IVCC

Annual Report

2021-2022

Dr Keziah L. Malm,
Programme Manager
National Malaria control, Ghana

"Government and the public sector alone cannot tackle the complex and daunting challenge of ending malaria especially now that the world faces the devastation caused by the COVID-19 pandemic; the private sector plays a critical role. There is an urgent need to invest and improve on malaria prevention and management.

The National Malaria Control Programme of the Ghana Health Service is committed to intensifying a formidable collaboration with the private sector and all stakeholders to step-up investment in malaria as we race towards elimination."

Dr Perpetua Uhomoibhi,
Nigeria National Malaria Elimination Programme

"Accelerating reductions in malaria incidence and deaths cannot be achieved without a multisectoral, multi-partnership approach in targeting interventions that are evidence-based'.'

Baltazar Candrinho,
Programme Manager,
The National Malaria Control Programme, Ministry of Health, Mozambique

"Since Mozambique introduced the new ITN in 2020, we have seen significant changes in the malaria incidence. The main current challenge is to maintain the 50% reduction in the incidence of ITN recorded in the first year of implementation."

Afito Amido Nacotho,
Malaria focal point in Guro, Mozambique

"The Interceptor® G2 net has a positive impact, considering the high rate of reduced malaria cases in our district, especially in the communities. Also, as a user of Interceptor® G2 nets, I would prefer to continue using them because the mesh is very light and easy to carry to the field – I am very satisfied."

Anifa Abdala,
Malaria focal point of Cuamba, Mozambique

"The new Interceptor® G2 nets , which were distributed in the last campaign carried out in 2019, brought us an advantage and significant improvement, since, in the last 2 years, cases of malaria registered in the District of Cuamba have reduced substantially. With these satisfactory results, the district would like that for the next campaign, the province of Niassa, together with MISAU, could acquire Interceptor® G2s for the next distribution cycle.

Contents

Front cover image credit: A to Z Textile Mills Ltd, Arusha, Tanzania

IVCC Milestones 2021-2022

2021

July 2021

Ifakara Health Institute (IHI) trials facility granted GLP Certification.

Publication of the first short- and long-term CHAI Malaria Commodities Forecast (2022-2025) on RBM Partnership website (CHAI led consortium of which IVCC is the partner in charge of vector control commodities).

August 2021

VECTRON™ T500 achieves first country registration (Mozambique).

Over 30 million nets distributed as part of the New Nets Project.

September 2021

New indoor residual spray product, VECTRON™ T500 submitted to WHO-PQT/VCP for assessment.

November 2021

Indoor Residual Spray (IRS) community trial begins in Papua New Guinea.

Start of three country epidemiological trials for ATSB®. Zambia (November 2021). Kenya and Mali follow in March and May 2022.

PBO net deep-dive market report (publication under the CHAI Malaria Commodities Forecast - CHAI led consortium of which IVCC is the partner in charge of vector control commodities).

December 2021

Completion of field entomological trial in Mondulkiri province, Cambodia, showing very positive performance of forest packs containing spatial repellent, topical repellent and insecticide-treated clothing.

2022

March 2022

Interceptor® G2 demonstrated an overall 44% reduction in malaria incidence in children 6 months to 10 years compared to a pyrethroid only net in paper published in The Lancet.

April 2022

Commitment by five countries (DRC, Ghana, Mozambique, Nigeria and Uganda) to adopt New Routes to Market approach, accepting leadership role and commitment of resources to engage private sector in expansion of vector control in collaboration with IVCC and GBC Health/CAMA.

May 2022

2nd year of IRS by private sector completed in Ghana covering an additional 4,000 people under the New Routes to Market Initiative.

June 2022

IVCC supports the launch of an MOOC on insecticide resitance management with over 800 participants across 43 countries enrolled in the first month.

July 2022

Analytical methodologies developed and validated for total vs surface available active ingredients in both coated and incorporated insecticide-treated nets (ITNs).

Construction completed on the new Belna entomological laboratory in Madang, Papua New Guinea, under the NATNAT project.

August 2022

Goodbye Malaria and IVCC publish – Empowering Women in Malaria Programmes report.

IVCC and MMV launch Global Health Priority Box.

Image Credit: Iñigo Garmendia of the Goizper Group, Antzuola, Spain

Chair's Foreword

Sir Stephen O'Brien KBE
Chair,
IVCC Board of Trustees

Foreword

As we emerge from the worst ravages of the global Covid-19 pandemic, we cannot help but be struck by the almost unimaginable disruption and devastation caused by the virus to so many people across the world.

At the same time, we owe a huge debt of gratitude to, amongst many others, the scientific community for developing, in rapid time, vaccines which have helped limit and prevent further deaths and suffering for those of us fortunate enough to receive them. Thankfully, whilst many populations across the continent of Africa may not have been hardest hit by the Covid-19 pandemic, despite inequitably not receiving their fair share of life-saving vaccines, we are reminded that this vibrant continent has for many centuries, and still today, endured its own year-round and seasonal pandemic - malaria.

As high and tragic as they already are, figures from the World Health Organization's 2021 World Malaria Report also illustrate the knock-on impact of Covid-19 on established vector-borne diseases such as malaria. In 2020, malaria deaths increased globally by 12% to 627,000 - the first and probably not the last rise in annual malaria deaths since 2000, which in part can be attributed to the knock-on impact of Covid-19.

Whilst encouraging progress is being made in the development of malaria vaccines, the need for increased funding and continued innovation across vaccines, drugs and vector control, which has been the mainstay of malaria prevention for decades, are still desperately needed.

The last two decades have demonstrated the evidence that to have effective, efficacious and sustainable impact in controlling malaria and bringing its incidence and deaths down, we will always need to have the full range of all the tools in the box to bring malaria down and keep it down - and that sustained and increased funding is thus a critical element to the goal of eliminating malaria.

None of us engaged in battling the scourge of malaria can allow the huge gains made over these past two decades, even though we know there is no 'magic bullet', to be put at risk - that goes as much for vector control as it does for all other parts of the malaria frontline.

Private sector organisations, so instrumental in the development of the Covid-19 vaccines, are equally pivotal in the development of vector control innovations. Since 2005, IVCC has been working with the agrochemical industry and other private sector partners to identify, develop and bring to market new public health insecticides for insecticidal treated nets (ITNs) and indoor residual sprays (IRS). Without these innovations, insecticide resistance will continue to accelerate and continue to severely inhibit our goal of eradicating malaria. The world, especially the populations affected in endemic malaria countries, has never needed IVCC more to ensure this work is intensified, expanded and to continue to bring in the high impact results to build on its real successes to date.

World Health Organization's 2021 World Malaria Report also illustrate the knock-on impact of Covid-19 on established vector-borne diseases such as malaria. In 2020, malaria deaths increased globally by 12% to 627,000.

Board of Trustees

I would like, once again, to thank my fellow trustees for their wise and thoughtful governance and oversight of IVCC during the year. Their expertise and strategic guidance, all given pro bono, is appreciated and respected by our funding partners and the whole IVCC team.

Professor Qiyong Liu and Dr. Pascal Housset have reached the end of their stipulated and, by agreement, extended terms of office and will step down from the board in December. On behalf of the other Trustees and everyone at IVCC, I would like to thank them for their extraordinary dedication, support and counsel over the years. They have been key to the success of IVCC over their terms on the board. The nominations and governance committee, in consultation with the other trustees and stakeholders, continues the process of identifying and appointing new trustees with the appropriate skills, experience and diversity to recommend to the board.

In addition to Qiyong's and Pascal's departures, I am also stepping down from my position as a trustee and chair of the board at the end of 2022. It has been as fulfilling as it has been a true privilege to have served as a trustee since IVCC was first incorporated in 2008, before having to step down on becoming a Government Minister in 2010, coming back onto the board in 2015, and taking up the Chair in December 2018 - completing a full 9 years in total. I am delighted that the board has recently elected our Vice-Chair, Sherwin Charles, as the new chair elect to succeed me. IVCC and its board are in dedicated and chair elect experienced hands for the future as we effect a seamless transition.

I wish to place on record my intense gratitude for the unfailing support of all my fellow trustees (including those who have retired from the board during my time, especially our Hon. President, my predecessor as Chair, Sir Mark Moody-Stuart). Our collective endeavour to govern and guide IVCC expertly and in the best interests of the people we serve in the malaria endemic countries, and of IVCC and its people who are its core, have been rewarded by the exceptional success of IVCC - an exemplar for the product development partnership (PDP) model, its proven impact, and its prospects, in saving lives, reducing suffering and hardship, and giving people health, hope and agency to survive and thrive.

