IVCC

Annual Report
2019 - 20

This annual report is dedicated to the memory of Dr Dan Strickman

Sadly, our dear friend and colleague, Dan Strickman, died on the 28th October this year, having fought, with typical good spirits, a rare form of cancer.

Dan leaves behind his wife Linda and three daughters, Rose, Leah and Rachael. Our sincere condolences to all of Dan's family and friends at this time.

Dan was IVCC's Senior Program Officer at the Bill & Melinda Gates Foundation for five years, up until he retired. After retiring, Dan carried on helping IVCC with scientific support and direction. Dan was much loved, admired and respected by all. Not only was Dan an outstanding scientist, he was a genuinely good human being and it has been an absolute privilege for all of us at IVCC to have worked with him as well as call him a friend.

Just before he died, Dan co-authored a seminal study entitled 'Mosquitoes of the World', the definitive reference on the biology, evolution, ecology, and diversity of all known species of the world's mosquitoes. A great scientist, enthusiast and communicator to the end, Dan was a cheerleader for malaria eradication. IVCC and the malaria community will miss him tremendously.

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Perspectives from Funding Partners

For all of us 2020 has been an unimaginable year.

A year in which lives, plans and activities have been turned upside down. As we approach 2021 the global situation remains very uncertain, but our goal for a world without malaria still holds true. We want a world where a preventable and treatable disease doesn't cut short lives, or hold back so many countries from realising their full potential.

While COVID-19 has thrown us many challenges it does not change that goal.

We need innovation to develop new tools and we need to engage the very best partners in that endeavour.

This is why the UK Government is supporting IVCC to develop new nets and insecticides.

During the last year we have been struck by the professionalism, creativity and commitment of the IVCC team in such a complex and fluid time. We are proud to partner with IVCC and we thank them for being such a great team and for demonstrating determination, leadership and grit to get the job done.

Dr Jo Mulligan
Head of Health Research
Foreign, Commonwealth and Development Office
UK Government

IVCC demonstrated strong commitment and perseverance while facing unprecedented challenges due to COVID-19.

In 2018, Unitaid and IVCC launched a new effort to evaluate the malaria-fighting power of mosquito nets with new insecticide combinations. The New Nets Project leverages joint-funding from Unitaid and the Global Fund to unite a consortium of partners under IVCC's leadership to generate evidence on this new class of vector control products. The urgency of growing resistance to pyrethroid insecticides has catalysed the need for new nets and we are proud to be collaborating with IVCC to advance and evaluate these products to inform policy recommendations.

When the COVID-19 pandemic took hold in March 2020, the New Nets project was hit with substantial challenges. The production of nets was suspended in China and Thailand and all field work and data collection was halted from March until June. IVCC responded to this unprecedented situation with agility, resourcefulness, and a level-headed calm that is worthy of great respect. As restrictions were lifted, they were quick to implement COVID-19 mitigation measures to protect health workers and beneficiaries. These measures included a transition from community to door-to-door net distribution as well as the use of personal protective equipment and adoption of social distancing. Through strength of leadership, rapid problem-solving, and a well-coordinated mitigation plan across all partner organisations, IVCC was able to ensure continuity and progress.

As the pandemic continues, the need for effective preventative tools for malaria is greater than ever.

New nets have the potential to prevent and reduce the number of malaria cases, lessening the strain on an already overburdened health system. We look forward to continuing our partnership with this excellent partner.

Philippe Duneton
Executive Director
Unitaid

BILL & MELINDA GATES *foundation*

For years, insecticide resistance has threatened the efficacy of the most powerful tools available to fight malaria.

IVCC has been a leader in ensuring innovation outpaces this threat, by working with partners to develop novel chemistry and formulations to power the next generation of vector control tools.

In the face of both existing challenges and new ones like COVID-19, these tools – and the partnership delivering them – have never been more important.

The Bill & Melinda Gates Foundation is grateful for these efforts and proud to be supporting IVCC's work with a range of donors.

Helen Jamet, Ph.D
Deputy Director,
Malaria, Bill & Melinda Gates Foundation

Australian Aid

We are still in the early phases of this ambitious partnership with IVCC, but are pleased that, despite the challenges posed by the COVID-19 pandemic, with strong engagement from implementing partners.

IVCC are proving to be a strategic, adaptable partner in the development of tools that combat the mosquitoes causing the malaria epidemic. This year has seen them successfully build the appropriate partnerships to begin testing novel tools in Papua New Guinea and the Great Mekong Subregion, as well as modelling what the impact of these tools may be.

IVCC also demonstrated its exemplary leadership by co-sponsoring a session of the Malaria Gamechangers roundtable series hosted in August 2020 by the Asia Pacific Leaders Malaria Alliance. The session engaged health ministries in the region and other key stakeholders on best practice regulation of vector control tools and using innovative delivery channels to access to new and existing tools.

The initiative highlights one of IVCC's key strengths; the ability to bring both people and organisations together around a common goal.

We look forward to continuing this work with IVCC in the years to come.

Robin Davies
Head of Indo-Pacific Centre for Health Security
Department of Foreign Affairs and Trade (DFAT),
Australian Government

Sir Stephen O'Brien

Chair's Foreword
Rising to the Challenge

Working intensively to control the transmission of disease is a challenge that IVCC is certainly familiar with. Since 2005, IVCC has been working with industry and funding partners to discover chemistry to support the development of new Indoor Residual Sprays (IRS) and Long-Lasting Insecticidal Nets (LLINs) to kill malaria-carrying mosquitoes, a disease which is still responsible for the deaths of more than 400,000 people annually.

Today, the COVID-19 pandemic has brought the dangers of disease transmission and the importance of health security into sharp focus for everyone around the globe. Across the malaria community much focus has been on how COVID-19 would impact on the lives of those already dealing with the daily challenge of living in malaria-rife areas of the world. Whilst under-5s and pregnant women remain the most vulnerable, the resurgence caused by the COVID-19 pandemic are predicted to affect a greater number of people across wider age ranges and demographics.

The challenge therefore of keeping malaria control programmes operational has presented significant hurdles, particularly to those working on the 'ground-level' and in the field. As many countries approach their wet season, there is increased urgency and need to ensure that bed nets are distributed, and Indoor Residual Spray (IRS) campaigns are implemented in a COVID-19 secure manner to avoid already fragile health infrastructures becoming completely overrun.

Funding

It is no surprise that the global funding environment for disease control has had to adapt to current events. IVCC's strong funding base has given some funding partners the flexibility, where appropriate, to reschedule their grant renewal timetable. This means that IVCC will restart its grant renewal process with the Bill & Melinda Gates Foundation and the UK's newly formed Foreign and Commonwealth Development Office (FCDO) into which DFID has been folded in 2021. Earlier in the year, however, we were delighted to confirm the renewal of our grant with the Swiss Agency for Development and Cooperation (SDC). SDC has been an active supporter of IVCC's mission since 2014 and this new grant of 4.4M CHF (4.85M USD) will run for a further 4 years until 2025. We are extremely grateful for their continuing support.

Before the COVID-19 exigencies struck, IVCC had undertaken a major strategic review. The outcome, in a combined rigorous analysis between the Executive, the Board of Trustees and its funders, was strongly affirming of IVCC's momentum and direction, and the means by which it will deliver a well-honed plan to get there. As part of this comprehensive approach, a strong organisation-wide succession plan has been pulled together, along with a clear implementation plan to ensure that IVCC adapts in step with the demands of the strategy and resources, to deliver the outcomes and impacts we have set our high ambitions to achieve. I wish to place on record here the leadership throughout of our CEO, Nick Hamon, in successfully guiding and involving the whole organisation through such a challenging and rigorous process.

Board of Trustees

During the year a number of Trustees stepped down from the Board in accordance with the maximum term limits in the Companies Acts rules, having completed their final 3-year tenure and any extensions. I speak on behalf of everyone in the IVCC family, past and present, in paying a deep and heartfelt thank you to each and all three who have helped underpin and drive our continuing success. We are immensely grateful to David Brandling Bennett, Martin Cooke and Karmen Bennett for the outstanding service, insight and countless commitments they have provided IVCC during their respective terms.

We have been delighted to welcome Elizabeth Chizema onto the IVCC Board of Trustees. Elizabeth is a Board member of the End Malaria Council National and is Coordinator at the Ministry of Health Zambia and the African Leaders Malaria Alliance (ALMA).

Photo Credit: PSI Mali

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She also sits as Co-Chair on the Bill & Melinda Gates Foundation Malaria Strategic Advisory Panel and was appointed to the RBM Partnership Board in 2020.

Qiyong Liu was due to retire after his final 3-year tenure but has accepted to remain on the Board for a further year as the representative for the Indo-Pacific region and as we seek as suitable successor to maintain our strong engagement with that part of the globe.

Pascal Housset who would be due to retire in December 2020, has agreed to remain as a Trustee for a further 12 months to give the Board time to find a replacement, particularly given the importance of IVCC's strong, maybe unique, link and partnership with the agro-chemical industries worldwide.

I am immensely proud to see how, in the face of a global pandemic, everyone at every level at IVCC has risen to the challenge of not only 'keeping the show on the road' but making significant advances in delivering on its mission.

Whilst remote working was something IVCC already had good experience of managing, the speed and flexibility demonstrated by the IVCC workforce, has meant that IVCC remains on track with relatively little slippage in terms of time to delivery. For that and all their continuing determination, skill and collective endeavour, on behalf of the Board of Trustees and all our many funders, partners and other stakeholders, not least those in malaria-affected areas of the world I congratulate our CEO, Nick Hamon, for his clear and decisive leadership, all his Executive team in strong support, and all the IVCC teams in every part of the organisation, for their dedication and commitment during these challenging times.

