



A Vector Control Research Alliance

## NOTES

### Ethics Committee Meeting June 7<sup>th</sup> – June 8<sup>th</sup> 2017 London, United Kingdom

#### Present:

- Allan Ronald, University of Manitoba
- Claire Divver, BAE Systems
- Laurie Zoloth, Northwestern University
- Dominic White, WWF UK
- Paul Ndebele, Medical Research Council of Zimbabwe
- Rashmi Narayana, uMotif
- Austin Burt, Target Malaria
- Delphine Thizy, Target Malaria
- Olivia Majorin, Target Malaria
- Isabelle Coche, Emerging Ag
- Hapsa Dia, Emerging Ag

#### By phone:

- Fred Gould, North Carolina State University
- Stephanie James, FNIH

#### Apologies:

- Paulina Tindana, Navrongo Health Research Center

### 1. Introductions and update (Delphine Thizy)

Delphine introduced the meeting and updated the Committee on recent events.

#### Project's achievements

Target Malaria signed a 4-years grant for 17.5 million USD from the Open Philanthropy Project. This grant will allow the project to further develop training programmes (courses on gene drive), increase outreach activities, research potential ecological effects of releasing gene drives and develop the project's operational capacity and add regulatory support.

#### Scientific update

The team at Imperial College made great progress in developing the final technologies. There is an on-going work to address resistance issues in the female fertility gene drive technology. The team also works on advancing the "Y-drive" technology, to get the sex-distortion modification from an autosome to the Y chromosome.



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### **Project updates in Africa.**

Burkina Faso successfully imported sterile males in November 2016, which is the first import of a genetically modified mosquito for work under containment in Africa. A similar application for contained use of a sterile male mosquito strain is under review in Mali. There has been a large increase in team's human resources, with recruitments of new engagement team members, communication officers in each country, a cross-country compliance officer and a project manager in Burkina Faso. The project is also waiting for final approval from national authorities for new insectary building in Uganda.

The next step is to make an application for controlled releases of the sterile male strain. Burkina will be the first one to make this application this fall followed by Mali then 2 or 3 years later Uganda. This will be done only in one village per country.

### **Stakeholder engagement update**

Delphine then gave several updates on stakeholder engagement:

- Austin Burt presented the project to WHO's VCAG (vector control advisory group last year and received a very good feedback. They will publish a report which is expected to be positive. Once published, the report should be a strong advocacy tool.
- Delphine noted that Target Malaria, and gene drive more broadly, was receiving more coverage. This is positive but creates greater pressure on the teams. For instance the [Stat news](#) piece was the most popular one and was also good publicity for the project, it was also a very good coverage on engagement. However, there is still a little coverage from Africa.
- There is an increased interest from EU regulators on gene drive. So far the positions from countries that have been engaged is quite balanced. Compared to last year, gene drive starts being increasingly mainstreamed in the malaria sector. It is now regularly being mentioned as a tool for elimination.

### **Other achievements**

A new testing facility was opened in Terni, Italy, which is additional to the existing one in Perugia. The facility will be at ACL2 level and will provide increased capacity for large cage testing.

During last year's Ethics Committee meeting, the committee recommended Target Malaria to document and publish about its engagement efforts. Delphine informed the group that a paper will be submitted in June to American Journal of Tropical Medicine about Target Malaria's co-development approach. In addition, FNIH and McMaster University are co-organising a workshop on engagement best practices. Participants will come from other innovative vector control projects to provide 'on the ground' expertise, as well as a few academic experts with experience in designing engagement programmes. The expected outcome will be a white paper that can be used as a reference for guiding SE efforts in this field. Delphine and Stephanie are also discussing whether the paper or a version of it could be endorsed by the Funders and Supporters of gene drive group. This workshop is scheduled for November 2017.

## **Pan African engagement**

A roundtable on gene drive was organized with African scientists in partnership with the African Academy of Sciences (AAS) to present the technology and the project and to discuss the issue of capacity building, engagement and communication in the region.

