

Fostering the Introduction of Innovative Vector Control Tools for Public Health:

**Report from a Stakeholder Workshop held in Paris
on 1-2 March, 2012**

This report is compiled of many contributions from the workshop attendees and issued on their behalf
by IVCC.

BCG



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Executive Summary

Insecticide resistance and the limits of our current vector control tools threaten our global progress against vector-borne diseases. Innovative vector control tools are therefore urgently needed, but some technical, financial and programmatic barriers may hinder innovation. In October 2011, a gathering of stakeholders including individuals from IVCC, WHO, donor institutions, industry, and other partners issued a joint call for a mapping of the current process to introduce new vector control tools for public health and the need to identify the challenges faced today in this process.

As part of a broader consultation process of more than 70 individual stakeholders from ~40 institutions, a workshop was convened in March on the subject of fostering innovation in vector control. This workshop, attended by 29 participants, was a critical interim step to gather a small group of the main constituencies involved in vector control innovation, with the view to discussing the initial findings and collecting feedback on the process of mapping innovation.

The workshop was a constructive, forward-looking endeavour with the goal of beginning a dialogue on how partners throughout the community can collaborate to accelerate the pace at which new vector control tools can be developed and ultimately introduced in endemic countries.

Eight “key themes” or major areas for improvement in the vector control innovation process were identified during the interviews and discussed in this workshop:

- Establishing a predictable and viable market
- Protecting investments while allowing competition
- Recognizing innovation
- Facilitating breakthrough innovation
- Reducing costs and improving efficiencies for time-to-market
- Ensuring high quality products
- Developing products that respond to the needs of end-users
- Building strong collaboration between stakeholder groups

By the end of the workshop, it was clear that all stakeholders are working towards the same shared goal – developing innovative, safe and effective vector control tools and introducing them as quickly as practicable in endemic countries to lower disease burden and save lives. Participants uniformly recognized that collaboration was vital to overcoming the challenges identified; no single stakeholder group has the power to overcome these challenges on their own. The workshop closed with a discussion on an ambitious but achievable target for the community: to cut the time from proof of concept to the introduction of a new product in endemic countries by 30%, while maintaining the highest standards in terms of safety, efficacy and acceptability.

Though this workshop was the right venue for the initial incubation of ideas, it was recognized that the discussion must be expanded to include a larger number of individuals and institutions. Participants were encouraged to return to their constituencies and share the initial ideas discussed. All partners should take action and volunteer, in coordination with WHO, IVCC and/or others, to continue the dialogue and trigger initiatives to accelerate innovation in vector control.

Background to the Project

Despite the significant progress made in scaling up public health vector control interventions in the past decade, most notably in malaria control, the need for innovation is growing rapidly. As endemic countries push towards universal coverage of vector control interventions for all populations at risk, new tools are needed to address insecticide resistance and other threats, such as outdoor resting and biting vectors. Development of cost-effective, safe, and operationally acceptable tools is a condition to keep vector control at the heart of our efforts.

At the end of 2011 a gathering of stakeholders including individuals from IVCC, WHO-GMP, WHOPES, donor institutions, and industry along with other partners met at the Malaria Forum organized by the Bill and Melinda Gates Foundation and issued a joint call for a mapping of the current process to introduce new vector control tools for public health and the need to identify the challenges faced today in this process.

Interview Consultation Phase

In response to this call, a "working team" composed of representatives from IVCC, GMP, WHOPES, and academia was formed. On behalf of the team, BCG carried out over 70 interviews, across different constituencies of the community (including industry, WHO regional and country offices, national malaria control programs and vector control programs, national registration authorities, donor organizations, and academia) over the next four months. These consultation interviews focused on two major axes:

- Mapping the current system of vector control innovation
- Identifying the current challenges that may hinder or halt innovation, and the potential opportunities to solve these challenges

Workshop on Fostering Innovation in Vector Control

1. Objectives and format of the workshop

In order to continue this consultation exercise, a workshop was convened in Paris on 1-2 March to discuss fostering innovation in vector control. This workshop was a critical interim step to gather a small group of the main constituencies involved in vector control innovation, to discuss the initial findings from the interviews and collect feedback on the draft mapping of the innovation process. This meeting convened 29 participants, from major donors organizations, procurers, industry, product development partnerships, WHO (GMP, NTD, WHOPES), academia, and endemic countries.