Finally, I would like to express my admiration and enormous gratitude to Dr. Nick Hamon, who will retire at the end of this year as IVCC's CEO after more than nine years in the role. In that time, Nick has transformed IVCC into a world-leading and universally respected product development partnership that is today, through Nick's tireless efforts and dedication, sustainably funded by multiple national governments, non-governmental organisations (NGOs) and philanthropic organisations, which, in turn, have given Nick and the IVCC team the means and ability to advance its life-saving and innovative work. What began as an insecticide-screening programme back in 2005 supported by a single funder has, through Nick's leadership, delivered a powerful portfolio of new public health insecticides. Through innovative market entry programmes such as NgenIRS and the New Nets Project, these insecticides are today being deployed cost effectively across malaria endemic counties at scale and as rapidly as possible. Many thousands of lives have been saved through the work of IVCC and for this, Nick, whilst he will be the first to disclaim it, should justly feel proud of his considerable achievements and his personal legacy. The IVCC board is taking the necessary time to undertake a global search for his successor, and an announcement of the appointment of an equally inspirational CEO who can lead IVCC into the next phase of its work will be made in due course.

If there is one thing that the Covid-19 pandemic has taught us, it's that with the appropriate sustained funding, political will, and the dedication of inspirational scientists working in organisations like IVCC, public health challenges the scale of Covid-19 can be successfully overcome. We owe it to those who have to suffer the misery of malaria, year in year out, to break this cycle and defeat malaria for good. IVCC is poised to sustain and enhance its core role in that global and noble mission.

CEO Overview

Dr. Nick Hamon
CEO

IVCC emerged from the Covid-19 pandemic with some inevitable delays in project timelines and concerns about the impact on funding.

But it also emerged perhaps an organisation more effective at communicating externally and internally and better prepared for the future. However, Africa still faces its own annual pandemic of malaria with the number of deaths starting to rise again. Even with the emergence of more effective vaccines, never has there been a more important time for innovation. Vector control interventions are recognised as critical and IVCC's role as the only product development partnership (PDP) working in this space, along with its partners, is central to the delivery of these important tools.

Fortunately, IVCC's product development pipeline has never been stronger and already today we are seeing our investment, and that of our funding and industry partners, manifesting in the delivery of life saving vector control tools across endemic countries, facilitated through innovative market shaping access strategies.

IVCC has evolved its insecticide-treated net (ITN) strategy to focus on the further development of nets with single novel active ingredients and bringing to market more diverse products at lower cost in a much shorter space of time. If appropriately used in rotation, these novel products will prevent premature insecticide resistance development. Our product pipeline for next generation indoor residual sprays is almost complete. Actellic® 300CS, SumiShield™ 50WG and Fludora® Fusion are now established in the market and with Mitsui's VECTRON™ T500 expecting a prequalification listing in 2022, along, hopefully, with Sylando®, it will enable best practice and affordable insecticide resistance management to be robustly implemented across countries.

2022 will mark the end of the New Nets Project (NNP), the second catalytic market entry mechanism which IVCC has led on behalf of the Global Fund, Unitaid and the Bill & Melinda Gates Foundation. Whilst we await the results of the randomised controlled trial (RCT) from Benin, data from the earlier Tanzania RCT, published in the Lancet in early 2022, evidenced a significant impact on malaria prevalence through the introduction of innovative next generation nets, such as BASF's Interceptor® G2. Based on the Tanzania data, it can be reasonably be estimated that 35 million nets distributed in 13 countries could have averted an estimated 8.5 million malaria cases and over 20,000 deaths. The novel indoor residual spraying (IRS) products developed and distributed through the NgenIRS project since 2016 and the 2018-2022 Interceptor®G2 nets from the New Nets Project have cumulatively averted an estimated 20 to 34 million cases of malaria and 65,000 - 88,500 deaths.

During 2022, three large scale epidemiological trials began in Mali, Zambia and Kenya for ATSB® public health impact evaluation. The expected results of these trials, due in 2023/24, will pave the way for this new product class, which will target outdoor malaria transmission.

Semi-field trials of bite prevention tools completed in Thailand, and Cambodia field entomology trials of forest packs, showed significant and perhaps an unexpected reduction in mosquito landing - highlighting the potential of personal and spatial repellents as well as treated protective clothing. In 2018, supported by the Australian Government's Department of Foreign Affairs and Trade (DFAT), IVCC started the Indo-Pacific Initiative with the expectation that we would identify, and where appropriate adapt, the best of technologies developed for Africa in the Asia Pacific region. For ITNs and IRS, this may well prove true. However, evidence suggests that some of the bite prevention tools in forest packs, volatile emanators/spatial repellents, and residual insecticides for temporary shelters such as tents in refugee camps, along with improved delivery of targeted larvicides, are demonstrating encouraging protection of mobile populations and may well have a place in the management of last mile malaria in Africa.

> "The New Nets Project have cumulatively averted an estimated 20 to 34 million cases of malaria and 65,000 - 88,500 deaths."

IVCC continues to explore new market entry opportunities through its New Routes to Market Initiative which we hope will facilitate additional cost-effective entry of new innovations across endemic countries.

Keeping industry partners engaged in vector control innovation is central to the continued evolution of the product pipeline. Whilst incentives for the agrochemical industry to stay the course are limited, IVCC, along with the malaria community, recognises and hugely appreciates their commitment to this critical mission. Working alongside Duke University, IVCC has been exploring the possibility of introducing a Vector Expedited Review Voucher (VERV) to further incentivise industry partners to continue their innovative work. Based on the established FDA Priority Review Voucher, our goal is to have Congressional approval of PRIA (Pesticide Registration Improvement Act) 5, which now contains VERV language, by end of the calendar year.

As IVCC has been doing with its IRS portfolio, the priority now is to deliver additional novel and highly effective ITNs with new modes of action to ensure we can rotate chemistries and preserve performance. Modelling shows that even in the most optimistic coverage scenarios using ITNs, IRS, ATSB®s, seasonal malaria chemoprophylaxis and vaccines, there will be a gap in protection due to residual transmission beyond the reach of current tools. This gap will almost certainly widen due to climate change, urbanisation and a rising number of displaced and hard-to-reach populations.

In 2013, I was privileged to join the IVCC as CEO. I will retire at the end of December 2022 after more than nine years in the role - about three more than I had intended. I feel honoured and privileged to have been trusted with a rare late career opportunity to put my industry training in science and business to such a potentially impactful use. I started in the role with a team of seven, inheriting the tail end of a single 5-year grant and an annual income of $10m. Our mission over the years has not changed: to deliver a complete and robust toolbox of vector control interventions for malaria eradication. What has changed is we now operate in Asia as well as Africa, are a 'bench to impact' PDP and with a full and part time staff of 40 based not just in the UK but in Africa, USA, Europe and India. In the last nine years, we have signed more than 14 grants totalling well in excess of $300m, rising hopefully to more than $400m with the grant renewals pending. The pending grants alone will not get all of IVCC's intervention portfolio across the finish line.

I have worked with some amazing and inspirational people in organisations too numerous to mention. All have one thing in common; an uncanny ability to communicate, create a plan, inspire loyalty and confidence and truly leverage the difference between partnership and a transaction. I would like to thank all my colleagues at IVCC, including Sarah Rees who, like me,

> IVCC's portfolio has never been stronger, enabling lifesaving products to be delivered at pace and scale to those that need them most.

has decided to retire this year. As Portfolio Director, Sarah has played an instrumental role in the evolution of our emerging product pipeline for which we are truly grateful. We all wish her a happy retirement. I would also like to thank our amazing board of trustees and the inspiring past and present board chairs, Sir Mark Moody-Stuart and Sir Stephen O'Brien, all of whom selflessly donate their time to IVCC and its malaria eradication mission. I also want to acknowledge our industry partners and other stakeholders across the vector control and public health communities who have helped IVCC play such a pivotal role in the global battle to eradicate malaria.

With the continued support of all our partners, IVCC will develop, deliver and manage the portfolio of innovative vector control tools and market shaping interventions it has promised, enabling lifesaving products to be delivered at pace and scale to those that need them most. I wish my replacement, whomever they may be, a wonderful experience of this great opportunity to complete the task started in 2005 at the formation of IVCC. Whilst the evolving product portfolio remains strong, its progress and success are dependent on the continued support of our funders. Like any institution, IVCC is not immune from the economic challenges that are being experienced across all sectors of society. The recently announced Global Replenishment Funding target which fell short of its $18bn target is a prime example of this. During the remainder of 2022 and into early 2023, IVCC will be working with its funding partners to renew its grants so that the delivery of its strategy can continue.

Image Credit: Ifakara Health Institute, Tanzania

Product Portfolio

Mathias Mondy
Director - Business Development and Strategy

Danielle Brennan
Project Manager

VECTRON™ T500

VECTRON™ T500 is a new indoor residual spray (IRS) product, based on the active ingredient TENEBENAL™, being developed by Mitsui Chemicals Agro Inc. (MCAG).

TENEBENAL™ provides a new mode of action for IRS programmes (IRAC Class 30), affecting the $GABA_A$ receptor of the insect nerve, offering a new component to insecticide resistance management strategies when deploying IRS products in rotation.

Following the submission of the WHO prequalification (PQT) dossier in September 2021, much of last year focussed on the following items:

- **Registration of VECTRON™ T500 across key markets in sub-Saharan Africa.**
- **Demonstrating excellent residual efficacy of the product against pyrethroid-resistant strains in laboratory, experimental hut and community trials.**
- **Developing market launch plans for target countries in 2023.**
- **Developing key communications materials such as the launch of the VECTRON™ T500 website, information video by MCAG (available on the VECTRON™ T500 website).**

PQ listing of VECTRON™ T500 is imminent, with market launch expected in early 2023.

