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## Research Article

# DESCRIPTION OF SOCIAL ASPECTS SURROUNDING RELEASES OF TRANSGENIC MOSQUITOES IN BRAZIL

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## ABSTRACT

PAT (Projeto *Aedes* Transgênico) agreed upon to test, in urban areas, the social, technical and operational aspects of a genetic control program releasing transgenic male mosquitoes of *Aedes aegypti* in the field. Here we show the social aspects, regarding the regulatory issues, action plan and strategies used before and during the mosquito release. This work also evaluated people's perception when the studies were finished and releases stopped. The evaluation considering the areas used in this study showed that different population levels (local, regional, national and international) did not presented negative opinion about the actions taken place in Brazil. It was also possible to evaluate people's perception regarding their positivity about the project and the activities (monitoring, mosquito release and others) carried out.

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## INTRODUCTION

*Aedes aegypti* is the main vector for arbovirus transmission in Brazil, such as dengue, chikungunya and zika [1]. These diseases and vector became the most important target for the Brazilian government and its public health system [2]. New attempts to suppress mosquito population are being under evaluation; and one of them is the use of genetically modified mosquitoes (GMM) that cannot reach adulthood and dies before being capable to transmit the disease [3].

The first record of an open-field evaluation for the effect of transgenic male mosquitoes release was in Cayman Island. Oxitec (a Biotech company in UK) had used the OX513A line in order to evaluate the possibility to suppress *Aedes aegypti* population [4]. Briefly, they have released

transgenic males, which delivers a lethal gene to the offspring, when these males mate with wild-type females. The offspring can only complete its development in the presence of tetracycline in the larval rearing water, otherwise dies before reaching adulthood [5]. This technology, based on SIT (Sterile Insect Technique) programs [6], consists in a large scale production of insects and release these modified adult males in the field to achieve population suppression [7].

The field trials conducted by Oxitec and its partners, in the Cayman Island produced the technical expected results, although it has been target of social objections. According to an Editorial from Nature [8], which mentions: "(...) there is no suggestion that any of the releases was unsafe or contravened any law (...). If the release of GM organisms is handled badly, it could generate an unnecessary and unhelpful climate of

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suspicion". The main issue was the way public engagement was handled by Oxitec and partners. The reaction of the scientific community and the public in general (regarding Oxitec and its partners' activities) is about claiming lack of transparency and low public dissemination of information [8,9].

A badly conducted community engagement has already happened in the past, during a classic SIT program in India against *Culex fatigans* [10,11]. According to the WHO (World Health Organization), in the Indian program, the technique itself was not the reason for the program's failure, but the way social and political issues were handled [10,11].

More recently, some articles attempt to provide an initial discussion for establishment of criteria for community engagement in order to avoid or minimize adverse events that may prevent the continuation of certain experiments and also more complex vector control programs [9,12–15].

A second attempt using Oxitec's transgenic line (OX513A) started in Brazil in 2010, and it also demonstrated good results such as in Cayman Island. However, the Brazilians counterparts conducted the public/community engagement/information. This paper provides the Brazilian experience regarding the social activities carried out before, during and after the GMM releases in two areas of Juazeiro (BA), northeast of Brazil; it also provides information regarding the regulatory aspect conducted in the country as being pioneer.

### General Overview

PAT stands for *Aedes* Transgenic Project (in Portuguese) and is a joint project involving three different institutions; it involves Biofábrica Moscamed Brazil (a nonprofit social organization using SIT for fruit flies), the Laboratory of Genetically Modified Mosquitoes in the University of São Paulo (USP) and Oxitec Ltd (previously mentioned). The objective of PAT was to evaluate the feasibility of using a transgenic line (OX513A - same used in the Cayman Island trial) in Brazil in order to suppress *Ae. aegypti* population [16]. For this request, PAT not only get involved into the process of rearing, releasing [17] and monitoring them [16], but it also get involved in regulatory issues and social activities before, during and after the releases (figure 01). The sequence of steps in order to turn PAT operational is described as follows: 1. Contact with the public health system (PHS); 2. Site selection coordinated by the PHS; 3. Submission for regulatory approval at CTNBio; 4. Public engagement through CTNBio and for local community through mosquito trap monitoring/surveillance; 5. PAT information dissemination (schools presentation, public events participation and general interviews in TV and radio); 6. House visiting program; 7. Post-release evaluation.