Workshops were also organized by NEPAD with regulators (one per sub-region). The first one was held last November with ECOWAS, two more are scheduled for this month with Eastern and Southern Africa. The workshop got a positive response and was useful for awareness-raising and network-building. One of the key messages from the workshop was the need for ECOWAS regulators to improve for harmonization and coordination.

Delphine also noted that the project is currently doing outreach to WHO AFRO, with a visit hopefully by the end of 2017.

Austin presented the process that went on with the African Union High Level Panel on emerging technologies. This high level panel was commissioned to review emerging technologies and gene drive was one of them. The presentation made by Austin received positive feedback and the project was told that it will be one of the technologies presented to the African Union meeting next January.

## **2. Working groups report**

### **Ensuring African and the environmental community concerns and perceptions are addressed: Dominic, Fred, Paul**

The group suggested that engagement with environmental NGOs should be a priority. It recommended Target Malaria starts through individual outreach to selected NGO before going to a workshop/meeting.

In order to develop the best stakeholder engagement, it will be important to engage with favourable groups to make sure they understand the technology.

Delphine will start meeting personally the contacts in those organisations and see what comes from the UK, US and then Africa.

A number of questions were raised during the discussion on this topic:

- The different perspectives between Western countries (“we should not manipulate nature”) versus tangible health issues in Africa
- Whether environment groups from Africa would have views significantly different or similar concerns with European or North American groups?
- The question of ownership was also raised: how to highlight the needs of the affected nations in Africa and how valid is UK position to this technology?
- Several issues that could be highlighted were identified:
  - o Issues about the unknown “what happens if we fail to control them?”
  - o Issues around perception if small scale releases are not introduced the right way

- Issue with media in Africa and perception of african countries being used as “guinea pigs”
- The group agreed that the African PIs should be fully involved to be local ambassadors for the project, listening and taking immediate steps to address those issues
- To address the issues about suspicion, the project should ensure information is simple and easily understood to ensure that African partners are fully on board
- Local media plays a very important role to disseminate correct information and in highlighting the work of the team, so engaging them should also be considered
- The group noted that there is a clear need for making sure there is a sense of ownership by African stakeholders. Stephanie noted that FNIH is sponsoring a series of workshops with NEPAD to bring biosafety and health regulators together

**Action item:**

- **Committee members to share relevant contacts in environment NGOS to integrate in the outreach with Delphine.**

**Managing stakeholder fatigue: Paulina, Allan, Paul**

The group noted that the engagement of populations and continuous communication over time is a challenge.

The working group offered some suggestions to manage stakeholder fatigue:

- Give a sense of community to those who are part of this research and encourage them to talk among themselves
- Monthly or regular lunch/celebrations during long term studies to help create a sense of progress and involvement
- T-shirts/badges which will identify people as participants to the project
- Continually engage with a physical presence
- Give direct and indirect benefits
- Plan ahead, realize that fatigue will be an issue and give constant feedback
- Let the public know about various activities going on
- Scale up the benefits over time
- Encourage the community to identify with the project “We are in partnership with Target Malaria”
- Monitoring mechanism should also be in place to manage any arising issue.

The group discussed these recommendations and came with additional suggestions and remarks:

- Giving benefits is a good idea however those benefits would need to make sense for the project – a feasible option could be to collaborate with people who are already working with bed nets / theatre forums / more educational programs for schools
- Before giving benefits the project should start with a mapping of the number of people in village / socio economic needs / expectations
- It was also flagged that being clear and careful about the right script regarding benefits giving will be essential to avoid any misunderstanding



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**Action item:**

- **Delphine will consider how to integrate the suggestions made and report back to the group. No further work is needed from this working group.**

**Mapping of opportunities for training and mentorship and components of an ethics and engagement training: Paulina, Claire**

The members of that group were not present. Delphine briefly gave her input on the work of the group. Claire and Paulina were to check mentoring and training possibilities on community engagement and advocacy/policy level and come back with options.

