect on implementation results and research outputs.

The NNP team and the broader partnership of national malaria programs, donors and implementers worked closely to address these challenges, jointly ensuring the continuity and progress of the project. Initiatives put in place to address these COVID-19 impacts include: Manufacturers splitting up production lots into smaller quantities to aid in securing containers and vessel space; flexibility of project budgets to absorb higher freight costs; and planning orders as far in advance as possible to ensure nets are available on time and that implementation is not interrupted through the life of the project. Also, once COVID-19-related restrictions were lifted, mitigation measures were introduced to protect health workers and beneficiaries. These included the use of door-to-door net distribution in place of community distribution, practicing social distancing and using PPE. The project team also continued to monitor COVID-19 case numbers closely in all NNP countries, with additional protection measures introduced as required.

3.4 Impact

Criteria	Not achieved	Slightly achieved	Moderately achieved	Largely achieved	Fully achieved	Strength of Evidence
Impact (What difference did the intervention make?)						Strong

To what extent has the investment generated, or is expected to generate, global/national-level effects across two of Unitaid's dimensions of impact: i. Public health impact ii Economic impact iii. Equity Impact and iv. Strategic benefits and positive externalities.

Public Health and Economic Impact

Finding 1. Through NNP and associated NTI and PMI procurements, an estimated 13 million malaria cases and 24,614 deaths were averted. Imperial College (Consortium Member) modeled the Impact of dual-AI ITNs across NNP countries through the life of the project. The estimates reveal that NNP copaid IG2 nets averted an estimated 6 million malaria cases and 11,815 deaths. The impact increases to 13 million malaria cases, and 24,614 deaths averted when NTI and PMI procurements are included. These were expected to result in \$17m for NNP-copaid nets, and \$29m for NNP, NTI, and PMI nets, in financial savings to the health system. Five-year modeling projections also estimate an additional 38 million malaria cases and 73,091 deaths compared with standard pyrethroid nets, resulting in financial savings of \$99m based on the current forecast for dual-AI ITNs from CHAI.⁴⁸

Equity

Finding 2. There were no project-specific efforts in design and implementation to identify and address issues related to gender, social inclusion, and equity, such as intersectional and people-centered approaches. However, the project contributed to equity and inclusion through the greater focus of malaria programs on pregnant women and children under age 5, who are at higher risk of malaria. Also, the project countries have higher malaria burdens and mortality rates. Furthermore, ITN campaigns are inherently inclusive as the intervention is an all-population intervention, providing nets to all households in campaign locations.

Finding 3. There were reports of inequitable distribution of ITNs in general (not just dual-AI ITNs) in Burkina Faso, Mozambique and Nigeria, captured through the projects' anthropological studies.

Project anthropological reports reveal inequities in net access, distribution and ease of use. In all countries, there were qualitative reports of inadequate numbers of nets in households. Respondents also report inequity in net allocation and distribution processes in Burkina Faso, Mozambique and Nigeria, with distributors said to prioritize people they know or to supply less nets than allocated during the sentinel, with the assumption that families inflate their household numbers to get more than their net entitlement.

In Nigeria and Mozambique, respondents noted that families that lived in remote areas had a harder time collecting nets. In addition, in all four countries, the recommendation to share nets between two people did not align with family sleeping arrangements and family compositions (especially a gap in consideration for adolescent girls who often have their own separate sleeping arrangements). Priority was, however, given to traditionally vulnerable groups (children, the elderly and pregnant women). Key informants, primarily project implementers, alluded to needing to have more differentiated approaches that prioritize net allocations, especially catering to adolescents.

⁴⁸ NNP Modelling Outputs by Imperial College

Strategic Benefits and Externalities

What additional benefits has the health system experienced due to the introduction of the project? What unintended effects have been experienced as a result of the project to either beneficiaries or the health system?

Finding 4. The introduction of the project resulted in a number of additional benefits to institutions and individuals in beneficiary countries. These strategic benefits included:

- Increased understanding of how to manage multi-product campaigns in the different country contexts.
- Expanded capacity building of local/national institutions (research organizations, universities, individual consultants, etc.).
- Increased collaboration and multi-sector alliances amongst regulators, implementers, and government at country level, with these actors gaining a better understanding of their interdependence and improved ways of working together for future products, beyond nets.
- Accelerated the use of routine surveillance data (both epidemiological and entomological data) to help guide evidencebased decision-making at country level in terms of determining the mix of vector control measures for implementation areas.
- Improved understanding of managing door-to-door net campaigns, mostly due to the COVID-19 pandemic.

"Capacity transfer to incountry human resources, especially those working in the evaluation countries. The project engaged relevant national institutions and strengthened local capacity for research." **Consortium Member**

3.5 Efficiency



How timely, cost-efficient and cost-effective was implementation (consider both allocative efficiency and technical efficiency)?

Finding 1. The NNP project was moderately time-efficient, delivering most project activities within the fouryear project life. It, however, experienced significant delays due to internal and external factors, most especially the COVID-19 pandemic, which exacerbated other existing delays.

The project kicked off on time, leveraging a collaboration with BMGF (through a supplemental grant to IVCC) to facilitate key start-up of activities. This allowed for very early stakeholder engagement in Burkina Faso and preparatory activities towards the pilot design. This grant also supported the enhancement of entomological and behavioral elements of the Tanzania RCT to increase complementarity to the NNPs planned RCT in Benin. This was done prior to contract signing with Unitaid. Further, negotiations towards the BMGF/MedAccess volume guarantee agreement also pre-dated the project and primed time and cost efficiency. On project inception, and as project activities were initiated in each country, NNP successfully established the required agreements with partner countries and co-payment agreements with relevant procurement agents in a largely time-efficient manner. The project also submitted relevant documentation to VCAG in a timely manner. There were, however, delays in consortium partner contract signing, finalizing the MoU with USAID (due to challenges at the USAID end) and delayed recruitment of some key positions among a few consortium partners.

During implementation, there were a number of other delays, including delays in finalizing the volume guarantee until the second year of the project; thus, the negotiation of a separate agreement to cover 2018-19, affecting only Burkina Faso. There were also delays in delivery of orders due to inadequate production capacity at BASF, which was addressed by an immediate scale-up in production. The deliveries were further delayed by the effect of COVID-19 on factories, as earlier described. Orders were delayed in most countries. Other

"There were delays in the timeline of deliveries across the different countries. Burundi was the only country that had the deliveries on time." **Consortium Member**

country-specific time inefficiencies include the delay in huts construction within the Benin RCT related to LSHTM contract negotiations, and further delays in data collection after the huts were constructed due to delays in receiving IG2 nets, and a requirement to align with the Programme National de Lutte contre le Paludisme's (PNLP) national campaign. A health workers' strike in Burkina Faso limited early access to pilot study data. There were implementation delays in Rwanda due to a range of factors, including the limited experience of specific staff assigned at RBC and University of Rwanda in conducting large cross-sectional surveys, restrictive sole sourcing policies, and an impasse between RBC and BASF on the terms of the procurement. In Mozambique, there were also delays in order placement due to protracted discussions between the NMCP and Global Fund on specifications, quantities, and deployment targets for dual-AI ITNs.

Among the many factors that contributed to inefficiencies, COVID-19 was said to be the most impactful. Implementers described additional costs incurred due to COVID mitigation, including procurement of PPE, testing, and use of additional vehicles to minimize exposure. Some additional cost estimates include \$45,000 incurred by LSHTM for their work in Benin (\$30,000 on leasing vehicles and \$15,000 on PPE); PATH also incurred additional costs due to COVID-19 in 2020, up to \$80,000 in Mozambique, \$7,000 in Rwanda and \$5,000 in Burkina Faso. These expenses were, however, offset by dramatically reduced travel, meetings and other project savings, with minimal impact on project implementation.

Generally, through the life of the project, outstanding project activities were rolled over to subsequent years, with all project objectives achieved at closeout. The project was, however, granted a 3-month no-cost extension to cover closeout activities such as an end-of-project event and publication costs for journals.

Finding 2. The NNP was largely cost-efficient, improving its absorptive capacity annually and expending 99% of its budget as of December 2022.

The NNP's absorptive capacity increased annually from a 6% burn rate in 2018 to 94% in 2022. The lower budget consumption in its first year was due to slight delays in partner contract signing, delays in negotiating the first co-payment for Burkina Faso as well as recruitment delays, as described earlier.

In 2019, expenditure increased significantly to 65%, primarily due to co-payment of 4.1M nets worth US\$9M. Other expenditures beyond co-payment also increased with preparations toward the Benin RCT and the project commencing in additional countries, associated with increased travel expenditure. The underspend in 2019 was mostly due to recruitment delays, unused external professional fees and lower travel expenditure than planned, as well as the additional delays earlier described with starting the Benin trial.

In 2020, the burn rate remained at 65%, with the \$10m underspend largely attributed to the impact of the COVID-19 pandemic, delaying production, delivery, and travel. These stalled project implementations limited in-person technical assistance and also caused the co-payment to be underspent. There were also delays in reprogramming savings from previous years, which resulted in late sub-agreements under PATH for work in Mozambique and Nigeria.

In 2021, the burn rate increased to 78%, with lingering COVID-19-related constraints being primarily responsible for the underspend. This includes the global supply chain challenges and their effect on delaying implementation, the associated unspent co-payment, limited travel, limited inperson meetings, unused external professional fees, and unused project staff budgets.

During the final year of the project, the burn rate was 94%, with underspends on external professional fees, a postponed large-scale project meeting, lower project staff expenditure (vacancies, overbudgeting, and shared personnel covered by other organizational funds) and historical ineligible costs that were found during the last audit.

Through the life of the project, the 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. At closeout, all co-payments were fully paid. A review of expenditure by country and output, as at the end of the project, showed over 89-100% expenditure by output. The project completely delivered all planned objectives under budget by 1% as of 2022.

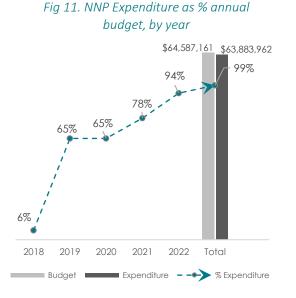
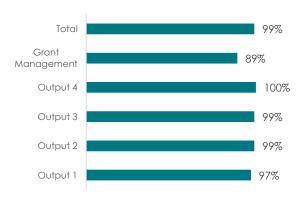


Fig 12. Expenditure as a % of cumulative budget, by output



Finding 3. The NNP also created internal efficiencies and leveraged external resources towards significant cost savings, mostly related to its market-shaping interventions.

The highest volume guarantee threshold and the exit price was achieved over a year ahead of schedule. The agreement was also applied retroactively to the initial procurements under the earlier IVCC-BASF volume guarantee agreement in 2018. This significantly reduced the co-payment expenditure by \$4.2M, representing 9% savings. The savings were reprogrammed towards expanding the procurement of nets and

implementing additional M&E activities. The project's agreement with PMI also resulted in significant savings in co-payment, with PMI procuring both IG2 and RG nets at the project exit price. Another early cost-saving measure was leveraging the BMGF supplemental grant to start up activities in Burkina Faso, as well as to enhance the entomological work in the Tanzania trial towards better alignment with the planned work in Benin. The project also had unintended savings due to transition to virtual activities during the COVID-19 pandemic.

"Getting to the highest volume guarantee threshold at an accelerated rate helped to get more value for money and through increased savings that were redirected to additional activities." **Consortium member**

Was the funding allocation/split to cover commodities/supplies versus other costs appropriate and effective to achieve project objectives? What best practices, if any, could be learned for similar grants in the future?

Finding 4. The funding size for the NNP project and the allocation across outputs were sufficient to achieve its objectives.

The funding allocation across outputs was sufficient to complete activities per the program design. Implementers were satisfied with the budget allocations, with most expense areas fully expended at the close of the project and corresponding activities completed.

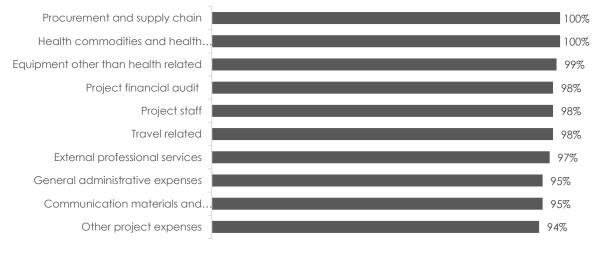


Fig 13. Actual expenditure as a % of budget, by expense type

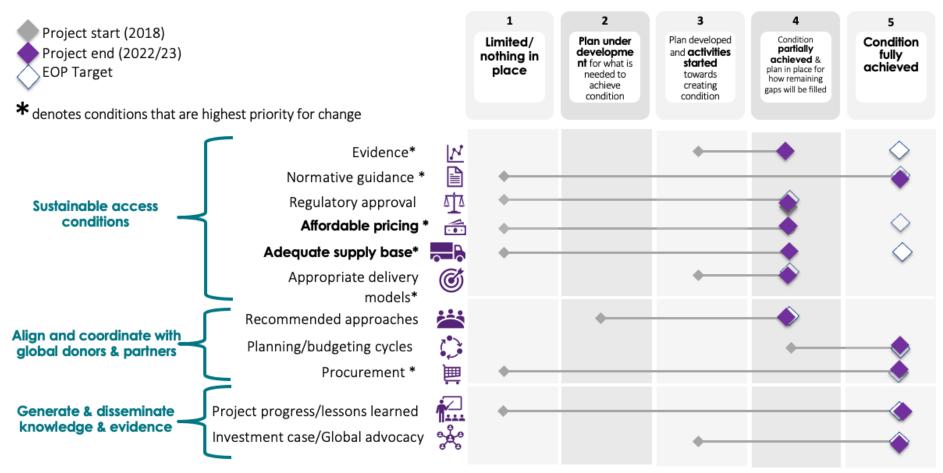
Could the project have achieved its aim with fewer implementation pilots (on feasibility and cost-effectiveness) conducted?

The number of pilots was optimal for the funding size and required sample sizes for the number of pilot countries. Key informants generally felt that the more important factor was having a representative mix of countries with different vector profiles in order to capture several scenarios. A few key informants, however, suggested that the number of pilot countries should have been increased, especially due to the level of variation seen in results across countries. They also linked the number of pilot countries to the acceleration of scale-up and the sufficiency of evidence for WHO recommendations.

3.6 Sustainability

To what extent (and how effectively) has the project contributed to building an enabling global environment and country readiness for scale-up? +To what extent have core elements of the intervention been transitioned? What factors have contributed towards, or limited, scalability and transition? And What gaps remain?

Fig 14. Scalability Matrix – Baseline and final status of global conditions





Evidence Generation $\frac{|N|}{|N|}$

At baseline, there was limited evidence on the epidemiological efficacy of dual-AI ITNs, with only one RCT in progress in Tanzania. There was also a gap in evidence on comparative cost-effectiveness to support the development of operational guidance and country decision-making on deploying dual-AI ITNs. To meet the WHO/VCAG evidence requirements for consideration of a policy recommendation on dual-AI ITNs, a second RCT was needed. The project has created and disseminated the required evidence on efficacy through the Benin RCT, as discussed earlier. Entomological correlates were also explored to aid future PQ processes and policy recommendations. Evidence of operational use, effectiveness and cost-effectiveness of dual-AI ITNs were also created and are being disseminated.

Although the project successfully generated evidence within its planned research agenda, key informants describe additional evidence required for the sustainability of the intervention post-project, such as further research to understand durability and efficacy up to 36 months, evidence to understand the differences in new net's efficacy across countries/sites; and evidence comparing the cost-effectiveness of new nets to other new vector control tools such as 3rd Generation Indoor Residual Spraying (3GIRS), new SMC guidance or other combinations of vector control tools to better guide countries' resource allocation. Lastly, it is widely agreed by stakeholders that innovation and evidence on newer dual-AI ITNs (with different AIs) would be needed in the very near future as alternatives to pre-empt potential resistance to chlorfenapyr.

Normative Guidance



WHO's recommendation on dual-AI ITNs is a precondition for large-scale adoption by countries and major funders. The recommendation is important for country policy adoption and guidance on introduction, planning and implementation of dual-AI ITNs and IRM plans. It is also critical for procurement by major funders, with unrecommended products referred to as pre-market research products, and only added to donor procurement lists when they receive a WHO policy recommendation. At baseline, only pyrethroid-PBO nets had an interim policy recommendation; there was no dual-Al ITN that had received a recommendation. The project worked closely with the WHO Global Malaria Programme (GMP), VCAG and Guideline Development Group (GDG), getting approvals for research design, validation of research quality and sharing required data (entomological, epidemiological, operational, cost-effectiveness) at specified times, towards the receipt of a WHO recommendation for dual-AI ITNs in March 2023, as described in detail in Section 3.3 Effectiveness.