The workshop was a constructive, forward-looking endeavour. It was acknowledged as only the first step in the process of developing a shared vision for fostering innovation. The goal was to begin an open and frank dialogue on how diverse partners can collaborate and align themselves to accelerate the pace at which new vector control technologies can be conceived and introduced in endemic countries.

The challenges identified during the consultation phase were extensively discussed, providing an opportunity for the individual organizations and constituencies to voice their needs and constraints. This created a mutual understanding of the key priorities, and limitations, for each of the stakeholder groups.

A presentation and report, presented by WCI Group in collaboration with IVCC, offered examples of how other sectors, including pharmaceuticals, diagnostics and vaccines, dealt with similar challenges.

In addition, the workshop served as an incubator for the first brainstorming sessions on jointly tackling the challenges surfaced and gathering key points for eventual inclusion into an optimal process.

2. Key themes discussed during the Workshop

Eight major areas for improvement in the vector control innovation process were identified through the course of interviews and discussed in the workshop.

A viable and predictable market. The vector control market for public health is seen as being small and unpredictable – "high risk and low reward" for industry participants – due to high reliance on a handful of donors. Better predicting the size and growth of the market would decrease risk levels and enable manufacturers of pesticide products to better sustain their commitments. In addition, creating incentives for innovation would also increase manufacturers' long term commitment to a viable public health vector control market.

Protection of investments while allowing competition. Data protection is viewed as limited by some partners in the community since trial results of pesticide products evaluated by WHO are fully published for transparency towards WHO Member Countries and other stakeholders. The indirect use of trial data generated for "original" products accelerates access to market for new entrants and fosters competition, through a procedure of "extension to specifications". This has been perceived by original product manufacturers as creating a disadvantage for them. Numerous suggestions were proposed concerning this topic, but the consensus was that dialogue is needed to bring in other groups (e.g. manufacturers of generic products, experts on intellectual property, and individuals from national regulatory authorities).

Recognition of innovation. There is limited recognition of the "added-value" of new products within established product categories; defining "innovation" itself has become increasingly challenging for manufacturers developing product claims and testing protocols. Tendering is quite often based on the lowest price per unit rather than cost per year of effective prevention. There is a need for coordinated efforts from all stakeholder groups to have a better fit between end-user needs and new products, to develop guidelines and

standard criteria by which performance of new products could be assessed, and to support donors to better inform their procurement processes and to attempt to quantify the added value of new products over existing ones in order to maximize value-for-money.

Facilitation of "breakthrough innovation". Currently, there is no formal process for the introduction of new paradigms for public health vector control (reviewing/assessing evidence, recognizing the public health value of such a new paradigm, developing a new policy recommendation). In the past, these activities have always been performed on an ad-hoc basis, without clarity for product developers on the appropriate path to follow. In addition, setting up and conducting epidemiological trials has grown increasingly difficult and expensive. Clarifying the roles and responsibilities of all groups involved in vector control innovation and defining a broadly accepted pathway to introduce new tools and technologies will accelerate the development of such tools and remove some important risks for product developers. In particular, participants felt that there was a clear need to establish soon a new a high-level group that would advise WHO on the public health value of new tools and technologies for the control of malaria and other vector borne diseases.

Cost-effective process and short time-to-market. Several important factors were discussed. Firstly, there is limited capacity both at WHOPES (including collaborating centers, secretariat, and working group) and within national authorities for the assessment and evaluation of pesticides. Secondly, most steps of the innovation process are sequential today. Thirdly, country national regulatory processes are often not harmonized, creating duplication in data needs and decreasing the speed at which new products can be introduced in endemic countries. There are two clear recommendations that fit well with the urgency of preserving the gains in malaria control and of addressing insecticide resistance as an emergency with new vector control tools: 1) strengthen the capacity of WHOPES and that of the national regulatory authorities, and 2) make deliberate attempts to shorten all steps of the innovation process. While achieving this goal, it is essential to maintain full confidence of endemic countries in the independence and high quality of the evaluation process.

High quality products. There is limited capacity and policy for quality control of procured public health pesticide products in vector-borne disease-endemic countries. For this reason, more than 70% of such countries rely on WHOPES recommendations for procurement of pesticide products. The recent reports of sub-standard products that failed to meet WHOPES specifications, when tested, are however, worrying. The upcoming joint publication by WHOPES and GMP on procurement guidelines for pesticide products will be helpful to countries, donors and international institutional buyers, but is not enough. The current quality control system in public health vector control needs to be strengthened.