### Contact with The Public Health System (PHS)

PAT team gets in contact with the municipal (Juazeiro) and state (Bahia) health Public Health Agents' (PHA) and their supervisors. They had fundamental participation giving opinion and suggestions regarding the best approach and language for each community also to comprehend local community habits and to define technical procedures.

Based on PHAs experience and the activities conducted by them preconized by the National Plan for Dengue Control (Plano Nacional de Controle da Dengue – PNCD) [18], the social sphere was planned to have a list of activities, which were used in different frequencies according to the efficiency level reached by each of them. All these activities aimed to clarify as much as possible the nature of the project in the target community, starting from the assumption that people had low or no information about the use of GMMs for mosquito control.

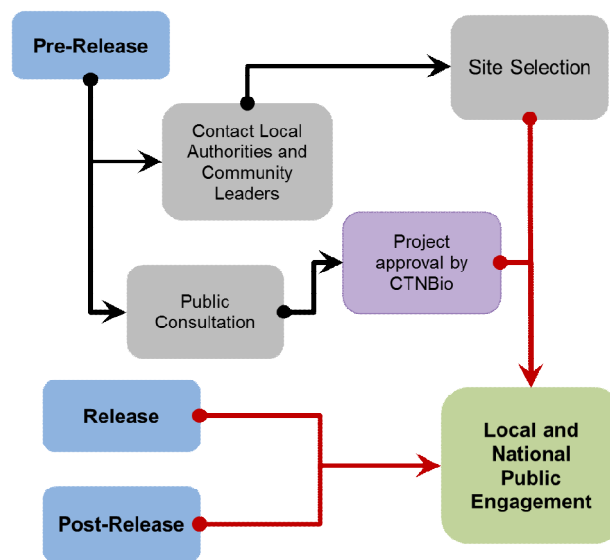


Figure 01 Flow chart illustrating the key activities of the public engagement element of PAT

PHA stakeholders and PAT social team then divided those activities in three different classes, according to the perception of importance level, based on local cultural aspects and determining those activities that would be more efficient in reaching the target audience (Table 1). So those that were considered mandatory are activities carried out locally more intensely; those considered recommended, easy to handle with good population outreach in order to maintain the population informed about the upcoming results and activities, and at last, those considered suggested activities, those that show good outcome but they are not essential for PAT establishment.

Table 1 Types of strategies employed during the public engagement plan and the authorities involved.

STRATEGIES		
Mandatory	Recommended	Suggested
- Visit sample/every house in the target area	- Lectures at community centers/churches	- Action in parallel with local events (parade, carnival, street fairs)
- Meetings with local leaders, school principals, district managers	- Broadcast radio spots, jingles and messages	- Truck with loudspeakers in the targeting area – jingle and messages
- Lectures at schools	- Press releases by Moscamed journalists	- Social media: Facebook and twitter
- Press coverage at local/regional level of PAT activities	- PAT technical team interviewed by local/regional/(inter)national radio stations	- Press coverage at international level of PAT activities
- Interview sample/every house in the target area	- Press coverage at national level of PAT activities: production, releases	

The federal government, through the Ministry of Health and correlated Agencies (at federal and state levels), has tracked the progress of PAT. This federal evaluation was made by annual meetings and more frequently (quarterly) by state level. In a regular base, information about the project was broadcasted through press releases done by the Moscamed press office. Hence, PAT introduced and strengthened the communication channel between researchers, policy makers and local population in order to understand the concerns of each party regarding the use of this technology and how to address them when planning releases.

#### **Site Selection Coordinated By The Phs**

As mentioned previously, the local health authorities at municipal and state level were contacted to help selecting target areas and also to design an action plan during the project period regarding operational and social fronts. The requirements for site selection are not well established yet by any Brazilian regulatory organization or any international ones. Therefore, site selection was based on suggestions described in the scientific literature [19–21]. The involvement of health agents and local authorities was critical to select the most suitable sites [20,21]. The PHA and their supervisors in regular meetings with representatives of Moscamed, USP and Oxitec selected two areas in Juazeiro to evaluate effect of releasing transgenic mosquitoes. During these meetings researches and PHA's discussed crucial points to rank villages, such as mosquito presence/absence, difficulty to access population (talking and entering people's house – e.g., for trapping), isolation/distance from facility and village structure (e.g., water source, sewer, type of houses, etc.). According to PHAs experience, the communities in Juazeiro are very open to new initiatives regarding public health and development programs. They also mention that the population often expresses a positive opinion towards novel approaches and even an active desire for an innovative project to be developed in their neighborhood.