In some experimental hut and community trials, VECTRON™ T500 has demonstrated residual efficacy of at least 12 months.

The need for insecticide-treated nets (ITNs)

Pyrethroid resistance is now widespread and is reducing the efficacy of pyrethroid-only nets. The market entry of BASF's Interceptor® G2 has demonstrated that introducing new tools restores the protective effect of ITNs. To maintain this gain, we need to develop new generations of ITNs with alternative insecticides which are safe, efficacious and affordable. This will allow national malaria control programmes to implement effective insecticide resistance management through product rotation.

Currently, IVCC supports two ITN projects in the pre-development stage based on novel active ingredients. Other projects are in earlier stages.

As these products are expected to be higher cost than standard nets, IVCC has been exploring different approaches to ITN design to keep the cost of new ITNs as low as possible, looking at technical solutions to minimise the total insecticide loading of ITNs while maintaining robust efficacy.

In addition to net design options, IVCC continually screens the chemical libraries of our industry partners for repurposed or novel chemistries that could be used in new ITNs products to combat insecticide resistance and strengthen the ITN market through availability of a wider range of chemistries.

Developing new technologies is critical to create a complete toolbox adapted to endemic countries.

IVCC is progressing two novel insecticides to be formulated for use in ITNs products.

New product class opening

ITNs and IRS deployments have contributed to reducing the malaria burden for decades. It is now critical to bring to market a new class of products that prevents outdoor transmission. This is technically challenging as products placed outside need to remain efficacious long enough to break the transmission cycle.

IVCC carried out a call for proposals in 2015 to identify projects with potential to address this technical gap. Three projects were selected and evaluated through an at scale proof of concept. The Attractive Targeted Sugar Bait (ATSB®) station developed by Westham Co. (Westham) was tested in Mali and demonstrated a significant impact on the mosquito population. In 2018, the product started an optimisation process to simplify manufacturing and increase quality. Additional studies were carried out in Mali, and further testing was performed in Zambia and Kenya. After review by the WHO Vector Control Advisory Group (VCAG), the protocol for epidemiology evaluation was finalised and the study started in November 2021 in Zambia, March 2022 in Kenya, and April 2022 in Mali. Results are expected in 2024. This project is high risk as this is a completely novel intervention type. These studies will help establish the public health value of the ATSB® product.

Developing new technologies is critical to create a complete toolbox adapted to endemic countries. They help by adapting to the very diverse environments across sub-Saharan Africa and will help mitigate insecticide resistance build up.

Keeping the pipeline open

IVCC is progressing two novel insecticides to be formulated for use in ITNs products. Two other compounds are available at early-stage development. IVCC is engaging with funders to mobilise the necessary resources to continue their development.

IVCC maintains ongoing monitoring of all insecticides to identify leads with potential for vector control product development. Whilst we have now largely exhausted every compound available from the agrochemical industry IVCC continues to progress three strategies to identify potential candidates:

- **We are expanding our screening process to identify chemistries that may work on new product classes such as ATSB® (i.e., by ingestion rather than by contact).**
- **We are investigating the potential of biorationals to check their biological, safety and cost structure profile.**
- **We are collaborating with organisations in the drug environment (e.g., MMV, GSK) to check the potential of their technologies in a vector control delivery mechanism.**

Image Credit: IVCC, Liverpool, UK

IVCC Product Development Portfolio

Enabling Innovation

Capacity Building

IPI - NatNat
(Testing capacity - PNG)

GLP certification
(Testing capacity - SSA)

Automated surveillance

Mosquito attractants

Application technologies

ATSB
Biorationals for ATSB®

Innovation Pool

New insecticidal compounds screening

Bioavailability optimisation

Creating Solutions

Optimisation

ITN
MEA / IXA ITN
Envu
xxxx

Pre-development

ITN
ITN X
Company A
xxxx

ITN
ITN Y
Company A
XXXX

ITN
Sherlock ITN
IVCC
IVC-5743

ITN
TENEBENAL™ ITN
Mitsui Chemicals Agro
TENEBENAL™ Coated

ITN
TENEBENAL™ ITN
Mitsui Chemicals Agro
TENEBENAL™ incorporated

Development

ATSB
ATSB®
Westham
Dinotefuran

Regulatory review

IRS
Sylando®
BASF
Chlorfenapyr

IRS
VECTRON™ T500
Mitsui Chemicals Agro
TENEBENAL™

In Market Evaluation

Market uptake

IRS
Actellic® 300CS
Syngenta
Pirimiphos methyl

IRS
SumiShield™ 50WG
Sumitomo Chemical
Clothianidin

IRS
Fludora® Fusion
Envu
Delta. & Clothianidin

IRS
K-Othrine® Polyzone
Envu
Deltamethrin

ITN
Interceptor® G2
BASF
Alphacy. & Chlorfenapyr

Integrated Vector Mangement

IPI - BITE
(Forest pack - GMS)

IPI -iDEM
(Urban deployment - Malaysia)

ATSB® Project

Dr. Angela Harris
ATSB Consultant

It's been a landmark year for the ATSB® project, with the launch of three large field-based epidemiological studies; the conclusion of which we hope will result in the opening of a new product class of vector control tool for the prevention of malaria.

This year over 353,000 Attractive Targeted Sugar Baits (ATSB®) stations have been shipped to sub-Saharan Africa from the Westham Co. (Westham) facility in Israel where they have been deployed in field sites in Zambia, Kenya and Mali. The project employs over 1,250 personnel across the three countries, including staff, casuals and volunteers in a range of roles from hanging and monitoring the baits, to working with communities to engage residents and educate them on ATSB® stations, to project and data management and coordination. These trials are a truly collaborative effort and a testament to the strong partnerships that have been built over the past 5 years of working together with multiple organisations spanning ten time zones.

> These trials are a truly collaborative effort and a testament to the strong partnerships that have been built.

Our story of collaboration

We have been diligently partnering with Westham to support the development of the ATSB® station since 2015 when we issued a call for proposals to identify innovative solutions against outdoor biting. The encouraging results that followed from a proof-of-concept study in Mali in 2016-2017[1] convinced us that the role of sugar feeding by vector mosquitoes in the peri domestic environment was an innovative approach worthy of pursuit.

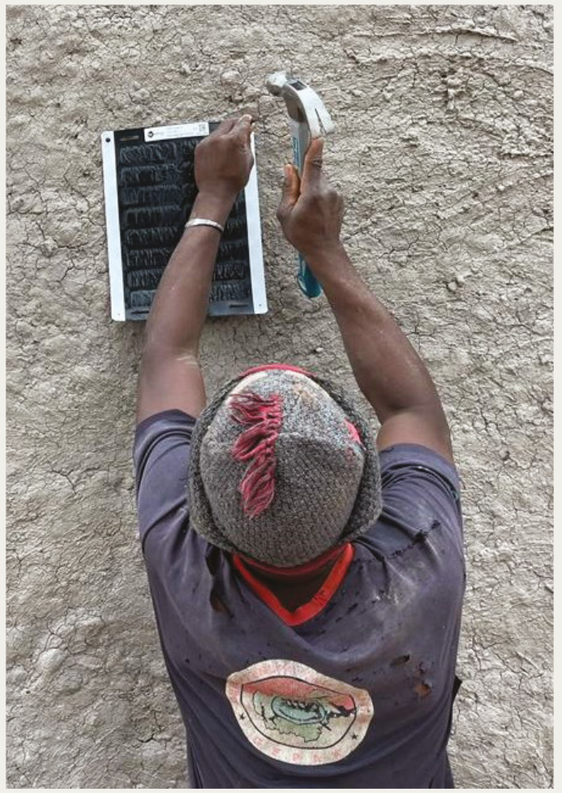
The following years saw the continued development and optimisation of the Westham ATSB® design with rigorous testing of multiple prototypes to ensure field durability. This marked the beginning of the development of the ATSB® station multi-partner collaboration, bringing in teams of researchers in western, southern and eastern Africa to support this field testing and ATSB® stations were put through their paces in the types of environments where ultimately these products will, in future, be rolled out.

In early 2021, together with Westham and the Bill & Melinda Gates Foundation, it was decided to freeze any further product development. This was because we had a tool to take to the field that is durable for at least six months when deployed under the eaves of buildings, and that is effective against a range of vector mosquitoes due to inclusion of the proprietary attractive bait and the use of dinotefuran. Dinotefuran is an insecticide that acts by ingestion, is effective in environments where resistance to traditional vector control compounds is an issue, and via the ATSB® station is presented in a format that means minimal access to non-target organisms.

Our current phase

With the finalisation of the field ready product, pre-trial studies were carried out in all three countries to determine the daily feeding rates of vector mosquitoes on Westham ATSB® stations. With support from modellers at Imperial College London it was confirmed that, in these small trials, feeding by mosquitoes on the ATSB® station was likely at an appropriate level to have an impact on malaria prevalence in our field sites.

> In field trials, feeding by mosquitoes on the ATSB® station was likely at an appropriate level to have an impact on malaria prevalence.



