

Implementation of a Novel Malaria Management Strategy Based on Self-testing and Self-treatment in Remote Areas in the Amazon (Malakit): Confronting a-priori Assumptions With Reality

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Methodology

Keywords: border malaria, mining population, remote health, process evaluation, implementation outcomes

Posted Date: August 5th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-764314/v1>

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Version of Record: A version of this preprint was published at BMC Public Health on April 15th, 2022. See the published version at <https://doi.org/10.1186/s12889-022-12801-0>.

Abstract

Background: An innovative strategy to combat malaria was tested with a methodology adapted to a complex setting in the Amazon region and a hard-to-reach, mobile population. The intervention strategy tested was the distribution, after training, of self-diagnosis and self-treatment kits to gold miners who cross the Surinamese and Brazilian borders with French Guiana to work illegally in the remote mining sites in the forest of this French overseas territory. The main evaluation criterion was the reported behavioral change in case of malaria symptoms, measured by pre- and post-intervention surveys.

Method: This article informs on the quality of delivery, content adherence and facilitation strategies, exposure to the intervention, participants responsiveness and unintended consequences. The information sources are the post-intervention survey, a short data collection carried out in a very isolated gold mining site, continuous data collection during the intervention, observations made during supervision visits, and in-depth feedback from the project players.

Results and Discussion: As expected, being part of or close to the study community was an essential condition for facilitators to overcome the usual wariness of this population. Regarding the content of the delivered messages, the main issue with facilitators was the excess of information rather than the omission of information but was corrected over time. The content of the intervention was overall in line with what was planned. With an estimation of one third of the population reached, the exposure was satisfactory considering the challenging context, but improvable by increasing *ad hoc* offsite distribution according to the needs. Participants' responsiveness was the main strength of the intervention but could be enhanced by reducing the duration of the process to get a kit, which can be disincentive in some places. The expected decrease in malaria became a source of reduced interest in the kit. Expanding the remit of facilitators may be a suitable response. Better integration of the articulation with the existing malaria management services is recommended for sustainability.

Conclusion: These findings provide valuable implementation outcomes to complement the evaluation outcomes for assessing the relevance of the strategy and information useful to sustain and transfer it in analogous contexts.

Trial registration: [ClinicalTrials.gov](https://clinicaltrials.gov)

Registration number: NCT03695770

Date of registration: 10/02/2018 "Retrospectively registered"

Contributions To The Literature

- In French Guiana, the only European territory in South America, providing malaria diagnosis and treatment to a mobile and illegal gold mining population using recommended strategies is unfeasible due to regulatory, geographic and security constraints.
- Testing an intervention consisting in providing malaria self-management kits to lay people by non-health professionals at border resting sites, along with appropriate training and resources, is unprecedented.
- These findings complement the evaluation results by presenting what was actually implemented, adherence to what was planned, quality of delivery, exposure to the intervention, participant responsiveness, and

unintended consequences.

Background

Ineffective programs can be implemented well while useful programs can be badly implemented (1,2). Knowing the degree to which an intervention that was implemented corresponds to the intervention initially designed may be very helpful when assessing the sustainability, applicability or transferability of a strategy (3,4).

In any kind of research, the experimental design is considered as the most rigorous methodology to ensure the highest level of evidence (5–7). In some contexts however, random allocation of individuals or clusters is not feasible: this may actually be an opportunity in disguise. Indeed, the quest for the gold standard methods may overshadow the relevance of a more pragmatic design, and some of its advantages, such as transferability (3,8,9). Such circumstances are met in the Guiana Shield located in the Amazon region, more specifically in the French overseas territory of French Guiana, neighbored by Suriname and the Brazilian State of Amapá. The mining potential of the area inherited from its rich geological history attracts a highly mobile and disperse community mainly coming from the poorest regions of Brazil. The living and working conditions – long working days, stagnant water due to alluvial gold mining, etc. – of these gold miners are conducive to malaria, which is endemic in the region (10–13). Identified as a reservoir and a barrier to elimination of the disease, this neglected population was addressed by an innovative research project called Malakit(14–16). This international collaborative project aimed at evaluating the preventive distribution of malaria self-management kits to gold miners, on resting sites at the borders, with information and training, to be used when isolated in the forest (15,17). The great geographical constraints and the cross-border context involving a sensitive undocumented migrant population raised serious methodological challenges (18). A before-after study design was set up using measurable, realistic and comparable variables and specific indicators with different modes of collection. The main evaluation criterion was based on the comparison between the estimated proportion of reported good practice of diagnosis and treatment, before and after the intervention using cross-sectional surveys (15,17). To complete these indicators, continuous and longitudinal data collection was implemented to assess the correct use of the kit. Between April 2018 and March 2020, 4,766 kits were distributed to 3,733 participants, among whom 631 returned to a distribution site to answer questions about their experience, 223 of whom used at least one malakit (19). This ongoing evaluation was complemented by an independent qualitative study aiming at exploring:1) the opinion, perception and responsiveness of participants, facilitators and also key actors who are community members not eligible to the intervention, 2) levers and barriers to the use of the malakit, 3) facilitators' role and 4) contextual elements (20).