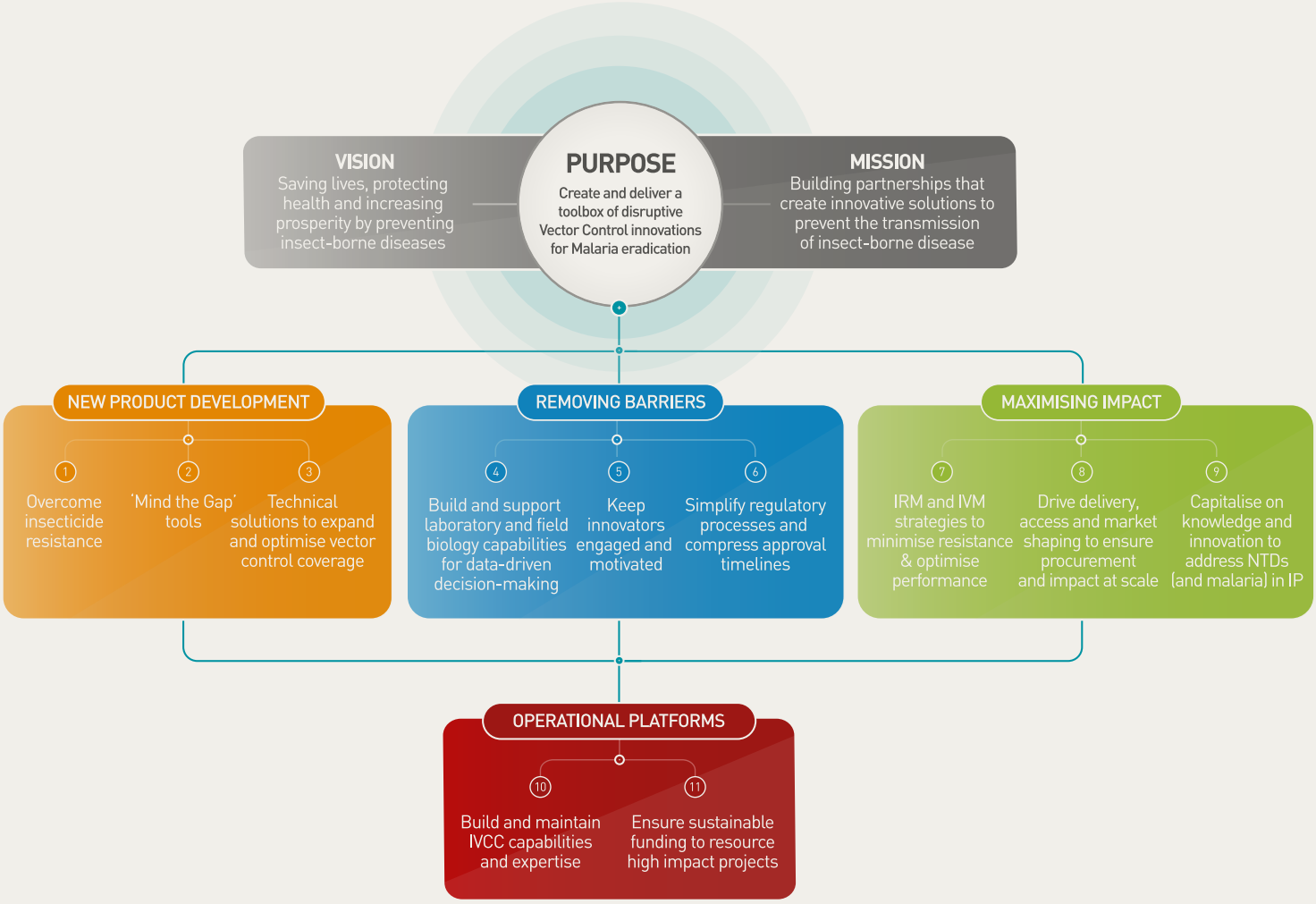
I should also like to record my thanks for the wisdom, mutual support, strong governance and challenge of the Board of Trustees, and their collective confidence in IVCC and our partners, especially through this global emergency.

This foreword is intended to strike a positive and optimistic note in a global atmosphere which feels like it is under an unrelenting low dark cloud – IVCC is showing its resilience, nimbleness and adaptability to keep a constant focus on its goals and how its people will work together to overcome and rise to this unprecedented challenge of our time.

The Right Honourable Sir Stephen O'Brien KBE
Chair - Board of Trustees
IVCC

Strategy Overview

At the end of 2019, IVCC set out to take a fresh look at its strategic roadmap. We started our strategy refresh by answering one simple question: In the context of vector control, what does modelling, good science and experience tell us is needed for malaria eradication?



CEO Overview

Dr. Nick Hamon

There are few organisations, particularly those working in public health, that have not been negatively impacted by the COVID-19 pandemic.

However, we refuse to let the pandemic define IVCC or detract from the incredible progress made over the past year. We have adapted the way we communicate and learned a great deal about our relationship with funding and industry partners, who have continued to work together to support each other and to minimise the impact on programmes, timelines and deliverables; for that we thank them all.

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We identified six simple deliverables. We need:

1. Proven tools (Long Lasting Insecticide Treated Nets and Indoor Residual Sprays) that will work against resistant mosquitoes right through to malaria eradication.
2. New disruptive tools such as Attractive Targeted Sugar Baits (ATSB®) to block outdoor transmission of malaria.
3. To ensure impact, we need to increase intervention coverage by optimising intervention costs through improved efficacy of new and existing tools.
4. Data driven decision making supported by surveillance tools, recognising that universal coverage of interventions is not feasible,
5. 'Last mile' innovations to protect mobile populations and those that live in vulnerable urban settings
6. And finally, and perhaps the most challenging, full collaboration of all stakeholders in the delivery of interventions.

These six specific deliverables are underpinned by four pillars: new product development, removing barriers to delivery, maximising impact and delivering an effective operational platforms.

IVCC now has three new insecticide in full development with novel modes of action, allowing for insecticide resistance management. Broflanilide IRS, partnering with Mitsui Chemicals, is in development as VECTRON™ T500 and two additional novel AIs in development, one owned by IVCC and the other by Syngenta, with a focus on novel LLIN formulation.

This has resulted in the need for new capabilities, including establishing a strategic alliance with Avient Corporation to support masterbatch formulation on non-registered chemistry, with further formulation partnerships under consideration for development of coating formulations and experimental net production. This capability allows IVCC to act as broker for exploring dual insecticide LLINs between manufacturers owning different Ais. At the same time, we are keeping the novel active ingredient pipeline open, continue to monitor all intellectual property and evaluate candidate compounds with suitable entomological, toxicological and physical profiles as well as re-screening selected novel chemical leads to see if slower acting chemistry with potential for LLINs.

To address outdoor transmission, the new Attractive Targeted Sugar Bait (ATSB®) station has passed the non-inferiority test and the design is being fine-tuned for durability. Entomological data looks encouraging, leading to more evaluations in 2020 and 2021 and a revised epidemiology plan aimed at triggering field studies in 2022. To increase coverage and lower costs, we are demonstrating the technical feasibility of long-lasting IRS through improved bioavailability on porous surfaces and nets, looking at new generation sprayer available to improve IRS application and training efficiency as well as exploring consumer vector control products through new business models. We have also started a major Net Design Initiative with the objective of delivering the same efficacy with less insecticide, assessing fabric and net construction with the goal of making dual active ingredient nets as cost-effective as possible

All IVCC industrial partners are still actively engaged in vector control and innovation.

Three workstreams have been established by ZERO by 40 industry partners; building an IRM/IVM platform, addressing technical challenges and 'One Voice' communications - One industry partner has agreed to provide access to patented formulation technology and know-how to help its competitors see if it can improve bioavailability, longevity, reduce costs.

The IVCC-led NgenIRS initiative came to a close in 2019 having achieved its goal of establishing a sustainable, growing and competitive market for next generation, longer lasting and resistance-breaking insecticides for indoor residual spraying, and in doing so saved or protected many thousands of lives, leaving a solid platform upon which IVCC and others can build. The NgenIRS team, made up of colleagues from PATH and Abt Associates, worked in partnership with 16 malaria control and elimination programmes across Africa, the US President's Malaria Initiative (PMI), and three insecticide manufacturers to increase the use of next generation indoor residual spraying products. Today, because of this partnership, there are three new insecticide products for countries to choose from, affordable prices and a stable market. More countries are introducing or re-introducing IRS, a powerful tool that can stop mosquitoes and help meet the challenge of ending malaria. The downward trend in IRS use was reversed and the resulting expansion of use has resulted in significant public health impact.

IVCC now leads a partnership on the New Nets Project (NNP) which is piloting insecticidal nets treated with new insecticide combinations in moderate to high transmission areas throughout sub-Saharan Africa. This consortium of partners seeks to establish the evidence needed to support a WHO policy recommendation. Since its inception in August of 2018, IVCC has established partnerships with 2 net manufacturers (BASF and DCT) and 10 national malaria programmes to conduct a randomized control trials (evidence pilots to measure both epidemiological and entomological impact and operational pilots to develop best practice guidelines for the introduction of multi-product campaigns including dual-AI nets.

The focus is on suitability for urban environment and migrating populations (outdoor protection), addressing regional access and regulatory hurdles and modelling to predict the impact of novel vector control interventions in selected areas of the Indo-Pacific Region.

We are making progress on selecting a portfolio of vector control products available for South East Asia, targeting Anopheles and Aedes with malaria tools developed for Africa.

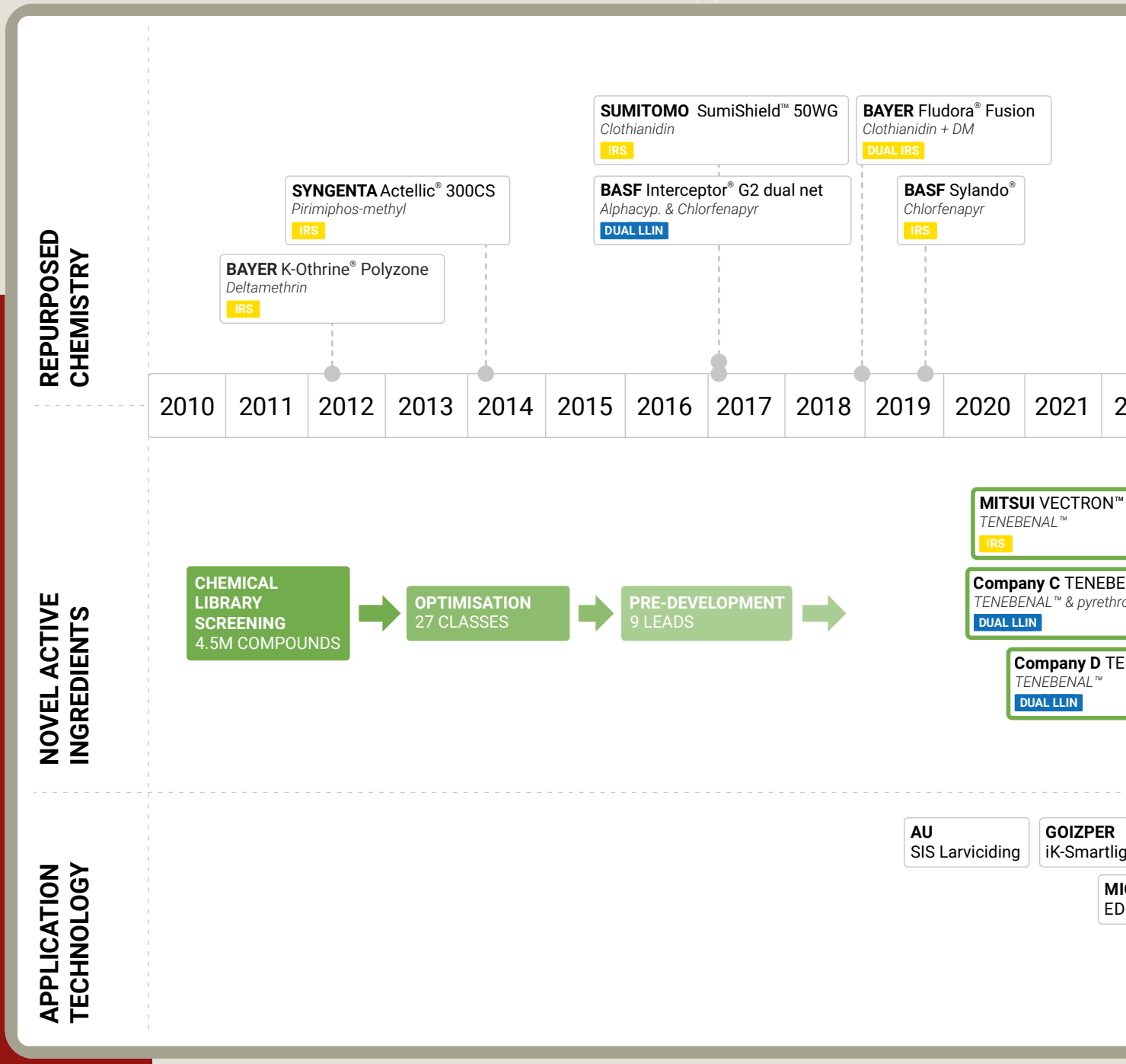
We are also investing in the rapid assessment and adoption of vector control tools in Papua New Guinea; Project NATNAT with field and semi-field-testing capabilities and effective bite prevention tools and Project BITE in forest packs amongst forest workers.