Regulatory Approval



At baseline, there was only one dual-AI ITN (Interceptor G2) that had a PQ listing. PQ listing of additional products was necessary to increase the number of quality-assured products on the market, towards supply security and to create a competitive market for dual-AI ITNs. Even though pre-qualified products can be procured in most countries, the requirements vary, with some countries requiring product registration prior to procurement of new products and others providing waivers for PQ-listed products. The absence of registration, therefore, precludes order placement in certain countries, and therefore, pre-registering in more countries increases the ease of scale-up. The project supported the pre-qualification of an additional product: RG by DCT, which obtained PQ in 2019. Also, IG2 is now registered in 26 countries and RG in 5, as earlier listed, with many of these registrations facilitated by NNP. This is a sizeable number of countries registered prior to the WHO recommendation, especially for IG2. It is also a higher number of registrations compared to other similar medicines/product innovations on other Unitaid funded Malaria projects

evaluated in the last three years. Further, these countries represent the most endemic countries globally, accounting for over 70% of malaria cases globally. Key informants also reported uncertainties around the current WHO pre-qualification processes due to the recent transition of the recommendation process of vector control products (VCP) from the WHO Pesticide Evaluation Scheme (WHOPES) to a pre-qualification listing. Pre-qualification standards are still being defined, including how the term "long-lasting" is qualified. This may have implications for dual-AI ITNs and upcoming new ITN types.

Adequate Supply Base



A key step in the development of the dual-AI marketplace is the entry of more products. At baseline, only IG2 was pre-qualified, and as a result, it was expected to be the only product used in the first three years of the project. During the life of the project, there were production capacity concerns with BASF, as the project experienced extended lead times, leading to late deliveries during the manufacturer's scale-up process. BASF successfully scaled up production with capacity optimized throughout the project life. DCT's Royal Guard was introduced early, subsequently increasing the supply base for the project. However, based on evidence from the RCTs, RG received a conditional recommendation from WHO with concerns about cost-effectiveness in relation to standard ITNs. Implementers, however, report that the cost that WHO used here to compare pyrethroid- pyriproxyfen ITNs and PBO nets was significantly more than the current price of Royal Guard net. Since both IG2 and PBO were recommended over RG, RG may not be prioritized in the market by buyers with respect to strengthening the supply base of dual-AI ITNs.

BASF is currently scaling production to 50 million nets per year through factories in China and Thailand. In addition to increasing their supply capacity, early orders from countries will also be critical to mitigate scale up risks. Vestergaard's product (PermaNet Dual) received WHO pre-qualification in March 2023 and is ready for commercial introduction, with plans to manufacture up to 10 million PermaNet Dual in 2023 and scale-up very quickly in coming years based on demand. Vestergaard has also reported that they are also able to scale up to 50 million nets annually without major Capex investments. This will help increase supply in order to meet the expected rapid increase in demand. Vestergaard, however, has concerns about the available market share on entry with the long ITN lead times and a large share of orders already placed with BASF. It will be important that there is a concrete forecast to justify the early scale up of their production. Key

informants expect a rise in demand for this product that will require at least three manufacturers to ensure adequacy of supply and maintain competition. There are also feelers that there will be an influx of additional suppliers in the next few years.

"There are also other suppliers besides Vestergaard that would come into the market maybe next year." Global respondent

Further, the project's resistance evolution assumptions, from 2027 onwards, expect that dual/new AI nets will represent a third of the nets market (over 70 million nets per year), while PBOs will still be present with approximately 50 million nets per year. The deployment of these volumes indicates a potential for new resistance to emerge. As a result, there is an urgent need for other new AIs to alternate with or replace chlorfenapyr.⁴⁹

Affordable Pricing

At baseline, dual-AI ITNs were expensive, with prices more than double that of standard ITNs. Without the price reductions and information on cost-effectiveness in different settings, adoption of these tools was expected to be slower, even in the presence of a policy recommendation. The project successfully reduced the price of IG2 through leveraging the BMGF-supported volume guarantee mechanism, as well as attaining the highest volume threshold/lowest price earlier than expected. This was complemented with a co-payment, enabling countries to procure at similar prices to standard nets. Co-payments were funded via the Global Fund's strategic initiatives and Unitaid, through this project-NNP and the NTI (GF only). These

⁴⁹ NNP Update Steering Committee Meeting, September 13, 2022

initiatives are not available in the next Global Fund Grant Cycle (Cycle 7), and country's funding ceilings within Global Fund programmatic grants are expected to remain relatively constant. It is unclear how countries will prioritize the procurement of dual-AI ITNs after NTI without an increase in funding levels or further reduction in dual-AI ITN prices. In addition, further market dynamics (competition) are not expected to drive prices lower but to at least keep prices constant, especially since the volume guarantee negotiation enabled the product to be priced at single-digit margins to the manufacturer (lower than already thin ITN profit margins).

Key informants, including manufacturers, implementers and other wider global stakeholders, affirm that the current price may be the lowest possible at this point. However, it is important to note that the fee for negotiating the volume guarantee agreement was factored into the pricing of interceptor G2 nets, so there is the potential for some marginal future price reduction. Also, for new products entering the market, the current pricing of IG2 may not be sustainable as they will need to recoup their R&D investments. There may also be different cost bases for AIs, and it may not be feasible to bring their products to the scale that IG2 has achieved in the absence of any concrete demand forecasts/volume commitments. As a result, these may come to the market at slightly higher prices. Manufacturers interviewed reported these considerations.

With respect to transition, PMI already procured dual-AI ITNs at about the same cost they had budgeted for procurement of PBO nets, allowing an earlier transition to the exit price than was originally anticipated. PMI funds a smaller percentage of country ITN needs than Global Fund, so the larger proportion of procurements still require co-payments. The NNP transitioned co-payment for new IG2 orders very smoothly to NTI in 2021. Ongoing procurement of IG2 through NTI further accelerated market growth through 2023 via a top-up payment mechanism (similar to co-funding). Although NNP has already transitioned co-payments to the NTI, it is unclear how countries supported by Global Fund will cover the co-payment gap after NTI. The co-payment gap post-NTI, from 2025 to 2030, is expected to range from about USD 44 million in 2025 to USD 79 million in 2029.⁵⁰ Majority of key informants felt that affordability of the new nets would be a major factor that may limit scalability and sustainability. They did acknowledge that the gap was addressed in the short term. However, they expressed concerns about the heavy dependence on donors for both co-payments as well as the larger funding for ITNs in the long run and a need for countries to begin to commit funds towards this intervention.

The project expected that the co-payment model would not be necessary post-WHO recommendation, as the procurers would be positioned to leverage wider procurements and negotiate directly on price and supplier relationships. However, this may not be the reality, as the exit price is still somewhat challenging for countries to navigate. At inception, the implementers' preference was to structure the copayment so that the exit price would be same as the PBO price instead of the standard net price, but this was not feasible for Global Fund because there was no

"The co-payment could have been structured a bit differently for sustainability. There still needs to be an urgent discussion and intervention to help maintain the successes recorded with the NNP and NTI." **Global respondent**

"The marketing strategies were well designed. The challenge was more with the exit strategy." Global respondent

epidemiological evidence of superiority of IG2 over standard nets at the time. This was expected to be a more sustainable price point. Also, NTI applied a co-payment that was linked with 2019 pricing for standard LLINs rather than the updated reference pricing. This approach will also lead to a more significant adjustment than had the co-payment been pegged to annual adjustments in the GF reference pricing. Lastly, willingness to pay has not been tested due to the artificial market dynamic created, and at the close of NTI in 2024, countries will need to prioritize amongst malaria treatment and prevention commodities within their largely static funding pots.

⁵⁰ Secondary analysis based on exit price point, proportion of nets procured by GF and CHAI Global Malaria Commodities Forecast project on the RBM website.

Other external factors that also have the potential to affect the cost of production and, subsequently price of dual-AI ITNs are the effect of the war in Europe (shutting down two chemical industries), higher inflation rates and increase in the cost of petroleum (polyester/polyethylene) prices. Also, the upcoming product (PermaNet Dual) does not have the same cost base as Interceptor G2 since Vestergaard was not granted access to BASF's chlorfenapyr, so it's available at a slightly higher price point.

Although price seems to be the key factor in the decision-making process, some key informants describe the expected reduction in malaria incidence and prevalence to hypothetically reduce treatment expenses, creating an opportunity for reallocation of some of these savings to new nets or other new interventions or requirements such as the needs based on the revised SMC guidelines, and growing interest in malaria vaccines.

Appropriate Delivery Models 🥮 & Recommended Approaches

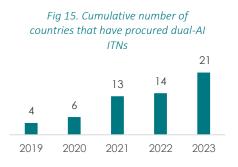
The deployment of new nets has helped to further expand the range of vector control tools that countries can use. They have also aided the adaptation of country operational processes to cater to the planning and deployment of multi-product type campaigns. At baseline, there was no operational experience or evidence to guide the deployment of dual-AI ITNs in the context of a multi-product campaign. The project introduced relevant guidance through AMP's work and the pilot implementation learnings. The project was led by NMCP's in-country, who integrated the new products and adapted/improved deployment processes within their standard campaigns. As such, these delivery models are already transitioned.

Procurement 🛱

The project has scaled up procurement of dual-AI ITNs, from no procurements prior to over 65 million nets procured through the life of the project (37 million were co-paid nets). This includes project countries and non-project countries. Through the NNP, 21 countries have procured dual-AI ITNs, 14 pilot countries and 7 non-project countries (Senegal, Guinea, Uganda, Equatorial Guinea (Bioko Island), Kenya, Sierra Leone, and Papua New Guinea). PMI has also procured IG2 nets outside of NNP for Senegal, Guinea, Cameroon, Mali, and Burundi. AMF also procured IG2 nets for DRC and Royal Guard nets for Uganda and DRC without any co-payment. These are already contributing to scaling up the dual-AI ITN market beyond NNP. Also, in addition to the 26 countries where IG2 is already registered, registration processes are underway in 7 additional countries. These will contribute to the expected scale-up of dual-AI ITNs. Further, procurement is also feasible in several countries without registration, as these countries accept a WHO PQ listing.

Planning ••• & Budgeting Cycles

The major funders of ITN procurement are the Global Fund, PMI, and United Nations Children's Fund (UNICEF) and AMF. The project engaged effectively with these to enable implementation of its market shaping strategies: volume guarantee and co-payment, with Global Fund inherently also involved as co-funder. Other Global Fund and PMI funding and procurement mechanisms were leveraged to introduce dual-AI ITNs. Initially, there were concerns that delays in receiving a WHO policy at the end of the project would create a gap in access since programmatic Global Fund grant budgets are not structured to cover the cost of pre-market products. The

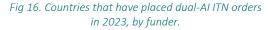


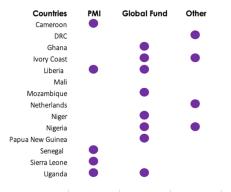
recommendation was, however, obtained in time. In addition, the overlap between NNP and NTI provided immediate continuity, with agreements on frontloading NNP co-payments in its earlier years and NTI covering the final years of NNP up to 2024 when NTI ends. Countries can continue procurement of dual-AI ITNs through the Global Fund, PMI, and other donor grants with the WHO recommendation now out. There will, however, be a need for effective decision-making and prioritization of procurement across multiple interventions and products, within available budgets. There are 14 countries that have placed new orders

for IG2 in 2023 based on IVCC's market intelligence and monitoring. *Fig. 16* summarizes the countries by funder. Also, in consultation with PMI, there are ten countries that have included dual-AI ITNs in their 2023 Malaria Operational Plans (MOP23), which extend to 2024; they are Burundi, Cameroon, Ghana, Liberia, Madagascar, Mali, Nigeria, Senegal, Sierra Leone, and Uganda. There are, however, still ongoing reprogramming discussions that might change these plans.

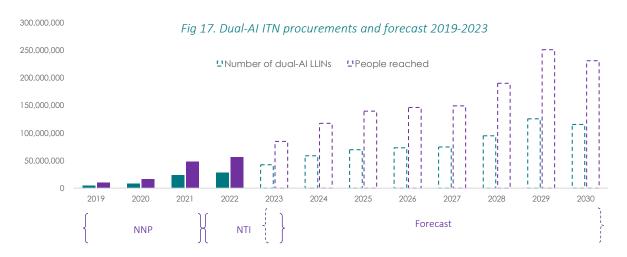
Scale Up Status & Forecasts

Commodity Scale-Up and Potential Reach





Data from IVCC and the Global Fund NTI team shows progressive scale-up of dual-AI ITNs through the NNP and NTI project life. The project procurement was catalytic and contributed to "unlocking" the scale-up of dual-AI ITNs, through leveraging the two largest funder's procurements (Global Funds programmatic funds and PMI), with the project becoming the primary procurement channel for dual-AI nets (pre-WHO recommendation) from 2021. Despite concerns about countries prioritization of these nets post-NTI, the Clinton Health Access Initiative (CHAI) Global Malaria Commodities Forecast project on the Roll Back Malaria (RBM) website shows further scale-up till 2030, from over 20 million nets procured annually in the final years of the project through NNP and NTI to about 100 million annually from 2028 to 2030.



Market Share Projection

The forecasted volumes are based on multiple assumptions around market evolution, resistance rates, population growth, price evolution and others. Detailed methodology and assumptions are referenced.⁵¹ The forecast also takes into account PMI, Global Fund and other donors' procurement and scale-up plans. The forecast reveals an increasing shift towards PBO and new AI nets as pyrethroid resistance spreads. It estimates that new AI nets will comprise 54% of the market by 2031, especially with the strong WHO recommendation for their adoption and use; PBO nets are expected to retain 27% of the market (countries experiencing moderate insecticide resistance); and



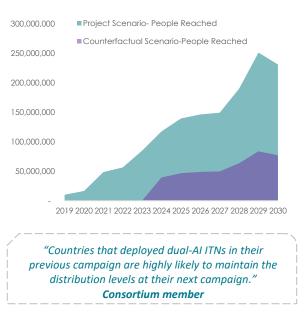
⁵¹https://dashboards.endmalaria.org/forecastingCommodities/long-term-forecast

standard nets 19% of the market (countries with low insecticide resistance).

Additional People Reached

Secondary analysis to determine additional people reached with dual-AI ITNs during the project life and beyond reveals that there would have been no dual-AI ITN procurements from 2019 to 2023. This is assumed based on the absence of a WHO recommendation, which is a pre-requisite for Global Fund procurements. Also, even though PMI were able to procure based on the PQ listings of IG2 and RG, they were somewhat constrained by price and, to a certain extent, limited evidence. The analysis shows a gradual scale-up of dual-AI ITNs from 2023 in the counterfactual scenario, assuming а WHO recommendation was still obtained in 2023, two chlorfenapyr-based products are available (IG2 and PermaNet Dual), a gradual increase in manufacturer production capacity, similar funding levels for ITNs and a higher price that reduces based on market competition. With these assumptions, the intervention is estimated to reach an additional 816 million people from 2024 to 2030, with an average additional reach of 117 million people annually, compared to the counterfactual scenario.

Fig 19. Number of people with access to dual-AI ITNs, assuming one ITN for every two people (2019-2030)



Dual-AI ITN Contribution to Global ITN Coverage Goal

An estimated projection of dual-AI ITNs contribution to global ITN coverage, based on the 2022 World Malaria Report trends of coverage since 2019 and the CHAI Global Malaria Commodities Forecast, reveals a gradual increase in coverage of ITNs to 73% in 2030, at which point dual-AI ITNs will account for more than half of nets distributed. The estimates assume two people reached with every net distributed.

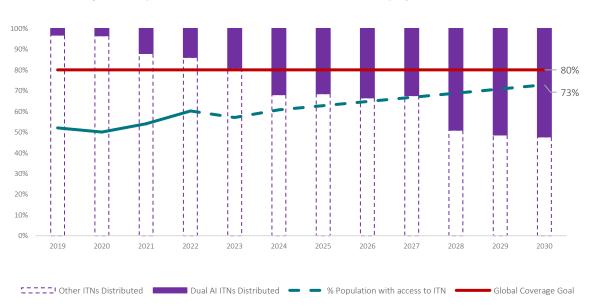


Fig 20. % Population with access to ITNs and dual-AI ITNs projected contribution

Project Progress

The project leveraged key partners, working groups, its steering committee, and conferences consistently towards effective dissemination of evidence from the project to guide global policies, as well as to support country implementation. The project has collaborated with the Global Fund, PMI, UNICEF, RBM leadership and the Country/Regional Support Partner Committee (CRSPC) to share progress and disseminate lessons. Key fora where project results were presented include the annual AMP and Vector Control Working Group (VCWG) meetings, VCAG review, American Society of Tropical Medicine and Hygiene (ASTMH), and the Pan-Africa Mosquito Control Association (PAMCA).



Investment Case ^{et B} Global Advocacy

The NNP has a well-established steering committee with representation from PMI, BMGF, Global Fund, Unitaid, ALMA, Innovation to Impact (i2i) and the NNP team, with other stakeholders, e.g., WHO and BMGF invited to participate as needed. The community constitution aided the accelerated introduction, adoption and scale-up of new nets. This platform essentially brought together the most important stakeholders who guided the delivery of the project towards accelerated introduction, adoption and scale-up.

There was a high level of consensus on the intervention among decision-makers at all levels, enabling effective global advocacy towards the project's interventions. The engagements with RBM leadership, the CRSPC mechanism, and PMI have also contributed to expediting the registration and procurement of dual-AI ITNs to meet country vector control needs and improve IRM strategies. RBM/CRSPC, in their normative capacity, are also expected to continue supporting countries, advocating for the adoption of new policies, expediting registration and procurement of new vector control tools, and advocating for internal and external funding.

