Policy Setting Landscape for Malaria Vector Control

Meeting of the Malaria Policy Advisory Committee
Geneva, 11-13 September, 2012

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Global Malaria Programme
Outline

- Progress and challenges in malaria vector control
- Potential threats and the need for new tools/technologies
- Establishment of a vector control advisory group (VCAG)
- Other proposed advisory mechanisms beyond VCAG
- Request to MPAC for action/recommendation
Malaria control and elimination – a decade of progress

- Unprecedented progress in malaria control over past decade, with increased funding leading to major scale-up of vector control interventions, diagnostic testing, and effective treatment.

- Estimates suggest more than one million lives saved over 10 years.
  - Primarily attributed to increased coverage with indoor residual spraying (IRS) and long-lasting insecticidal nets (LLINs).
  - Vector control will always remain a central pillar in the control and elimination of malaria.
Insecticide resistance: we are ahead of the curve but need to act now

- Mosquito resistance to at least one class of insecticides reported from, or confirmed through independent studies in 64 countries with on-going malaria transmission
- Existing prevention tools (LLINs and IRS) remain highly effective in all endemic countries

- Urgent action needed to prevent further development of insecticide resistance, and to preserve effectiveness of vector control interventions and remarkable recent gains in malaria control
Some of the challenges/threats include

- Insecticide resistance management
- Lack of adequate new products and technologies
- Inability to take into account expected life span of products on procurement decisions (e.g. LLINs)
- Weak systems to deliver and manage vector control interventions i.e.
  - Optimize resources by maintaining coverage in financial hard times
  - Capacity for entomological monitoring and vector control
- Lack of clear policy advisory mechanisms for malaria vector control
Capacity for entomological monitoring and vector control

Collection
Insecticide resistance: 64 countries to date, and mostly to pyrethroids

Areas of particular concern are Sub-Saharan Africa and India due to reports of widespread resistance and high rates of malaria transmission

Countries with ongoing malaria transmission and resistance to at least one insecticide

Countries with ongoing malaria transmission and no reports of insecticide resistance

From WHO regional entomologists in WHO Regional Offices, completed by literature review by the Global Malaria Programme.

1. Includes countries with confirmed susceptibility to all insecticides used and countries where susceptibility testing is not currently conducted or results are not available.
2. The map provides no indication of how widespread resistance is within a country; therefore, a single report of resistance would be sufficient to mark a country as having resistance.
GPIRM strategy: a window of opportunity to improve sustainability and impact of vector control

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<th>Five pillars of strategy</th>
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Innovative new vector control tools are urgently needed

- Current pipeline for reformulations of existing insecticides and new active ingredients is promising but more investment is required to speed up the research and development process.
- The Innovative Vector Control Consortium (IVCC) is a product development partnership playing a key role in bringing together public and private sectors to accelerate the development of new vector control tools.
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<th>Needs</th>
<th>Issues faced today</th>
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<tr>
<td>Viable &amp; predictable market</td>
<td>Small public health vector control market with unpredictable size and growth</td>
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<td>Facilitation of &quot;breakthrough innovation&quot;</td>
<td>No formal process to generate evidence for new paradigms, recognize their public health interest and develop recommendations (done ad hoc)</td>
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<td>VCAG – to facilitate breakthrough innovation</td>
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<td>Protection of investments while allowing competition</td>
<td>Data protection viewed as limited since trial results of products evaluated by WHO are fully published for transparency</td>
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<td>Indirect use of trial data generated for original product in evaluation of &quot;me too&quot; products accelerates access to market for new entrants &amp; fosters competition, but seen as creating a disadvantage for product developers</td>
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<td>Limited &quot;recognition&quot; of added value of innovative products within established product categories</td>
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<td>Value for money</td>
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<td>Recognition of innovation</td>
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<th>Needs</th>
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<td>Cheap process and short time-to-market</td>
<td>Limited capacity at WHOPES (secretariat, collaborating centers, working group meetings etc.); limited capacity within national authorities for assessment and evaluation of pesticides</td>
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<td>High quality products</td>
<td>Country regulatory processes not harmonized</td>
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<td>Products that respond to end user needs</td>
<td>Limited capacity and policy for quality control of procured PHPs</td>
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<td>Strong collaboration between groups</td>
<td>Feedback loop from users / procurers limited</td>
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<td>Visibility on innovation pipeline limited for countries and procurers (restricting their possibility to plan ahead in procurement)</td>
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<td>Local researchers request more information on how to get support to develop ideas to products and bring to market</td>
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<td>Frequent communication between groups to align on objectives and outcomes before launching resource intensive phases required</td>
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The need for a Vector Control Advisory Group to facilitate innovation