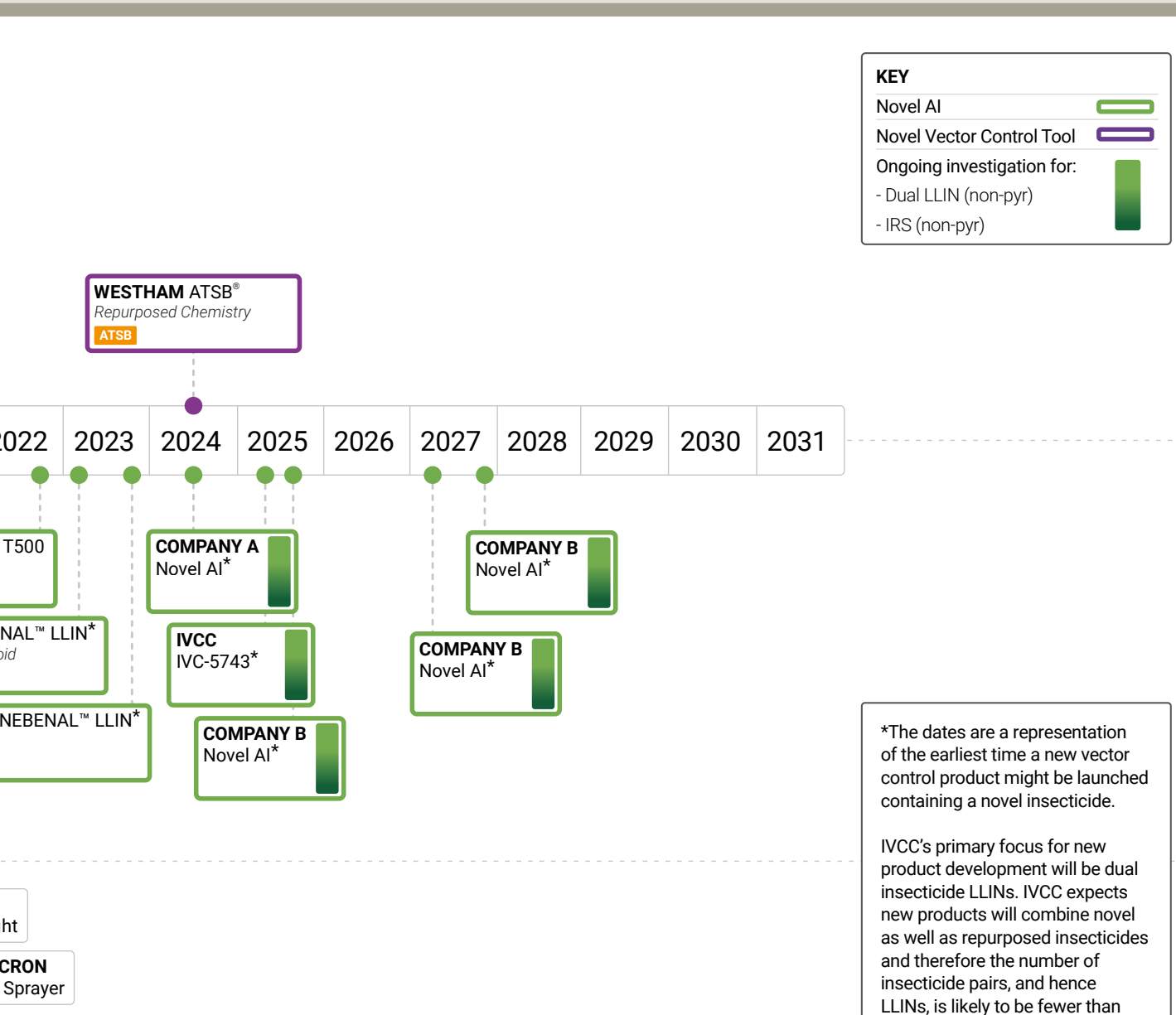
To ensure IVCCs capabilities and are fit for purpose, we have adapted our strategy, leadership and resource management to reflect IVCCs growth and impact. IVCC has entered a challenging transition period between closing current grants and opening new ones, allowing us to tighten alignment with malaria needs and funder strategies. IVCC product development timelines are not-unexpectedly experiencing delays. However, IVCC has demonstrated extreme resilience under pressure. What we need now is the continued long-term commitment from funders to sustain and accelerate progress.

Dr. Nick Hamon
CEO
IVCC

Photo Credit: Bayer

Product Development Portfolio




KEY
Novel AI
Novel Vector Control Tool
Ongoing investigation for:
- Dual LLIN (non-pyr)
- IRS (non-pyr)
WESTHAM ATSB®
Repurposed Chemistry
ATSB
2022
2023
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CRON
Sprayer
*The dates are a representation of the earliest time a new vector control product might be launched containing a novel insecticide.
IVCC's primary focus for new product development will be dual insecticide LLINs. IVCC expects new products will combine novel as well as repurposed insecticides and therefore the number of insecticide pairs, and hence LLINs, is likely to be fewer than the number of insecticides shown.

Product Portfolio Review

Dr. Sarah Rees
Director – Portfolio Management

IVCC's strategy to deliver effective control of malaria-transmitting mosquitoes is to discover insecticides with which to develop new IRS and LLINs to kill pyrethroid resistant mosquitoes.

Significant progress continues to be made and during the past year we have seen the progression of two novel insecticides into the development stage, both of these compounds were discovered as part of our partner discovery screening investments, and provide insecticides with new modes of action for vector control.

The insecticide development stage means that work is now focussed on the scale up and process optimisation of these insecticides for manufacturing, and initiation of the essential regulatory toxicology study programmes necessary for the registration of a new insecticide. Both novel insecticides are fast-acting and kill pyrethroid-resistant mosquitoes and as such offer significant potential as insecticides for use in LLINs.

However, the design and development of LLINs comprising new insecticides presents significant challenges to manufacturers and funders alike. The use of new insecticides for vector control brings the obvious advantage that there has been no selection pressure for resistance in the target mosquito populations, however as with many new products the manufacturing process takes a while to realise economies of process optimisation and of scale.

This presents a real challenge in creating products which are going to be competitive on price in a market historically dominated by generic, old insecticides which are available at low prices. IVCC is exploring ideas for innovation in fabric and net design to find ways to reduce insecticide loading and thereby cost, while maintaining performance.

A further challenge is to ensure that funders realise a worthwhile return on their investment, the cost of new insecticide discovery and product development can total up to $50M and take 10-15 years. Insecticide longevity is imperative as it is increasingly difficult to find new insecticides to replace those which lose efficacy due to resistance and so it is essential that new insecticides provide effective reduction of malaria transmission for as long as possible.

To deliver vector control, and to reduce the risk of resistance, insecticides should be efficacious and with a residual activity commensurate with product cycle. In the case of LLINs a net is expected to demonstrate 80% mortality in hut studies and to be effective for 3 years to meet WHO performance requirements. For an insecticide on a net this represents a significant technical challenge, a tailor-made formulation is required for each insecticide to match their unique properties. IVCC works in partnership with the industry experts to optimise formulation recipes for each new insecticide that will deliver the target performance parameters.

The sustainability of new insecticides requires that products are designed and deployed in ways to avoid insecticide resistance happening. In terms of product design this means that a 'fully effective dose' of insecticide should be present throughout the product's life, to give full vector control; for example, it should not wash out during the normal upkeep of nets. To avoid emergence of insecticide resistance the use of a different, second insecticide to quickly kill any newly resistant mosquitoes is advisable.

A typical strategy to achieve this for LLINs is to make a mixture of two insecticides, but as already indicated this is both technically and economically challenging. In the case of designing dual insecticide LLINs it is often the case that the insecticides which might make a good mixture match belong to different manufacturers.

IVCC can play a useful role in bringing manufacturers together to explore collaborative product design and to develop the most robust solutions to drive down malaria transmission.

Technical Projects

Dr. Derric Nimmo
Director - Technical Development

The recent extraordinary changes in the world brought about by the COVID-19 pandemic have been challenging. However, it has highlighted the incredible commitment and resilience of the IVCC team and its partners near and far.

We realise the need to ensure that vector-borne diseases, such as malaria and dengue, are not neglected. Our mission is to build partnerships that create innovative solutions to prevent the transmission of insect-borne disease, and we cannot do this without the commitment of funders and partners across the world. 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) and more recently Avient. Our partners have been working hard to provide a COVID-19 safe environment for their staff so that we can continue the essential research required to keep on track and bring new insecticides and tools to the market.

As we move forwards with the development of Long Lasting Insecticide Treated Nets (LLINs) with these new insecticides, IVCC is investing in strengthening manufacturing platforms for development and testing. A significant gap across the net production industry is the capability to create medium-scale masterbatch materials for research and development for non-registered active ingredients. This gap is currently a rate-limiting step in the progression of several IVCC projects to bring novel LLINS to the market. In collaboration with Avient, a masterbatch facility, with high levels of containment, disposal and specialist staff, with the capability to use non-registered actives ingredients will be operational early 2021. Throughout the challenges of the past year, IVCC and its partners have continued to make significant progress.

