Integrating stakeholders’ perspective into environmental risk assessment: case study

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ILSI/NASEM gene drive symposium
19th July 2017
Our Challenge: Malaria
Malaria: the problem

The burden:
• More than 200 million infections & half million deaths each year, ~90% in Africa, mostly the poor, mostly infants & children
• Economic losses in Africa ~$12 billion a year

The biology:
• Malaria is caused by a parasite called *Plasmodium*
• In Africa most transmission is by 3 closely related species (*Anopheles gambiae*, *Anopheles coluzzii* and *Anopheles arabiensis*), plus *Anopheles funestus*
  • There are ~3500 species of mosquito, the vast majority of which do not transmit malaria
  • Other species can be important in specific locations
• Only female mosquitoes bite and only those infected can transmit the parasite
Extrapolating use of current interventions

WHO Global Technical Strategy (2016-2030)
Geographical distribution of *Plasmodium falciparum* malaria under the most optimistic scenario between 2015 and 2030 (with increase up to 9 billion USD/year) - Griffin et al., 2016
Who We Are

TARGET MALARIA
A Vector Control Research Alliance
Target Malaria: who we are

- A not-for-profit research consortium, including:
  - Scientists: protein engineers, molecular biologists, medical entomologists, population biologists, and social scientists
  - Risk, regulatory and community engagement advisors
  - With teams from Africa, Europe, and North America
  - Working on a unique way to reduce malaria transmission by modifying mosquitoes from the target vector populations
  - That will be freely licensed for use by authorities in countries where it has been approved
Our Vision, Mission and Values

Our vision is a world free of malaria

Our mission is to develop and share new, cost-effective and sustainable genetic technologies to modify mosquitoes and reduce malaria transmission.

We will:

• Achieve **excellence** in all areas of our work, creating a path for responsible research and development of genetic technologies

• We will **co-develop** both our technologies and the associated knowledge base

• Ensure our work is **evidence-driven** so we can deliver safe and effective technologies

• Be **open** and **accountable** in how we work, in our relationships and in our decisions
Abdoulaye Diabate
IRSS Bobo Dioulasso

Mamadou Coulibaly
MRTC Bamako

Jonathan Kayondo
UVRI Entebbe
Our work
A Targeted Approach

Worldwide, there are over 3,500 species of mosquitoes.

837 of those species are in Africa.

Targeting these mosquitoes can help save many of the 395,000 people who die from malaria in Africa every year. The vast majority of which are children.

Target Malaria’s work specifically targets only 3 species:

- Anopheles gambiae
- Anopheles coluzzii
- Anopheles arabiensis
Our objectives

• To develop a novel biological technology for vector control of *Anopheles* mosquitoes to contribute to a reduction in the burden of malaria in Africa

• An approach which is complementary to existing methods, sustainable, long term, and cost-effective

• By reducing the population of the mosquitoes that transmit malaria, and therefore reduce transmission of the malaria parasite, through genetic modification of malaria mosquitoes
Built on three pillars

Science

Regulatory

Stakeholder engagement
Stakeholder engagement
From engagement to co-development

- Target Malaria is committed to engagement:
  - Dedicated team & budget
  - Acceptance as a pre-condition for next steps of activities
- Engagement is usually focused on acceptance only
  - “Knowledge-deficit model”
  - “Educating” stakeholders about an existing technology
- Target Malaria has a co-development engagement model
  - Engaging during technology development
  - Engagement stakeholders about their knowledge
  - Feeding back this knowledge to the project to support co-development of the technology
A multi-layered strategy

- International level
- Africa regional level
- Mali
- Burkina Faso
- Uganda

Different stakeholder groups
Different levels of acceptance needed
Different tactics and degrees of involvement
Overall the key challenges are:

• To identify key stakeholders to engage

• To bring and maintain the debate closer to those who could benefit from the technology,

• To find the right balance between engaging proactively and timely and not overpromising while the technology is still being developed,

• To ensure the decisions can be informed at each level

• To open an informed discussion on risks and benefits considering the context,

• Ensure stakeholders are being heard when they express their knowledge and inputs for the project’s development

• To ensure that stakeholders understand that this isn’t a silver bullet
Engagement and risk assessment
Commitment to risk analysis and management

- Risk analysis is an essential element for the success of the technology.
- Risk/benefit analysis should be at heart of decision-making from stakeholders about whether to do ahead with this technology.
- Internally we have dedicated risk, communication and stakeholder engagement teams working with scientists:
  - Identify plausible harms and from project activities
  - Identify concerns from stakeholders about project activities
  - Analyze the concerns and identify those with plausible pathway to harm
  - Carry-out risk analysis (hazard and exposure characterization and risk characterization)
  - Identify potential management strategies
  - Engage stakeholders about these risks and the proposed management to reach an informed decision on acceptability of activities.
Recognition of stakeholders’ knowledge

- Aligned with the value of co-development, Target Malaria recognizes stakeholders’ knowledge.

- For example for entomological collections, stakeholders are taking an active part:
  - Local guides supporting the team of entomologists.
  - Local casual workers, in particular for swarm catching.

- Knowledge exchange: project sharing the results of the research, communities sharing their knowledge of ecology and mosquitoes.

- Engagement on risk and benefits at all stages: recognition of stakeholders’ capacity to take informed decisions.

- Engagement about concerns that have no plausible pathway to harm, recognition of the concerns and information sharing.

- Importance of engagement to identify the values on which basis stakeholders assess the risks.
Initiatives for hazard identification with stakeholders

The engagement with external stakeholders has been done in different ways:

• Problem formulation workshop with experts in this area – 2016 in Virginia (led to a publication)

• Regional workshops organized by NEPAD for African regulators and other government representatives – Western Africa in 2016, Eastern and Southern Africa in 2017, Central Africa in 2018

• Workshops organized by EU-member states regulators

• Regular engagements with stakeholders in the three partner countries and record of concerns

• Regular engagements with the scientific community

• Meetings with civil society groups in Africa and internationally
Examples of integration

• Joint work on field entomological collection
  • Improvement of collection methods
  • Improvement of information and consent forms with clearer risk/benefit communication
  • Joint work to prepare for specific studies – e.g. Marked Release Recaptures

• Joint work on environmental concerns
  • Concerns from variety of stakeholders
  • Problem formulation workshops
  • Planning for specific studies on Anopheles gambiae ecology to improve knowledge and have an informed risk assessment.
Openness and accountability

• The project is committed to the values of openness and accountability.
• The independent risk assessment made for the first step of the technology development is public and available on the project website.
• The project intends to share the results of relevant studies with stakeholders to provide responses to expressed concerns.
• This sharing will be done in a culturally adapted and meaningful way (in particular for communities in Africa).
Acknowledgment: 14 Institutions, over 140 experts

- CDC Foundation, USA
- Fred Hutchinson Cancer Research Centre, USA
- Imperial College London, UK
- Institut de Recherche en Sciences de la Santé (IRSS), Burkina Faso
- Keele University, UK,
- Malaria Research & Training Center, Université des Sciences, des Techniques et des Technologies de Bamako, Mali
- Polo d’Innovazione di Genomica, Genetica e Biologia (Polo GGB), Italy
- Seattle Children’s Research Institute, USA
- Uganda Virus Research Institute (UVRI), Uganda
- University of Cambridge, UK
- University of Notre Dame, USA
- University of Oxford, UK
- University of Perugia, Italy
- University of Washington, USA

And the communities and stakeholders where we work
Acknowledgements

“Target Malaria receives core funding from the Bill & Melinda Gates Foundation and from the Open Philanthropy Project Fund, an advised fund of Silicon Valley Community Foundation”