It has been a year of intense activity in all three field sites with the requirement to take on and train vast numbers of personnel, as well as managing the logistics relating to identification of cohort participants. We've also needed to manage the hanging and maintenance of ATSB® stations as well as training cadres of entomology staff for the collection, sorting, identification and dissection of thousands and thousands of mosquito samples, as well as effectively engaging the communities where the studies are taking place. We are grateful for the support and collaboration of our partners in Zambia (including PATH, the Macha Research Trust and Tulane University), Kenya (KEMRI, LSTM and CDC) and Mali (UCRC, USTT-B and LSHTM) as well as our funders from the Bill & Melinda Gates Foundation.

Although, all epidemiological and entomological findings at this stage remain blinded, we have learned much in this past year from the deployment; particularly as relates to maintaining ATSB® stations in the field, ensuring they remain effective and from the interesting and useful feedback we have received from the communities interacting with this new tool. Perhaps one of the most promising findings to date, from the Zambia trial, is that ATSB® stations deployed in the field remained efficacious (so long as they weren't damaged) for their full eight-month deployment. Preliminary data from Kenya and Mali suggests a similar trend which could have far reaching consequences for how long ATSB® stations could be deployed in the field after roll-out in an operational context.

The future for ATSB® stations

As we continue marching forward together with the dedicated personnel supporting these trials, we are enthusiastic about what the next year will bring. We are immensely proud of the multinational collaboration that is the strength of our project and look forward with optimism to further positive results as the epidemiology projects close out in 2023 and early 2024.

Our ultimate goal for these trials is the opening of a new vector control product class; a moment in which we hope progress can be made for this additional tool in the vector control toolbox. An intervention capitalising on an area of mosquito biology not fully explored before, that can fit into resistance management programs and is suitable for domestic use, tackling outdoor active mosquitoes in rural Africa against the scourge of malaria.

Image Credit: Dr Siriman Samaké, Malaria Research and Training Centre, USTTB, Bamako, Mali

[1] Traore et al. (2020) Malaria Journal. 19(1) 1-16

Technical Development

Derric Nimmo
Director - Technical Development

Graham Small
Senior Technical Manager

Svetlana Ryazanskaya
Technical Manager

Janneke Snetselaar
Technical Manager

Stephania Herodotou
Material Scientist

Jason Richardson
Technical Manager

Developing new active ingredients and innovative approaches with partners is core to IVCC's mission to tackle the growing threat of insecticide resistance and prevent vector-borne disease transmission.

There are a limited number of novel insecticides in the mosquito control development pipeline, each costing around $50M to bring to market. These insecticides have utility for several mosquito control products, including indoor residual spraying (IRS), Attractive Targeted Sugar Baits (ATSB®) and insecticide-treated nets (ITNs). They must also be deployed appropriately, i.e., in rotation, to reduce the risk of resistance development and maintain their effectiveness. There is currently an urgent need for new active ingredients for ITNs, due to the lack of choice of different active ingredients and because they are expected to last up to three years, substantially increasing the exposure time of the active ingredients and the risk of resistance development.

The modelling of resistance development, along with the analysis of the challenges of formulation and manufacturing, cost of goods, market dynamics and funding, were used to guide the best strategy for developing and using ITNs over the next 5-10 years. IVCC's net development strategy aims to bring 3-4 efficacious, safe, affordable, insecticidal treated nets with different modes of action by 2030, enabling country malaria programmes to implement their insecticide resistance management (IRM) strategies.

Adding 3-4 efficacious, safe, affordable, insecticidal treated nets with different modes of action by 2030.

IVCC field trials tender process

IVCC has a network of technical support partners, including the Liverpool Insect Testing Establishment (LITE), a network of African field sites, the London School of Hygiene and Tropical Medicine (LSHTM), the Liverpool School of Tropical Medicine (LSTM), Avient and the Nonwoven Innovation & Research Institute (NIRI). Each of these technical support resources has particular expertise and resources that partners use to develop and deliver their products for malaria control.

Following the success of last year's laboratory trials tender process in identifying facilities to support IVCC and its industrial partners with testing insecticides and product prototypes, we launched an open tender process in February 2022 to provide field trial services to IVCC. This process was run through the Liverpool School of Tropical Medicine's Finance, Procurement & Research Services (FPRS), with Liz Wilson (Head of Procurement) coordinating the process.

IVCC is very aware of the continuing debate relating to the power imbalances that exist between global health research organisations in high-income countries (HICs) and those in low- and middle-income countries (LMICs). Therefore, African trial facilities conducting research on malaria vector control were asked to submit tenders directly to IVCC, with experts at organisations in HICs being included as collaborative partners on their tender bids. We believe this approach will help strengthen and sustain the capacity for malaria vector control research in sub-Saharan Africa.

After receiving several high-quality tender responses, tender bids were scored based on several predefined criteria: technical capability; quality control; safeguarding, equality, diversity, and inclusion in the workplace; academic and industry links; and budget. Q&A sessions were held during the tender process to answer queries, and budget clarification was sought.

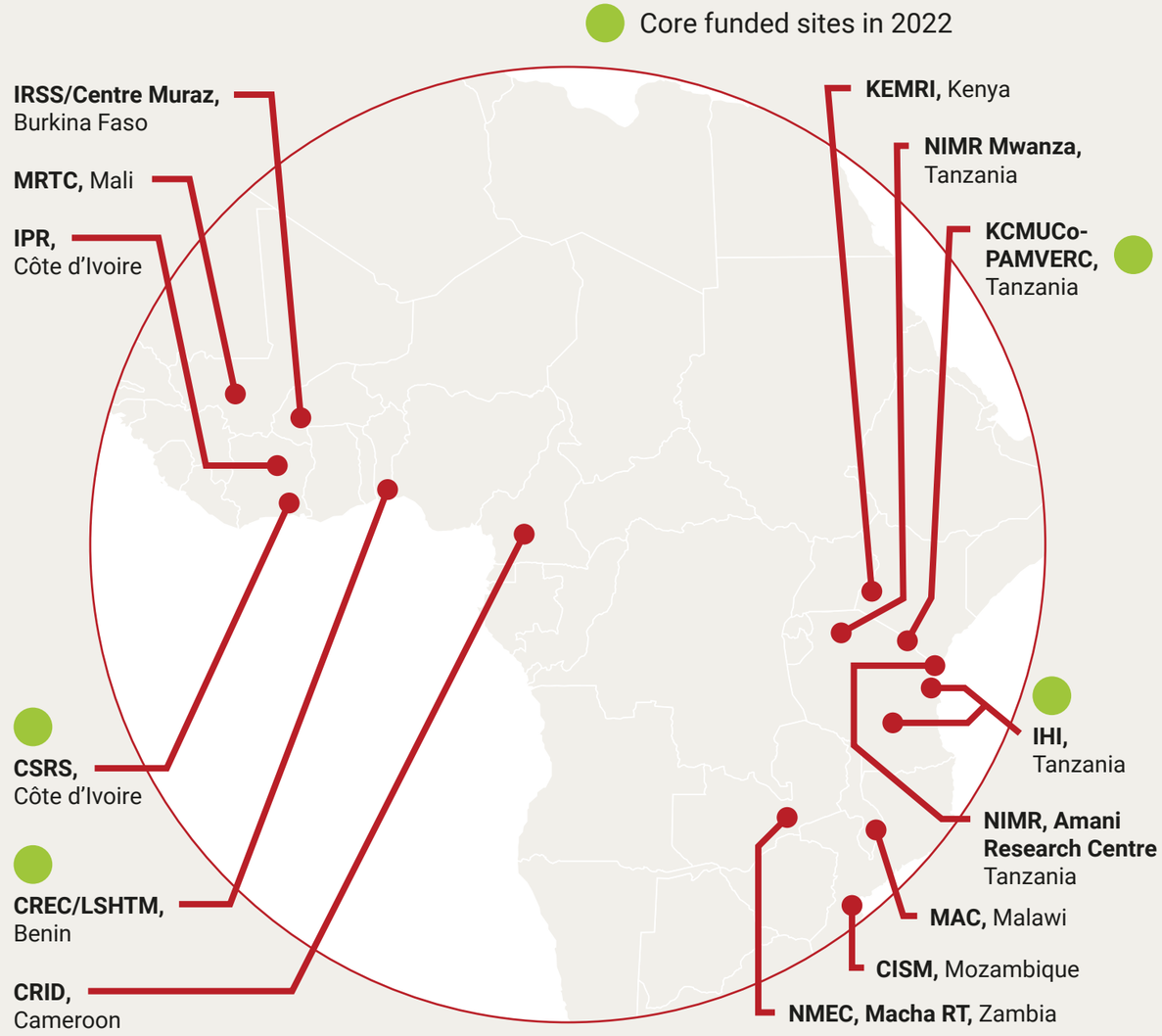
At the beginning of September, the results of the field trials tender process were fed back to all trials facilities who had submitted bids, with two facilities being awarded contracts: L'Institut de Recherche en Sciences de la Santé (IRSS) based in Bobo-Dioulasso, Burkina Faso; and the Vector Control Product Testing Unit (VCPTU) of the Ifakara Health Institute (IHI) based in Bagamoyo, Tanzania. Both trials facilities are well known to IVCC, having run laboratory and field trials in support of our IRS product and ITN development projects over many years.