Formulation and Bioavailability; Evaluating and Understanding New Insecticides

As we move forwards with the development of products with new insecticides, several challenges in the fields of product assessment and efficacy testing need to be addressed. Many of the new insecticides require different methods of evaluation to pyrethroids, requiring the development of modified or new assays through IVCC, LITE and LSTM teams. Also, pyrethroids are a well-understood class of insecticides that have properties well suited to the current mainstay of malaria control, IRS and LLINs. However, the different properties of new insecticides have presented challenges and have required substantial investment of time and effort to understand. Part of understanding a new insecticide is testing the efficacy of different formulations, and another is understanding the bioavailability of the insecticide. Several methods are being used to assess the relationship between the bioefficacy of a product and the surface concentration and structure of the insecticide. These include the standard SEM imaging techniques combined with more recent imaging systems such as MALDI-ToF and Raman spectroscopy. The aim is to accelerate formulation and product development through improved understanding of the relationship between how these new insecticides are presented on a surface and bioefficacy.

Registration of New IRS Product: VECTRON™ T500

In collaboration with LSHTM, IVCC has been supporting the conduct of laboratory studies and experimental hut studies in Benin and Tanzania of VECTRON™ T500 from Mitsui Chemicals. Together, we will also initiate two large-scale community studies, starting within the next year, which will include over 6000 households in Benin and over 3000 households in Tanzania.

These trials will provide data on the residual efficacy of the product on various surfaces and against a range of malaria vector species for WHO evaluation purposes. To meet the country requirements for registration of VECTRON™ T500, community studies and experimental hut studies will be conducted. The first of eleven in-country trials is scheduled to commence in December 2020 at the Noguchi Memorial Institute for Medical Research in Ghana, and will be followed by trials in Burkina Faso, Cameroon, Côte d'Ivoire, Ethiopia, Kenya, Nigeria, Tanzania, Uganda, Zambia and Zimbabwe in the coming two years.

Improved IRS

Indoor Residual Spraying (IRS) has been one of the most widely used and impactful vector control tools to date. It has played an essential role in each of the 37 or more endemic countries to successfully eradicate malaria in the 20th century and still protects approximately 135 million people worldwide today. However, a combination of environmental, entomological and economic challenges have limited the use of IRS solutions and reduced coverage. A market-shaping intervention project, NgenIRS, funded by Unitaid (2016 – 2019), has created a more stable, growing and competitive market for new long-lasting, non-pyrethroid insecticides, at affordable prices. Modelling indicates that there needs to be minimum of a 3X increase in coverage of IRS, in combination with increased coverage of other tools (LLIN's, ATSB®, SMC and vaccines) to achieve the eradication of malaria. The Improved IRS initiative aims to increase the coverage of IRS by reducing costs and increasing longevity; this is pivotal for the continued success and a critical component of future Integrated Vector Management (IVM) toolboxes.

iK SmartLight

As part of a broad interest in improving IRS delivery IVCC has partnered with the Goizper Group (www.Goizper.com) to build and test a tool to assist IRS programs during training, spraying and post spray monitoring. The features of the prototype iK SmartLight device include: (1) a buzzer that sounds every second to give an accurate time reference for the spraying speed, (2) a sensor that will measure the spraying distance from the nozzle to the wall, (3) a three colour LED light that will be in green, when the spraying distance is correct (45 cm), red if spraying distance is too far "sub dosing" (more than 50 cm), or blue if spraying distance is too close "underdosing" (less than 40 cm), (4) a memory card that will record all the spraying data and (5) a mobile application that will show the result of the spraying quality.

The prototype device has been tested with PMI, and Goodbye Malaria in Africa and results have been quite promising. The iK SmartLight was seen as a great training tool for improving IRS applications and consistently ranked as an easy-to-use tool that perceived to increase spray quality in the field. Goizper Spraying designing engineers are working on the latest upgrade of the iK SmartLight, and a large field trial is planned for 2021 to evaluate the operational benefits of using this new tool in real IRS programmes.

Targetted IRS for *Aedes* Control

As part of IVCC's work on improving IRS, a field entomological cluster randomized trial of the efficacy of targeted IRS (TIRS) for *?cbcq* control was conducted in Merida, Mexico. By spraying resting sites such as exposed low walls and under furniture, IRS application can be focalized, reducing unnecessary exposure to pesticides, as well as the time it takes to spray a premise.
The trial, completed this year, demonstrated significant and sustained reductions in Ae. aegypti abundance for up to 7 months for Actellic® 300CS and six months for SumiShield™ 50WDG. Applying both insecticides as TIRS led to an application time of ~nine minutes per house and insecticide use of 1 L per house, providing a strong operational cost-savings compared to classic IRS; which take three times as long to apply and use three times the insecticide.

An NIH-funded epidemiological trial is planned to generate additional evidence for TIRS for Aedes control, and the lessons learned from the project should lead to a more rational, targeted and cost-effective approach for *?lmnfcjcq* mosquito control to prevent malaria.

The Importance of Surveillance and Monitoring

Improved monitoring and surveillance was highlighted as a core intervention in the recent WHO Global technical strategy for malaria. Accurate and timely entomology data is crucial for understanding vector populations and associated risks, to best target new vector-control efforts and maximize the impact of new technology.

IVCC is addressing the need for improved surveillance and monitoring tools to facilitate country-level decision-making. To achieve this, IVCC is collaborating with leading research partners on three projects focusing on innovative monitoring techniques, rapid and accurate morphological identification of mosquito species, and novel attractants to improve trapping of Anopheline vectors. Projects entail a proof-of-concept approach to develop and evaluate tools that enhance existing efforts and have practical applications in the field.

Successful Delivery of Access to New Products Demands End to End Thinking

Dr. Tom McLean
Director - Access

The successful achievement of protective impact with products developed by IVCC and other PDPs requires that we rigorously challenge the routes to access to these products for protection of the populations at risk from the initial product conception through the development process and eventually in the lead up to launch, scale up and use. We do this by end to end engagement of the access team in the product development process.

David McGuire
Programme Director
New Nets Project

Business and Impact Cases

The Access team works with the product development partners to create both the impact case and a business case for the product.

The impact case addresses the questions of what contribution this product would make to the control and eventual elimination of malaria whilst the business case ensures that the product can be commercially viable at a price that is affordable to the malaria control campaigns. The impact and business cases are intimately interdependent because both depend on forecasts of uptake and usage at different price points. All the partners are seeking to find the sweet spot at which high uptake drives economies of scale which brings down costs for the implementers encouraging greater uptake in a virtuous spiral to high impact.

Total Cost of Ownership

At the heart of the business case process is the exploration of the costs of the product and IVCCs development partners have been generously transparent in sharing detailed internal information to understand this.

These studies go much further than the conventional Cost of Goods analysis and include all the internal costs of development, manufacturing marketing and administration of the product as well as company overheads. Extending the analysis of these costs over the complete lifecycle of the product has allowed us to show that products with short term cost challenges at the launch phase may be highly cost effective in their later years. This analysis was the foundation of the highly successful volume guarantee developed with MedAccess and the Bill & Melinda Gates Foundation for the introduction and scale up of the Interceptor® G2 net.

Malaria Commodities Forecasting

Business and Impact cases depend upon forecasting of demand and uptake of the product. However, these products do not exist in isolation and changing demand for one product will alter demand across all malaria control products including treatment and diagnostics. The imminent arrival of the RTSS malaria vaccine will also have a large and as yet unclear impact as countries turn some of their funding to malaria immunisation. IVCC has joined a partnership with the Clinton Health Access Initiative and Bill & Melinda Gates Foundation to develop integrated forecasts of malaria commodities demand in both the short and long term with the intention of understanding how the arrival of new products across the intervention spectrum will affect uptake.

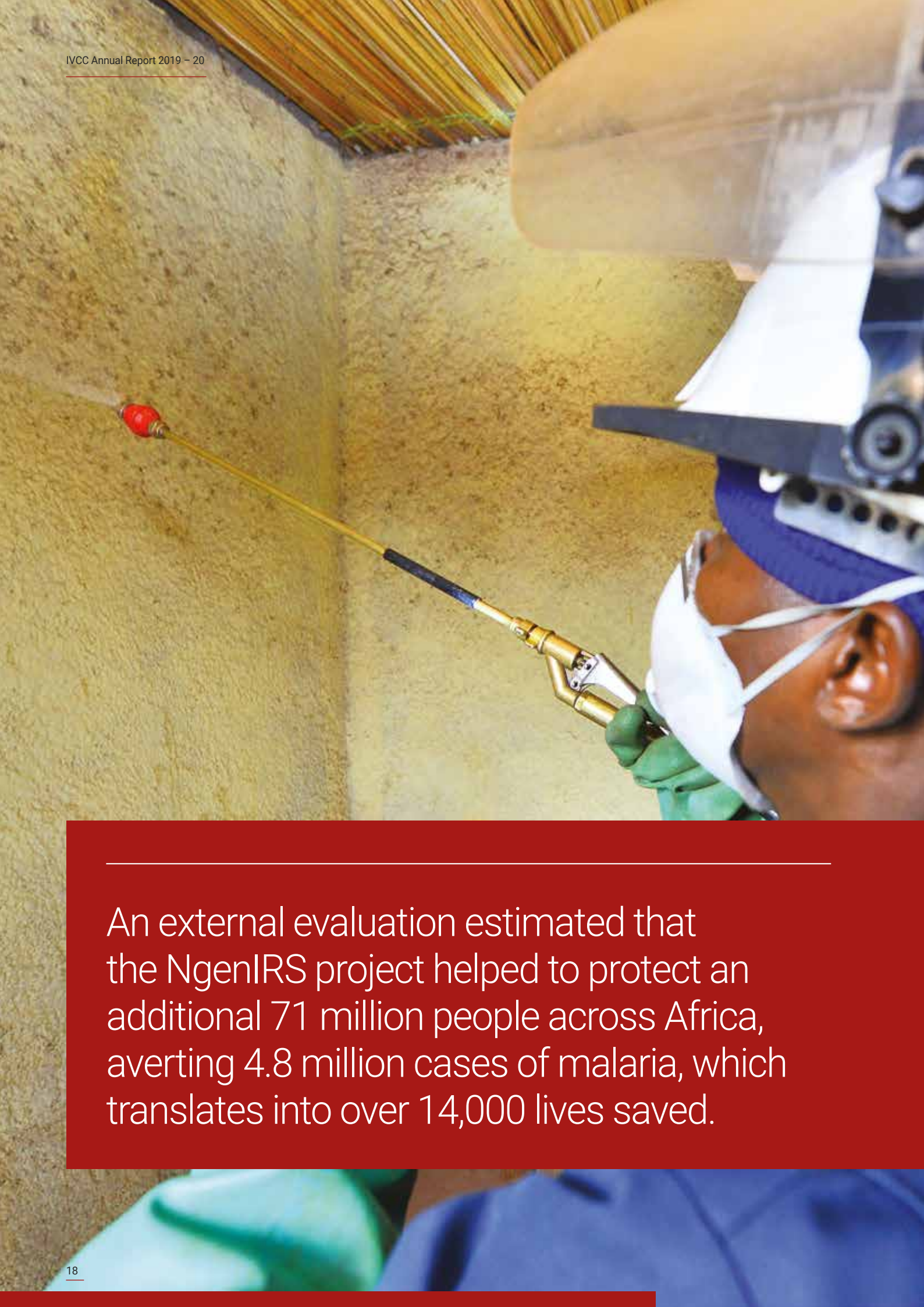
Life Cycle Canagement and Market Intervention Design

A common experience amongst PDPs has been that new products experience a wide variety of challenges on first entry into the public health marketplace that may slow or even completely prevent uptake. These include:- high initial costs at small volume, lack of evidence of impact and cost effectiveness, lack of awareness at country level, absence of forecast demand etc. In order to overcome these challenges a variety of market intervention approaches have been developed across the PDP access community. The IVCC team has become adept at optimising design of these interventions to suit the challenges facing particular products and developing partnerships to fund and implement these interventions.