Other IVCC-led global projects are also contributing to global advocacy, including: The BMGF-funded Malaria Commodities Forecasting project, which produced contextually appropriate short- and long-term forecasts for dual-AI ITNs. IVCCs New Routes to Market Initiative is also working with NMCPs and private sector partners to establish new and complementary distribution channels and funding streams for IRS, nets, and other VC tools as they enter the market. Lastly, USAID PMI is also planning to utilize peer-reviewed publications and the upcoming policy recommendation stemming from this project to update their technical guidance.





Case Study S1. Co-funding and Co-governance Accelerate Scale-Up and Sustainability

To what extent did the co-funded/co-governed effort lay the foundation for subsequent scale-up (including through NTI) and opportunities for future innovations?

Leveraging each other's comparative advantage

This co-funding and co-governance model between the Global Fund and Unitaid was described by key informants as catalytic for the scale-up of urgently needed innovations, as it harnessed Unitaid's product/technology innovation and upstream market-shaping expertise, and Global Fund's capacity for large scale funding of proven interventions. Global Fund's involvement was even more beneficial as the intervention type is already mostly funded by Global Fund globally. Unitaid's involvement was critical to generate evidence around dual-AI ITNs and make them available for market introduction, and without Global Fund's involvement, taking the product to scale would have been more cumbersome. Unitaid traditionally funds small pilot projects, with implementers required to conduct additional advocacy to scale-up partners (often Global Fund and the United States Government initiatives) to support the scale-up of their innovations. The presence of Global Fund as a donor on this project created an automatic link to leverage its larger resource base. Historically, Global Fund has also not focused on new technology and innovation and, therefore, has limited expertise in deploying new products or stewarding market entry.

Increasing power to leverage other high-level stakeholders.

The collaboration between these two important donors in the malaria space was said to influence the creation of an enabling global environment to introduce dual-AI ITNs. The partnership signaled the importance and urgency of the intervention and attracted an audience of all the major key stakeholders in the space, especially as both funders already had many years of ongoing relationships with these. The follow-on Global Fund project – NTI, has also benefited from this robust engagement of partners. Although each of the donors implements programs that collaborate with these stakeholders, key informants report that this was one of the rare occasions where these key stakeholders were collaborating effectively with a very high level of consensus. Some of this external coherence is attributed to the context of emerging resistance and the relevance of the project. This relationship has spurred conversations in the global malaria community about other interventions that will benefit from a similar funding model; however, these are still preliminary and informal.

Closing the time lag between new technology/ innovation discovery and adoption

The most important benefit of this funding and governance model was the efficiency it created with respect to both time and cost, but especially the speed. Through this model, it became apparent that the time lag between discovery and adoption of new technologies can be reduced significantly. The project, through the expertise and capacity of both donors, linked product introduction and evidence generation to immediate scale-up. Global Fund did not need to wait for several years for other actors to identify new products, support pre-qualification, facilitate affordability, generate evidence, and facilitate WHO policy recommendations before countries could consider including the product, if it arrived in time to align with their funding cycle. Unitaid and its implementers also did not have to conduct extensive advocacy globally and within each implementation country to identify and secure funding for the intervention to be scaled up post-project. The alignment was there from the start, and it closed the time lag, allowing this new product to become available (beyond the project period) to the end user almost immediately after WHO policy guidelines were released. Some key informants, however, reiterated that whilst these types of partnerships are very instrumental in scaling up (new) innovations, countries still need to begin to contribute more significantly to sustainability, with global declines in donor funding.

Case Study S2. Can Dual-Al ITNs be Scaled Back with Limited Effect on Impact?

To what extent, once dual-AI ITNs are deployed, is that coverage sustained?

Sustained coverage through NNP and NTI

The extent to which coverage is sustained after dual-AI ITNs are deployed can vary depending on a number of factors, including the frequency of replacement, the durability of the nets, and the availability of replacement nets. The lifespan of dual-AI ITNs is expected to be longer than that of standard nets, but they still need to be replaced periodically to maintain effectiveness. In addition to replacement, sustained coverage also requires ongoing support from local health systems to ensure that nets are being distributed and used correctly. This can include training community health workers and other health personnel on the proper use and maintenance of the nets, as well as ensuring that adequate supplies of replacement nets are available. Overall, sustaining coverage of dual-AI ITNs requires a coordinated effort from a range of stakeholders, including national governments, international organizations, and local communities. With appropriate support and resources, sustained coverage of dual-AI ITNs has the potential to significantly reduce the burden of malaria in affected areas. All respondents agreed that the coverage of dual-AI ITNs established during NNP has been sustained and, with current projections, will be sustained till 2024. There are also reports of countries increasing their coverage of dual-AI ITNs. It will, however, be important to ascertain the sustenance of coverage after the NTI project has concluded, with countries now making critical prioritization decisions.

Is coverage scaled back in some cases? If scaled back, what are the reasons for this?

Limited cases of scaling back coverage

There are only two countries where the coverage of dual-AI ITNs has been scaled back (Rwanda and Tanzania). The scale-back in Rwanda was evidence-based, as the country is satisfied with the effectiveness of PBO nets, and has a relatively lower malaria burden. As a result, the country could not justify spending more money on slightly more expensive nets. In Tanzania, it was the absence of a WHO recommendation that caused the discontinuation of new nets in the country. Overall, the market is well stimulated for penetration and scale-up of the new dual-AI ITNs, and there is not yet any evidence of a decline in uptake in any other country following introduction.

Could coverage be scaled back to a certain level without impacting public health impact due to the increased effectiveness of dual-AI ITNs as they replace standard and PBO nets?

Feasibility of scaling down and maintaining impact

The high level of impact of dual-AI ITNs on malaria incidence and prevalence is an indication of the possibility that the coverage of dual-AI ITNs could be scaled back to a certain level without significantly affecting their public health impact. The increased effectiveness of dual-AI ITNs, compared to standard and PBO nets, could potentially compensate for the reduction in coverage. However, the level at which coverage could be scaled back will also depend on other factors, including the baseline coverage of vector control interventions in the target population, the malaria transmission intensity, as well as the level of insecticide resistance. The NNP modeling team did indicate that scaling down coverage of dual-AI ITNs without reducing PH impact was feasible based on their estimates. However, in the presence of other opposing variables, such as the growing resistance to pyrethroids, it is critical to maintain or scale up coverage. Majority of respondents were unable to comment on this, rightly pointing out that further evidence is required to determine the feasibility of achieving a similar impact with lower coverage.

3.7 Learning

What have been the lessons learned, and how have they been incorporated in the lifetime of the grant or across other interventions?

About the Intervention and Implementation

1. Dual-Al ITNs containing a pyrethroid and chlorfenapyr are superior and likely to be cost-effective. The project successfully proved the superiority of BASF's IG2 dual-Al ITN, with the RCT results in Benin complementing the previous BMGF, MRC and Wellcome-funded Tanzania RCT. These RCTs proved the efficacy of the IG2 over a pyrethroid-only net in reducing malaria morbidity. The second dual-Al ITN tested (Royal Guard) did not show significantly superior results.

2. A multi-product approach is necessary to address malaria resistance and, subsequently, malaria elimination, and messaging on ITNs should emphasize the benefits of all net types. Implementers, research partners and funders described the need for a more holistic approach to malaria elimination comprising several well-tailored prevention interventions, with multiple current and upcoming control strategies combined (IRS, a variety of ITNs, spatial repellents). They also warned about the potential to vilify standard ITNs (which are still useful in non-pyrethroid-resistant areas) due to the introduction of superior dual-AI ITNs. The multi-product approach will contribute towards preventing/delaying resistance. Messaging on ITNs should emphasize the benefits of all net types. This was reiterated by a wide range of global- and country-level stakeholders.

3. The NNP implementation model (co-funded /catalytic funding, aggressive market-shaping, partnership with funding agencies) prior to evidence generation and policy recommendation primed early adoption and faster scale-up. The key elements of the model, such as catalytic funding from Unitaid and Global Fund, utilizing NMCPs as implementing partners in countries, and the aggressive market-shaping interventions (volume guarantee and co-payment) and partnership with funding agencies (PMI and Global Fund), facilitated product introduction and almost immediately scaled the intervention, with a faster speed of introduction compared to previous ITNs. PBO nets took almost ten years to be fully introduced.

4. The inclusion of implementation pilots alongside RCTs for new product introduction also contributes to the speed of introduction and scale-up, as the necessary operational learning and guidance for real-life settings are already available. Implementers, donors, manufacturers, and researchers agreed that it was important to include implementation pilots in this project as they increased their understanding of how to implement multi-product campaigns and drive community demand. They also contributed to the early adoption and scale-up of the intervention.

5. Local data generation at country level was important for effective decision-making around ITN campaigns, and strengthening this will be increasingly important as countries prioritize inclusion of dual-AI ITNs amidst other priorities. The project experienced improvements in local data generation in many implementation countries, informing ITN campaign forecasts and targets. This will continue to be critical as countries begin to prioritize products for multi-product campaigns, especially with the price differential between dual-AI ITNs and standard ITNs, and the many competing malaria program needs. Good quality routine health data also contributed to providing evidence of intervention effectiveness.

6. Advance planning and consideration for potential supply chain disruptions are critical. Key disruptions to campaigns included delays in net arrival (mostly COVID-19-related), as well as the desynchronized ITN arrival, especially since these were multi-product campaigns. These disruptions were subsequently mitigated through contingency planning and at the macro planning stage.

About Partnerships

7. Alignment with WHO pre-call for proposals is critical for new product introduction, from pre-qualification to policy recommendation; wider stakeholder consensus and advocacy can facilitate this. Delays in the pre-

qualification process of new products and subsequently obtaining a WHO policy recommendation can often serve as barriers to market entry. The project navigated these fairly well, with initial differences of opinion ironed out and WHO involved in establishing and agreeing on the evidence gaps and research design towards meeting WHO standards.

8. Working through country institutions instead of NGOs ("projectizing"), was challenging with some inefficiencies, but was necessary to foster integration and ownership, as net campaigns are already institutionalized. The project experienced delays, capacity obstacles and bureaucratic processes, working through country institutions – Ministry of Health (MOH) departments and universities. Even though working through in-country NGOs may have been more efficient, the project would have ended up "projectizing" an already institutionalized area of service delivery and lost out the opportunity to completely integrate the new intervention. Country institutions have an in-depth understanding of their needs and beneficiary preferences, and their experience conducting similar campaigns was important for the deployment of dual-AI ITNs. The projects' model, working through NMCPs, also fostered early adoption and introduction into country-led campaigns.

9. Donor flexibility, and coordination by the lead grantee were essential to the success of the project. Implementers described the partnership between the donors (GF and Unitaid) as very flexible and responsive to required changes and adaptations through the life of the project. Other stakeholders, including consortium partners and donors, stated that the coordination role played by IVCC was integral, with a myriad of stakeholders all actively engaged.

10. The broad partnerships established and convening power of the project was exemplary and ensured that the intervention became almost universally adopted by the larger malaria community at global and country levels. The successes of the project were attributed to the breadth of partnerships established, as the project brought together all the key players in the vector control/ITN space, including country governments, funders, implementers, civil society, as well as the regulatory and scientific community. The project also consistently held a core set of meetings with different sets of these stakeholders, ensuring alignment and ongoing communication.

About Suppliers & Price

11. New and better products will come in at higher prices, and it is not realistic to expect prices to be standardized across a product category.

Although the project successfully reduced the price of dual-AI ITNs significantly. The current price is still higher than previous ITN classes, and based on COGS, it is evident that this price point may not be reducible. For newer manufacturers, there are also other considerations, including recouping R&D costs, their production capacities and ability to scale, reasonable demand forecasts and potential volume commitments, that will be needed to enter the market at this lower price point.

12. At the initial stages of market introduction, competition was more critical than artificial market-shaping interventions such as the volume guarantee and co-payment. As there was only one prequalified product at the start of the project, there was no opportunity to create competition. However, majority of stakeholders agree that competition would have enabled a more natural market evolution towards price stability and predictability, maintaining manufacturer commitment beyond the initial volume guarantee period. Introducing competition subsequently is not expected to have any further effect on price, but it is hoped that this will help maintain prices.

13. Early planning for price-point transition and scale-up is also very important, with clear and feasible pathways for closing co-payment gaps.

Although the project had a seemingly clear plan for transition, the proposed plan which expects a sudden reactivation of natural market forces to close the co-payment gap after WHO recommendation is not feasible.

3.8 Risk Mitigation

How effectively have strategic implementation and sustainability/scalability risks been identified and managed over the course of implementation?

Strategic Risks

The project identified several strategic risks at design stage, including:

- A major change in global funding of ITN distribution.
- Change in Global Fund / PMI strategy (including Global Fund allocation envelops to countries for allocation period 2020-2022).
- Trials do not show improved efficacy or cost-effectiveness.
- Royal Guard and Olyset Duo do not get a PQ listing before 2021.

The only strategic risks experienced were the trials not showing improved efficacy for one of the dual-AI ITNs (Royal Guard) and the removal of Olyset Duo from market introduction process by Sumitomo. These risks were rated Medium to Low and Medium to High, respectively. However, due to the fact that for each risk, there was another successful product (IG2, which showed improved efficacy, and Royal Guard, which was prequalified), these risks did not have a significant effect on the project. There are, however, concerns about the adequacy of the supply base for the global market, with expectations that new manufacturers will enter the market soon as discussed previously.

Implementation Risks

The implementation risks identified in the project's design included:

- Delays in starting the pilots (registration, product availability, country campaigns, etc.) and data collection to be pursued outside of the 4-year project life.
- Delays in RCT implementation and data availability.
- A concern that neither co-payment nor volume guarantee lead to an acceptable price or implies volumes that cannot be contemplated on the horizon of the project.

The anticipated implementation risks experienced were delays in starting pilots and delays in commencing RCT implementation, mostly due to supplier delays. There were also some challenges with accessing data in a few countries, in some cases COVID-19 related. These risks were classified as Medium to High but were quickly resolved with little impact to the project. There were, however, two major unanticipated risks to implementation; these were the COVID-19 pandemic and its multifaceted effects, and the quality control issues related to the IG2 net. The COVID-19 pandemic affected many aspects of the project, as extensively described earlier in this report under challenges. Besides the disruption of AI production, nets production and shipment, halting local and international travel, limited access to data and limited in-person technical assistance, the pandemic also posed a risk to malaria diagnosis as COVID-19 could have been misdiagnosed as Malaria due to fever.

The project implemented an emergency plan including regular updates on travel risks, and the regular circulation of updated information to partners on a regular basis was key to managing this particular risk. IVCC also participated in the AMP-led RBM Task Force for Malaria Commodity Supply Chain during COVID-19, regularly collecting data for all vector-control products, including dual-AI ITNs and sharing information with stakeholders. COVID-19-related data collection suspensions in affected countries (Burkina Faso and Rwanda) were short-lived, and countries resumed, subsequently making data available to the project team. Previous gaps due to a health worker strike in Burkina Faso were estimated using 2018 health facility data to model trends in those missing months in 2019. Limited in-person technical assistance was addressed through the provision of additional virtual trainings in qualitative methods, Standard Operating Procedures (SOPs) and instrument instructions, and increased frequency of consistent data checks. Quality assurance issues in Burkina Faso and Rwanda were effectively resolved through re-inspection. In the latter half of the project, there were no further quality concerns reported.

Sustainability/Scalability Risks

The identified sustainability risks were:

- Rapid emergence of resistance to new Als.
- Acceleration of resistance intensity to pyrethroids.
- A concern is that demand from countries after the project remains low as prices negotiated with manufacturers are perceived as too high.

The only pre-identified risk that materialized are reports of emerging resistance to chlorfenapyr, as earlier discussed, with further investigation ongoing. However, there are two main sustainability risks that are emerging at project closeout. The first is the ability of countries to prioritize dual-AI ITNs at the exit price, as majority had previously only accessed the nets at the reference price of standard nets during NNP and also during NTI, which ends in 2024. There are concerns that without another intervention to bridge transition of this price point, countries may have to scale back on quantities of dual-AI ITNs procured as compared to quantities deployed during NNP and NTI. The other emerging risk is an anticipated shortfall for Global Fund in 2026 of about USD 1 billion. At the time of this evaluation, there was limited information on how this shortfall will be addressed and the impact it will have on Global Fund's Malaria portfolio in 2026. Countries are, however, frontloading their net procurements to ensure adequacy of supply for campaigns that may cut across this time period.

4. Conclusions

The main conclusions of the evaluation are as follows:

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. A new class of nets 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. 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 IG2; (2) Facilitating the prequalification of DCT's dual-AI ITN-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.

The NNP also achieved a high level of internal and external coherence. It was internally coherent, with its broad range of implementers, with complementary competencies required for different elements of the project. The project collaborated with key external stakeholders and was implemented through the existing country structures and led by NMCPs. The NNP established productive partnerships with BMGF, PMI, and the participating countries' national and state malaria programs, aligning with their integrated vector management strategies. It also implemented a largely comprehensive CSE around its research activities. The follow-on project to the NNP, Global Fund's NTI, was also complementary and well aligned with the NNP.