They are also collaborating facilities on IVCC's Good Laboratory Practice (GLP) certification project, with VCPTU having been awarded GLP certification in 2021 and IRSS awaiting their GLP inspection by the South African National Accreditation System (SANAS).

Jason Moore, Test Facility Manager at the IHI VCPTU facility, said: "The tender is an exciting opportunity for us to fulfil the IHI mandate to improve people's health and wellbeing through research, training and services. We look forward to assisting the IVCC in getting new vector control products to market as soon as possible in order to combat malaria and vector borne disease. It will also provide IHI scientists with welcome new research challenges and we are excited to get started."

Abdoulaye Diabaté, Test Facility Manager at the IRSS facility, also commented: "Progress toward the elimination of vector-borne diseases will never be achieved if the most affected countries are unable to make robust contributions. Winning the IVCC field trial tender is essential for the IRSS insecticide testing facility to achieve its vision of development. On the one hand, it will help to consistently improve the quality of the services we provide and, on the other, it will contribute to building the critical human skillset that is needed to develop high quality vector control products."

African Field Site Partners

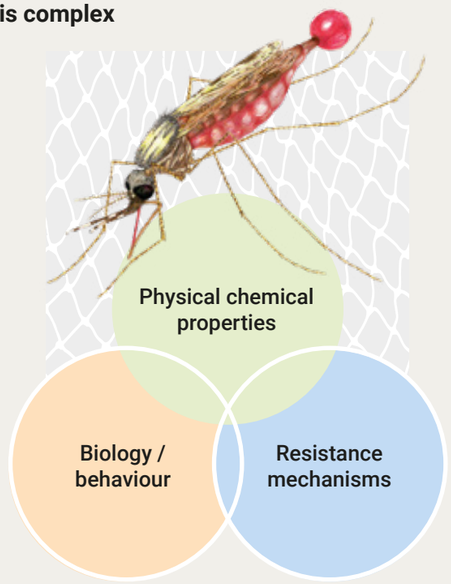


Technical Development

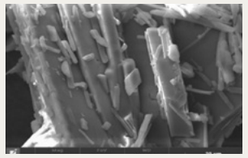
Supporting partners: analytical assessments of ITN formulation prototypes of novel insecticide

IVCC has supported our industrial partners in validating prototype-incorporated net formulations of novel insecticides. Prototype net formulations were evaluated before and after heat setting during the manufacturing process. IVCC provided analytical and LITE resources to show how the different formulations affected the amount of insecticide on the surface, its distribution and physical presentation, and its correlation with bioefficacy in laboratory bioassays. These data allowed rapid selection of the best formulations for further optimisation.

The insecticide-insect interaction with an ITN is complex



Better product development by improved:

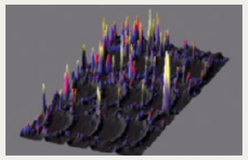


Optimising product formulation

- TGAI (production thermal affects, crystal structure/size)
- Physical state of insecticide (crystalline/amorphous)
- Effect of adjuvants
- Understanding insecticide interaction with substrate

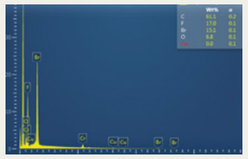
Understanding cuticular/insecticide interactions

- Structure of insecticide and transfer to cuticle/absorption (crystalline/amorphous)
- Effect of adjuvants (absorption through cuticle)
- Resistance (cuticular thickening, SAP proteins)



Linking insecticide properties and bio-efficacy

- What physical state of insecticide is the mosquito exposed to?
- Different crystal forms can affect bioefficacy and longevity
- Crystal size can affect bioefficacy and longevity



Understanding insecticide changes over product life-cycle

- Storage stability
- Changes over time: loss of a.i., changes in structure, regeneration
- Effects of environment (temperature/humidity)

Improving product quality control

Improving product performance, cost and efficacy

Improving the speed of formulation development

Image credits: (Top to bottom) **Image 1:** IVCC, Liverpool, UK, **Image 2:** Steve Gschmeissner / Science Photo Library, **Image 3:** IVCC, Liverpool, UK, **Image 4:** IVCC, Liverpool, UK.

Prototypes selected for further tes

Further formulation optimisation to increase surface area.

Washing the nets to investigate regeneration rate and for any improvements in efficacy.

Testing in hut studies, real-world performance.

Making indoor residual spray (IRS) delivery smarter with the IK Smart Light

Recent progress in developing and launching the next generation of novel public health insecticides should match the best application technology available. IVCC and the Goizper Group, working with IRS implementers PMI/VectorLink and the AngloGold Ashanti Malaria Program (AGAMal), are collaborating to develop a proof-of-concept tool, the IK Smart Light, to assist IRS implementers. The device provides immediate feedback to spray operators to help them deliver accurate target dosage of insecticide, enables programmes to train spray operators more efficiently, and each device collects data during use, allowing managers to monitor applications in real-time. The spray data, including accurate estimates of volumes applied, can be uploaded to the cloud and visualised remotely to immediately alert managers to potential problems.

Operational tests of early prototypes revealed design flaws and durability problems, but these have been resolved in the latest design. Given that the equipment costs for an IRS programme are a small fraction of the overall programme budget, we believe there is a strong business case to justify the addition of the IK Smart Light to IRS programmes. The combined benefits of the reduced training cost, improved quality in terms of accurate wall dosing, enhanced programme management and oversite through real-time monitoring of teams in the field, and the new ability to measure the volume of insecticide applied will not only have a significant impact on current IRS programmes but also promise to make this tool more accessible to a broader set of organisations and communities.

Image Credit: Inigo Garmendia, Goizper Group, Antzuola, Spain

> “Recent progress in developing and launching the next generation of novel public health insecticides should match the best application technology available.”

New Nets Project

David McGuire
Director - Access
& Market Shaping

New Nets Project

The New Nets Project (NNP) continues to expand the market for dual active ingredient (AI) nets, while generating the necessary data to support a WHO policy recommendation for these state-of-the-art vector control tools.

Thanks to the project's impact on catalysing increased availability and affordability, 20 African countries have been able to procure either BASF's Interceptor® G2 nets or DCT's Royal Guard® nets, representing 11% of the total insecticide-treated net (ITN) market. In total, over 35 million Interceptor® G2 and 1.6 million Royal Guard® nets have been ordered or delivered with support from NNP, and thanks to a combination of short-term co-payments and price/volume agreements, the end-of-project pricing targets were met over one year ahead of schedule.

Results from a Wellcome Trust-funded randomised controlled trial (RCT) on the efficacy of dual AI nets in Tanzania were published in the Lancet in early 2022. After two years, Interceptor® G2s were shown to have reduced malaria incidence by 44% over standard, pyrethroid-only nets. In the Royal Guard® net study arm, while no effect was seen on incidence, there was an indication of reduced prevalence, although not statistically significant. A second dual AI ITN trial supported by NNP in Benin was completed in March 2022. The publication of results from this trial is expected before the end of the year.

Results from the Tanzania and Benin RCTs have been submitted to the WHO in support of their policy decision on dual AI nets, which is expected in early 2023.

In addition to the efficacy data generated from the randomised controlled trials, effectiveness and cost-effectiveness data on dual AI nets is being collected by NNP through five evidence pilots across four African countries (i.e., Burkina Faso, northern and western Mozambique, Nigeria and Rwanda). Preliminary analyses support trial data in that distribution and use of dual AI nets seems significantly more effective at controlling malaria than standard ITNs. This data along with a cost-effectiveness analysis of dual AI nets based on these results will be published in 2023.

As NNP concludes at the end of 2022, there will be a focus on transition and scale up of the dual AI net market through both The Global Fund's Net Transition Initiative, as well as procurement by the President's Malaria Initiative and other donors and countries. It is expected that production capacity will expand in 2023 to meet the rapidly increasing demand of countries to distribute now affordable dual AI nets to protect their populations from pyrethroid resistant mosquitoes. To this end BASF are planning to double their annual production capacity and are exploring the possibility of establishing some production in Africa. At the same time, Vestergaard have developed another dual AI net that is currently under WHO-PQ review and could be available in the market by 2023, to meet growing demand driven by promising new data and prices in the range of currently available pyrethroid-piperonyl butoxide (PBO) nets.

“After two years, Interceptor® G2s were shown to have reduced malaria incidence by 44% over standard, pyrethroid-only nets.”

Image Credit: PSI, Mali

New Routes to Market

Andrew Deyi Saibu
African Regional Coordinator

As donor budgets become tighter, in a global economy seeing ever-increasing costs for shipping and raw materials, we must look for innovative strategies to expand access to new, life-saving vector control tools.

IVCC's New Routes to Market (NRM) initiative has partnered with a limited number of high burden countries including Democratic Republic of the Congo (DRC), Ghana, Nigeria, Malawi, Mozambique and Uganda to map out and engage private sector partners for the expanded deployment of indoor residual spraying (IRS). IVCC believes that it is only through these locally driven partnerships that vector control can be expanded beyond the current financial limitations of donor-funded programmes while also building locally owned, sustainable capacity. Based on preliminary assessment, IVCC hopes to help countries increase coverage of IRS by 25% over the next five years.