Partnership Mapping

A common mantra amongst the IVCC access team is "All these things need to be done to achieve access but not all by IVCC". Hence a core expertise of the Access team is to convene a network of the key partners who will deliver the multiple different facets of a successful access intervention.

Photo Credit: PSI Mali



An external evaluation estimated that the NgenIRS project helped to protect an additional 71 million people across Africa, averting 4.8 million cases of malaria, which translates into over 14,000 lives saved.

Alternate Routes to Market

Despite the great gains achieved under NgenIRS, IRS coverage in Africa remains relatively low and limitations on donor funding, particularly in the wake of COVID-19, are not sufficient to support further expansion. At the same time, demand for 3GIRS is growing among national programmes in response to the NgenIRS evidence. To meet this challenge IVCC is working with four "High Burden/High Impact" (HBHI) countries (i.e., DRC, Ghana, Nigeria and Uganda) to develop and implement a strategy to expand access through public/private partnerships.

NgenIRS demonstrated great potential in working with a limited number of private sector partners (e.g., mining, NGOs and mission hospitals) to increase coverage beyond the reach of donor-funded programmes. This work will build on that experience to establish new networks of distribution in four of the countries most impacted by malaria. With an initial focus on IRS, these networks will eventually allow expanded distribution of other vector control tools.

New Nets Project

The progress made against malaria since 2000 is threatened by the growing intensity and distribution of resistance to pyrethroids, previously the only insecticide class available to treat bed nets. However, by combining pyrethroids with new classes of chemistry, dual-active ingredient insecticide treated bed nets (dual-AI ITNs) have the potential to protect and save many more lives. The New Nets Project (NNP) was launched in 2018, jointly funded by Unitaid and Global Fund with additional support from the Bill & Melinda Gates Foundation and the President's Malaria Initiative. NNP has the goal of increasing access to newly developed dual-AI ITNs. IVCC has created a consortium of partners to ensure the rapid deployment of new dual-AI nets to a limited number of partner countries where a combination of randomised controlled trials in Benin and Tanzania, and pilots in several other countries, seek to establish the impact and cost-effectiveness data needed for a World Health Organization (WHO) policy recommendation that would be required for scale-up. The Bill & Melinda Gates Foundation, in collaboration with MedAccess, have entered into a volume guarantee agreement with BASF to offer reduced Interceptor® G2 pricing. The volume guarantee combined with a co-payment from NNP will enable countries to procure Interceptor® G2 for pilot deployments within their current net budgets. Two types of dual-AI nets are being deployed through NNP, Interceptor® G2 developed by BASF and Royal Guard® from DCT. Burkina Faso was the first country to receive Interceptor® G2 nets in October 2019. Due to COVID-19-related lockdowns and travel restrictions, there were some delays in net distribution and data collection in early 2020. However, once restrictions were lifted,

Rwanda and Mali were able to complete successful Interceptor® G2 distribution, as well as collection of epidemiological, entomological, and anthropological data, by shifting from community to door-to-door net distribution, adopting social distancing, and using personal protective equipment. By the end of 2020, net campaigns will also occur in Nigeria and Mozambique, contributing to a total of over 15 million Interceptor® G2 and one million Royal Guard® ordered since the start of NNP. Cote d'Ivoire, Liberia, Ghana, and Malawi will pilot dual-AI nets in 2021, and by the end of NNP over 35 million nets will have been distributed in sub-Saharan Africa.

Next Generation IRS Project Completion

The Unitaid-funded Next Generation IRS Project (NgenIRS) came to a successful end in March. The four-year, $65 million market shaping intervention was launched in January 2016 with the goal increasing the use of third generation IRS (3GIRS) products in Insecticide Resistance Management (IRM) programmes, creating a sustainable, growing and competitive market. This was in response to the development of widespread resistance to previously effective insecticides, high prices, only one product available in the market, unpredictable demand and lack of evidence demonstrating impact and cost-effectiveness. Led by IVCC, in partnership with PATH (Evidence), Abt Associates/AIRS & VectorLink Projects (implementation) and in close collaboration with 16 African Malaria Programmes, Global Fund and the US Presidents' Malaria Initiative (PMI), NgenIRS helped to reverse the downward trend in demand for IRS and address the various elements of market failure that jeopardised future access to effective IRS.

By early 2020 NgenIRS had established a robust evidence base showing that 3GIRS could reduce malaria cases by 22%-47% when added to LLINs, and that it met the WHO criteria for cost-effectiveness. The market expanded from 1 to 3 products, enabling countries to implement rotation for resistance management for the first time while also introducing competition that helped in brining prices down by 35%. NgenIRS also contributed to market stability and lower prices by providing manufacturers with annual forecasts supported by volume guarantees and time-limited co-payments enabling partners to procure at reduced pricing from day one.

An external evaluation estimated that the project helped to protect an additional 71 million people across Africa, averting 4.8 million cases of malaria, which translates into over 14,000 lives saved. The evaluation also predicted that the foundation put in place by NgenIRS would lead to a doubling of this impact over the next five years.

Attractive Targeted Sugar Bait (ATSB®)

Mathias Mondy
Director - Business Development and Strategy

In 2014 IVCC launched a call for proposals to identify new vector control tools to prevent outdoor malaria transmission, recognising through modelling that broad coverage of indoor residual sprays (IRS) and long-lasting treated nets (LLIN) would not alone be sufficient for malaria eradication.

After reviewing the proposal received, IVCC, supported by its External Scientific Advisory Committee (ESAC), reach a contractual agreement with Westham[1] for a proof of concept (PoC) in Mali. This work took place in 14 villages in 2016 and 2017. The table below summarize the promises of ATSB® and the remaining work to be done to confirm the role this product can play in the malaria eradication strategy.

An ambitious product development programme was established to evaluate ATSB®'s public health value. The first priority was to improve the quality of the bait stations so they could be tested at scale in Kenya, Mali and Zambia. New bait stations were evaluated in laboratory small cages, semi field and more recetly in field conditions.

The product design finalization has allowed enough time to establish a suite of protocols and Standard Operating Procedures to facilitate product evaluation across three teams. The risk assessment was fine-tuned and led to the addition of Bitrex™ to the bait matrix to prevent ingestion by children.

An ambitious product development programme was established to evaluate ATSB®'s public health value.

Additional entomological tests were conducted in Mali in a low endemicity area and to measure the bait station attraction distance in field conditions. Field evaluations have started in Zambia and in Kenya. The project team received support from Imperial College London, the Institute for Disease Modelling and the Swiss Tropical and Public Health Institute to use mathematical modelling to calculate the feeding rate on the bait stations that would be required to achieve an epidemiological outcome of 30% malaria incidence reduction.

This work has established the threshold needed to be reached to be successful during the next round of large-scale entomological field evaluations in Kenya and Zambia.

If results are positive, the team is aiming to launch a set of epidemiological studies starting in 2022 in Zambia, Kenya and Mali to demonstrate the impact of this product on malaria transmission in real conditions.

These results, in addition to the safety evaluation package, will constitute the backbone of the dossier which the team intends to submit to WHO-PQ Vector Control team to open a new product class.

IVCC would like to thank for their contribution all the partners involved in this project:
- PATH
- Tulane University Center for Applied Malaria Research & Evaluation
- University of California San Francisco
- Johns Hopkins Malaria Research Institute / Macha Research Trust
- Kenyan Medical Research Institute (KEMRI)
- Liverpool School of Tropical Medicine
- University of Miami Miller School of Medicine
- US Centers for Disease Control and Prevention
- University Clinical Research Center / University of Sciences, Techniques, and Technologies of Bamako, Mali
- London School of Hygiene and Tropical Medicine
- Institute of Molecular Biology and Biotechnology / Foundation for Research and Technology

The Promise	Already Demonstrated	To be Established
An effective vector control intervention to reduce the overall mosquito population in and around houses	Successful demonstration in Mali in high burden and low endemicity areas	Trial plan in place to assess entomological impact in Kenya and Zambia
An EIR (Entomological Inoculation Rate) drop[2] which should lead to a decrease of malaria prevalence	Proof of concept trial in Mali showed a very significant reduction of EIR in villages protected by ATSB®	Epidemiology trials are planned in Mali, Kenya and Zambia to establish if the impact on mosquito population leads to a reduction in malaria prevalence
A relatively cheap and easy to deploy intervention compared to IRS	Encouraging preliminary cost-effectiveness modelling of ATSB®	Development of a manufacturing platform for final product version which would support a reduced unit cost and increased manufacturing capability
A product remaining effective for 6 months when deployed in the field	Demonstrated in Mali, Kenya, and Zambia with prototype	Assess durability of final version in field conditions
A favourable human and environmental risk assessment	Favourable preliminary human and environmental risk assessment	Disposal options to minimize impact on the environment
A socially acceptable intervention when properly explained	Positive outcome of a social study in Mali during the PoC	Further social evaluation will be done in Kenya and Zambia during the epidemiology studies.

[1] www.westhamco.com
[2] Number of bites per person per year

GLP Certification of African Trials Facilities – Challenges and Successes

Dr Graham Small
Senior Technical Manager

Mosquito vector control products are a key component of malaria control programmes in sub-Saharan Africa. With increasing insecticide resistance in malaria-endemic countries, new vector control products are urgently needed, and these must be developed, tested and registered before they can be deployed.

Vital to the testing of these products are the African trials facilities. These facilities play a key role in assessing the effectiveness of vector control products against local mosquito populations in the environments where they will be used.

The data generated during studies at these trials facilities are used by manufacturers to support regulatory submissions for product approvals, including the World Health Organization Prequalification Team for vector control products (WHO PQ-VCT).

Data need to be of a high quality to be accepted by regulatory authorities. However, until recently, the trials facilities lacked formal quality management systems (QMSs) to help manage data quality.