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 13% in the final project year, over double the intended 5% target, enabling both project and non-project countries access 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-AI ITNs and data exploring entomological and epidemiological outcomes that met the WHO and VCAG requirements and subsequently informed the March 2023 consolidated WHO guidelines for malaria. IG2 is now registered in 26 countries, and RG in 5 countries, and these countries represent about 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. The volume guarantee reduced the price point of dual-AI ITNs by almost half, and the co-payment mechanism further bridged the price gap between dual-AI ITNs and 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, with over 37 million dual-AI ITNs procured via the co-payment mechanism, exceeding the 35 million life of project target.
- It also addressed the demand and adoption barriers, as evidenced by a strong WHO recommendation for the deployment of pyrethroid-chlorfenapyr ITNs (IG2) instead of pyrethroid-only nets, and a conditional recommendation for the deployment of pyrethroid-pyriproxyfen ITNs (RG) instead of pyrethroid-only ITNs. Also, 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-AI ITNs; instead they emphasize some general limitations of ITNs in general, within different country contexts.

- 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.
- Cost-effectiveness point estimates comparing next-generation nets to pyrethroid-only nets using net pricing as of April 2023, and excluding Nigeria, are \$0.66-\$3.56 per additional case averted for Interceptor®G2, \$0.84 for Royal Guard®, and \$1.33-\$4.34 per additional case averted for PBO nets. 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.

Impact modeling estimates of dual-AI ITNs across NNP countries, by Imperial College (Consortium Member), reveal that NNP copaid IG2 nets averted an estimated 6 million malaria cases and 11,815 deaths during the life of the project. The impact increases to 13 million malaria cases and 24,614 deaths averted when NTI and PMI procurements are included. These are expected to result in \$16m for NNP-copaid nets, and \$29m for NNP, NTI, and PMI nets, 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 ITNs from the CHAI global malaria commodities forecast project.

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 as well as implementation delays during COVID-19 pandemic. Through the life of the project, there were varied implementation delays related to manufacturer capacity constraints, protracted contract negotiations, a health worker 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 project was largely cost-efficient, improving its absorptive capacity annually and expending 99% of its budget by December 2022. The 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 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-AI ITNs. 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 copayment, 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, however, 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. Also, the current supply base is inadequate; however, BASF is currently scaling production of IG2, and Vestergaard's PermaNet Dual achieved WHO prequalification in March 2023, with other manufacturers expected to join the pool in subsequent years. 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, thus the need for new AI alternatives to sustain this intervention.

5. Recommendations

5.1 National Malaria Control Programs and Ministries of Health

- Messaging/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. SBC interventions should also be informed by social and behavioral science research, especially towards addressing barriers to access and utilization of ITNs.
- 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-AI ITNs.
- Utilize costing estimates and cost-effectiveness results from the project for country decision-making towards prioritizing dual-AI ITNs.
- Continue early forecasting and order placement, with the aim of aligning the arrival of different products to be deployed in multi-product campaigns.
- Before the scale-up of chlorfenapyr ITNs, resistance management strategies need to be well-defined to preserve their effectiveness: As the product scales, countries should closely monitor the development of chlorfenapyr resistance.

5.2 Global Fund, Unitaid, Other Donors & Global Policy Makers

Supplier Base Expansion

- Support expansion of the supplier base to ensure adequacy of supply to meet the expected increase in demand for chlorfenapyr-pyrethroid ITNs, by
 - Facilitating prequalification of at least two more products.
 - Conducting regular demand forecasts to inform decisions around potential market interventions to justify early scale-up for new manufacturers and improve supply security. Vestergaard plans to manufacture up to 10 million PermaNet Dual in 2023 and are ready to scale up very quickly in coming years based on demand.

Price Point Sustainability

- Explore additional interventions to sustain current dual-AI ITNs price point and address potential affordability barriers such as:
 - Considering another stop gap to phase out the co-payment price difference that reduces gradually over a 3- to 5-year period.
 - Facilitating AI sharing, enabling other manufacturers' access to BASF's chlorfenapyr AI or other similarly priced sources.
 - Incentivizing co-investment from private sector to expand coverage of dual-AI ITNs and reduce the burden on public funding.

Climate Sensitive Programming

- Explore more sustainable options and methods for ITN management to reduce the climate footprint of nets "cradle to grave", including:
 - o Identifying more innovative solutions for net manufacturing using recycled fabrics.
 - Funders prioritizing environmentally friendly innovations (materials, packaging) and deployment methods for future investments.

ITN Quality and Durability

- Increase focus on quality and durability of ITNs in general by:
 - Harmonizing and improving quality control systems across manufacturers and countries.
 - Exploring new net technology with the possibility of producing longer-lasting nets with less insecticides, that are potentially cheaper.

• Addressing user-driven durability issues (repurposing, discomfort, inconvenience, perceived lack of effectiveness, etc.) through user research, product optimization and improved communication.

Resistance Mitigation

- Mitigate chlorfenapyr resistance early by:
 - Exploring new AIs to be used alongside or replace chlorfenapyr, to begin mitigating resistance. The current dual-AI ITNs are only a stopgap as they still contain pyrethroids.
 - Developing a multi-faceted approach to address resistance, similar to Antibacterial Resistance (ABR).
 - Deploying similar market levers (VG, buy-down, co-pay) to support manufacturers working on novel AI nets.

Further Evidence Generation

- Generate and disseminate additional evidence to optimize the use of dual-AI ITNs and other vector control tools and malaria prevention interventions, including:
 - Conducting additional research to understand the variation in dual-AI ITN's efficacy and effectiveness across countries/sites.
 - Generating evidence comparing cost-effectiveness of new nets to other new vector control and malaria prevention tools, such as 3rd Generation Indoor Residual Spraying (3GIRS), new Seasonal Malaria Chemoprevention (SMC) guidance, and combinations of VC tools, to better guide countries' resource allocation and to maximize impact. Elements of these are already being achieved as part of the NTI's research agenda.
 - Disseminating preliminary evidence from NTI's research activities as they become available, especially related to the evaluation of the efficacy of dual-AI ITNs in their third year of life and other durability results.

Additional Programming Focus

- Strengthen program design and explore additional focus areas for future interventions:
 - Better defining the role of PBO nets. Dual-AI ITNs are rapidly gaining market share against PBO nets, so it is important that the role of PBO nets be better refined to ensure optimization of available ITNs.
 - Exploring more demand-side/ down-stream market-shaping interventions; for instance, policy advocacy to create budget lines, plan and reallocate government resources, as well as seek funding from other internal/private sector sources.
 - Increasing focus on social and behavioral science in product development to inform deployment strategies, especially towards addressing barriers to access and utilization of ITNs.
 - Strengthening community engagement throughout project life, and especially at project design and inception, e.g. planning for early engagement of country ministries and agencies, and strengthening implementation through these as lead implementers in-country, with INGOs providing technical assistance as needed.
 - Developing/adopting program frameworks and standards around equity, inclusion, intersectional and people-centered approaches, as applicable to different interventions and project types, to guide implementers and align expectations. These can be existing implementer systems, not necessarily a new Unitaid framework, e.g. PATH's Equity in Programming Benchmarks, Jhpiego's Gender Analysis Toolkit for Health Systems, Global Fund's Technical Brief on Equity, Human Rights, Gender Equality and Malaria (2023-2025), and RBMs Guide to Gender and Malaria Resources.

6. Risks, Limitations & Mitigation

6.1 COVID-19 Prevention Considerations

This evaluation was conducted during the COVID-19 pandemic, and as a result, contingencies and safety measures were put in place. The safety of participants and interviewers throughout the data collection phase was assured by limiting the number of in-person engagements to a bare minimum and utilizing more virtual interviews/group discussions with key informants. Where necessary and absolutely unavoidable, one-on-one in-person interviews were conducted, adhering to the MoH COVID-19 prevention guidelines in each country, using face masks, sanitizing hands, tools and surfaces, and practicing social distancing.

6.2 Evaluation Timing and Availability of Project Research Findings

The timing of the evaluation does not align perfectly with the availability of research results; however, available preliminary findings have been included in the report. Notably, entomological study results are completely omitted.

7. Country Case Studies

7.1 Case-Country; Mozambique

Country Context

Mozambique is situated on the east coast of Africa with a population of approximately 32 million people.⁵² It is one of the ten countries with the highest number of malaria cases in the world, with the disease accounting for about 29% of all deaths (42% in children under 5 years old).⁵³ Data from the National Malaria Indicators Survey (IIM) conducted in 2018 indicate that the prevalence of malaria in children under 5 years old was 39% in Mozambique, ranging from 1% in Maputo City and Maputo Province to 47.6% for Manica Province, 49% in Niassa Province and 57% in Cabo Delgado Province.⁵⁴ Mozambique registered over 10.2 million cases of malaria in 2021, a 3% increase compared to 2020. There were also 22,291 deaths, compared to 23,693 cases in 2020, a 6% decrease).⁵⁵

Mozambique's National Malaria Control Program - Programa Nacional de Controlo da Malária (PNCM) is responsible for developing policies, standards, planning, and coordination of all malaria control activities in the country and one of them is the distribution of ITNs.

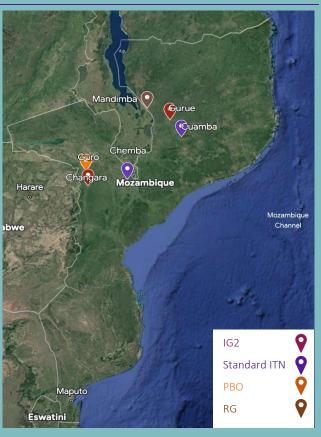


Fig 22. Map of Mozambique showing project locations

Project Scope

Unitaid and the Global Fund launched the New Nets Project in Mozambique in 2018. The country was designated an Evaluation Pilot country. The project was implemented in two regions of the country (Northern and Western Mozambique). In each region, three districts were covered, two intervention and one control district, with a total of six districts. The PNCM led mass distribution campaigns in 2019 and 2020, with logistical and technical support from World Vision (Global Fund Principal Recipient), the Federation Humana People to People (ADPP), the Foundation for Community Development (FDC) and the Food for the Hungry (FH) which are Global Fund Sub-recipients. Social Behavior Change Communication support was provided by Programa Inter-Religioso Contra a Malaria (PIRCOM), funded by a partnership between Comic Relief and GSK that aims to improve health services and control the spread of malaria at community level.⁵⁶

IG2 was deployed in two districts, Cuamba (Niassa Province/Northern Mozambique) and Guro (Manica Province/Western Mozambique). Royal Guard was deployed in Mandimba (Niassa Province/Northern Mozambique), PBO nets in Changara (Tete Province/Western Mozambique), and Standard ITNs in Gurue (Zambezia Province/ Northern Mozambique) and Chemba (Sofala Province/Western Mozambique), as seen in *Fig. 22* above.

⁵² World Bank 2022. https://www.worldbank.org/en/country/mozambique/overview

⁵³ Severe malaria observatory https://www.severemalaria.org/countries/mozambique

⁵⁴ 2018 National Malaria Indicators Survey

⁵⁵ World Malaria Report 2022

⁵⁶ https://fightingmalaria.co.uk/projects/pircom

Findings

The evaluation results are summarized in Fig 23. below. Detailed findings thereafter have been structured by evaluation **Criteria** and evaluation *questions*.

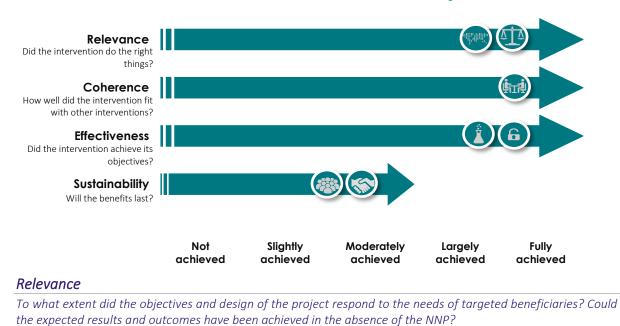


Fig 23. DAC Assessment Overview

Finding 1. The New Nets Project aimed at addressing malaria (which is a leading cause of morbidity and mortality in Mozambique), particularly among children under the age of five and pregnant women, and the

rise in pyrethroid resistance; by deploying dual-AI ITNs.

Malaria is a major public health issue in Mozambique, and ITNs have previously been effective in preventing the transmission of the disease. From 2010 to 2015, Mozambique experienced a 32% increase in the number of cases, from 8.5 million to 11.2 million cases.⁵⁷ Since 2015, there has been little progress, with the country still recording 10.7 million cases and 16,000 deaths in 2019, compared to 16,400 deaths in 2015.⁵⁸ The stall in progress has been attributed to the rise in pyrethroid resistance. The NNP aimed to increase the use of dual-AI ITNs in Mozambique and, as a result, reduce the number of malaria cases and deaths. The project distributed these new nets in high malaria transmission areas of the country. The project was also expected to have broader implications for public health in Mozambique, as reducing the incidence of malaria,

would improve overall health outcomes in the country, reduce healthcare costs, and increase productivity and economic growth.

Coherence

How well did the project maximize alignment/coherence and synergies with government, in-country stakeholders and CSOs?

Finding 2. The NNP was implemented primarily through the National Malaria Control Programme in Mozambique, PNCM and was efficiently integrated into existing health systems.

The PNCM played a crucial role in the implementation of the New Nets Project, as lead implementer in the country. The PNCM, in collaboration with other partners, was responsible for the planning, implementation, and monitoring of the distribution of the dual-AI and other nets. They led the co-creation of guidelines for the distribution of the new nets, the training of health workers and community volunteers on how to use and distribute nets and how to mobilize communities. The PNCM also led evidence-based planning and other routine M&E functions of the project. The program worked efficiently with other stakeholders to collect data

⁵⁷ WHO World Malaria Report 2016

⁵⁸ WHO World Malaria Report 2021

on malaria incidence, prevalence, and mortality rates before and after the distribution of the new nets. Overall, the PNCM was central to the implementation of the New Nets Project in Mozambique.

Finding 3. There was alignment across a broad range of stakeholders with the inclusion of other Government Ministries to support the messaging and communication around campaigns at provincial, district and lower levels.

The implementation of the NNP involved a broad range of stakeholders at the provincial and district levels. The PNCM leveraged CSOs as well as other ministries in other sectors to improve community engagement. For example, the Ministry of Social Action was involved in validating messaging and approaches to be used to introduce the new nets at the community level. Village leaders were consistently engaged, participating in promoting awareness and acceptance of the study activities in their village. Although door-to-door distribution of the nets (due to the COVID-19 pandemic) was more resource-intensive, involving community leaders, it was said to have increased acceptance among the population, as they were trusted and could effectively communicate, raise awareness, and encourage participation. District health authorities and

PNCM personnel also provided regular and frequent communication to village heads and other district-level stakeholders prior to each cross-sectional and durability monitoring survey. These engagements enabled seamless participation of sentinel households.⁵⁹ All respondents agreed that the project was coherent in that all the stakeholders involved were aligned on the same goal to address the ongoing pyrethroid resistance and reduce the malaria burden in Mozambique. Many respondents also commended the effectiveness of the engagements, despite the large numbers of stakeholders involved at different levels.

"The synergy - partnership and coordination - was led by the Ministry of Health, with the government and civil society partners working closely together. At the provincial level, all key partners also participated." GF Sub-Recipient

Effectiveness

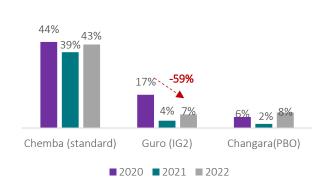
To what extent has the project contributed to increased availability of dual-AI ITNs that are commercially available for rapid introduction in LMICs?

Innovation, Availability & Affordability

Finding 4. The NNP successfully created and disseminated evidence on the efficacy and effectiveness of dual-AI ITNs. There are, however, concerns about the current price point and affordability of the nets post-project.

The NNP, through its market strategies, was able to procure and integrate dual-AI ITNs into routine campaigns in Mozambique. Findings from the pilot evaluation in Mozambique showed favorable results. Cross-sectional surveys showed an overall decrease in malaria prevalence in children under 5 in each district, with Guro (IG2) district experiencing the largest reduction at 59% in Western Mozambique. On the other hand, in Northern Mozambique, the largest decrease overall was in the district with standard nets (Gurue - 12%). The IG2 district Cuamba showed a slightly lower reduction (8%). However, routine health facility surveillance showed an overall decrease in case incidence in each district, with the IG2



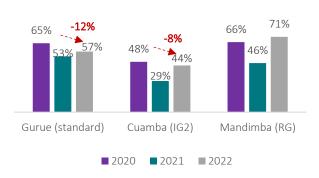


districts having the largest reduction at 56% in the West and 35% in the North. The study suggested that the distribution of any of the new ITN types (IG2, PBO, or RG) is more effective than standard pyrethroid-only ITNs in reducing malaria transmission in areas with moderate to high pyrethroid resistance up to 12 months

⁵⁹ NNP Annual report 2021

after distribution.⁶⁰ However, the availability of dual-AI ITNs in the country is heavily dependent on donor funding as the government has limited malaria prevention funding. Many in-country respondents also pointed out that in the absence of donor funding, the price of the nets remains a barrier to increasing availability and scaling it up across the country.