In its first phase, NRM's focus is on IRS since this highly effective tool has been traditionally under-funded in favour of nets. However, IVCC and its partners plan to use the new platform, once established, to expand the delivery of other highly effective tools coming through the product development pipeline such as dual and novel AI nets, Attractive Targeted Sugar Baits (ATSB®), etc.

To this end, IVCC has worked closely with AGAMal (Ghana) and partner malaria programmes to develop business cases for gas/oil, mining and agricultural companies showing the health, financial and reputational benefits of protecting their employees and host communities from malaria. IVCC is also assisting country partners by looking to build on its positive experience under NgenIRS in expanding distribution of IRS through NGOs and mission hospitals. In addition, the partnership is identifying banks, telecoms and other companies who do not have the ability to implement vector control programmes but are interested in providing financial support to expand coverage as part of their Corporate Social Responsibility (CSR). IVCC and AGAMal are assisting interested companies in assessing needs, costing interventions and mobilising technical and operational support to implement IRS campaigns. Local consultants are being recruited to assist in similar activities in Uganda, Nigeria and DRC under the guidance of the National Malaria Control Programmes (NMCPs) leadership. The Corporate Alliance on Malaria in Africa (CAMA) has become a regional collaborator with IVCC and will help identify potential private sector partners in Ghana, Nigeria and Uganda, while also collaborating on the development of business cases that will be used to convince companies why their investment in malaria prevention is in their interest.

IVCC provided technical support in the form of IRS spray operator training for the Benso Oil plantation (Ghana) during their 2022 IRS campaign. As a result, a total of over 4,000 employees and their families were protected through IRS.

IVCC and GIZ are assisting the Ghana NMCP and AGAMal to expand the partnership to several mining companies that will spray 18,532 structures to protect and an estimated population of approximately 120,000 in the Tarkwa municipality that was identified by the National Malaria Control Programme (NMCP) as a priority target for IRS. The NMCP has also started engaging the Health Select committee in Parliament to adopt two additional high-burden districts to implement IRS. With support from the Ministry of Health, the NMCP is also in the process of procuring the services of a local pest control company to cover the two new districts.

IVCC and **GIZ** are assisting the Ghana **NMCP** and **AGAMal** to expand the partnership to several mining companies that will spray **18,532** structures to protect and an estimated population of approximately **120,000.**

IVCC hopes to help countries increase coverage of IRS by **25%** over the next five years.

Over **4,000** employees and their families were protected through IRS.

Indo-Pacific Initiative (IPI)

Fred Yeomans
Project Manager,
Indo Pacific Initiative

Project NATNAT

Newly Adapted Tools Network Against mosquito borne disease Transmission
PAPUA NEW GUINEA

Whilst malaria rates are decreasing in much of the region, rising rates in Papua New Guinea (PNG) are increasingly recognised as an area of significant concern.

Building national capacities through NATNAT will provide a solid platform to address the unique vector control needs of the country.

Significant Milestone:

Completion of the Belna laboratory and insectary at the PNG Institute of Medical Research in Q2 2022.

A significant milestone was reached in the NATNAT project in Q2 2022 with the completion of the Belna laboratory and insectary at the PNG Institute of Medical Research (PNGIMR) in Madang. Semi-field facilities consisting of a tunnel system, experimental huts and experimental larval habitats are also close to completion, which will represent a significant upscaling of the capacity to evaluate new vector control tools. The bolstering of the entomological capacity within PNG is a cornerstone of the NATNAT programme, which aims to develop a robust framework nationally for the evaluation and adoption of novel products.

In addition to constructing the new facilities, PNGIMR and their partners (Burnet Institute and James Cook University) are also being supported by IVCC to conduct a range of laboratory, semi-field and field trials on indoor residual spraying (IRS), larvicides and spatial repellents - three intervention classes which the partnership believes could be impactful in the country and wider region. A 12-month community IRS trial is due to finish in Q4 2022 with interim read-outs indicating positive entomological impact and high levels of community acceptance. A full analysis including epidemiological indicators will be available early in 2023. This reintroduction of IRS in PNG is also serving as the basis for plans for a pilot in New Ireland province led by the national programme and supported closely by the NATNAT partners.

Planning for community trials of larval source management and spatial repellents has taken place this year ready for commencement in 2023, involving engagement with relevant manufacturers for sample products and the drawing up of trial protocols with experts within the Indo-Pacific Initiative (IPI) advisory group.

NATNAT is also working to support the development of a new generation of entomologists in PNG. For example, a scholarship has also been obtained allowing for a PhD candidate from PNGIMR to visit the Ifakara Health Institute in Tanzania to learn from their expertise in evaluating spatial repellent products.

Project BITE

Bite Interruption Toward Elimination

The last year has been an eventful one for Project BITE with much progress made despite significant challenges related to ongoing time and logistics impacts of Covid-19 and changing transmission rates in the Cambodian forests.

In Q4 2021, an entomological field trial in Mondulkiri province Cambodia, of forest packs containing a spatial repellent, topical repellent and insecticide-treated clothing, concluded with very positive performance of the products (more than 90% reduction in mosquito landing over a 30-night period). The field trial was designed to bridge from the semi-field trials that had been conducted earlier in the year in Thailand to the planned epidemiological study in 2022 in Cambodia.

However, a malaria prevalence survey conducted as a stage-gate before the commencement of the epidemiological trial indicated that the malaria incidence rates would be too low for the trial to be appropriately statistically powered. This risk had always been accepted as implicit when evaluating tools for use in an elimination scenario, but nonetheless dictated a change of direction in the project.

Given the primary aim of Project BITE was to identify tools that would be useful in near-term elimination efforts in the Greater Mekong Subregion, the decision was taken to adapt the original plan and instead run an implementation trial with entomological, feasibility and acceptability endpoints, and some secondary epidemiological indicators that may point to public health impact as an alternative to a traditional, fully powered randomised control trial. Consequently, this implementation trial will begin in Q4 2022.

IVCC is also conducting marketing analysis in Cambodia to map and analyse the consumer and institutional markets for bite prevention tools to understand what potential these markets have to complement donor pathways in promoting the use of quality and effective products.

Despite the challenges of the Project BITE trial, there remains interest amongst national stakeholders and funders in the region in the utility of forest packs, and particularly the spatial repellent. IVCC, along with project partner University of California San Francisco-Malaria Elimination Initiative (UCSF-MEI), remain confident that the tools have a part to play in malaria elimination and control amongst high-risk groups and in humanitarian emergencies. Moreover, Project BITE has helped demonstrate a new paradigm for staged evidence generation of novel products, as well as indicating that bite prevention tools go beyond personal protection to a community impact based on delayed feeding, lethality and reduced fecundity.

Together, NATNAT and Project BITE are providing the foundation and capacities for a significant expansion of the vector control toolbox in the Indo-Pacific.

Image Credit: Health Forefront Organization, Phnom Penh, Cambodia

Vector Expedited Review Voucher (VERV)

Alan Ayres
Consultant

A novel public health use insecticide has estimated development costs of $100-$250 million and often requires a decade of research. Other investments are more attractive creating a disincentive to invest in novel public health use insecticides.

Additional incentives can mitigate the manufacturer's losses which can reinvigorate interest in investments into vector control R&D. In 2017, Ridley, Moe & Hamon co-published a paper[2] in Health Affairs recommending the creation of a Vector Expedited Review Voucher (VERV) based on the Priority Review Voucher (PRV). The PRV programme of the United States Food and Drug Administration (FDA) expedites the review process for drugs that are expected to have a particularly great impact on the treatment of a disease, granting a voucher for priority review to a drug developer as an incentive to develop treatments for disease indications with limited profitability. To date, the U.S. FDA has awarded 60 PRVs over the 14 years since the programme was enacted in 2008.

VERV solution

In a similar way, the VERV would reward the registrant of a new public health use insecticide with a voucher for the expedited regulatory review of a second, more profitable product, with no sacrifices in safety requirements. Faster market entry of the second product would create a financial gain to mitigate the development cost losses on the vector control product. The new vector control chemistry could then become a valuable component of a vector control toolbox for disease eradication. Like a PRV, a VERV could be redeemed for an expedited review of any type of EPA-registered product, or it can be sold.

[2] A Voucher System To Speed Review Could Promote A New Generation Of Insecticides To Fight Vector-Borne Diseases David B. Ridley, et al. (2017) Health Affairs. 36:8, 1461-1468

Additional incentives can mitigate the manufacturer's losses which can reinvigorate interest in investments into **vector control R&D.**

VERV goals, achievements and milestones

US Congressional legislation will be required to authorise the Environmental Protection Agency (EPA) to create and administer the VERV programme.

IVCC's goal was for VERV to be included in FY '23 reauthorisation of the Pesticide Registration Improvement Act (PRIA). The timeline target was passage of the Bill by the end of 2022 or no later than when current PRIA authorisation expiries on September 30, 2023. Additionally, IVCC advocated for VERV funding to be included in the FY '22-'23 U.S. Congress Appropriations for annual EPA funding.