High level proposal for creation of the Vector Control Advisory Group

The Vector Control Advisory Group could validate paradigm

- The Vector Control Advisory Group could validate the epidemiological impact of a new paradigm, as well as promote coordination and dialogue of all stakeholders
- VCAG will answer the question: "Is this new intervention efficacious, for some defined public health purpose and in some defined circumstances, and will it be useful to and feasible for its intended users?"

The VCAG assessment would then feed into the work of WHOPES and GMP/NTD

- After VCAG validation, responsibility for policy recommendation is passed to MPAC/GMP and STAG/NTD...
  - Will establish role of new vector control tool specifically for one disease, and in relation to other interventions, answering the question: *In which circumstances would this new intervention be implemented for a specific disease?*

  ...and creation of testing guidelines will be passed to WHOPES
  - Will establish relevant testing guidelines for safety and efficacy and specifications for quality control

MPAC/GMP: Considers how new tool fits among other anti-malaria interventions

STAG/NTD: Considers how new tool fits among other interventions against NTDs

WHOPES: Standard tests to define efficacy, assess safety, specifications

Source: Interviews; BCG analysis
Vector Control Advisory Group (VCAG) on new forms of vector control

- GMP and NTD identified a need to establish a Vector Control Advisory Group (VCAG) for new forms of vector control
- Lack of a comprehensive process to assess new tools, technologies and approaches for vector control
- Standards.....focused on new products i.e. LLINs with no defined "entry point" or process for new forms or “paradigms” of vector control
● Delayed the adoption and implementation of new forms of vector control
● VCAG is intended to fill this gap, and provide a clear process for "proof of principle"
● Way in which new forms of vector control can gain an initial recommendation
  ▪ Process of VCAG started 2 years ago
  ▪ Funding for process secured in August 2012
  ▪ Now being constituted
Potential benefit of VCAG to vector control

- Process to introduce new forms of vector control into public health practice
- Reduce uncertainty for innovators through this clarification
- Accelerate the process of public health implementation of new forms of vector control
- A forum for dialogue and guidance to innovators
- Evidence-based advice on epidemiological mode of action and public health value of new forms of vector control
VCAG - Dual reporting

NTD (VEM)

WHOPES

STAG

Working Groups
(Temporary)

Expert Committees
(Standing)

Could tackle specific vector control topics on existing interventions

VCAG (Standing)

GMP (VCU)

MPAC

Technical Expert Groups
(Standing)

Evidence Review Groups
(Temporary)

Could tackle specific vector control topics on existing interventions

WG

Exp. C

VCAG

TEGs

JTEG

SAGE

World Health Organization
### Three VCAG major activities in the innovation process

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<th>Early notification</th>
<th>Initial interaction on data requirements for VCAG's review</th>
<th>Review of the public health value</th>
<th>Policy setting &amp; product evaluation</th>
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<td>Validation of product category &amp; associated Target Product Profile</td>
<td>Epidemiological trials</td>
<td>Validation of paradigm</td>
<td>WHOPES recommendation</td>
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<td>Implementation pilots</td>
<td>Major activities</td>
<td>Milestones/decisions</td>
<td>NRA approval</td>
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<td>Iterative process</td>
<td>Not part of VCAG activities – only with input from VCAG</td>
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VCAG input for policy development by MPAC

**Limited evidence**

Option 0: Additional evidence required
- Direct deliberations on data needs by MPAC/STAG and write-up of needs/pilots following VCAG's presentation

**Significant evidence**

Option 1: Low complexity and/or narrow application
- Direct deliberations and a policy statement write-up by the committee following VCAG's presentation

Option 2: Some complexity or broader application
- Policy statement prepared overnight by "drafting committee", deliberations on next day

Option 3: Complex issue and/or broad application
- MPAC/STAG secretariat asked to prepare draft statement, to be circulated post-meeting to committee members