According to the PHA's, the population from the study site understands that dengue is a severe human health problem; this information turns the project approach more comprehensible by public in general. This perception helped to garner support from the state government of Bahia and from the city of Juazeiro in the form of political good will and provision of human infrastructure for the project at different points, which was crucial for its successful implementation.

At last, the selected areas, Itaberaba and Mandacaru, are two distinct villages around 15 km from each other. Itaberaba covers an area of 55 hectares, comprising 1,400 houses where approximately 7,000 people live. Meanwhile, Mandacaru is a typical agricultural village of 33 hectares with 600 houses and approximately 1,800 people. Both sites are currently included in the PNCD [18].

#### **Ctnbio Approval and Relevant Legal Framework**

In slight contrast to some countries, in Brazil, activities involving any use of Genetically Modified Organisms (GMOs) must be submitted and approved by a legal framework, which operates at federal level. The national biosafety law (**11.105 law from March, 2005**) details the safety norms and inspection mechanisms required to be in place for activities that involve

any GMO or their by-products; it implements the National Biosafety Council (CNBS), the National Biosafety Technical Commission (CTNBio), Internal Biosafety Commissions (CIBios) and it provides substrate for the National Biosafety Policy (PNB). The CTNBio is responsible not only to judge the biosecurity issues but also to assess the impact a GMO may have on the community and surrounding areas. The CIBio, such like an ethics committee, are many local commissions in different institutes and they are responsible to inform CTNBio regarding the activities involving GMOs in their belonging institutions. The CIBios are composed by Ph.D. members from their own institution, who are able to evaluate and deal with GMOs issues with CTNBio.

The CTNBio is composed of several ministers and federal agencies, and their representatives' vote; so after a CTNBio decision there is no need for the project to be voted on by each organ separately regarding biosafety (for instance, a commercial registration and public usage need other national agencies to get involved on this process, such as ANVISA, IBAMA and etc.). In general, this process can be understood as an important path for general acceptance once it is composed by several different spheres in order to evaluate safeness.

All proposed research and commercial projects (looking for biosafety approval) have to be submitted to CTNBio executive secretary so that the claiming process can be published in the Federal Official Gazette (Diário Oficial da União – DOU), a nationwide distributed newspaper (available on internet). During 30 days, the process stills available under requirement. The CTNBio Normative Instruction (n° 19, from April, 19<sup>th</sup> 2000) determines how the discussion is conducted before the voting date gathering all the interested parts to discuss about the project. The CTNBio designates two members (a reviewer/referee) to evaluate the process, and these referees deliberate the process with recommendations, clarifications, diligence and other pertinent needed action. Only then, members decide a final date to vote in an open plenary. This was the first step for a public consultation for PAT. Regarding this process, only one non-governmental organization (NGO) asked for a copy of the process and it had no further issues. PAT process had 19 votes in favor out of 24; the remaining 5 votes were absent. In other words, CTNBio considered the release of this specific line safe to those who are dealing with, those who live in areas where the insect will be released, to the environment and to society in general. Every step regarding the decision making of CTBio is published in DOU for every project. There is an update web site with all process and agenda available on-line (ctnbio.gov.br). CTNBio meetings are public open hearings, in which public in general are welcome to participate and express their opinion, but only members can vote.

#### **Pat Information Dissemination**

PAT wanted to increase overall public awareness about the use of transgenic organisms in public health as part of the integrated pest management and about the possible risks and benefits in applying those insects into the environment. The activities conducted to increase awareness about the use of GMMs helped to prepare the community of Itaberaba and Mandacaru for field releases, explaining what is expected, how the insects will be treated and how they behave in the field, it



was also the opportunity to listen the population and their doubts.

In order to avoid misunderstanding regarding PAT activities, the project advocates transparency and an open communication channel between researchers, stakeholders, and community. By transparency, the team aimed to avoid being misunderstood, and defines it as the perceived quality of intentionally shared information by PAT and its information disclosure, clarity, and accuracy. It means that the information and actions have to be clear and fully comprehended by all parts involved. An external administrative panel was responsible to evaluate and deliberate about Moscamed/PAT actions and a report detailing all actions, which is annually available at their website (www.moscamed.org.br).