Congress is currently drafting PRIA reauthorisation legislation based on an outline agreed to by the PRIA Coalition, which includes the eight trade associations whose members register pesticide products and a variety of environmental non-governmental organisations (NGO) groups including the Natural Resource Defense Council, EarthJustice and Farmworker Justice. The agreed outline would establish a VERV programme based on IVCC's framework and eligibility criteria. It would also provide $500,000 per year in funding for the voucher programme. Congress, EPA, industry and the NGOs hope that PRIA reauthorisation legislation can be signed into law by the end of this year or early next year, at the latest.

In 2021, VERV language was included in the FY' 22 Consolidated Appropriations Act Report. The Act directs EPA to brief Congress on the merits of VERV. In 2022, IVCC successfully strengthened the FY' 22 language, when the U.S. House of Representatives passed FY '23 EPA funding. The report reiterated the need for EPA to brief Congress on the merits of VERV within 30 days of the Bill being signed into law.

In 2022-23, IVCC will continue providing guidance to the pesticide industry, NGO's, U.S. Congress, EPA and other stakeholders to establish the VERV programme. Increasing understanding and encouraging participation in VERV is a part of a broader initiative to raise awareness of the need for new global public health technologies.

We are hopeful that after four years of driving the VERV debate, we may finally have a programme in US law within the next six months. If PRIA is not passed by the Congress in the earlier timeframes, IVCC will keep pushing forward to have this finalised by the PRIA expiration date of September 2023.

"Congress, EPA, industry and the NGOs hope that PRIA reauthorisation legislation can be signed into law by the end of this year or early next year."

Finance report 2021/22

Duncan Preston
Director - Finance,
Liverpool School
of Tropical Medicine

Financial audit and governance

Financial governance

IVCC is a not-for-profit company limited by guarantee with charitable status. The annual statutory accounts of IVCC are audited by Grant Thornton UK LLP. This ensures compliance with FRS 102, the Companies Act 2006 and the Charities Statement of Recommended Practice (SORP).

IVCC benefits from shared accounting and audit arrangements with its host institution the Liverpool School of Tropical Medicine (LSTM). The LSTM research management team accessed by IVCC has extensive knowledge of all major funders within the sector and the expertise to comply with all external funder audit requirements.

A finance and investment committee made up of senior employees and trustees external to the organisation gives governance oversight on all financial operations of IVCC and meets 3 times a year. A specialist taxation service is provided by external parties to give expert advice on both UK and overseas taxation ensuring IVCC is compliant.

All internal audit work is carried out by RSM Risk Assurance Services LLP, part of a global group specialising in audit, tax and consulting services. In line with a rotational schedule, RSM carried out an internal advisory audit assignment on the topic of Equality, Diversity and Inclusion at IVCC.

A competitive tender process was undertaken during the year, following which RSM was reappointed. RSM's remit is to provide independent and objective assurance to add value and where appropriate make recommendations to strengthen governance and control processes and identify opportunities for operational efficiencies adopting a risk-based approach. An audit committee exists to oversee all recommendations made.

IVCC received an unqualified statutory audit report and no control issues were identified by the external auditor, Grant Thornton UK LLP.

Value for money (VfM)

Value for money is important to IVCC and its stakeholders.

Responsibility for the delivery of VfM is recognized at IVCC and LSTM by virtue of the group operating an integrated purchases and procurement function. This enables IVCC to benefit directly and indirectly from the synergies generated by this centralised procurement function.

The VfM Steering Group ("VfM") is responsible for monitoring the VfM programme and for driving forward the strategy.

Key VfM achievements

Energy Procurement

As reported in the previous year, LSTM group switched from a fixed-term purchasing model for its UK gas and electricity requirements to a contracting model linked to commodity markets and projected usage following a change in energy broker. Through the collaborative procurement contract with TEC (The Energy Consortia), the group has achieved relative insulation from the significant price increases that are impacting the energy market.

Process improvement activity

LSTM group is undertaking a major finance systems replacement project with the objectives of delivering enhanced technological benefits and process improvements in the areas of finance, procurement, and research management services. The group has engaged an enterprise resource planning consultancy.

In January 2022, LSTM commenced a professional services review that aims to consider how changes to ways of working could support future delivery. Finance, procurement, and research management services were in the scope of this project which also extended to other services including IT and human resources. Service providers and service users were also given the opportunity to participate in focus groups, workshops and one-to-one conversations. An external higher education consultancy has been engaged to facilitate the review and provide strategic and operational insights.

Procurement activity

As supply markets have continued to experience upheaval, the procurement team has had another challenging year in securing products within required timeframes and within acceptable cost parameters. Framework membership has offered some insulation from rising prices, but many prices have nevertheless increased.

Early in 2022, the group initiated a supplier change programme to switch IT providers for laptops and associated equipment, which resulted in a more reliable supply chain for IT equipment coupled with a reduction in lead times.

This year, the procurement team has delivered and assisted with a variety of procurement exercises. IVCC has benefitted from many of these procurements. IVCC has also tendered for services in the provision of field testing of insecticides and formulations and marketing strategy for bite prevention tools in Cambodia and other Greater Mekong Subregion countries.

Finance report 2021/22

Financial perfomance

Income for the year of £48.6m was £9.1m up from last year, with resources expended of £47.7m up by £9.3m giving a gain of £0.95m before other recognised gains and losses.

	2022/23*	2021/22	2020/21	2019/20	2018/19
Income	**£35.28m**	**£48.61m**	**£39.44m**	**£38.57m**	**£38.64m**
Expenditure	**£34.64m**	**£47.66m**	**£38.21m**	**£36.59m**	**£37.29m**
Surplus/(Deficit)	**£0.64m**	**£0.95m**	**£1.23m**	**£1.98m**	**£2.35m**

* forecast numbers

A total of £40.96m was spent on direct charitable project activities (2021: £30.9m) with a further £2.2m paid out on project activities undertaken in-house (2021: £2.4m). Core administration support costs of £4.9m (2021: £4.7m) were also incurred in the year.

Income from charitable activities in 2021/22 was budgeted at £43.9m (2021/22 actual - £48.6m, 2021/21 - £39.4m). Total income in 2021/22 of £48.5m represents an 11% uplift against budget (£43.9m).

The largest single variance in the level and composition of the 2021/22 budgeted income from charitable activities arose due to the Foreign, Commonwealth and Development Office (FCDO) income being budgeted at nil (2021/22 actual £5.9m). However, FCDO actually awarded IVCC £5.9m during the year and the active memorandum of understanding (MoU) was extended from March 2022 to March 2023. Growth in total income from charitable activities is driven by the evolution of the ATSB® project and the decision to progress to epidemiological studies, maintaining the trial site programme across three countries.

It is forecast for 2022/23 that income from charitable activities will reduce from 2021/22 actual - £48.6m to £35.3m in 2022/23 representing a contraction of 27% against 2021/22. The principal factor driving the reduction in forecast income for 2022/23 is that the New Nets Project is drawing to its conclusion during 2022/23 with implementing activities due to be completed by 31 December 2022. The New Nets Project accounted for £13.3m in 2021/22 and the 2022/23 budget allocation is estimated at £4.3m.

Image Credit: IVCC, Liverpool, UK/Mitsui Chemicals Agro Inc. (MCAG), Tokyo, Japan

Reserves policy and going concern

IVCC's principal grant with the Bill & Melinda Gates Foundation is currently subject to a no cost extension to 31 December 2022. IVCC was invited by the foundation to submit a proposal defining a further funding contribution from the foundation that would cover the period 1 October 2022 to 30 June 2023. The IVCC bridging grant provides IVCC with continuity of funding as the organisation undergoes succession arrangements at CEO and Board level and the handover of a novel active ingredient by Syngenta AG at the end of the calendar year. The proposal was formally submitted on 25 August 2022 and awarded on 28 September 2022, delivering a funding contribution linked to milestone-based deliverables of up to $16m.

Unrestricted reserves of £9.9m (2021: £8m) are used to finance activities currently out of scope with existing funders, but within the overall mission and objectives of the organisation. IVCC has also indicated to its principal core funder (the foundation) a willingness to allocate up to $4m of operating reserves over the period of the bridging grant and subject to authorisation by the IVCC Board of Trustees.

IVCC aligns with the group policy of ensuring that unrestricted reserves represent a minimum of 6 months' pay expenditure. Resources are managed and committed within a framework of financial planning that ensures it has both sufficient reserves and liquid resources to fulfil the commitments that it enters into.

No contract is entered into unless it can be resourced, including staffing, partner contracts and all contracts in the supply chain.

IVCC has a positive bank balance of £19.5m, investments of £12.9m and no loans outstanding. IVCC's strong asset base is representative of its significant year-end balance of deferred income on research grants. This reflects the holistic approach adopted by two of IVCC's major funding partners which is based on an advanced funding model. It is anticipated that the level of advanced funding will decrease as funders seek to align funds advanced to cashflow requirements over shorter time horizons.