Therefore, implementation of an appropriate internationally recognised QMS was required. After evaluating several QMSs, Good Laboratory Practice (GLP) was selected as being the most appropriate for the management of trials on vector control products. The purpose of a QMS compliant with GLP standards is to ensure that data generated during testing studies are reliable, repeatable and auditable. GLP is the gold standard for insecticide testing facilities and is advocated for by the WHO PQ-VCT.

The IVCC/I2I GLP Project

Funds have been made available to these facilities for the GLP certification process, provision of GLP training through workshops (1 in the UK and 3 in Africa), specialist training in quality assurance and data management systems, and infrastructure improvements required for full GLP compliance.

IVCC also joined with the Centre for Capacity Research (CCR) at the Liverpool School of Tropical Medicine (LSTM) to investigate the key barriers and enablers to sustainable GLP certification at the African trials facilities. The following captures some of our main findings.

Challenges in Implementing GLP in an African Context

The standards required for full GLP compliance are rigorous. Our experience supporting the 7 African facilities towards GLP certification is that in low and middle-income countries (LMICs), timelines may be significantly extended due to challenges related to infrastructure development and lack of regional capacity and expertise.

Whilst the OECD guidelines for GLP include requirements for laboratories to meet infrastructural standards, steps related to infrastructural improvements, including building construction and refurbishment required substantial time and effort. Whilst all staff at a GLP certified facility must comply with the requirements described in the OECD principles of GLP, some roles are of particular importance, namely Study Directors, the IT/Data Manager and the Quality Assurance (QA) Manager.

These roles were new or expanded positions at the facilities and identifying appropriately trained and experienced candidates from within country proved challenging. Therefore, IVCC supported the trials facilities in accessing external specialist training and on-the-job support.

Key Successes

To date, two of the 7 African trials facilities have been granted GLP certification by the South African National Accreditation System (SANAS): the KCMUCo-PAMVERC facility in Tanzania (certified in 2017) and the CREC/LSHTM facility in Benin (certified in 2019). In March 2020, the LITE facility, based within LSTM, UK, became a provisional member of the UK GLP Monitoring Authority programme. Four of the remaining facilities have submitted their applications for GLP certification to SANAS with one, the Ifakara Health Institute (IHI) facility in Tanzania, now awaiting their SANAS GLP inspection.

KCMUCo-PAMVERC and CREC/LSHTM have been conducting GLP laboratory and experimental hut studies on an indoor residual spraying (IRS) product that was developed in a collaboration between IVCC and one of our industry partners.

In addition, both facilities will soon be initiating community trials on this IRS product, the Tanzania trial being managed through a collaboration between KCMUCo-PAMVERC and the National Institute of Medical Research Amani Research Centre, another facility that IVCC is supporting towards GLP certification.

After evaluating several QMSs, Good Laboratory Practice (GLP) was selected as being the most appropriate for the management of trials on vector control products.

Data generated during these studies will form part of the dossier submission for evaluation of the product by WHO PQT-VC.

These and other IVCC collaborating facilities have also been conducting GLP studies for industry partners (each facility must have completed at least on GLP study before they can be formally granted GLP certification). They are, therefore, providing an important network of facilities for manufacturers of vector control products, allowing them to generate high quality data on product performance for regulatory purposes.

The project was initiated by IVCC in 2010 and moved into a new phase in 2016 with IVCC supporting 8 trials facilities (4 in West Africa, 3 in East Africa and 1 in the UK) towards GLP certification with funding from the Bill & Melinda Gates Foundation.

The opportunities provided by WHO PQ are significant with a clear, regulatory-based framework for evaluation of new tools, it has the flexibility to rapidly evaluate the various new insecticides and tools currently under development; I2I's challenge is now to capitalise on them.

Innovation to Impact Summary

Angus Spiers
Director
Innovation to Impact

The past 4 years have seen a seismic shift in the way new vector control tools are evaluated with the formation of the WHO prequalification (PQ) process for vector control. As one of the primary objectives of the Innovation to Impact (I2I) process, this can be seen as a major achievement for both WHO and the vector control stakeholders whose input helped guided the process.

To achieve this goal, I2I has supported a number of complimentary objectives to ensure the product development infrastructure is aligned with PQ requirements. A core feature of this work has been clear communication and dialogue between all partners, with I2I's signature Convenings in Washington DC, Geneva and Beijing providing opportunities for a diverse group of stakeholders to learn about developments in product evaluation and discuss the implications of the new PQ system.

The opportunities provided by WHO PQ are significant with a clear, regulatory-based framework for evaluation of new tools, it has the flexibility to rapidly evaluate the various new insecticides and tools currently under development; I2I's challenge is now to capitalise on them.

Building Solid Foundations

It is imperative that we capitalise on the solid foundations that have been built and provide the supporting infrastructure to maximise the opportunity that PQ presents.

A good example of this would be I2I's support to the 16 prospective GLP sites being supported by IVCC (in Africa) and WHO (rest of the world). These sites are key to providing the high quality data that is needed to evaluate new tools. I2I has worked to coordinate the scientific capacitation efforts and also provided business planning support to these facilities to ensure they develop and maintain strong business plans and remain self-sufficient.

2I is also committed to ensuring new vector control tools are rapidly available at country level to those who need them most, and have worked with a number of country regulators to understand bottleneck and opportunities for product introduction.

This information will be crucial to target efforts to surmount regulatory barriers to access that are present in a number of countries.

An Eye to the Future

As the WHO PQ system ramped up, I2I has had to evolve to ensure its focus remains on areas of need and to build on the foundations that are now in place. This evolution has necessitated a change in the way I2I works and we are pleased to say that I2I recently received a new grant from the Bill & Melinda Gates Foundation to continue its work.

This new grant recognises the progress made thus far while addressing key remaining aspects of the vector control product evaluation process.

Core among this is the need for high quality, consistent data on for regulators and WHO PQ to base decisions on. The robust vector control pipeline has the potential to turn the tide in the fight against malaria and other vector borne diseases, but without clear and validated data innovation risks being stymied. I2I will also work with its stakeholders to ensure key groups remain informed and involved in the development of the WHO PQ process, and explore ways to ensure its outputs aid more rapid registration, procurement and implementation decisions.

This new grant will also see I2I changing its hosting arrangement from IVCC to the Liverpool School of Tropical Medicine. This change will not affect the strong collaborative relationship that both organisations enjoy and we are committed to working closely to facilitate access to the many exciting new technologies being developed throughout the community.

Indo-Pacific Initiative (IPI)

Australian Aid

Robin Davies
Head of Indo-Pacific Centre for Health Security
Department of Foreign Affairs and Trade (DFAT), Australian Government

Recognising the threat of vector-borne disease to regional health security, the Australian Department of Foreign Affairs and Trade (DFAT) provided the IVCC with a five-year grant in 2018 to support the development of a Vector Control Product Toolbox for the Indo-Pacific region.

As a first step, IVCC commissioned three landscaping studies: a Technical Landscape conducted by the University of California, San Francisco Malaria Elimination Initiative; a Market Access Landscape; and a Regulatory Landscape study. Launched in May 2019, the studies were informed by a desk review of 19 countries, in-depth consultations and key informant interviews with governments and partners in focus countries (Cambodia, Indonesia, Malaysia, Myanmar, Papua New Guinea (PNG) and Vietnam) and consultations with over 20 industry partners. Each study identified key challenges (technical, regulatory and market access) and potential solutions for improved vector control in the Indo Pacific region.

Out of this work, DFAT and IVCC jointly developed two pilot projects in the Indo-Pacific region. In PNG, we facilitated a partnership between the PNG Institute of Medical Research, Australia's Burnet Institute and James Cook University to initiate the NATNAT project (Newly Adopted Tools Network Against mosquito-borne disease Transmission). Its goal is to develop a framework for the rapid assessment and adoption of vector control tools; strengthen the national regulatory framework; and engage funders and other PNG implementing partners to ensure that investments in vector control are sustainable.

This work includes mathematical modelling by the Imperial College London to guide operational research and predict the impact of new vector controls on PNG. In the Greater Mekong, DFAT and IVCCC are working with a partnership led by University of California, San Francisco - Project BITE (Bite Interruption Towards Elimination) to enable the testing and evaluation of new products to reduce exposure of high-risk forest dwellers, workers and forest ranger groups to mosquito bites.

Working in concert with national governments, national institutions, implementing partners, regional structures (including the Asia Pacific Leaders Malaria Alliance and the Asia Pacific Malaria Elimination Network) and other DFAT investments, these projects aim to evaluate and bring to market tools such as next generation Indoor Residual Sprays (IRS) and support effective intervention strategies that address human resource, market access and regulatory challenges, with a view to region-wide implementation.

The Technical, Market Access and Regulatory Landscape reports which were commissioned under IPI and guided its priority-setting, were launched publicly at the VCAP (Vector Control Platform in Asia-Pacific) regulatory workshop in Hanoi, Vietnam in November 2019.

Fred Yeomans
Project Manager
Indo-Pacific Initiative

Under the Indo-Pacific Initiative (IPI), 2019-2020 has been a year of strengthening partnerships, initiating project start-up activities and managing the delays caused by COVID-19.

NATNAT (Newly Adopted Tools Network Against Mosquito-borne Disease Transmission)

In October 2019, a team from IVCC travelled to Madang in Papua New Guinea (PNG) for a series of planning meetings with project partners and national stakeholders to kick off the NATNAT project.
It has 4 aims:

- Create a national stakeholder network for vector control tools and interventions
- Strengthen laboratory, semi-field and field capacity to test new tools in PNG
- Conduct rigorous field evaluations of new tools (IRS, Spatial Repellents and Larvicides)
- Investigate the community and health system acceptability and cost analysis of new tools

The first half of 2020 saw contractual arrangements between all major partners being finalised, the development of an overall project protocol and technical implementation plan and the recruitment of a Project Manager and Post-Doctoral Fellow. Discussions with manufacturers began regarding sourcing and testing products, and designs for the new laboratory and semi-field infrastructure were also drawn up.

Because of COVID-19, delays were caused to the recruitment of some key posts in PNG, the development of the national stakeholder network and to the start-up of the infrastructure development. These activities remain priorities so semi-field testing can begin in 2021.

Project BITE (Bite Interruption Towards Malaria)

Project BITE aims to evaluate and quantify the epidemiological and entomological protective and residual efficacy of bite prevention tools delivered via Forest Packs. Community acceptability and cost-effectiveness are also being evaluated. The use of Forest Packs containing Insecticide-Treated Clothing, a Spatial Repellent and a Topical Repellent, will be compared to standard of care among high risk populations (forest dwellers, forest goers and forest rangers) to reduce exposure to Anopheles bites and drive down malaria transmission in Cambodia.