Borders and migrations are challenging for health interventions, notably for malaria. Border malaria has long been a problem, notably in South East Asia (border between Myanmar and Thailand and between Cambodia and Thailand, for example) where antimalarial resistance has repeatedly emerged in a particular mix of local circumstances (21–23). Throughout the history of malaria programs, there have been great efforts to target this complex transnational context (23–26). Furthermore, certain activities, often illegal (guerrilla warfare, logging, mining), have been important drivers of malaria epidemiology. In South America (Venezuela, Colombia for instance) malaria has been linked with mining or more largely with extractive activities (10,27–30). The malaria problem on the Guiana shield is thus specific but related to situations found elsewhere in the world.

The communication of results does not always take into account how interventions were implemented and how context affects implementation and outcomes (4,31). The objective of the article is to detail the solutions that have been implemented locally, and how the planned intervention unfolded in the reality of a challenging context in order to extract applicability and transferability to other contexts with their set of interventional constraints (3,32).

Methods

The context, the content of the intervention, the actors and the stages of development have been described in previous articles (15,17). Defining properly the research type of a study is useful since clarity may avoid duplications, funding inefficiencies and difficulties in seeking and understanding information by the end-users of research evidence (33). The Malakit project, by developing an unprecedented approach to malaria management, can be classified as intervention research. At design phase, its evaluation aimed at determining intervention effectiveness with health and behavioral outcomes. However, intervention and implementation research do not always have clear boundaries and may closely overlap (33). Indeed, Malakit could also be considered as an implementation strategy for the “Test and Treat” intervention with Rapid Diagnostic Tests (RDTs) and Artemisinin-based combination therapy (ACTs). In support of this, several implementation research outcomes were also included in the evaluation. Therefore, the term of Type 2 effectiveness-implementation hybrid trial can be attributed to the Malakit study (34–36). This article presents elements of implementation fidelity targeted according to Carroll et al.’s conceptual framework, and unintended consequences and aspects of context as defined by the Medical Research Council (MRC) framework (4,37). Adherence to content was analyzed based on observations during regular supervision and monitoring visits. Dose, also called exposure, was estimated or quantified through a post-intervention survey on resting sites, onsite data collection after one year of implementation in a remote and hard-to-reach clandestine gold mining site (Repentir mission), and continuous monitoring data (Malakit intervention) (38). Participants responsiveness explored by the external qualitative study mentioned earlier are further documented in this article (20). More specifically, opinions from gold miners were collected quantitatively during the post-intervention survey and Repentir mission. Facilitators' opinions and perceptions were self-recorded through videos in which facilitators responded to a list of questions written by sponsor team (20). Quality of delivery and facilitation strategies are evoked as part of adherence to content analysis.

Information collected from informal in-depth debriefings all along the implementation were also useful to analyze these indicators.

Key components of the intervention

The “logic model of the Malakit intervention” is described in Fig. 1. The principle of the intervention was the handing over of a self-diagnostic and self-treatment kits at borderer resting sites to persons working illegally on gold mining sites in French Guiana, to be used inside the forest, far from the health care system (Fig. 2). This “malakit” included three diagnostic tests, a full artemisinin-based combination therapy (ACT) course, a single dose of primaquine, and paracetamol (15). Illustrated instructions were printed directly on the plastic pouch of the kit (Fig. 3). The role of facilitators was to recruit, provide information and training with specific tools, and decide if the participant fulfills the conditions to get a malakit *i.e.* meets the eligibility criteria: performs and interprets a self-test under supervision and understands when and how to take the medication of the kit. Facilitators were

also in charge of collecting longitudinal data at inclusion visit and subsequent follow-up visits of participants, when they come back to get a new kit or kit replenishment (Fig. 2).

The main objective of the project was to increase the use of an appropriate and complete malaria treatment against *P. falciparum*, the most prevalent species at the beginning of the study among *garimpeiros* (Portuguese term for small-scale and/or illegal gold miners) (14), with ACT, also effective against *P. vivax* malaria attacks (but not relapses), promptly after the onset of the disease (14,15,39–41) .

Results

The total length of the interventional research was 24 months in Suriname and 18 months in Brazil, between April 2018 and March 2020. Seventeen supervisory missions were held in Suriname and 15 in Brazil. In both countries, the first mission was held within one month after the launch, and the last one took place one month before the end of the study, *i.e.* until it became impossible to travel due to the closure of borders in the context of the Covid-19 pandemic. In Brazil, 21 inclusion visits and 10 follow-up visits were the objects of observation. In Suriname 15 inclusion visits and four follow-up visits were the objects of supervision reports, although more were actually observed.