Fig 25. Malaria prevalence in children under 5 in districts in Northern Mozambique



To what extent, in a context of limited resources, did country decision-making prioritize deployment of dual-AI ITNs? What was the rationale behind the selected approach and level of deployment of dual-AI ITNs? How was effective coverage determined?

Demand & Adoption

Finding 5. Mozambique has prioritized the distribution of dual-AI ITNs in areas of high pyrethroid resistance and malaria burden, with over 2.6 million dual-AI ITNs distributed in these areas during the project life.

Between 2019 and 2020, 17,372,482 ITNs were distributed; this included 11.3 million standard ITNs in Nampula, Zambezia, Sofala, Gaza, and Inhambane provinces; 3.4 million PBO ITNs in Cabo Delgado and Tete provinces; 2 million IG2 ITNs in Niassa and Manica; and 655,293 Royal Guard ITNs in Niassa province. IG2 and Royal Guard ITNs were distributed in sites with a high rate of malaria prevalence and pyrethroid (high/moderate) resistance, PBO ITNs were distributed in sites with a medium rate of prevalence and high pyrethroid resistance and standard ITNs were distributed in areas without pyrethroid resistance. The country made this decision based on existing data on endemicity and pyrethroid resistance. These nets have since then contributed to the reduction of malaria cases in the country.

What are the drivers for dual-AI adoption (e.g., price, ease of implementation, increased effectiveness, etc.)? Which is the predominant driver among these, if any?

Demand & Adoption

Finding 6. The major drivers for dual-AI adoption were the notably increased effectiveness of the dual-AI ITNs in comparison to other nets and the affordability of the new nets.

An important driver for adoption of dual-AI ITNs in Mozambique is the effectiveness of these new nets. The results in the project intervention districts are well known across key informants who are very excited about the performance of the dual-AI ITNs. However, the more critical factor for adoption and scale-up of dual-AI ITNs is the price of these nets. Country respondents report not having domestic funds to purchase and distribute ITNs in general. Also, the budget of the entomological control and surveillance unit responsible for generating evidence of vector susceptibility on a regular basis is also said to be very inadequate. This unit is central to ensuring evidence-based dual-AI ITN allocation and for ongoing resistance monitoring. Mozambique is heavily dependent on the contributions of funders including Global Fund and PMI, who support its malaria prevention and treatment programs including ITN procurement and distribution.

Finding 7. Challenges with ITN quality and durability, delayed dual-AI ITNs deployment in Mozambique, with an order of IG2 nets failing Global Fund quality assurance testing.

At the early stages of the project, the orders for Mozambique were delayed due to protracted discussions between the PNCM and Global Fund as to the specifications, quantities and deployment targets for dual-AI ITNs. Once the orders were placed, the lead time became longer due to other large orders in the pipeline.⁶¹

⁶⁰ Preliminary results of the New Nets Project pilot evaluations in Mozambique: Epidemiological trends through twelve months ⁶¹ NNP Annual report 2019

Due to COVID-19, BASF was unable to source raw materials from their usual suppliers for a part of the year. This led to a situation where some nets produced for Mozambique failed Global Fund quality assurance testing due to higher-than-specification fabric weights, lower-than-specification bursting strengths, and not meeting flammability criteria. Mozambique eventually decided to accept these IG2 nets, with the stipulation that durability monitoring was conducted on the nets.⁶²

Finding 8. The NNP-supported campaign significantly increased the use of nets, with over three times more households reporting using ITNs in study districts.

The communication strategy employed by the PNCM was not to inform communities about the differences between ITN types during the sensitization of communities to prevent rumors and perceptions of ineffectiveness of standard nets. Only the provincial and district management authorities were informed about the differences in the nets. The project also implemented additional CSE around NNPs research activities (in addition to standard community engagement activities during national net campaigns), resulting in increased sensitization, awareness and utilization levels of all net types by over 3-fold in study districts.

Sustainability

To what extent has the project helped establish country readiness for scale-up? To what extent have dual-AI ITNs been scaled up across the country? How does the speed of uptake compare with other similar products?

Finding 9. The results from the project incentivized the inclusion of the new nets as a priority in the upcoming national strategy for malaria elimination and vector control in Mozambique.

The previous National Strategic Plan for Malaria (2017–2022) focused on reducing the malaria burden in high-endemic areas while sustaining gains in low-transmission areas to accelerate elimination. The plan emphasized strengthening case management, universal access to diagnosis and treatment, strengthening malaria surveillance systems, and the continuation of universal coverage of ITNs as the main vector control strategy. The preliminary results from the NNP pilot study in Mozambique was the rationale for the inclusion of new nets in subsequent campaigns. Respondents also confirm that the review of the 2017-2022 National Malaria Strategic Plan, together with the results from the pilot study, made it clear that the introduction of new nets should be a priority in the countries' 2023-2027 Malaria Strategic Plan, developed at the end of 2022. The new plan also includes conducting universal ITN distribution campaigns every 2.5 years instead of the three years previously due to the durability findings from NNP.

Finding 10. The malaria program intends to scale up dual-AI ITNs nationwide, but this depends on the availability of 100% funding from donors.

Mozambique has made significant progress in scaling up ITN distribution and use in recent years. In 2019, about 10 million ITNs were distributed across the country, achieving a coverage rate of 70% among households, with challenges in providing access in hard-to-reach areas.⁶³ Additionally, the COVID-19 pandemic had an impact on ITN distribution and other malaria control efforts, as resources and attention were diverted to the pandemic response. Based on in-country pilot results, the country scaled up both PBO and IG2 (as part of its multi-product campaign) to targeted sites in its current 2022-2023 campaign. The campaign distributed new nets (PBO and IG2) to 9 of 11 provinces in the country (7 received PBO ITNs and 2 received IG2 ITNs) based on the resistance endemicity rates in these locations; 16 million ITNs are being distributed, of which 13 million are PBO ITNs and 2.5 million IG2 ITNs. Two provinces, Maputo City and Maputo Province, are excluded from the net distribution program as they have a low endemicity rate. Through NTI, just under 2.8 million IG2 nets were ordered for routine and mass campaign distributions. Although the country plans to continue deploying dual-AI ITNs, sustaining access will depend heavily on available funding. There has also been some support from the private sector with ProservÒ (a private health equipment, consumables, and mosquito nets distributor) making dual-AI ITNs available at a fee in all provincial capitals.

⁶² NNP Annual Report 2021

⁶³ World Health Organization. (2021). World malaria report 2021: 20 years of global progress and challenges. Geneva: World Health Organization.

To what extent, once dual-AI ITNs are deployed, is that coverage sustained? Is it scaled back in some cases? If scaled back, what are the reasons for this?

Finding 11. The more effective dual-AI ITN (IG2) has been sustained at similar levels through a second campaign round (2022-2023), and the country hopes to maintain coverage levels based on resistance endemicity rate prioritization in different regions of the country. There, however, seems to be a drastic shift to PBO nets.

A comparison of the 2019-2020 and 2022-2023 net campaigns shows an increase in the deployment of PBO nets, in place of standard ITNs, with dual-AI ITNs maintained at similar levels. PBO nets were deployed to 7 districts as compared to only 2 in the previous campaign. There seems to be a shift from standard ITNs to PBO nets. IG2 ITNs, however, have been implemented in the same provinces (Niassa and Manica) as the previous campaign and at similar volumes: 2.5 million ITNs for the 2022-2023 round against 2 million in 2019-2020. These provinces were prioritized for IG2 ITNs based on a high prevalence of malaria in the under-5-year-old population estimated during the 2018 Malaria Indicator Survey, as well as suspected pyrethroid resistance in the dominant vector populations. It is also important to note that over 600,000 Royal Guard ITNs were also deployed in the 2019-2020 campaign.

7.2 Case-Country; Rwanda

Country Context

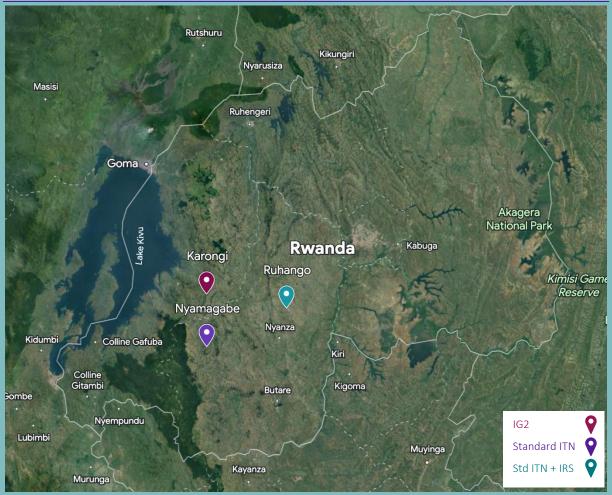


Fig 26. Map of Rwanda showing project location

Rwanda is situated in East Africa with a population of approximately 13.2 million people.⁶⁴ The country has made significant progress in reducing malaria incidence from 400 per 1000 in 2016 to 148 per 1000 in 2020. Rwanda has continued to witness a decrease in malaria cases from 4.8 million in 2017 to 1.8 million in 2020, a decrease in severe malaria from 18,000 in 2016 to 3,000 in 2020, and malaria-related deaths decreased from 700 in 2016 to 148 deaths in 2020.⁶⁵ These achievements have been possible with the visionary leadership and accountability of the Ministry of Health and the Rwanda Biomedical Centre, through the implementation of high-impact preventive interventions such as Indoor Residual Spraying (IRS) and ITN distribution, prompt diagnosis and treatment of all cases at the level of the community health worker (currently, 56% of all malaria cases are managed by CHWs), and innovations such as community-based interventions like Integrated Vector Management (IVM), access to community health insurance, and performance-based financing. Rwanda also piloted the use of drones to deploy larvicides in collaboration with private operators (CHARIS and SFH Rwanda) and introduced mosquito-repellent products through social marketing.⁶⁶ Despite important strides, malaria remains a public health priority in Rwanda, with the entire population at risk of infection.

 $^{\rm 65}$ Rwanda Biomedical Center (2021). Rwanda celebrates progress against Malaria. Available at

⁶⁴ The fifth Rwanda Population and Housing Census (RPHC5)

https://rbc.gov.rw/index.php?id=100&tx_news_pi1%5Bnews%5D=604&tx_news_pi1%5Bday%5D=28&tx_news_pi1%5Bmonth%5D=4&tx_news_pi1%5Bday%5D=2021&cHash=ba64f0bbb7f492fd0a2ff5e4f9e42144_

⁶⁶ RBC (2021). Rwanda commemorates World Malaria Day. Accessed on the 23rd March 2023 at

https://rbc.gov.rw/index.php?id=100&tx_news_pi1%5Bnews%5D=603&tx_news_pi1%5Bday%5D=25&tx_news_pi1%5Bmonth%5D=4&tx_news_pi1%5Byear%5D=2021&cHash=a1612f7fe9243757ff4313411b13ce6a

Project Scope

In 2018, with the support of the Global Fund, Unitaid, and other stakeholders, Rwanda has designated an Evaluation pilot country with access to dual-AI ITNs through the New Nets Project. The aim of the project was to address mosquito resistance to pyrethroids and provide evidence of the efficacy of the new nets. The National Malaria Prevention Committee working in the Rwanda Biomedical Centre (RBC) implemented the project. The project collaborated with a host of local and international partners, including the University of Rwanda, PMI, REACH, and USAID, among others. The project was implemented in Karongi District (IG2 arm) in the Western Province, Nyamagabe District (Standard ITN arm) in the Southern Province and Ruhango District (Standard ITN and IRS arm) in the Southern Province of Rwanda, as seen in *Fig. 26* above.

Findings

The evaluation results are summarized in Fig 27. below. Detailed findings thereafter have been structured by evaluation **Criteria** and evaluation *questions*.

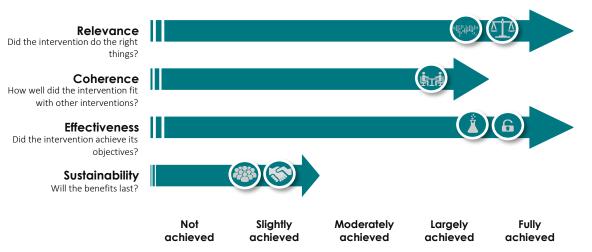


Fig 27. DAC Assessment Overview

Relevance

To what extent did the objectives and design of the project respond to the needs of targeted beneficiaries? Could the expected results and outcomes have been achieved in the absence of the NNP?

Finding 1. The New Nets Project was responsive to Rwanda's malaria prevention focus, as it addressed an immediate threat to the remarkable progress the country had made in malaria prevention over the last decade, with the potential to halt the spread of pyrethroid resistance in the country.

According to the World Health Organization (WHO), the prevalence of malaria in Rwanda has been decreasing since 2010. In 2010, Rwanda reported approximately 4.9 million malaria cases. However, by 2015, the number of reported malaria cases had dropped to 4.6 million, representing a decline of about

6%.⁶⁷ pyrethroid resistance became a significant concern in 2016, affecting both disease vectors and agricultural pests. The widespread use of Pyrethroids in both agriculture and public health may have contributed to the development of resistance. A 2016 study found that mosquitoes exhibited increased resistance to pyrethroids, with a mortality rate of less than 50%.⁶⁸ The success already being recorded in the fight against malaria in Rwanda was threatened by the existence of mosquito resistance

"The objectives and design new nets project responded to the needs of our country mainly to the challenge of the mosquito resistance Rwanda experienced in 2016." **Rwanda Biomedical Centre**

⁶⁷ World Health Organization. (2016). World Malaria Report 2016. Retrieved from https://www.who.int/malaria/publications/world-malaria-report-2016/report/en/

⁶⁸Hakizimana, Emmanuel & Karema, Corine & Munyakanage, Dunia & Iranzi, Gad & Githure, John & Tongren, Jon & Takken, Willem & Binagwaho, Agnes & Koenraadt, Sander. (2016). Susceptibility of Anopheles gambiae to insecticides used for malaria vector control in Rwanda. Malaria Journal. 15. 10.1186/s12936-016-1618-6.

to pyrethroids. The initiation of the NNP was timely to provide an innovation to tackle resistance and sustain the progress towards eliminating malaria in Rwanda.

Coherence

How well did the project maximize alignment/coherence and synergies with government, in-country stakeholders, and CSOs?

Finding 2. The project was inherently coherent as it aligned with Rwanda's malaria strategic plan, was led by the in-country NMCP, and supported by the University of Rwanda for research activities. The project also leveraged other partners, CSOs and community stakeholders.

In Rwanda, the NNP was led by the Rwanda Biomedical Centre (RBC), which serves as the country's NMCP and is also the Global Fund Principal Recipient. The RBC led the design of the project in-country, including the development of guidelines for the distribution of ITNs as well as the training of health workers and community volunteers on proper net use and maintenance. As part of its responsibilities, the RBC also led coordination and project management at the national level, working closely with district health teams and other partners. RBC also conducted regular monitoring and evaluation activities and utilized local leaders and community health workers for community sensitization on the benefits and use of ITNs. For research activities, studies were led by the University of Rwanda (the foremost academic and research institution in the country). At the grassroots level, village leaders and community health workers also facilitated introductions of activities and research assistants to community members, and community health workers assisted research assistants with finding selected households during the cross-sectional surveys.^{69,70}

Finding 3. At the early stages of the project there were coordination challenges between RBC and the University of Rwanda which led to delays in campaign and project research activities.

The coordination issues between the RBC and the University of Rwanda were mostly related to bureaucratic and time-consuming recruitment processes at the University. As a result, the team available at inception had limited experience planning for and conducting large cross-sectional surveys. The issues were quickly resolved once the recruitment processes were completed and the surveys were conducted successfully. Working through this government-owned research institution allowed for sustenance of the knowledge transferred through the evaluation pilot. However, some stakeholders suggested that working through an NGO may have been more efficient, though not necessarily sustainable.

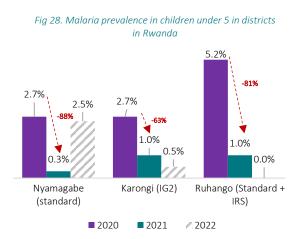
Effectiveness

To what extent has the project contributed to increased availability of dual-AI ITNs that are commercially available for rapid introduction in LMICs?

Innovation & Availability

Finding 4. Preliminary findings of malaria prevalence measured in all ages, and incidence in study locations do not show superiority of dual-AI ITNs when compared to the combination of standard ITNs and IRS.