Potential application of Forest Packs across the region will also be explored. Project BITE is led by the University of California, San Francisco's Malaria Elimination Initiative (UCSF-MEI) and comprises a number of partners including University of Notre Dame, AFRIMS, Kasetsart University, Swiss TPH and the Cambodia Centre for Parasitology, Entomology and Malaria Control (CNM). It responds to the growing demand for and donor interest in Forest Packs in the context of malaria elimination in the Greater Mekong Subregion.

All main contractual arrangements have been completed for this project, a Research Manager has been recruited and a number of protocols have been developed. Semi-field testing of products started in July 2020 at the AFRIMS and Kasetsart University trial sites in Thailand. Thus far, programme visits to oversee the trials and to engage regional stakeholders have not been possible because of the pandemic, but the project is progressing nonetheless via the partners in Thailand and Cambodia. The next steps in BITE are the small-scale entomological field trial followed by a epidemiological field trial, both of which will take place in Cambodia.

Building Partnerships

In addition to the programmatic activity under IPI, IVCC has also worked to build its profile and strengthen its network in the Indo-Pacific region, contributing to its strategic objective of capitalising "on knowledge and innovation to address malaria and other vector borne diseases outside sub-Saharan Africa in order to maximise the impact of our work and the products being developed'.

IVCC gave technical advice to WHO Vanuatu on their plans to scale up IRS usage in their malaria control programme; co-sponsored APLMA's Malaria Gamechangers online seminar on vector control; joined the Australian Government's Vector Surveillance and Control partners network; and also presented at a Rotarians Against Malaria conference, a key organisation in malaria control in PNG, Solomon Islands and Timor Leste.

A number of new experts also joined the IPI Advisory Group in 2020 to support with protocol development and implementation of the projects.

Finance Report 2019-20

Duncan Preston
Director of Finance
Liverpool School of
Tropical Medicine

Financial Audit and 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 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 organization gives governance oversight on all financial operations of IVCC and meets 4 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 specializing in audit, tax and consulting services. 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 significant 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 centralized procurement function.

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

LSTM group estimates that 68% of impactable spend activity, as defined by the British Universities Finance Directors' Group 'BUFDG' for procurement survey assessment purposes, has been influenced by the procurement team, which represents an increase of 12% against the previous year. This highlights wider engagement with the procurement function leading to increased savings.

The LSTM group's eProcurement platform was extended to incorporate IVCC in February 2020. The integrated system has in-built surveillance functionality and preventative controls that trigger online approval flows and guide users through the complete procurement process.

In harmony with the objectives of the VfM Steering Group, IVCC is leveraging the enhanced strategic service offering of the procurement team and working in cross functional collaboration on complex procurement engagements.

FlowForma (a Business Process Management tool on the Sharepoint platform) continues to expand and evolve. The workflows were initially launched for paper-based completion with the ultimate vision to achieve paperless flows introduced through subsequent updates. In 2019-2020 the need for paperless flows became business critical when the UK went into lockdown to slow the spread of COVID-19.

The development work undertaken by the Finance Department to date on paperless workflow functionality enabled IVCC to adapt quickly to the urgent technological demands brought about by the switchover to a remote working model.

During the previous financial year, IVCC's Portfolio Management team launched a project management tool using a leading CRM software house tailored to IVCC's unique specifications and internally branded as 'VectorPath'.

This centralized planning and management tool is primarily used by the project delivery teams, with the added benefit of making real-time project update dashboards readily available to the wider IVCC team and informing data provided to the finance team for budget and forecasting purposes. During 2019-2020, IVCC commissioned a series of new features and process improvements for VectorPath based on user feedback and insights gained under the live operating environment. External refresher training incorporating the new features was rolled out in the autumn of 2020 through a series of remote sessions.

Environmental Working Group

This year has seen the establishment of an Environmental Working Group ('EWG'). The EWG will be working to enhance the LSTM group's contribution to improving sustainable value.

The group is divided into 5 subgroups, each focusing on a particular area of priority. The 5 subgroups are:

- Carbon and Travel; an employee survey was carried out with a view to developing an action plan.
- Data Collection; assessing the impact of remote working on the group's environmental footprint.
- Communication and Engagement; working with the Carbon group on communicating the survey findings and converting the results into agreed actions.
- Green Working; the development of a "Green Labs" guide to deliver improvements in environmental working practices
- Strategy; long-term planning activities revisited to deliver enhanced sustainability.

Impact of Decision to Leave the European Union

On 23 June 2016, the UK voted to leave the European Union. In January 2020, the government signed a deal with the EU to manage the UK's exit from the EU.

Brexit is a standing item considered by group management and a Brexit working group meets on a regular basis to discuss issues pertinent to IVCC. The principal risks, uncertainties and the associated mitigating controls are monitored in the context of a scenario-based risk register.

Whilst IVCC's funder portfolio continues to strengthen and diversify, an inherent key risk area specific to IVCC is currency volatility and the weakening of the pound giving rise to an increase in project costs. IVCC enters into forward currency contracts and hedging instruments to manage the cash flow exposures of foreign currency research income. It should be noted that these are medium-term instruments linked to individual grants awarded in US dollars and the associated timelines. Furthermore, hedge effectiveness can be materially impacted by complex project-related and macro-economic factors. Longer term, risk mitigation is focused on ensuring that cost estimates are underpinned by realistic assumptions with respect to foreign exchange.

Other factors of potential relevance to IVCC include the following: The general macro-economic position and consumer confidence;

- Ability to apply for EU research and capital funding;
- The UK may experience a loss of influence over EU policy in areas such as science and public health;
- Restriction in the movement of labour across borders;
- General Data Protection Regulation (GDPR) data risks.

This year has seen the establishment of an Environmental Working Group ('EWG'). The EWG will be working to enhance the LSTM group's contribution to improving sustainable value.

Financial Performance

Income for the year of £38.6m was £1.1m down from last year, with resources expended of £37.2m up by £0.9m giving a gain of £1.3m before other recognised gains and losses. During 2016/17 IVCC commenced hedge accounting under FRS102 in relation to forward contracts.

	2020-21*	2019-2020	2018-19	2017-18	2016-17
Income	£40.80m	£38.57m	£39.64m	£28.50m	£20.81m
Expenditure	£39.72m	£36.59m	£37.29m	£28.86m	£19.16m
Surplus/(Deficit)	£1.08m	£1.98m	£2.35m	£(0.36m)	£1.65m

*forecast numbers

The statement of financial activities reflects an amount of £0.6m of foreign exchange gain which has been taken to the hedging reserve and £0.2m foreign exchange loss taken to expense in the year. This compares to the previous year when £0.9m loss was taken to the hedging reserve and £0.2m loss was expensed in the year.
A total of £30.0m was spent on direct charitable project activities (2019: £27.3m) with a further £2.6m paid out on project activities undertaken in-house. Core administration support costs of £4.2m (2019: £5.9m) were also incurred in the year.

Income from charitable activities in 2019-2020 was originally budgeted at £40.8m (2019-2020 actual - £37.3m) and represents growth on prior year actual income of 3% (2018/19 actual - £36.0m). Total income from charitable activities in 2019-2020 of £37.3m represents a 9% shortfall against the original budget of £40.8m. The largest single factor driving this variance is in relation to IVCC's NgenIRS project, a 48-month market shaping initiative funded by Unitaid. A key assumption was that the unspent funds projection set in 2018/19 would be fully utilised in 2019-2020 being the concluding year of the programme. An element of this planned expenditure included a contingency fund that can be drawn upon to meet the exposure if volume commitments agreed with product suppliers are not met by in-country order levels. Due to the success of the project in stimulating local demand for the next generation indoor residual spraying products, the contingency fund was not drawn upon.

It is forecast in 2020/21 that income from charitable activities will stabilise around the original budget estimate for 2019-2020 being £40.8m. The budget composition for 2020/21 was adjusted to reflect current travel patterns under pandemic conditions which at the time of budget assessment had been assumed to cover the calendar year 2020. Key assumptions underpinning the 2020/21 budget are that no projects suffer an outright suspension as a result of COVID-19 restrictions, but a remodelling of extended lead times was approximated. It is assumed that 2020/21 income will be sourced through existing funder awards.

Other income of £0.7m represents amendment of service level agreement charges from prior year payments to LSTM.

Reserves Policy and Going Concern

Unrestricted reserves of £6.9m (2019: £5.5m) are used to finance activities currently out of scope with existing funders, but within the overall mission and objectives of the organisation. IVCC aligns with the group policy of ensuring that unrestricted reserves represent a minimum of 6 months' pay expenditure.

No contract is entered into unless it can be fully resourced from beginning to end; this includes staffing contracts, partner contracts and all contracts in the supply chain.

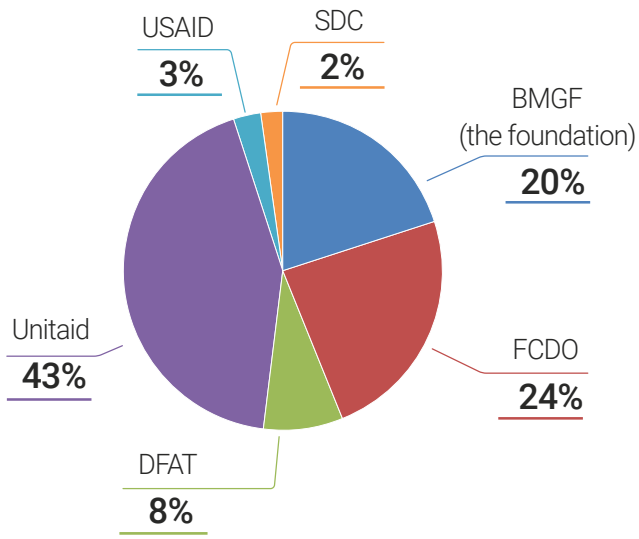
IVCC has a healthy positive bank balance comprised largely of advanced grant funding from its partners, no loans outstanding and a strong, well balanced portfolio of active grant agreements.

The impact on the charity arising from the recent COVID-19 outbreak has been considered by the Trustees. There are no adjusting or non-adjusting events which have come to light at the current time.

Investments

IVCC continues to adopt a conservative investment strategy using a combination of money market deposits and secure US government and corporate bonds, in line with current unsettled market conditions. Consequently, returns are modest on both the sterling and dollar funds held. Interest received during the year will be used, where permissible under prevailing funder terms and conditions, to fund future project activity.

Funding Mix



Bill & Melinda Gates Foundation (the foundation) provided 20% of the charity's restricted income from charitable activities in the year, down from 25% on a like for like basis in 2018/19 which is a measure of growth in the overall grant funding base.

Funding from the Foreign Commonwealth and Development Office (FCDO) formerly DFID, as a percentage of the charity's restricted income from charitable activities is 24%, down from 27% in 2018/19.