An important example also regarding the transparency is about the project itself. The use of the word *sterile* to describe this insect line by its developer (Oxitec) has led to frequent misunderstanding by the general public, researchers, non-governmental organizations (NGOs) and other companies (as mentioned before) causing some discomfort [22]. So then, to avoid misunderstanding regards the type of organism we were using, PAT incorporated the word “transgenic” in the project’s name. The main reason for doing so was to clarify which strain we were using in the program are fertile *transgenic* male insects and not *sterile* ones.

A logo was also developed, for easy identification, and to use in all dissemination materials, and on cars/trucks, uniforms, buttons, hats etc. A jingle and a spot were also developed, so these sound messages could be used in order to disseminate information regarding the project and announcing activities to be held on that area or time period.

Different types of media were used to disseminate information about PAT. This way, a massive and intense information distribution could be more efficient regarding the explanation about the overall plan; operational aspect; monitoring system; and results from GMM releases in Itaberaba and Mandacaru. The press was an important tool, through newspapers; radio; TV (conventional or on-line); blogs and Internet (social networks). Most of them were employed at local level and for regional and national levels the intensity was lower.

Action	Period			
	Pre-release	Release		Post-release
	2010*	2011	2012	2013*
Domiciliary visit				
Internet	Social Network			
	Web site			
Interviews / appearances	TV			
	Radio			
	Newspaper			
	Magazines			
Jingle broadcast				
Leaflets distribution				
Meeting local leaders				
Questionnaires				
School presentations / lectures				
Monitoring system				
Truck loudspeakers				

\* - In both years, the columns are representing the last two semesters and the first two respectively.

Figure 2 Distribution of social activities during PAT operational process

During the social campaign, the strategies mentioned in table 1 were employed at different intensities (Figure2) in accordance with their impact, size of community reached and the broadcasting level, i.e. the number of interviews on TV can be

lower than the number of radio interviews, but TV can reach more people at national level.

Dissemination of scientific concepts and project objectives through nationwide mass communications have served as a means to assess how Brazilians reacted to the technology employed, mainly by the local population after the regulatory approval. Table 2 presents an estimate of the number of people at different geographical scales that might have received some knowledge/information about the project. Regarding TV, radio and newspapers, they were based on the Brazilian Institute of Public Opinion and Statistics (IBOPE) calculation, which measure audience, linked to the number of appearances on TV, the distribution and outreach of newspapers and radio. Using this reference, it was possible to estimate number of people reached by these dissemination techniques.

The general coverage on TV, nationwide newspapers and print magazines surrounding PAT had reported no complaints about the use of transgenic insects in public health, additionally some stakeholders from other areas of the country started asking to also be part of this initiative, using their own cities/states as field trials. This unalloyed positive response was unexpected, based on previous experiences from other countries, and could, be at least partially attributed to the full transparency and efforts from the communication professionals and PHAs participation.

Table 2. List of actions performed during the PAT public engagement plan carried out in Juazeiro (Bahia), for 26 months, with the estimated number of people reached.

Action	Target pop. Level	# Events	# People
Presentations/Lectures	Local/Regional	10	962
Leaflets (*)	Local	-	10,000
Jingle (*)	Local	-	-
Meetings	National/	39	6,020
	International		
Interviews (radio)	Regional	15	1,500
Interviews (TV)	Regional/National	12	17,160,364 (**)
Interviews (newspaper/magazine)	Local/Regional/	21	-
	National		
Internet (website / social network)	Regional/National	24	-(***)
Houses visited/interviewed with residents	Local	1043	4,202
Meetings with local leaders, health agents	Local	16	820
Presentations at school	Local	08	452
Presentation at community center/city hall/others	Local	06	456
Truck with loudspeakers in the releasing area	Local	-	500
Spots, jingles and short messages broadcasted in local radio station	Local	52	1,200 (**)
<b>TOTAL</b>			<b>17,188,817</b>

(\*) - Those strategies that ensure that most of people have read/listened to the information and comprehended it – the number means the total production/distribution.

(\*\*) - Those strategies based on the Brazilian Institute of Public Opinion and Statistics (IBOPE) data.

(\*\*\*) - Unknown, since some websites do not provide the number of accesses.

Radios interviews were conducted during establishment of the ovitrap placement to monitor mosquito populations in the target communities in July 2010, seven months prior to the first

planned release. These interviews aimed to contact the local population and answer all people’s questions. Those interviews were available also on-line by the radio stations or through Moscamed website and in the social networks, in order to broadcast not only for locals, but also for all those who have Internet access.