Preliminary findings from the pilot evaluation in Rwanda showed the IG2 district recorded lower performance than the standard ITN and IRS district. At baseline, there were substantial differences in incidence rates between the pilot districts; incidence was 1.62 times more in Karongi (IG2) and three times more in Ruhango (standard ITN and IRS) when compared with



⁶⁹ NNP Annual report 2020

⁷⁰ NNP Annual report 2021

Nyamagabe (Standard). After one-year, cross-sectional surveys showed a decrease in malaria prevalence in children under 5, in all study districts, with the district that received standard ITN and IRS (Ruhango) experiencing the largest reduction at 81%, whereas the IG2 district (Karongi) reported a 63% reduction. Routine health facility surveillance also showed a decrease in case incidence in each district, with the standard ITN and IRS district having the largest reduction (28.7%), while IG2 showed a 13.4% reduction compared to standard ITNs.⁷¹ It was reported that the initial baseline measures in February 2020 were not directly comparable to the year 1 prevalence measures due to the possibility that the observed changes primarily reflected the seasonal fluctuations in malaria transmission rather than the intervention's absolute impact.⁷² This resulted in the use of prevalence data collected in October 2020 which were more comparable, as baseline. Also, the year 2 cross-sectional survey data was compromised due to the introduction of new standard nets in the standard ITN district, it showed similar results with the Standard ITN + IRS district having the least prevalence of malaria (0.0%). Survey results indicate very low levels of malaria burden, with no study district showing all-ages prevalence greater than 1.2%. Given that each survey has shown low prevalence across districts, it may not be possible to detect statistically significant differences over time. In Rwanda, PBO nets were distributed in the mass campaign, but there were no areas comparable to those receiving IG2 ITNs, and therefore the PBO ITN districts were not incorporated into the NNP analysis. However, key informants in Rwanda report that PBO ITNs have been as effective as IG2 ITNs in combating malaria and mosquito resistance to Pyrethroids, but were unable to provide evidence to support this.

Finding 5. The NNP was instrumental in making the new nets commercially available in Rwanda, with a waiver that allowed procurement in 2019 prior to the registration of the IG2 in the country. There were, however, other procurement challenges due to conflicting procurement policies.

The NNP was instrumental through its market-shaping strategies, in making new nets commercially available. About 1 million IG2 nets were procured through the waiver. The first challenge with procurement was a restrictive national policy that generally discourages sole sourcing as it is less competitive and may lead to higher costs of goods for the government. However, there are some exceptions where sole sourcing may be allowed, such as in cases of emergency or where the goods, works, or services required are only available from a single supplier. Once the sole supplier justification was complete, there was also another dispute with payment terms. BASF required full payment prior to shipping, and RBC was only willing to pay 20% at the time of the order and the rest following reception and successful inspection of goods. This resulted in protracted negotiations and delays that ended in BASF ultimately agreeing on an exceptional basis to accept 20% at the time of the order.⁷³

Finding 6. There were also quality assurance standard variations between the manufacturer and RBC, with Rwanda's standards being more rigorous than international standards. This resulted in failed quality control inspections.

There were quality assurance issues with the IG2 nets delivered to Rwanda. These were reported by RBC after the inspection of samples showed an unacceptable rate of production flaws (i.e., size, seam failures, holes etc.) and damage. Similar inspection failures reportedly occurred with nets from other manufacturers of standard ITNs, which led to a discussion as to whether RBC's inspection standards were more rigorous than international standards. The nets that failed initial quality control were re-inspected under an agreement negotiated between RBC and BASF, who took financial responsibility for the re-inspection, repair and re-packaging of 1.2 million IG2 nets. At the end of the process, there were about 61,000 (5.1%) of the 1.2 million nets that were rejected and about 9,200 (0.8%) that were not re-inspected due to insufficient funds. An agreement was reached to return all the rejected/uninspected nets (5.9%) for forensic audit. Delays due to the procurement process and quality assurance issues were exacerbated by the COVID-19 pandemic, thereby pushing campaign timelines.

⁷¹ Preliminary results of the New Nets Project pilot evaluations in Mozambique: Epidemiological trends through twelve months

⁷² New Nets Project interim results Preliminary evidence from the pilot evaluations August 2022

⁷³ NNP Annual Report 2019

To what extent, in a context of limited resources, did country decision-making prioritize deployment of dual-AI ITNs? What was the rationale behind the selected approach and level of deployment of dual-AI ITNs? How was effective coverage determined?

Demand & Adoption

Finding 7. Rwanda prioritized the deployment of dual-AI ITNs using available data on malaria burden and areas of resistance, as well as the affordability of the dual-AI ITNs.

To decide where to deploy different vector control tools, the government of Rwanda utilizes a data-driven approach. The RBC relies on epidemiological data (efficacy and effectiveness of interventions), data on resistance to standard nets, and affordability (including cost-effectiveness data). Indoor residual spraying (IRS) was deployed in 12 districts in the entire Eastern Province and five districts of the South, where there is mosquito resistance to pyrethroids and a high burden of malaria. In districts with a moderate number of cases and moderate to high mosquito resistance, IG2 or PBOs were deployed. In districts with no mosquito resistance and few cases, standard nets were deployed.

Finding 8. Effective coverage of dual-AI ITNs in Rwanda was determined through the utilization of survey and routine monitoring data.

Sentinel surveys of households conducted prior informed nets deployment efforts and served as a strategy for assessing ITN needs and planning for campaigns. Subsequently, post-distribution monitoring surveys were used to collect evidence on household ownership and use of mosquito nets, including dual-AI ITNs, to ascertain coverage levels. In addition to these surveys, routine monitoring data collected through the national health management information system (HMIS) was another evidence source for nets distributed through routine channels. All of these data sources were utilized to understand effective coverage.

What are the drivers for dual-AI adoption? Which is the predominant driver?

Demand & Adoption

Finding 9. There are several drivers for the adoption of dual-AI ITNs, but the most important in Rwanda were effectiveness and affordability.

There is already a high level of awareness among Rwanda's population about the impact of malaria prevention interventions, specifically ITNs, with many past mobilization campaigns conducted in partnership with CSOs who support awareness creation and community sensitization. The ITN intervention is also well-valued and widely used. Almost all nets provided by the project were distributed and are in use, so questions around adoption of dual-AI ITNs focus on their superior effectiveness and affordability in comparison to previous net types. The primary driver at the start of the project was the expected effectiveness of these new nets against pyrethroid-resistant mosquitoes, with a need for an alternative approach to malaria control. However, the more predominant driver for the adoption of dual-AI ITNs at the end of NNP is currently affordability. The perception that PBO ITNs and IG2 ITNs are similarly effective in combating malaria and mosquito resistance to Pyrethroids in Rwanda, and the fact that PBO nets are still slightly cheaper than IG2, has resulted in Rwanda continuing to use PBO nets instead of introducing IG2.

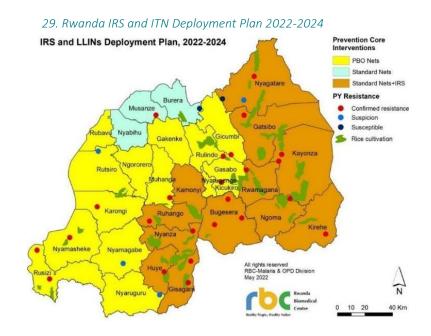
Sustainability

To what extent has the project helped establish country readiness for scale-up? To what extent have dual-AI ITNs been scaled up across the country? How does the speed of uptake compare with other similar products? To what extent, once dual-AI ITNs are deployed, is that coverage sustained?

Finding 10. Dual-AI ITN coverage will not be sustained post-NNP due to the reported similarity in PBO and IG2's effectiveness in and subsequent cost-effectiveness of PBO over IG2 in Rwanda. The country plans to sustain and expand its use of IRS in high malaria-incidence districts.

The reported similarities in effectiveness between PBO and IG2 and budget constraints have led to the government of Rwanda opting to use the slightly cheaper PBO nets. As a result, the country has not procured any dual-AI ITNs post-NNP (no procurements through NTI) and has excluded this net type from their 2022-2024 deployment plan. Instead, they have opted to focus primarily on the use of PBO nets, a combination

of standard nets and IRS, and standard nets, as seen in *Fig 29*. In-country and global malaria stakeholders expect that as the implementation context evolves, with future changes in price, new evidence, changes in the malaria epidemiology/vector resistance, or shifting priorities and resources, this decision may change. Key stakeholders in Rwanda plan to continue monitoring and evaluation activities that assess the effectiveness and sustainability of the current method mix and to make informed decisions on whether to continue, scale up, or modify their selected vector control tools in an evidence-based manner.



7.3 Case-Country; Nigeria

Country Context

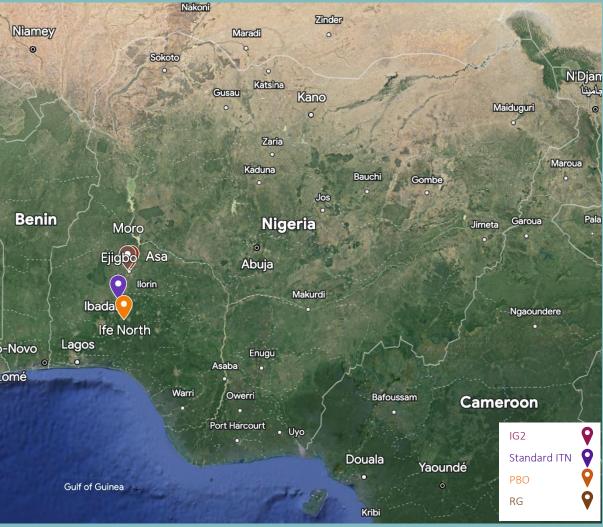


Fig 30. Map of Nigeria showing project locations

Nigeria is situated in West Africa with a population of approximately 211 million people.⁷⁴ The 2022 World Malaria Report, revealed that Nigeria had the highest number of global malaria cases (27% of global malaria cases) and the highest number of deaths (31% of global malaria deaths) in 2021. The country accounted for an estimated 55.2% of malaria cases in West Africa in 2020.⁷⁵ Case numbers increased by 5.3% between 2017 and 2020, from 298 to 314 per 1000 of the population at risk. Deaths increased by 4.7%, from 0.92 to 0.97 per 1000 of the population at risk during that same period.⁷⁶

Microscopy data from the 2018 Nigeria Demographic and Health Survey (NDHS) show that the prevalence of malaria parasitaemia in children under five years of age is 23% (a decrease from 27% in 2015 and 42% in 2010), although there are significant regional, rural-urban, and socioeconomic differences: prevalence ranges from 16% in the South and Southeast Zones to 34% in the Northwest Zone. In rural populations, prevalence is 2.4 times that in urban populations (31% vs. 13%). Compared to the highest socioeconomic group, prevalence among children in the lowest socioeconomic group is seven times higher (38% vs. 6%).⁷⁷

⁷⁴United Nations Population Division. World Population Prospects: 2022 Revision

⁷⁵ World Health Organization. WHO Malaria Report 2022

 $^{^{76}}$ World Health Organization. WHO Malaria Report 2022

⁷⁷ National Malaria Indicator Survey (NMIS), 2015

The National Malaria Elimination Programme (NMEP) is domiciled in the National Malaria and Vector Control Division in the Department of Public Health of the Federal Ministry of Health in Nigeria. It is mandated to formulate policy and guidelines, as well as coordinate the activities of partners and other stakeholders on malaria control activities in Nigeria. The national vector control strategy includes providing at least 80% of the targeted population with appropriate preventive measures by 2025, using vector control tools, such as ITN, IRS, and in some cases, Larval Source Management (LSM), which are needed to combat insecticide resistance and reduce malaria transmission. The use of ITNs is the most common vector control intervention in Nigeria. On average, mass ITN campaigns occur every three to four years in most states, in addition to routine delivery at antenatal care (ANC) services to ensure pregnant women who attend have at least an ITN.⁷⁸

Project Scope

Nigeria served as an Evaluation Pilot country, with the project implemented in two Local Government Areas (LGAs) in Kwara State, Asa (IG2 ITNs) and Moro (RG ITNs), and two LGAs in Osun State, Ejigbo (standard ITNs) and Ife North (PBO ITNs) as seen in *Fig 30.* above. The four study LGAs were chosen due to similar malaria transmission dynamics—including malaria prevalence, incidence, vector species composition, insecticide-resistance status, and general climate and geographic similarities—and consistencies in other planned malaria control interventions. While Kwara and Osun experience year-round transmission, the high-transmission season occurs from July to November⁷⁹. The NNP was implemented in Nigeria with the overall aim of comparing effectiveness and cost-effectiveness between the different net types. The project was implemented by the National Malaria Elimination Program (NMEP) in collaboration with the respective State Malaria Elimination Programs (SMEPs) for Osun and Kwara, PATH, IBOLDA Health, Tropical Health, PMI, the WHO and other Partners.

Findings

The evaluation results are summarized in Fig 31. below. Detailed findings thereafter have been structured by evaluation **Criteria** and evaluation *questions*.

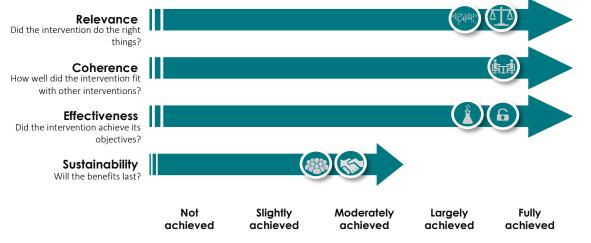


Fig 31. DAC Assessment Overview

Relevance

To what extent did the objectives and design of the project respond to the needs of targeted beneficiaries? Could the expected results and outcomes have been achieved in the absence of the NNP?

Finding 1. The NNP was instrumental in addressing the growing pyrethroid resistance and improving access to and use of ITNs in project locations.

⁷⁸ US President's Malaria Initiative FY 2022 Nigeria Malaria Operational Plan

⁷⁹ New Nets Project Interim Results July 2022. Output 3: Evidence of effectiveness and cost-effectiveness of dual-AI ITNs created and disseminated.

Malaria is one of the leading causes of death in Nigeria. According to the 2022 World Malaria Report, Nigeria accounted for 27% of malaria cases globally and 31% of deaths from the disease in 2021.⁸⁰ However, the earliest report of pyrethroid resistance was made in 2002⁸¹ and was already widespread across the country by 2018.⁸² pyrethroid resistance had become a major challenge to malaria control efforts in Nigeria. The NNP was a timely intervention to introduce the use of ITNs with new active ingredients and provide evidence of their effectiveness in the context of widespread pyrethroid resistance.

Coherence

How well did the project maximize alignment/coherence and synergies with government, in-country stakeholders, and CSOs during planning, implementation, and assessment to promote adoption and scale-up? To what extent was the project consistent with national vector control strategies?

Finding 2. The projects' early engagement through the NMEP, with relevant government departments, other implementing partners, CSOs and philanthropic organizations, enabled these key actors to contribute significantly to project implementation and success. The NMEP was very active as they played the role of coordinating the project. This enabled the institutionalization of the intervention within existing national malaria control efforts and alignment with other players in the malaria space. NMEP led the project kick-off meetings and ongoing program management meetings to review project progress on a regular basis, as well as ongoing advocacy and stakeholder management as needed.

Leaders at the sub-national level (State and LGA) were engaged early to inform them of the objectives of the project, ask for any considerations, and seek their assistance in facilitating community participation. Community mobilization and engagement meetings were held to inform the community leadership about study activities. In addition, village leaders, community health workers, and health facility staff were consulted prior to the start of each study component and helped facilitate the introductions to their communities.⁸³ The project relied more on community leaders and CHWs to facilitate community engagement instead of CSOs. Some respondents in Kwara State suggested that CSOs would have been more efficient, eliminating the slight delays in participant identification encountered during the baseline there.

"The LGA, the state and even the communities and wards worked closely during the implementation of the NNP. The communities were very receptive. Even up till now, the communities still call to ask for the continuation of the project." Moro LGA Health Department

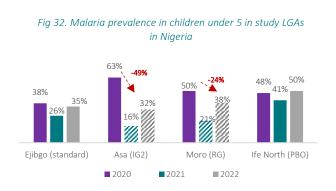
Effectiveness

To what extent has the project contributed to increased availability of dual-AI ITNs that are commercially available for rapid introduction in LMICs?

Innovation & Availability

Finding 3. The NNP was pivotal in making dual-AI ITNs available and providing evidence of their effectiveness against pyrethroid resistance in Nigeria through its pilot in the two states.

Through the NNP, about 5,067,000 IG2 nets (routine 1.6M); and 500,000 Royal Guard nets (routine 0.19M) were procured through import waivers and licenses and



⁸⁰ World Malaria Report 2022, accessible at https://www.who.int/teams/global-malaria-programme/reports/world-malaria-report-2022 ⁸¹ T.S. Awolola, B.D. Brooke, R.H. Hunt, M. Coetzee. Resistance of the malaria vector Anopheles gambiae s.s to pyrethroid insecticide in southwestern-Nigeria. *Ann. Trop. Med. Parasitol.*, 96 (2002), pp. 849-852, 10.1179/000349802125002581

⁸² T.S. Awolola, A. Adeogun, A.K. Olakiigbe, A.T. Oyeniyi, Y.A. Olukosi, H. Okoh, T. Arowolo, J. Akila, A. Oduola, C.N. Amajoh pyrethroids resistance intensity and resistance mechnisms in Anopheles gambiae from malaria vector surveillance sites in Nigeria PLoS One, 13 (12) (2018), pp. 1-13,

10.1371/journal.pone.0205230

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were distributed in both states by the end of December 2020. The year 2 evidence from the evaluation pilot in Nigeria shows the largest decreases in prevalence were observed in Asa (49%) (IG2 nets) and Moro (24%) (RG nets).⁸⁴ These decreases reflect the combined impact of the new net distribution and newly implemented SMC campaigns with four rounds of mass drug administration. There was additional modeling ongoing at the time of this evaluation to tease out the results of dual-AI ITNs. However, based on the impact seen in other countries, the prevalence reduction in Nigeria is still expected to be high. Incidence results were confounded by certain factors (migration, suboptimal reporting, and inconsistent use of public sector health facilities).