Allan noted the importance of ensuring scientific training options are also available. Delphine noted that the Open Philanthropy Project grant will go in part towards funding Phds and Masters. However, it is more difficult to find opportunities with masters in the engagement field and this skill set lacks within the project.

**Action item:**

- **Claire and Paulina to share their suggestions and recommendations about what they found for training/mentorship opportunities in SE.**

**3. Evaluating Strategies for reversing CRISPR-Cas9 Gene Drives (Austin Burt)**

Austin and Fred briefed the committee about the topic of gene drive reversal or "recall". He noted that several options are currently under consideration. One of the options is to build an enzyme that targets female population to restore female fertility, and which spreads by natural selection in order to make gene drive disappear.

They noted that while this is very important to investigate, it should not be considered as an excuse or reason for being more lax about the risk assessment for any gene drive technology. Austin added that the project should not rely on recall mechanisms as a 'safety mechanism' when considering whether a release was acceptable.

Laurie and others in the group agreed that even if a recall mechanism may work, the public's perception of using such a mechanism would likely be very negative. If initial gene drive doesn't work in the first place, it is unlikely the public will trust the use of another drive to fix the problem.

Laurie noted that from an engagement perspective, if the project wanted to consider a 'reversal' mechanism, it would be important to introduce the concept from the very beginning. This would help shape public perception of the second drive mechanism not a second thought to fix a problem, but instead as being a normal part of managing a gene drive technology.

## 4. Updates - Engagement and communications (Isabelle Coche)

### Coalition updates

Isabelle noted that the CBD meeting in December 2018, combined with growing interest in gene drive, had put the Target Malaria team on spot. It was able to reach out to a large group of like minded researchers and advocates and is now working to capitalise on this early effort by supporting efforts to build an advocacy coalition.

The coalition will aim to provide engagement coordination and work-sharing. It will be an informal, bringing together gene drive researchers, advocates, funders and others working on gene drive for "public good" applications, not commercial applications.

Stephanie noted that there will also be a coalition of funders. A principles document was circulated in response to the recommendations made to funders and 13 organisations have signed. The group hopes to publish the paper in the coming weeks. She also noted that a meeting took place in March, where topics of mutual interest were identified (data sharing/regulatory capacity building/advocacy/stakeholder engagement) which will form the basis for further work for the group.

### **Action items:**

- **Isabelle will inform the committee of progress on the advocacy coalition. The group agreed that the coalition will be a great tool to support good science for gene drive and anticipate public perception.**
- **Stephanie will share the Principles paper with the committee.**

### Mission, Vision, Values

Isabelle informed the committee that the project had recently agreed to a Mission, Vision, Values statement for Target Malaria. This will become part of the project's communication and help guide its activities.

Transparency being a key aspect of the Mission, Vision, Values; the Committee suggested using the website for more transparency and to consider options on how to showcase the work of the Committee.

## 5. New committee members

The Committee agreed that new members with different backgrounds and new skills set would be highly valuable to the group. However, it felt the current shortlist did not offer the right profiles in terms of diversity of backgrounds.

The group would be looking for someone from the following profile:

- NGO community/development with malaria background
- Community engagement people/
- Experts in ecology and conservation or interested in bio-control
- Experts from Africa with experience in public health
- African NGOs



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**Action item:**

- **Committee members will provide suggestions in the next two weeks so that a short list can be circulated to the group to consider and prioritize. Deadline for submitting names is July 14<sup>th</sup>.**

**6. Speakers presentations**

**Mike Bonsall** - Professor of mathematical biology, former member of DEFRA's Advisory Committee on Releases to the Environment - presented on the ecological, economics and policy implications of the use of GM insects (population suppression & self-limiting technologies).

[Powerpoint presentation will be available in DropBox]

**Robert Valadez** - Director of Communications, Campaigns and Special Initiatives for the Office of the UN Special Envoy for Health in Agenda 2030 and for Malaria – discussed the Special Envoy's team communications strategy. He highlighted the fact that the narrative on malaria was changing because of new health priorities but also because of different perceptions of success.