Products that respond to the needs of end-users. There is minimal feedback between product developers and product users, while procurers have limited insight into product pipeline and cannot plan for new products or paradigms. There is therefore a need to set up a mechanism to obtain and make use of feedback from end users to improve the quality of products by manufacturers. Moreover, in order to plan procurement, countries and procurers need to know in advance what innovations are in the pipeline.

Strong collaboration between groups. One of the areas identified as currently weak, but essential in getting products to the market, was the area of cooperation. Multiple facets of cooperation were discussed, including the importance of each group making itself available as a resource for others. Going forward, it will be essential to create an environment in which cooperation becomes the right choice for every partner working to achieve the collective goal of bringing innovative vector control tools as quickly as possible in order to save lives. With this in mind, participants left the workshop with a new spirit - a spirit of working together for the benefit of each stakeholder group. Achieving this will require applying flexible rules, being willing to give up some degree of individual achievement, and fully understanding the cost of not cooperating.

3 Lessons in fostering innovation from other industries

To help stimulate fresh ideas, IVCC and the WCI Group presented case studies on similar challenges to innovation in other industries and provided information on solutions developed in those industries that may have applicability in the vector control industry. A detailed summary of this benchmarking work will be available.

Workshop Outcomes and the Way Forward

The workshop was an important, but interim step to improve systems to foster innovation in vector control tools and strategies. It was not a forum with authority to produce binding recommendations or organizational commitments. Rather, it was an opportunity to refine the framework and develop a better mutual understanding of the specific issues that hinder vector control innovation, and how each, within their own constituency or organization may consider an appropriate response.

Participants uniformly supported the workshop's emphasis on collaboration and cooperation. By the end of the workshop, it was clear that all stakeholders are working towards the same shared goal – developing innovative, safe and effective vector control tools and introducing them as quickly as practicable in endemic countries to lower vector-borne disease burden and save lives.

Many of the stakeholders are already working on initiatives to improve the process of innovation. These may include harmonization of the country regulatory processes; field evaluation of currently deployed tools and operations research on new products; training and capacity building for the personnel and infrastructure needed to assess and deploy new tools. Communication and coordination will be essential in synchronizing these initiatives and jointly developing a better process to develop and deploy new tools.

Participants recognized that the key themes require a broader discussion and engagement with the larger community so that solutions can be found. Moving forward requires that all stakeholders abandon pre-conceived notions of what can and cannot be done, and work together in the short and medium term to design solutions and implement solutions to the challenges.

The workshop closed with a discussion on an ambitious but achievable target to reduce the time from proof of concept to the introduction of a new vector control product in endemic countries by 30%, while maintaining the highest standards of safety, efficacy and community effectiveness.

Next Steps

Participants to the workshop were encouraged to return to their constituencies to continue the discussion and share the initial ideas and early proposals made during group discussions. In addition, several key needs and next steps were identified at the workshop for the community.

- Continue to work towards constructing and implementing an advisory body to WHO to assess the public health value of new vector control tools and technologies for malaria and other vector-borne diseases
- Clarify how the key needs within the public health community for vector control innovation could be expressed and communicated
- Clarify and articulate the respective roles of key groups currently working towards innovation in vector control, including MPAC, a potential new WHO advisory group on new vector control tools, the IVCC's External Scientific Advisory Committee 3, GMP, WHOPES, the WHO's Neglected Tropical Disease Scientific and Technical Advisory Group (NTD – STAG), and others
- Continue the dialogue initiated through the interview process and in Paris on the agreed-upon list of challenges and others that may arise from the dialogue. This dialogue should enable to cooperatively develop consensus solutions as a response to such challenges and propose them to the various constituencies for implementation
- Map current initiatives being executed by individual stakeholders in order to better coordinate activities
- Encourage partners to take action and volunteer, in coordination with the WHO, IVCC and others, to trigger initiatives to accelerate innovation
- Mobilize sufficient resources to ensure that WHOPES can perform its normative function at all levels. In parallel, there is a need for strengthening the capacity of national regulatory authorities

Though the workshop was a powerful first step, continued progress can only be made by the community as a whole. The consultation must be expanded to the vector control innovation community so that a larger, truly representative group can take action in the near-term to foster vector control innovation. A process to continue the dialogue on these points is currently being developed and will be proposed to partners in the community to gather their input.

Workshop Attendees

The following persons attended the workshop and contributed to the creation of this report:-

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Benoit Bouato	Inter-state Pesticides Committee of Central Africa Cameroon
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