To what extent, in a context of limited resources, did country decision-making prioritize deployment of dual-AI ITNs? What was the rationale behind the selected approach and level of deployment of dual-AI ITNs? How was effective coverage determined?

Demand & Adoption

Finding 4. The NMEP relied on available data on epidemiology and resistance to standard nets for the planning of vector-based control activities across Nigeria.

The deployment of dual-AI ITNs to Kwara and Osun states was guided by documented widespread pyrethroid resistance in both states. The choice to deploy these nets was seemingly straightforward, especially because the Global Fund was a co-funder on the NNP and a major donor for the ITN mass campaign in Nigeria. Also, the intervention was already well aligned with NMEP and other in-country partners' vector control strategies. Based on available epidemiological data and resistance trends, the country's strategy was to deploy IRS in areas of high resistance and high malaria burden and a combination of standard nets, IG2 and PBO in areas of moderate/intense malaria transmission.

Finding 5. NNP increased demand for ITNs, with up to 60% coverage of the population in both study locations.

The primary mode of distribution was mass campaigns, coupled with routine distribution through ANC visits. The campaigns were adapted due to COVID, to a door-to-door mode of distribution to ensure proper coverage. NMEP also deployed the use of champions and ambassadors as part of its Behavior Change Communication (BCC) strategy. These BCC activities were well embedded in community -evel programs and were led by prominent persons in the community, such as opinion leaders, political leaders, and traditional rulers. Many respondents report that ITN uptake increased in project communities by up to 60%; however, there continues to be low/average utilization of ITNs in the country as a whole.

Finding 6. The project increased health worker capacity significantly, which especially improved health worker attitudes towards BCC and data collection activities.

The NNP capacitated a pool of trainers, training over 300 MoH staff (nurses, M&E officers, logisticians and Community Health Extension Workers). These trainings spanned M&E/data management, clinical diagnosis and community mobilization. Key informants reported that these trainings have motivated Health Workers, influencing the quality of BCC activities and improving data quality.

What are the drivers for dual-AI ITN adoption? Which is the predominant driver?

Finding 7. The two main adoption drivers in Nigeria are the effectiveness and the cost of the new nets. However, respondents report that effectiveness is the predominant driver and that the country benefits from significant donor support due to its high burden; as a result, cost is secondary.

Stakeholders suggest that the effectiveness of dual-AI ITNs in reducing malaria burden in the presence of pyrethroid resistance is the predominant driver for their adoption. Although there are concerns about the price (affordability), key stakeholders believe that support from international partners and the private sector will be sufficient to ensure affordability. There is no evidence that points to the sufficiency of funding, but in-country stakeholders seem optimistic and are already planning to scale up dual-AI ITNs to five new

⁸⁴ Preliminary results of the New Nets Project pilot evaluations

locations. With shrinking donor budgets globally, the cost of these nets is likely to resurface as a barrier to adoption in the future.

Sustainability

To what extent has the project helped establish country readiness for scale-up? To what extent, once dual-AI ITNs are deployed, is that coverage sustained?

Finding 8. The transition of the Intervention to NTI has allowed continuity and a short-term sustenance in deploying dual-AI ITNs.

There have been no mass campaigns since the NNP supported one in 2020. However, through the NTI, in preparation for the upcoming campaign, an order of just under 3 million IG2 nets (2.9 million for mass distribution and 26,958 for routine distribution) has been placed with an additional planned order of 17,281 nets for routine distribution.

Finding 9. The results of the pilot in Nigeria, showing the effectiveness of the dual-AI ITNs, have been a critical factor for both adoption and scale-up of dual-AI ITNs.

Nigeria has planned to continue using IG2 and is scaling up its use to five additional states in the next mass campaign. The planned States are Adamawa, Gombe, Kano, Katsina, and Oyo. The new National Malaria Strategic Plan is expected to detail the inclusion of IG2 and its scale-up plan. This scale-up is largely supported with Global Fund programmatic funds.

Finding 10. At the end of NTI, there is no intention to scale back the use of dual-AI ITN because of Nigeria's malaria burden, its stable transmission all year round and widespread resistance. The country intends to continue to use a multi-product mix of ITNs, including dual-AI ITNs, PBOs, standard nets, as well as other vector control interventions. There have been recent conversations on scaling up Larval Source Management, but these additional vector control methods are not expected to displace ITNs.

8. Appendices

8.1 Evaluation Approach

The evaluation framework and methodology were based on elements of Unitaid's evaluation framework, strategic Key Performance Indicators (KPIs) and scalability framework applicable to the NNP project as well as the Terms of Reference (TOR) requirements.

The evaluation employed a parallel and convergent mixed-methods approach that comprised:

- Desk reviews of existing project documents (project plan, Log frame, annual reports, publications, conference presentations and other information products) and non-project documents (co-financing agreement, strategy documents, terms of reference for the steering committee) to harness qualitative and quantitative data on project outcomes.
- Virtual and in-person qualitative interviews (key informant interviews and group discussions).
- Site visits, combined with qualitative interviews.
- Case studies (topical and country specific studies).
- Triangulation of data from different sources/stakeholders to establish the strength of evidence and level of contribution to achieved results.
- Lastly, the evaluation embodied utilization-focused and participatory approaches.

8.1.1 Mixed Methods

The evaluation collected primary qualitative data through key informant in-person/virtual interviews with a wide variety of stakeholders from community groups and civil society organizations, Ministries/NMCPs, implementers, manufacturers, national and global technical working groups/fora, other donors, lead grantee (IVCC), Consortium partners (AMP, Imperial College, LSTM, LSHTM, PATH, and PSI), Unitaid staff and Global Fund staff. Other qualitative data was extracted from project documents such as: project plans, annual reports, conference abstracts, manuscripts, publications, tools, and guidelines developed. Quantitative data was mainly secondary data extracted from project annual report indicator tables and obtained from other stakeholders' post-interview. The evaluation utilized both the document review and the qualitative interviews to reconstruct 2018 project baselines retrospectively.

8.1.2 Site Visits

Qualitative interviews with key stakeholders at national and subnational level were conducted alongside site visits as these enabled the evaluation team to validate the reported findings and access stakeholders who had limited teleconferencing capabilities. In line with Unitaid's effort in reducing carbon footprints related to procurement activities, our country focal points did not travel internationally as they were already resident in proposed countries. These consultants already had an in-depth understanding of the malaria programs landscape of their respective countries and could easily identify stakeholders and coordinate inperson interviews.

8.1.3 Assessing Scalability

The team determined the degree to which the grants contributed to laying the ground for scale-up, by comparing the status of scale-up conditions in 2018 with 2022. The evaluation retrospectively mapped and documented Unitaid's scalability framework indices at the start and end of the project life through desk reviews and key informant interviews. This assessment incorporated the sustainability section of the evaluation report and final results were presented graphically. The evaluation estimated Dual-AI ITN's reach by 2030, through scale-up partner (GF and PMI) data such as planned procurement volumes and factoring in growing resistance trends.

8.1.4 Case Studies

The team developed two sets of complementary case studies. Topical case studies highlighted: 1) The partnership model between Unitaid and the Global Fund and the model for country engagement, and the degree to which engagement of country stakeholders was effective; and 2) The market shaping strategies employed (volume guarantee, co-payment mechanism). Country case studies focused on three prioritized countries, with a focus on how country decision making prioritized deployment of dual-AI ITNs, the rationale behind the selected deployment approach, level of deployment, coverage targets determination, how coverage has been sustained or not, and understanding drivers for dual-AI adoption.

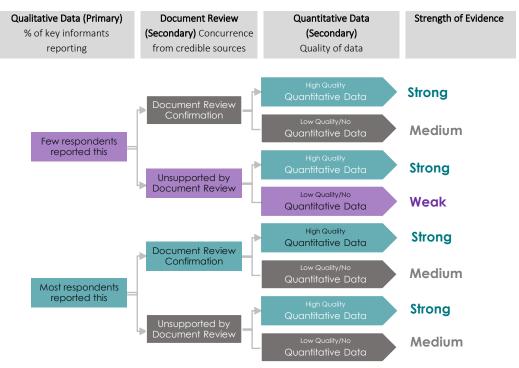
8.1.5 Participatory & Utilization-Focused

The team established effective working relationships with all key stakeholders listed below throughout the duration of the evaluation. The selected stakeholders informed the evaluation design and methods, others validated findings at strategic points throughout the evaluation process. Lastly all stakeholders received feedback on evaluation findings through various avenues or information products per Unitaid's evaluation standards.

8.1.6 COVID-19 Prevention Considerations

The COVID-19 pandemic has significant implications for how field work is implemented. Our contingency plan ensured the safety of participants and interviewers throughout the data collection phase by limiting the numbers of in-person engagements with some national and sub-national stakeholders with limited teleconferencing access. All in-person activities were conducted according to current MoH COVID-19 prevention guidelines in each country, using face masks, sanitizing hands, tools, and surfaces, and practicing social distancing.

8.1.7 Strength of Evidence Pathway



We consider high-quality quantitative data sources to be objective; consequently, any results backed with verifiable quantitative data is considered strong, irrespective of the presence of qualitative interview feedback or document review confirmation. Qualitative data is often more subjective and prone to a number of biases from both the interviewer and responder, thereby affecting the validity and reliability of findings. The strength of qualitative interview data increases where a large volume of respondents provided the same feedback, and increases further when complemented by the document review and quantitative data findings. Our framework emphasizes this. This framework guided the final compilation of evaluation findings and recommendations.

8.2 Evaluation Matrix

Questions and sub-questions (+) are listed by DAC criteria, culled out from Annex 1 of the Evaluation Terms of Reference and adapted where necessary.

Objectives	Questions, Indicators & Methods Document Review Key Informant Interview Group Discussion (main source indicated first) Priority Case Study Questions	Respondents
1. To assess the relevance of the NNP towards addressing the emerging pyrethroid resistance and	 1. To what extent did the objectives and design of the project respond to the needs of targeted beneficiaries (among vulnerable populations including women and children, community and civil society organizations, government/national health systems, scale-up partners)? + Could the expected results and outcomes have been achieved in the absence of the NNP. 	Unitaid Staff, Global Fund Staff, Other Co- funders, Grantee, Consortium Members, MoH (National Level- Govt. Malaria program focal points), CSOs, Community Groups, Malaria technical working groups/global stakeholders.
•	2. Have design and implementation approaches been appropriately adapted/course-corrected to respond to any changes in context (for example, at the policy level – globally or within a national context, emerging and competing technologies/products/approaches)?	Unitaid Staff, Global Fund Staff, Other Co- funders, Grantee and Consortium Members
	 3. To what extent has the project's design and implementation identified and addressed issues related to gender, social inclusion and equity in line with Unitaid's overall mission to reach the most disadvantaged populations in developing countries using innovative global market-based approaches? + To what extent did the investment align with Unitaid's strategic principles and commitment to equitable, intersectional and people-centered approaches? 	Unitaid Staff, Global Fund Staff, Other Co- funders, Grantee, Consortium Members, CSOs.
	 4. Were the market shaping strategies employed (volume guarantee, co-payment mechanism): suitable? +How critical were these mechanisms to achieving the results and outcomes of the investment (e.g., affordable price, adoption by countries and scale-up)? + Could anything have been done differently – both in terms of how these mechanisms were implemented and whether a different type of market shaping mechanism might have been more appropriate? + Did any of the approaches limit or de-incentivize (unintentionally) other potential suppliers or innovators in this space? + What lessons can be gleaned from this experience to inform future investments, by Unitaid or by other funders? 	Unitaid Staff, Global Fund Staff, Other Co- funders, IVCC, Other Donors, Wider Global Stakeholders, and Manufacturers.
	1. To assess the relevance of the NNP towards addressing the emerging pyrethroid	Document Review Key Informant Interview Group Discussion (main source indicated first) Priority Case Study Questions 1. To assess the relevance of the NNP towards addressing the emerging pyrethroid resistance and declining ITN coverage. 1. To what extent did the objectives and design of the project respond to the needs of targeted beneficiaries (among vulnerable populations including women and children, community and civil society organizations, government/national health systems, scale-up partners)? + Could the expected results and outcomes have been achieved in the absence of the NNP. 2. Have design and implementation approaches been appropriately adapted/course-corrected to respond to any changes in context (for example, at the policy level – globally or within a national context, emerging and competing technologies/products/approaches)? 3. To what extent has the project's design and implementation identified and addressed issues related to gender, social inclusion and equity in line with Unitaid's overall mission to reach the most disadvantaged populations in developing countries using innovative global market-based approaches? 4. Were the market shaping strategies employed (volume guarantee, co-payment mechanism): suitable? +How critical were these mechanisms to achieving the results and outcomes of the investment (e.g., affordable price, adoption by countries and scale-up)? 4. Could anything have been done differently – both in terms of how these mechanisms were implemented and whether a different type of market shaping mechanism might have been more appropriate? + Did any of the approaches limit or de-incentivize (unintentionally) other potential s

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	Objectives	Questions, Indicators & Methods Document Review Key Informant Interview Group Discussion (main source indicated first) Priority Case Study Questions 	Respondents
Coherence	To assess the complementarity and synergy between key stakeholders, and other donor investments, including the Global Fund Nets Transition Initiative.	 5. To what degree does the work undertaken by the project fit with other interventions within targeted countries, sectors or institutions (e.g., creating synergies between relevant interventions and consistent with other initiatives/international norms and standards within the same space)? + How well does the intervention align with priorities/needs identified by partners/the global disease response? + To what extent did the project contribute to further development of global alliances to support scale up and sustainability of dual-AI ITNs + How well did the project maximize alignment/coherence and synergies with government, in-country stakeholders, and CSOs during planning, implementation and assessment to promote adoption and scale up? + What is the level of interplay and complementarity of the NNP and NTI and the effectiveness of the interface between them. + How effective was the governance structure of the project including the steering committee and program management at donor level? 	Unitaid Staff, Global Fund Staff, Other Co- funders, Grantee & Consortium Members, Other Donors, MoH (National Level- Govt. Malaria program focal points), and Malaria Technical Working Groups, Manufacturers, Wider Global Stakeholders.
		6. To what extent was the project consistent with national vector control strategies, especially in areas where overlapping vector control tools were targeted for use (e.g., IRS and net campaigns)?	IVCC, PSI, AMP, MoH (National Level- Govt. Malaria program focal points), and Malaria Technical Working Groups.
		7. To what extent has Unitaid's investment in new nets added value (and not duplicated efforts or established parallel systems)?	Unitaid Staff, Global Fund Staff, Other Co- funders, Grantee & Consortium Members, Other Donors, MoH (National Level- Govt. Malaria program focal points).
		 7. What synergies did the partnership model between Unitaid, and the Global Fund create at global and country level? +What are the lessons from this experience and what recommendations can be gleaned for future partnership / co-funding, as well as engagement of country stakeholders? + What elements worked well / should be retained? + What elements can be improved / should be revised? + What were the benefits of a co-funded effort compared to sole funding? 	Unitaid Staff, Global Fund Staff, Other Co- funders, Grantee & Consortium Members, Other Donors
Efficiency	To assess the efficiency of the project including cost and time- efficiency and cost- effectiveness.	 8. How timely, cost-efficient and cost-effective was implementation (consider both allocative efficiency and technical efficiency)? a. What factors have been considered to ensure that value for money has been achieved from an efficiency standpoint? + Could the project have achieved its aim with fewer implementation pilots (on feasibility and cost-effectiveness) conducted? + Are countries willing to scale-up the dual-AI ITNs interventions based on evidence and pilots done in similar countries? + Could the design of the NNP and NTI have been better, towards complementarity and efficiency. 	Unitaid Staff, Global Fund Staff, Other Donors, Grantee, Consortium Members, MoH (National Level- Govt. Malaria program focal points).

	Objectives	Questions, Indicators & Methods Document Review Key Informant Interview Group Discussion (main source indicated first) Priority Case Study Questions 	Respondents
		9.Was the funding allocation/split to cover commodities/supplies versus other costs appropriate and effective to achieve project objectives? What best practices, if any, could be learned for similar grants in the future?	Grantee and Consortium Members
		10. How well did the grant implementers collaborate with national authorities in project planning, implementation and assessment to promote integration into existing health systems?	Unitaid Staff, Global Fund Staff, Grantee, Consortium Members, MoH (National Level- Govt. Malaria program focal points).
Effectiveness	To assess the performance of the New Nets Project against the original Afl	 11. To what extent did the project achieve its objectives and expected outcomes in addressing targeted access barriers within the specified timeframe and budget? +To what extent were target access conditions for dual-AI ITNs achieved? +What were the main factors influencing the achievement or non-achievement of the intended outputs or overall outcomes? 	Unitaid Staff, Global Fund Staff, Other Co- funders, Grantees & Consortium Members.
	objectives, Theory of Change and Pathway to Impact, i.e., the extent to which the investment met the objectives to secure relevant access conditions.	 Innovation & Availability (Products that are better (new, adapted, superior); are commercially available for rapid introduction in LMICs 12. To what extent has the project contributed to increased availability of dual-AI ITNs that are commercially available for rapid introduction in LMICs? + To what extent has the project contributed to development or access to innovative products (better, new, adapted, superior) in resource-limited settings? + To what extent has the availability of better products increased for the target groups/region? + Have the products supported through the project been registered for commercial use in relevant project countries or are plans in place for their registration after project closure? + Has the project contributed to eliminating intellectual property barriers (if exist), or ensuring that such barriers are not created, which may prevent equitable access to a product? 	Unitaid Staff, Global Fund Staff, Other Co- funders, Grantee, Consortium Members, MoH (National Level- Govt. Malaria program focal points), Wider Global Stakeholders, and Manufacturers.
		 Affordability (Products available at lowest price, sustainable for suppliers, and not unreasonable for governments, donors and patients, with a view to increasing access for the underserved.) 13. To what degree has the project contributed to making dual-AI ITNs available at lower prices that are affordable for governments and other donors? + To what extent has the project secured appropriate equitable access commitments (including affordable pricing commitments) from developers/ manufacturers and/or suppliers benefiting from Unitaid support (directly or indirectly)? + How has the project supported improved access to affordable products for the most vulnerable? + What are the complexities around co-payment and long-term pricing, and how has the project addressed these? 	Unitaid Staff, Global Fund Staff, Other Co- funders, IVCC, Other Donors, Wider Global Stakeholders, and Manufacturers.