On gene drive, he noted that communicate about this technology was exciting but also challenging because of the complexity and remaining unknowns. The challenge will be for projects like Target Malaria to make it easy for the stakeholders to understand the technology and its role.

He also noted that careful choices around language and messaging would be key to success. His team has seen the value of being able to tell stories rather than only focus on facts as a way of making the issue personal and relatable, and this is something that will be important for the project.

**7. Introduction to working group topics (Delphine Thizy)**

**Working group session 1 - Audits**

The Committee reviewed the checklist and provided detailed feedback. They agreed it formed a strong and sound basis for the audit. Dominic noted the challenge of providing something sufficiently detailed without being too long or inflexible. Isabelle noted the value of a detailed approach so that team understood how the conclusions were reached and what needed to be done to be successful.

**Action items:**

- **Delphine will take the suggestions under consideration and amend the document accordingly and will transmit to the teams. The Secretariat will share the updated form with the committee**
- **Secretariat will consult with the committee to identify volunteers to attend the next audits:**
  - September 18<sup>th</sup> Burkina Faso
  - Around May 2018 for Mali

## **Working group session 2 – Evaluation framework**

The committee discussed the approach for the evaluation. It noted that there could be different approaches, either a more internally focused one where the team self-evaluate or a more externally-driven one where an outside auditor carries out the evaluation. They agreed that both had value but served distinct needs. An externally-led evaluation can serve to provide validation and legitimacy to external stakeholders and be used as a reference point if the project comes under scrutiny, in the same way that independent risk assessments do. An internally-driven evaluation places more emphasis on learning and is more about the teams improving their practices than about providing validation.

Delphine noted both aspects were important. Isabelle noted that even a team-led evaluation could benefit from having an externally-provided benchmark to start from so there was some concrete elements to discuss for progress. The group suggested the project could combine the two, with an external evaluation providing the benchmark and then the team leading an internal evaluation exercise to work on improvements, possibly with the help of a facilitator.

Several committee members noted that in their experience, it was valuable for teams to visit each other and to serve as evaluators of each other's work as it brought a knowledgeable but semi-external perspective. They also noted that cultural and personality differences were important to take into consideration as not everyone would be comfortable assessing another team's work.

The committee then discussed the basis for the evaluation. It noted that an evaluation could be outcomes oriented but could also be focused on process and whether the teams' way of working is aligned with the values of Target Malaria. All agreed that process could not be the only consideration but should be an important element. Paul noted that Paulina had been working on evaluations recently and could potentially provide some useful insights.

### **Action items:**

- **Delphine to draft the scope of work for the external consultant**
- **Rashmi to consider the audit checklist and see how the values could be integrated**
- **Delphine and Rashmi to consult with Paulina on the draft before sharing it back with the committee.**

## **8. Conclusion, next steps and dates of next meetings**

### **Next meeting**

It was decided that instead of the working groups calls, there will be 2 meetings in person during the year 2017/2018. A working group meeting of one day and half will be held in London by end of this year or early January 2018 and the yearly meeting in May/June 2018. Dates to be decided by end of the month. The committee discussed whether the in-person in May/June may be held in one of the African partner sites so that they could visit the labs and the sites and have presentations from the teams.

Allan flagged that he might leave the Committee in 2018.





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**Action item:**

- **Secretariat to send out a doodle poll to fix the dates for the next meetings.**

**Possible next topics of the working groups**

The committee discussed what it should consider next:

- Transparency and sharing information & data
- Review SE best practices paper
- Publications and sharing information about the project
- Follow up on engagement to environment / conservation groups
- Conflict of interest (funders...)

**Additional action items:**

- Secretariat will consult with the Committee on the topics for the working groups
- Committee to suggest speakers for the next in-person in May/June by January 31st
- Secretariat to set up a Dropbox for the Ethics Committee
- Secretariat to explore options to show more transparency on the website regarding the Ethics Committee and their work:
  - Publish on the website, what the working groups advised and what was applied
  - Documents: what the Committee has already worked on and check what documents could be shared on the website