Also before the releases, the municipal health secretary advised us to visit all schools in the release areas and integrate them by giving lectures for students and teachers about the activities in their neighborhood. This activity was carried out during all project period (figure 02). The health secretary has been using this strategy, and they said that young student scan became tools to disseminate information at home, raising curiosity in parents/relatives and instigating them to find out more information about an issue.

PAT also hosted meetings and gave speeches at community centers with local leaders, district managers, and the general public, deemed a mandatory strategy for public engagement (table 01) in order to answer possible questions the population might have about the project before and during its evolution. Since information may have been forgotten over time and further doubts have arisen once releases had started.

Moscamed communication professionals prepared press releases to call attention to PAT and to provide basic information regarding planned activities in the study areas (figure 01) before and during the releases. These materials were also a guide for any PAT technical staff in preparing for interviews on local radio and TV stations, helping them to explain the concept of genetic control of mosquitoes to a wide audience of non-experts.

In line with the project’s policy of transparency, PAT was always willing to receive visits from community, the general scientific community, public health managers, stakeholders, and the media when approached, and also it had invited visitors on a regular basis so they can be updated or give their suggestions.

**House Visiting Program**

Every house in the release area was visited by a PAT uniformed instructor and the resident was primary informed about the project, and a folder was distributed for more information. A total of 425 houses were visited in Itaberaba and 618 in Mandacaru (reaching around 4,202 persons – table 02).

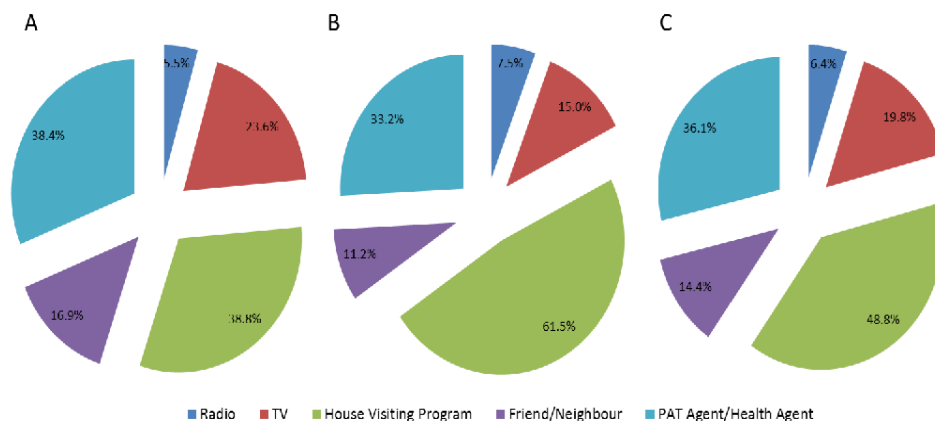
At both sites the approached householders accepted the visit and PAT team was able to talk about PAT. Some houses were grouped as “closed houses” and “house with teenagers/kids”. A second visit was done for these two groups and in the case where it was again not possible to meet the householder during week working days, another visit was made during the weekend. As outcome, in none of the houses the technology was rejected and additionally householders mention that they understood the objectives of PAT.

In release area of Itaberaba, the PHA’s informed PAT that there is a high level of migration, which in turn means that many recent householders were not involved in the project from the beginning. This provided further impetus to continue public engagement activities throughout the release period on both areas. As an outcome, according to the testimony of PAT instructors only a couple of time during the releases there was registered few negative reactions. However, these reactions were concerned about generic issues and not specifically regarding the project, the mosquito transgenic release or the use of this methodology. For instance, one local woman mentioned that they need more medical doctors in local basic health units and another one said they need more investment in basic sanitation conditions.

**Post-Release Evaluation at Local Level**

All references mentioning the use of mosquito releases (sterile or transgenic) and its disclosure activities, describes activities taken previous to the releases and some during them. However the evaluation regarding the post-release period perception was not common. As part of the social plan, PAT provided final information regarding the study results one month after the last release. The operational monitoring process was carried out for additional 12 months and a final meeting to present all the results and to collect people’s opinion regarding the activities was set up in the release areas.

The post-release survey had eight simple questions (table 03), and it was conducted to evaluate the perception of the project locally (only in release areas) and only among adults (over 18 years old). This questionnaire approach was approved by the ethics commission of USP, Protocol 1115/CEP. A total of 482 residents were randomly selected to answer this questionnaire (282 in Itaberaba and 200 in Mandacaru) during a final meeting with the community. As outcome, 88.8% were aware about the PAT, where 84.0% in Itaberaba and 93.5% in Mandacaru.