	Objectives	Questions, Indicators & Methods Document Review Key Informant Interview Group Discussion (main source indicated first) Priority Case Study Questions	Respondents	
		Demand & Adoption (Countries, programs, and end users introduce and adopt the most cost-effective products within their local context. Proven service delivery models for LMIC settings exist. 14. What progress did the project make in facilitating increased demand and uptake for scale-up of cost-effective dual-AI ITNs within target countries and beyond? + How effectively have implementers partnered with/engaged and supported communities and civil society organizations to support research activities, increase demand, political support and financial commitments? + To what extent do the piloted delivery systems reach underserved/ vulnerable populations? + How effectively has implementation generated demand and the ability to reach the priority target population? + To what extent, in a context of limited resources, did country decision making prioritize deployment of dual-AI ITNs? What was the rationale behind the selected approach and level of deployment of dual-AI ITNs? + How was effective coverage determined? + What are the drivers for dual-AI adoption (e.g., price, ease of implementation, increased effectiveness, etc.)? Which is the predominant driver among these, if any?	Unitaid Staff, Global Fund (Staff, CCM, PR, SR), Other Co-funders, IVCC, PSI, AMP, PATH, Wider Global Stakeholders, MoH (National & Sub- national Level- Govt.), CSOs, Community Groups.	
Impact	To determine the difference the NNP investments made in enabling equitable access to dual-AI ITNs.	 16. To what extent has the investment generated, or is expected to generate, global/national-level effects across Unitaid's dimensions of impact: i. Equity ii. Strategic benefits and positive externalities 	Unitaid Staff, Global Fund Staff, Grantee, Consortium Members, MoH (National & Sub- national Level- Govt.), CSOs, Community Groups, Health Workers.	
calability & Sustainabilit	To determine the status of access and scale-up of dual-Al ITNs in LMICs in 2022- 23 using the Unitaid scalability framework,	 17. To what extent (and how effectively) has the project contributed to building an enabling global environment for scale-up, including generating evidence, normative guidance, affordable pricing, tools to support country adaptation and uptake and advocacy, and stronger partnerships among global actors? + To what extent did the co-funded / co-governed effort lay the foundation for subsequent scale-up (incl. through NTI) and opportunities for future innovations? 	Unitaid Staff, Global Fund (Staff, CCM, PR, SR), Other Co-funders, Grantee, Consortium Members, Other Donors (especially PMI) & Wider Global Stakeholders.	
	including the extent of the grant's contribution to progress achieved.	 18. To what extent has the project helped establish country readiness for scale-up, including securing ongoing political and financial commitments by national governments and other partners, supportive policies and enhanced health system capacity for delivery, and partnering with communities and civil society to mobilize ongoing community demand and engagement? +To what extent have dual-AI ITNs been scaled up across project countries and beyond. + How does the speed of uptake compare with other similar products? 	IVCC, PSI, AMP, MoH (National Level- Govt. Malaria focal points), Other Donors (especially PMI) and Global Fund.	

Objectives	Questions, Indicators & Methods Document Review Key Informant Interview Group Discussion (main source indicated first) Priority Case Study Questions 	Respondents
	+ To what extent, once dual-AI ITNs are deployed, is that coverage sustained? Is it scaled back in some cases? If scaled back, what are the reasons for this (e.g., cost, results are no different from previous nets/vector control tools)? Could coverage be scaled back to a certain level without impacting public health impact due to the increased effectiveness of dual-AI ITNs as they replace standard and PBO nets?	
	19. To what extent have core elements of the intervention been transitioned to ensure that the benefits of the intervention will continue beyond the life of the investment? +What factors have contributed towards, or limited, scalability and transition such as presence/absence of multiple suppliers in the market, quality issues, ability to forecast demand, among others?	IVCC, PSI, AMP, MoH (National Level- Govt. Malaria focal points)
	20. What gaps (if any) remain or what additional work needs to be undertaken to ensure continued scale-up and sustainability?	
Learning	 21. What have been the lessons learned and how have they been incorporated in the lifetime of the grant or across other interventions? + Have lessons learnt been widely disseminated by grantees, Unitaid and Global Fund? 	Other Donors, Unitaid Staff, Global Fund Staff, Other Co-funders, Grantees, Consortium Members, MoH (National & Sub-national Level).
Risk Mitigation	22. How effectively have strategic, implementation and sustainability/scalability risks been identified and managed over the course of implementation?	Unitaid Staff, Global Fund Staff, Grantees, Consortium Members

8.3 Sampling & Sample Size

The sampling for the qualitative interviews was purposive and took into consideration: **representativeness** of all key stakeholders in each of the four target countries and globally; **variation** by including a range of stakeholders with different dimensions of interest; and **cost optimization** by limiting the number of operational areas from which respondents were selected. 75 participants were interviewed one-on-one and/or in groups, these included 38 country-level participants and 37 global respondents. This sample was sufficient as we were able to achieve saturation.

8.3.1 Distribution of Participants by Organization and Country

Respondent Type	Global	
Lead grantee (IVCC)	4	
Consortium Partners (AMP, LSHTM, LSTM, PATH, and PSI)	8	
NNP/NTI Steering Committee Members	8	
Wider global stakeholders indirectly involved with the respective grants such as BMGF, MedAccess, WHO, TWGs		
Manufacturers – BASF (IG2), DCT (Royal Guard), Vestergaard (PermaNet Dual)	4	
Global Fund (NTI team, sourcing team, malaria team)	3	
Unitaid Secretariat (project team, senior management)	5	
Global Interviews Sub-total	37	

Respondent Type	Benin ⁸⁵	Mozambique	Nigeria	Rwanda	Total
MoH/ NMCP Managers and Vector Control Advisors/ Consortium Representatives	4	2	3	4	13
In-country Malaria Technical Working Group/INGOs Implementing Malaria Programs		1		2	3
In-country PMI Representatives		1			1
Global Fund Country CCM, PR, SRs	1	2	1	2	6
Other Government Stakeholders	2		2	1	5
MoH/NMCP- Sub-National		3	3		6
CSOs /Community Group Representatives		1	2	1	4
Country Level Interviews Sub-total	7	10	11	10	38
				Total	75

⁸⁵ Benin was covered virtually; sub-national level interviews were excluded due to expected communication limitations.

⁸⁶ In Benin, the NMCP also served as the Global Fund CCM

8.3.2 Global Participants

S/No	Organization /Participant Type	Title	Names
1.	IVCC / Lead grantee	Technical Coordinator	Christen Fornadel
2.	IVCC / Lead grantee	Director, Access and Market Shaping	David McGuire
3.	IVCC / Lead grantee	Africa Regional Coordinator IVCC	Andrew Saibu
4.	IVCC / Lead grantee	Senior Insights and Access manager	loana Ursu
5.	AMP / Consortium partner	Senior Health Officer, Malaria International Federation of Red Cross and Red Crescent Societies	Marcy Erskine
6.	AMP / Consortium partner	Senior Health Officer, Malaria International Federation of Red Cross and Red Crescent Societies	Giovanni Dusabe
7.	Imperial College / Consortium partner	Professor of Infectious Disease Dynamics	Tom Churcher
8.	LSTM / Consortium partner	Senior Technical Officer	Rosemary Lee
9.	PATH / Consortium partner	NNP Project Director	Joe Wagman
10.	PATH / Consortium partner	NNP Liaison Officer	Peder Digre
11.	PATH / Consortium partner	NNP Liaison Officer	Christelle Gogue
12.	PSI / Consortium partner	Deputy Director, Malaria	Chris Laurenco
13.	BMGF	Senior Program Officer	Ingrid Etoke
14.	BMGF	Senior Program Officer	Dave Malone
15.	BMGF	Deputy Director	Helen Jamet
16.	MedAccess	Implementation Executive	Evans Mburu
17.	Innovation2impact / Steering Committee member	Director	Angus Spiers
18.	ALMA / Steering Committee member	Chief Technical Advisor	Melanie Renshaw
19.	Centro de Investigação em Saúde de Manhiça (CISM) / Steering Committee member	Director General	Francisco Saute
20.	Cama – GBC health / Steering Committee member	Corporate Director	Ochuko Keyamo
21.	Cama – GBC health	Programs Officer	Richard Iddrisu

S/No	Organization /Participant Type	Title	Names
22.	USAID/PMI / Steering Committee member	Chief, Malaria Supply Chain	Lisa Hare
23.	USAID/PMI / Steering Committee member	Vector Control Team Lead	Jen Armistead
24.	USAID/PMI / Steering Committee member	ITN Lead	Lilia Gerberg
25.	WHO / Normative Partner	Head, Vector Control & Insecticide Resistance Unit, GMP	Jan Kolaczinski
26.	BASF	Director	Achim Reddig
27.	BASF	Project Manager	Susanne Stutz
28.	DCT	Managing Director	Andy Butenhoff
29.	Vestergaard	Director, Market Development & Access, Public Health	Melinda Hadi
30.	Global Fund	Senior Specialist, Malaria Vector Control and Catalytic Funds	Kate Kolaczinski
31.	Global Fund	Specialist, Malaria Strategic Initiatives	Htin Kyaw Thu
32.	Global Fund	Global Sourcing Specialist, Vector Control	Clarisse Morris
33.	Unitaid	Program Manager	Matthew Black
34.	Unitaid	Technical Officer	Kelsey Barrett
35.	Unitaid	Program Officer	Rachel Evans
36.	Unitaid	M&E Manager	Denitza Andjelic
37.	Unitaid	Senior Technical Manager	Ali Cameron

8.3.3 Country Level Participants - Benin

S/No	Organization/Participant Type	Title	Names
1.	NMCP/ Vector control advisor	Vector control advisor	Dr Rock Aikpon
2.	Centre de Recherche Entomologique de Cotonou / NMCP Subnational level	Director	Dr Gil Padonou
3.	Centre de Recherche Entomologique de Cotonou/ NMCP Subnational level	Researcher	Boulais Yovogan
4.	LSHTM / Consortium Partner	Professor of Entomology	Akogbeto Martin
5.	LSHTM / Consortium Partner	Associate Professor of Entomology	Corine Ngufor
6.	LSHTM / Consortium Partner	Associate Professor of Entomology	Natacha Protopopoff
7.	PMI/Global Fund CCM rep	PMI Resident Advisor	Dr Patrick Condo

8.3.4 Country Level Participants - Mozambique

S/No	Organization/Participant Type	Title	Names
1.	NMCP	Entomologist Technician	Albertina Chihale
2.	CDC/ In-country PMI representative	Resident CDC Advisor	Yari Torres
3.	Mandimba District Health Services / NMCP subnational level	District Malaria Focal Point	Zito Ernesto
4.	World Vision / Global Fund- Principal Recipient	Project Director	Chandana Mendis
5.	PIRCOM/CSO	Project Director	Liliana Pinto
6.	FDC/GF-Second Recipient	National Manager	Olinda Muguande
7.	Cuamba District Health Services / NMCP Subnational level	District Malaria Focal Point	Anifa Abdala
8.	Niassa Province Health Directorate / NMCP Subnational level	Provincial Malaria Manager	Nilton Manuel
9.	PROSERV / Implementer	Executive Director	Enid Nkini
10.	NMCP National level	Deputy Head of ITN unit	Leonor Rafael

S/No	Organization/Participant Type	Title	Names
1.	NMEP	Coordinator	Dr Perpetua Uhomoibhi
2.	NMEP	Head/Integrated Vector control/NMEP	Philip Okefu Oyale Okoko
3.	Nigeria Institute of Medical Research	Research Fellow	Dr Dapo Adeogun
4.	SFH/Global Fund sub-recipient	Program Manager	John Ocholi
5.	IBOLDA Health/Civil Society organization	Director	Dr. Dele James Babarinde
6.	Tropical Health / Community group/organization	Technical Director	Hannah Koenker
7.	WHO	Malaria Specialist WHO	Dr Lynda Ozor
8.	SMEP	PM Kwara State MEP	Alhaji Nageri
9.	SMEP	IVM Kwara	Silas Adenuike Abigail
10.	RBM	RBM	Yunusa Magaji
11.	NMEP	ТА	Prof Olugbenga Mokuolu

8.3.5 Country Level Participants - Nigeria

8.3.6 Country Level Participants - Rwanda

S/No	Organization/Participant Type	Title	Names
1.	Impact Malaria PMI Implementing Partner/Jhpiego	Chief of Party	Dr Noella UMULISA
2.	PMI Implementing Partner/ IntraHealth	Malaria Specialist	Claire Abimana
3.	RBC/NMCP	Malaria Prevention and SBCC Officer	Epaphrodite Habanabakize
4.	RBC/NMCP	Director of Unit	Michee Kabera
5.	RICH/CSO	Executive Secretary	Gatete Jean
6.	RBC/NMCP	ITNs Specialist	Yvette Muyirukazi
7.	NMCP	Program Manager	Dr Aimable Mbituyumuremyi
8.	Global Fund CCM Rep	CCM Permanent Secretary	Cyiza Innocent
9.	MOH/Global Fund PR	SPIU Coordinator/MOH	Mike Habinshuti
10.	University of Rwanda	Principal Lead	Dr Kato Njuguna

8.4 Documents Reviewed

The evaluation team reviewed the following documents including grant specific documents and other general documentation.

Background Documents

Disease Narratives - Call for Proposals

- 2015 Afl: Accelerating the adoption of innovative vector control tools
- 2017 Call for Proposals: Catalysing the market introduction of next-generation, long-lasting insecticidal nets
- 2019 Malaria Disease Narrative

Updates to Operational Management Team

- October 2019 update Grant Reprogramming
- December 2020 update Aligning with Nets Transition Initiative

Steering Committee

- Terms of Reference (original)
- Terms of Reference (v2, following NTI launch)
- Slides from most recent Steer Co (e.g., on NNP accomplishments, state of the market of dual-AI ITNs, etc.)

Donor Partnership

- MoU and co-financing agreement
- Funders decision body agreement

Unitaid's Evaluation Framework and Strategy

• Unitaid strategy 2023-2027

New Nets Project Documents

Grant Agreement documents

- 2018 Original Project Plan
- 2018 Original Logframe

Grant Amendments

- 2019-2020: Reprogramming Reprogramming to increase number of dual-AI ITNs procured + reprogramming for variances and additional M&E
 - Original reprogramming request
 - Project plan amendment
 - o Updated Logframe
 - Reprogramming changes between Sep and Dec 2029
 - 2021 Reprogramming Extension of co-funding mechanism
 - o Project plan amendment

Annual Reports

- 2018 Annual Report
- 2019 Annual Report
- 2020 Annual Report
- 2021 Annual Report
- 2022 Semi-Annual Flash Report
- 2022 Annual Report

Disbursement Documents/ Unitaid Assessments

- Disbursement package (2018)
 - Disbursement memo
 - Grant Brief Analysis (GBA)
 - Grant Brief Overview (GBO)
- Disbursement package (2019)
 - Disbursement memo
 - Programmatic Performance Annex
 - GBO
- Disbursement package (2020)
 - Disbursement memo
 - Programmatic Performance Annex
 - GBO
- Disbursement package (2021)
 - Disbursement memo
 - Programmatic Performance Annex
 - GBO

Evidence & Publications

- September 2022 <u>Updated evidence base for dual-AI ITNs</u>
- August 2022 PPT evidence summary: Interim results (Aug 2022)
- July 2022 New Nets Project Interim Results: Output 3, Evidence of effectiveness and costeffectiveness of dual-AI ITNs created and disseminated: <u>https://www.path.org/resources/new-nets-</u> project-interim-results-output-3/
- 2022 <u>Design and methods for a quasi-experimental pilot study to evaluate the impact of dual active</u> ingredient insecticide-treated nets on malaria burden in five regions in sub-Saharan Africa, Malaria Journal
- 2019 Multi-product campaign process evaluation, Burkina Faso

Other Relevant Documentation

- Nets Transition Initiative Detailed Investment Plan.
- Nets Mapping Project mapping by AMP.
- CHAI Global Malaria Commodities Forecast Dashboard

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.

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