Being part of the LSTM group gives security for IVCC in case of any future cash flow issues, or financial difficulty that may arise. The organisation benefits from this synergistic relationship in terms of high-quality shared services and scientific resources and knowledge.

The Trustees are satisfied that the use of the going concern accounting principle remains applicable.

£40.96m spent on direct charitable project activities.

Resources are managed and committed within a framework of financial planning that ensures sufficient reserves and liquid resources to fulfil the commitments that IVCC enters into.

The organisation benefits from this synergistic relationship in terms of high-quality shared services and scientific resources and knowledge.

Finance report 2021 - 2022

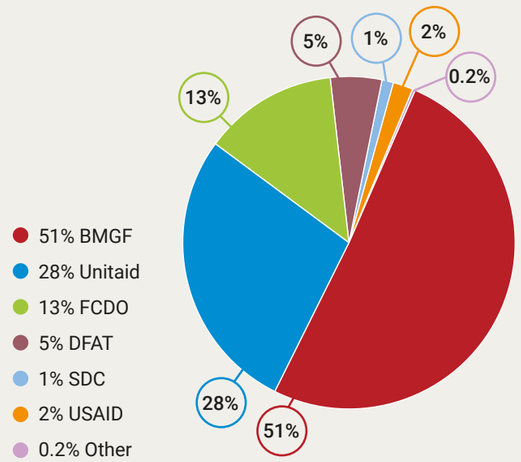
Investments

IVCC continues to adopt a conservative investment strategy.

Short-term surplus cash held is invested in high interest-bearing accounts as part of an overall cash pooling arrangement with the parent company to maximise potential returns and minimise risk. Medium to longer-term cash is invested in low-risk company and government bonds.

The Finance and Investment Committee of LSTM acts as a review body for all finance and investment related activities. A member of the IVCC Board sits on the committee and reports between both organisations on any matters that should be brought to the Board's attention for further discussion.

Income split by funder 2021/22



Funding Mix

The Bill & Melinda Gates Foundation (the foundation) provided 51% of the charity's restricted income from charitable activities in 2021/22, an increase of 22% against 2020/21 actual. Grant income from the foundation rose from £10.6m in 2020/21 to £23.7m in 2021/22, a 124% increase. The foundation has not awarded additional funds to IVCC in 2021/22, and this significant increase is driven by higher utilisation of funds previously awarded in line with a growth in project activity, alongside compensating for a reduction in funds awarded by FCDO in 2021/22 of £2.3m.

Funding from the FCDO, as a percentage of the charity's restricted income from charitable activities is 13%, down from 22% in 2020/21. IVCC's MoU with FCDO was subject to a further extension from an end date of March 2022 to March 2023. By 31 March 2022, IVCC had received all funds scheduled for payment and at this stage, no additional funds have been made available under the active MoU. The 2022/23 budget does not reflect grant income from FCDO however, IVCC is in ongoing discussion with FCDO on appropriate timescales for exploring follow-on opportunities.

Unitaid provided 28% of the charity's restricted income from charitable activities in 2021/22, a reduction of 8%, which is in line with timelines for the final phase of this project which runs to 31 December 2022. This money is ring fenced for specific implementation work on this large-scale market intervention project.

The Australian Government operating through its Department of Foreign Affairs and Trade (DFAT) represents 5% of the charity's restricted income from charitable activities for 2021/22 (2020/21 – 6%). IVCC's Indo-Pacific initiative is due to conclude in June 2023 and negotiations are in progress for a possible no cost extension within the calendar year 2023.

The remaining 3% of income includes 2% USAID and 1% SDC.

The 2022/23 budget reflects a contribution from the foundation accounting for around 78% of the total funding received, with Unitaid at 12% and funding from DFAT, USAID and the Swiss Agency for Development and Cooperation (SDC) making up the remainder. In the event IVCC's combined income falls short of the resource requirement for the established workplan, IVCC will address this through an adjusted workplan reflecting project prioritisation and in consultation with the foundation.

Funding projection 2023 - 2027

Predicted model of IVCC expenditure to 2027

Forecasting provides a base analysis for fundraising activities aimed at financing the portfolio in line with latest projections, operational updates and serves as a framework for negotiation with recipients of IVCC sub-awards as well as a platform for stakeholder engagement.

The sub-grantee cost category is the key driver of IVCC's level of expenditure by period with the novel active ingredients in development being subject to notable sensitivities in terms of the absolute level of development cost per novel chemistry and the phasing of costs linked to a workplan which can be influenced by scientific decision making and other actions linked to the development plan. Workplans are subject to a series of stage gates and the predictive model of IVCC expenditure aims to reflect the higher costs associated with the development stages of the product lifecycle.

Projected expenditure is currently structured around the planned stages of IVCC's existing portfolio of activities and will evolve in line with future vector control outcomes and priorities. The modelling of costs in respect of market shaping interventions is limited to IVCC's established project being the New Nets Project (NNP). IVCC will continue to pursue funding for market shaping activities beyond the NNP project in line with its strategy.

As noted in the Going Concern and Reserves section, IVCC has two active core grants with the foundation running concurrently to 31 December 2022 and 30 June 2023 respectively.

IVCC's active grant with USAID, effective 1 January 2017, is due to conclude by 31 December 2022. The associated budget originally covered the five-year period to 31 December 2021 and during the year, the budget ceiling was increased by $2m and resulted in obligated expenditure of $1.8m for the calendar year 2022.

IVCC participated in a call for proposals which was recently launched by the Dutch Government and is targeted at global Product Development Partnerships.

IVCC is engaging with the Bill & Melinda Gates Foundation, FCDO, USAID and DFAT (Australian Government) in the exploration of potential future funding opportunities.

IVCC Team 2021 - 2022

Funding Partners

Thank you to our generous funders, whose partnership makes life-saving vector control possible.

The Bill & Melinda Gates Foundation and IVCC are a long-standing partnership. The foundation works to tackle critical problems worldwide through building partnerships across the globe. The Global Development Division seeks to help the world's poorest people help themselves in alleviating hunger and poverty, harnessing advances in science and technology to save lives in poverty-stricken areas in the world. The foundation emphasises collaboration, innovation, risk taking and results, which fits precisely with IVCC's mission and achievements. The foundation recognised the urgent need for new vector control tools to fight malaria and other insect-borne diseases and supported the establishment of IVCC as a product development partnership to make it happen.

UK aid is the public face of the newly formed Foreign, Commonwealth and Development Office (FCDO), which is the UK government department with a mission to promote sustainable development and eliminate world poverty. FCDO aims to halve the number of people living in extreme poverty and hunger, combat HIV, AIDS, Malaria and various other diseases, and build partnerships across the world to support development. FCDO's partnership with IVCC has provided a substantial boost to the practical task of developing effective vector control approaches, such as insecticidal treated nets, that have substantially reduced child and maternal deaths and the overall incidence and death rate from malaria.

The Australian Government's Health Security Initiative for the Indo-Pacific region, launched by the Minister for Foreign Affairs on 8 October 2017, contributes to the avoidance and containment of infectious disease threats with the potential to cause social and economic harms on a national, regional or global scale. With funding of AU$300 million over five years from 2017, the Health Security Initiative aims to inform evidence-based planning, help prevent avoidable epidemics, strengthen early detection capacity, and support rapid, effective national and international outbreak responses.

Unitaid is engaged in finding new ways to prevent, treat and diagnose HIV/AIDS, tuberculosis and malaria more quickly, affordably and effectively. It turns game changing ideas into practical solutions that can help accelerate the end of the three diseases. Established in 2006 by Brazil, Chile, France, Norway and the UK to provide an innovative approach to global health, Unitaid plays an important part in the global effort to defeat HIV/ AIDS, tuberculosis and malaria, by facilitating and speeding up the availability of improved health tools, including medicines and diagnostics. Unitaid funds the IVCC NgenIRS market interventions programme to address factors hindering wide-scale use of new resistance breaking insecticides.

The Global Fund is a 21st-century partnership organization designed to accelerate the end of AIDS, tuberculosis and malaria as epidemics. Founded in 2002, the Global Fund is a partnership between governments, civil society, the private sector and people affected by the diseases. The Global Fund raises and invests nearly US$4 billion a year to support programs run by local experts in countries and communities most in need.

USAID is the leading US Government agency, which works to eradicate extreme global poverty, and allow for resilient, democratic societies to realise their own potential. USAID's mission seeks to promote economic prosperity, protect human rights, provide humanitarian assistance in all disasters, strengthen and promote democracy and improve global health.

The Swiss Agency for Development and Cooperation (SDC) is Switzerland's international cooperation agency. SDC's humanitarian aid seeks to reduce global poverty through a variety of methods. This is promoted through fostering economic self-reliance and state autonomies, finding solutions to environment problems, problems in regards to access to education and basic healthcare, and enabling access to resources and services to the greatest number of people. SDC's support to IVCC acknowledges that many of the poorest countries in the world suffer from endemic malaria, which not only kills and incapacitates large numbers of people, but also seriously damages economic development.

IVCC would also like to acknowledge additional NNP funding support provided by the Clinton Health Access Initiative and MedAccess.

IVCC

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Image Credit: Bayer, Monheim am Rhein, Germany