**Figure 03** Local media influence regarding people’s knowledge about PAT

The increase can be explained by the difference when the project started and also in response to the migration process in the areas, where people do not stay for long periods.

From those that were aware of PAT, the type of media or which action made them remembered it, this data can be visualized for each release site on figure 3 (A and B), to summarize around 48.8% due to home visits; 36.1% through activities conducted by PAT team and the public health agents (monitoring activity, school presentations); TV represented 19.8% where people mention they have seen at least one of the interviews; 14.4% heard about PAT from one of their neighbors or friends; and 6.4% heard about it on the radio (Figure 3C).

The most effective activity to inform people at the local level was through the home visiting program, however this kind of activity would be unpractical for larger study areas, such as whole cities, states or countries, and for areas of dense population, so other kind of strategies should take place, such as more frequent TV infomercials regarding the strategy as it already been done by the Brazilian Ministry of Health about dengue transmission.

In both areas, 95.7% respondents were aware that frequent mosquito releases had occurred in their villages. And 91.5% of the respondents said that the releases had not affected their routine, and of those who had ovitraps installed in their houses (around 400 houses in both areas) only 1% of them were bothered by the weekly collection of the traps (Table 03).

Due to the time lag between when the PAT activities were started in each area, the level of understanding of the project by the communities was quite different. In Itaberaba (the first place in which mosquitoes were released), 66.3% of respondents claimed to understand the results achieved by the mosquito release efforts. On the other hand, in Mandacaru (which started the project later) 84.4% of respondents claimed to understand the results obtained in this community. A corresponding increase was recorded when respondents were asked whether PAT should be carried out in their village, from 91.4% in Itaberaba to 96.8% in Mandacaru (Table 03).

**Table 03** Percentage of Yes/No answer for the questionnaire in the two release areas

Question	Itaberaba		Mandacaru		Both areas	
	Yes	No	Yes	No	Yes	No
Do you know or heard about PAT?	84.0%	16.0%	93.5%	6.5%	88.8%	11.2%
Do you know if releases occurred in this area?	94.1%	5.9%	97.3%	2.7%	95.7%	4.3%
Did the releases have impact your routine?	12.7%	87.3%	4.3%	95.7%	8.5%	91.5%
Do you believe the project can help the mosquito control?	91.4%	8.6%	96.8%	3.2%	94.1%	5.9%
The visit of PAT agents to service traps in your home bothered you?	0.8%	99.2%	1.1%	98.9%	1.0%	99.0%
Did you understand the results of PAT?	66.3%	33.7%	84.4%	15.6%	75.4%	24.6%
Do you want the PAT continues with the releases in this community?	97.3%	2.7%	97.8%	2.2%	97.5%	2.5%
Are you aware that other measures for control mosquitoes should be carried out?	98.7%	1.3%	98.4%	1.6%	98.6%	1.4%

Certainly, this difference reflects the time period of involvement of PAT in each area. Although the conducted activities were aimed at the target population in the main release area, it would be important for other areas of the city to be aware of events. This would have the benefit that when the same activities were started in other districts of the city the population would already have previous knowledge of the project activities, or at least know about the releases of these modified mosquitoes.

The proportion of respondents that understood the use of GMO technology and the current control methods was almost the same in both areas: 98.7% in Itaberaba and 98.4% in Mandacaru, asking them to shortly explain what they understood. This result can be explained through the success of the project in achieving its goal, which was to inform people of the proper use of this technology, and a result of the way public engagement was conducted in these villages in Brazil.

Percentage of the total Yes/No answers given for the questionnaire for each release area conducted the post-release evaluation and the percentage for both areas.

## CONCLUSIONS

It is worth to mention that, even with international researchers' involvement, all social activities were planned and conducted by Brazilians (researchers and other professionals) to avoid cultural and language issues between foreign researchers and Brazilian (local) community.

Considering that this study was pioneering in Brazil (and indeed in continental America), its results were positive and provide lessons for the design of similar social engagement plans which can be extrapolated to more complicated circumstances in Brazil or abroad, such as larger urban areas or even areas inhabited by indigenous tribes, where serious dengue or malaria outbreaks might happen. We expect that through the efforts described in this review the local communities in study sites will gain a stronger capacity for interacting with research and government representatives, and thereby be empowered and prepared for consultation on the details of a larger suppression program.

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