Option 4: Highly complex issue and broad application
- MPAC/STAG requests an Evidence Review Group, Expert Committee or Working Group to prepare a policy statement to be submitted at next meeting

MPAC/STAG may develop policy recommendations

VCAG presents findings

MPAC/STAG may advise on data needs

Option 0: Additional evidence required
- Direct deliberations on data needs by MPAC/STAG and write-up of needs/pilots following VCAG's presentation

Limited evidence

Significant evidence
Product evaluation by WHOPES in relation to VCAG

● WHOPES will develop standard definitions, testing/assessment methods (efficacy and safety) and quality control criteria of product

● WHOPES will be in close contact with the VCAG secretariat and participate in VCAG meetings/communications

● WHOPES will proceed to a larger consultation of the draft guidelines for finalization and publication

● WHOPES will build on VCAG's work, for a "first-in-class" commercial product
Membership of VCAG

- Provide high quality and well considered advice – an internationally recognized group (geography & gender balance to extent possible)

- Comprised of 11 members representing
  - Practical vector control skills
  - Vector biology
  - Ecology and management
  - Insecticides (product development) and insecticide resistance
  - Epidemiology of vector-borne diseases (malaria) – including statistics and study design

- Secretariat (GMP, NTD, other WHO departments, Regional Offices, and TDR) plus additional experts as needed
Selection of Members

- Open call – posted on WHO web site
- Members and Chairperson appointed by a panel
- Serve for 2 years - could be renewed but not more than 4 years out of every 6 years
- Chairperson invited to MPAC meetings as a resource person
VCAG working procedure

- Meet once a year (open and closed meetings)
- Possibility of *ad hoc* meetings depending on needs
- Open to observers – depending on agenda
- Closed – VCAG members and independent experts as needed
- Establishment of a web page
  - Draft procedural guidelines
  - Solicit for suggestions and comments – broader stakeholder
  - Disseminate recommendations and VCAG reports
Malaria Vector Control Beyond VCAG
Current malaria vector control policy environment

- Need potentially different skill sets
  - New vector control technologies (VCAG)
  - Insecticide resistance management (GPIRM)
  - Implementation of malaria vector control programmes

- According to RBM/HWG, failure of GFATM proposals are often related to last category

- RBM has a vector control working group (VCWG); active, vibrant but self-selected group, including partners with a financial stake
  - Although no mandate for policy setting, has at times attempted to do so

- Creation and implementation of MPAC rectifies existing confusion
VCAG not designed to address full range of malaria vector control policy issues

• VCAG:
  - Not a malaria-specific body; deals with all forms of vector control
  - Upstream proof-of-principle decision-making for new technologies
  - Members need knowledge of technology, chemistry, biology, and product development, not deep expertise in public health management

• Many other issues are malaria-specific and more downstream - connected to practical programme management at country level
  - Examples of topics include:
    ○ role of IRS in malaria epidemics
    ○ combining alternative LLIN distribution systems
    ○ LLIN procurement quantification in relation to lifespan of LLINs
  - Members need to be malaria experts with public health training and experience
Two options for MPAC decision: Option 1 - TEG

- Create a TEG for malaria vector control with “task forces” on perennial issues (e.g. insecticide resistance)

- Advantages:
  - Respond quickly to issues needing policy recommendations
  - Allow a synthetic view of issues for policy recommendations

- Disadvantages:
  - Goes against original concept of MPAC to rely more on ERGs
  - Since vector control issues are heterogeneous – requiring highly specialized skills – TEG may still need to convene an ERG – adding a third layer
Two options for MPAC decision: Option 2 - ERGs

- Convene time-limited ERGs as required
- Potential advantages:
  - Nimbly responsive without creating further architectural components
  - Convene highly specialized experts making recommendations directly to MPAC
- Disadvantages:
  - ERG might consider a single vector control policy recommendation without the broader context of vector control
  - With so many pending issues of vector control – means continuous convening and disbanding of ERGs – time consuming and not efficient
In either case – VCAG would remain a distinct and smaller entity for upstream technologies – reporting directly to MPAC.

Request MPAC to consider carefully the needs of the global community for policy advice on vector control.

Recommend to WHO:

- whether to establish a standing TEG for malaria vector control
- or to convene time-limited ERGs as the need for policy decisions arises
I thank you for your attention