The contribution from Unitaid for work on the NgenIRS programme and the New Nets Project was the largest aggregate funder contribution (43% of funded activities in the year). This money is ring fenced for specific implementation work on these market intervention projects and includes the cost of planned co-payments on orders placed with IRS and net manufacturers.

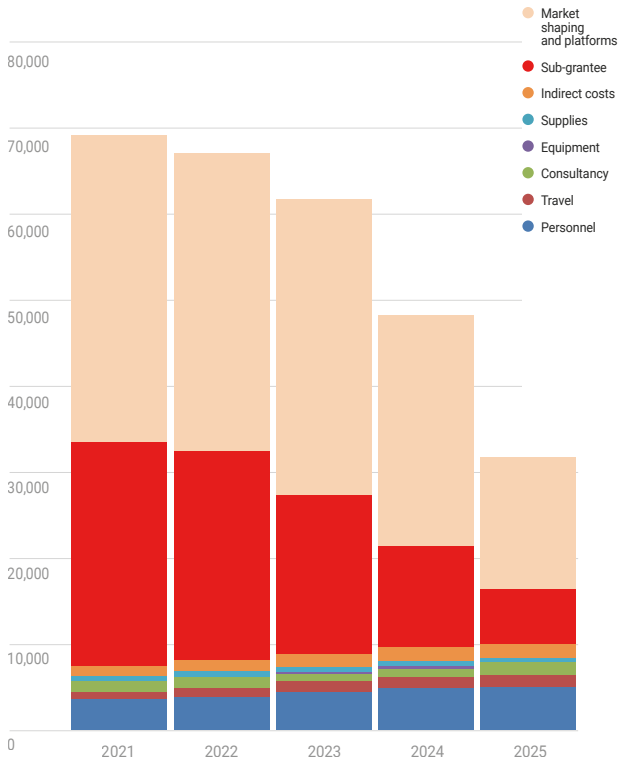
After an initial period of establishment, IVCC's first grant with the Australian Government operating through its Department of Foreign Affairs and Trade 'DFAT' represents 8% of the charity's restricted income from charitable activities for 2019-2020.

The remaining 5% of income is split 3% USAID and 2% SDC. Other sources of unrestricted income comprise grant income by way of overhead contribution, bank deposit interest of £0.6m, foreign currency fluctuations and £0.7m of other income as identified in the Financial Performance section.

It is forecast for 2020/21 that the contribution from BMGF will account for around 32% of the total funding received, with Unitaid at 34%, FCDO at 22% and funding from DFAT, USAID and SDC making up the remainder.

Funding Projection 2021-2025

Predictive Model of IVCC Expenditure to 2025



Forecasting long term funding and income scenarios enables IVCC to manage its portfolio activity more effectively. It provides a base analysis for fundraising activities aimed at financing the portfolio in line with latest projections, operational updates and provides a framework for negotiation with recipients of IVCC sub-awards and the generation of updates to key stakeholders including IVCC's funding partners.

Planned expenditure beyond 2023 is currently structured around the life cycle of IVCC's existing portfolio of activities and will evolve in line with future vector control outcomes and priorities.

IVCC's principal grant with BMGF was scheduled to conclude by 30 April 2021 and is subject to a no cost extension to 30 April 2022. IVCC and BMGF are progressing negotiations in relation to the grant renewal cycle which is being integrated with the utilisation timeline for IVCC's predecessor grant with the foundation.

IVCC's Memorandum of Understanding (MoU) with the former Department for International Development (DfID) has been automatically transferred to the Foreign, Commonwealth & Development Office (FCDO) and the MoU end date extended from March 2021 to March 2022. IVCC will be guided by the FCDO on appropriate timescales for exploring follow-on funding opportunities.

In line with the renewal pattern for IVCC's other principal grants, 2019-2020 has been a quiet period for grant renewal developments. IVCC has increased the frequency of its communications with funders and other key stakeholders during this unprecedented period of uncertainty in the global health arena.

During this financial year, IVCC entered into a $265k contract for services with MedAccess Guarantee Ltd ("MedAccess") to support the monitoring of a volume guarantee agreement that is expected to have a material impact on the medium-term global access strategy for Long Lasting Insecticidal Nets ("LLINs"). This is the first time that IVCC has secured a supply of services arrangement with MedAccess.

New Starters 2019-2020

Janneke Snetselaar
Registration Trials Support Manager

Janneke's responsibility is to support the registration of products in the IVCC portfolio. She is part of the technical team, working on designing and implementing study protocols for laboratory work and field trials.

Janneke holds a BSc and MSc in Biology from Wageningen University, with a specialisation in bio-interactions, and is currently undertaking a PhD in Medical Entomology at the London School of Hygiene & Tropical Medicine.

Larry Norton
Senior Project Manager

Larry works on the Research and Development portfolio, offering support and expertise across collaborations with industry and academia, to ensure IVCC delivers its objectives.

Larry holds a BSc in Horticulture from Kansas State University, an MBA in Marketing from National University and a PMP (Project Management Professional) certification. Prior to IVCC he had a 22 year career at Bayer, and its legacy companies.

Vasanthan Paul John
Consultant and ESAC Member

Vasanthan is an independent consultant and facilitator on Regulatory Pathways for IVCC. He is also an ESAC board member.

Vasanthan has a master's in Agricultural Sciences and Specialization in Agricultural Microbiology. He has over 20 years' experience in agri-inputs companies in the role of product development, business development and regulatory affairs.

Jameel Bharmal
Trials Support Consultant – East Africa

Jameel is a consultant working with the technical team on designing and implementing field trials in East Africa. Jameel's responsibility is to support the registration of products in the IVCC portfolio.

Jameel holds a BSc in Biochemistry from Lancaster University and a MSc in Medical Parasitology from the London School of Hygiene and Tropical Medicine (LSHTM).

Welbeck Oumbouke
Trials Support Consultant - West Africa

Welbeck's responsibility is to support the registration of products in the IVCC portfolio, focusing on trials in West Africa. He works with the technical team as a consultant.

Before working with IVCC, Welbeck worked at the CREC-PAMVERC test facility in Benin and the Institut Pierre Richet in Cote d'Ivoire, supervising and coordinating WHOPES Phase 1 and 2 vector control studies.

Dr Angela Harris
Consultant

Angela is a consultant with the IVCC technical team, specializing in field entomology and supporting a number of different initiatives across the portfolio.

Angela holds a PhD in insecticide resistance and genetic control of Aedes aegypti from the Liverpool School of Tropical Medicine and a MSc in Medical Parasitology from the London School of Hygiene and Tropical Medicine.

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 gamechanging 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.

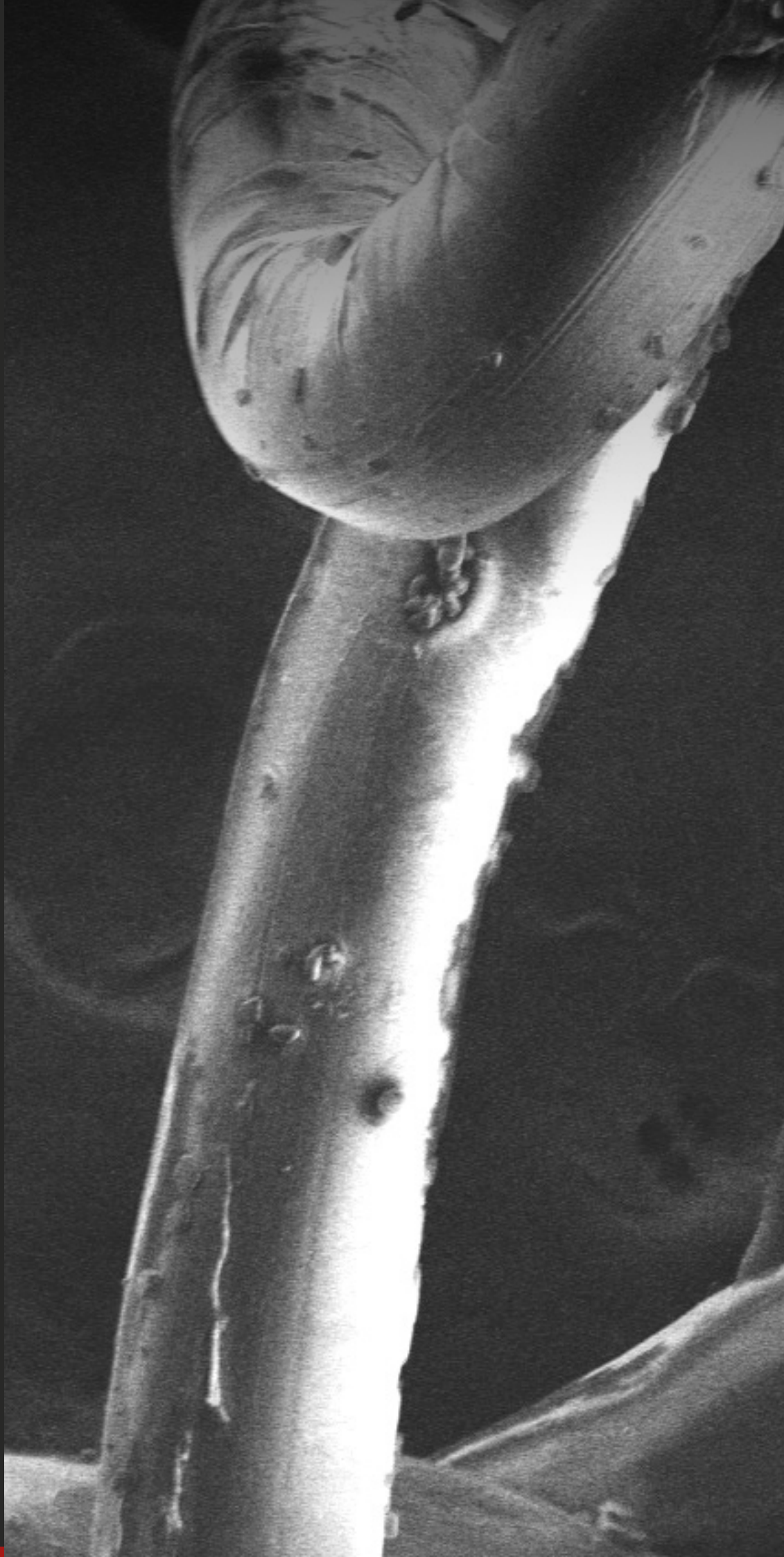
The Global Fund is a 21st-century partnership organization designed to accelerate the end of AIDS, tuberculosis and malaria as epidemics. Founded in 2002, the Global Fund is a partnership between governments, civil society, the private sector and people affected by the diseases. The Global Fund raises 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.

Where appropriate, permission has been sought for the photographing of individuals and use of imagery.

Image:
Novel insecticide crystals protruding the surface of the polymer on a bed net.



IVCC

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