Adherence to protocol

Additional file 1 details the adherence to content, adaptations and facilitation strategies of the key activities of Malakit *i.e.* inclusion, training, kit distribution and replenishment or re-distribution.

During rollout of the intervention on the distribution sites, some planned components of the intervention had to be abandoned during the development phase of the project, even before the setting up. One example is that of the places identified to be training and distribution points. Those were the most important resting sites on the two border rivers, on the Surinamese and Brazilian side but some were also located on the French Guianese side. However, implementing the intervention on the French territory was finally not included in the protocol. Higher costs mainly due to the high price of the ACT in the European Union, and poor added value in terms of coverage of the intervention, have led to the abandoning of attempts to overcome regulatory constraints, such as the absence of marketing authorization for the use of the Carestart™ test on oneself, or the fact that the targeted persons do not have French health insurance.). Another example was the opening of the five distribution sites, initially planned over a short period of time to allow a massive distribution of kits and thus drastically reduce their value on the black market, thereby discouraging trade by participants (42). In practice, the intervention was progressively scaled up due to logistical and regulatory constraints. The bright side of this sequential initiation was an opportunity to capitalize and learn from experience, and eventually to improve the implementation which in the end did not lead to massive black market sales according to Malakit data and informal sources of information. The intervention had to adapt to different contexts depending on the location and features of the distribution sites (see Table 1).

Table 1

Characteristics of distribution sites of the Malakit intervention in Suriname and Brazil (April 2018-March 2020)

Name of distribution site	Number of full-time facilitators	Turn over of facilitators	Premise type	Location	Distance for place of referral	Characteristics
Suriname						
Albina	1,5	No	Small prefabricated. Already a "malaria clinic" before the project start.	Logistic base, near shops and resting place gold miners	In situ, a facilitator is also a malaria "test and treat" worker (MSD)	Most of gold miners are there in transit for a very short period of time. First mining sites are very close.
Antonio do Brinco	2	No	No fixed facility,	Mobile facilitators in a gold miners village, or in a church (when the level of water does not allow walking)	Malaria clinic with a MSD within the village, but not used by the facilitators	Most of gold miners live and stay there for a rather long period of time. First mining sites are very close.
Paramaribo	1 (initially 6 part-time)	Yes	Office in a hotel	Brazilian quarter in the capital of Suriname, hotel frequented by gold miners. The facilitator also works in the hotel.	Tropclinic is 5 minutes away by taxi.	Short stay of the majority of gold miners. Passage of gold miners working specifically in French Guiana is less frequent.
Brazil						
Oiapoque	2	Yes	Fixed office in a flat	Small town, within the goldminers' quarter	Health centers and a hospital in the town but not in the quarter.	Departure place for goldmining sites, but no sites in the vicinity. Many gold miners have a permanent accommodation in the town.
Ilha Bela	2	Yes	Shack	Within a small spontaneously founded village (not recognized officially) of gold miners	No malaria care in situ. Oiapoque is the first referral place at 4–5 hours by boat.	Isolated villages. First mining sites are very close. Facilitators are based in Ilha Bela and go to

Name of distribution site	Number of full-time facilitators	Turn over of facilitators	Premise type	Location	Distance for place of referral	Characteristics
Vila Brasil			Health center	Village at 30 minutes from Ilha Bela		Vila Brasil twice a week.

Human resources and coordination

Human resources are the most important elements in most community-based approaches. The workers in this project were called “facilitators” (“*mediadores*” in Portuguese, “*médiateurs*” in French). They may not be named “community health workers (CHW)” in the sense that they were not active gold miners, were not chosen by the community and were more accountable for their employer than for the community (43). Nonetheless, belonging to or being close to the community of *garimpeiros* and being fluent in Portuguese, were fundamental. Having sufficient literacy skills for tablet and smartphone use was desirable competencies. Partners in both countries reported that recruitment was difficult due to lack of eligible candidates. Solutions to address this problem are not yet identified. Two facilitators were assigned to each of the four border sites (see Fig. 4). In Paramaribo, tasks related to Malakit were added to the duties of the National Malaria Control Program (NMCP) staff, but after an obvious failure in the quality of service, the strategy was reviewed and a full-time facilitator was assigned to this site (see Additional file 1). Some persons recruited were not native Portuguese speakers despite the initial recommendations. Three of them reported a wary attitude at initial contact from the gold miners, attributed to their accent betraying the fact that they were not Brazilian. Most of facilitators had little or no knowledge of malaria and had various occupations, such as pastor or boatman. Facilitators without medical background revealed a better ability to adapt the discourse to the needs of the study population. High turnover on the Brazilian side was a constraint to smooth capacity building. One of the explanations was that a person was detrimental to the functioning of the local team. The late payment of wages due to the international fund transfer delays, and the uncertainty regarding the end date of the pilot phase related to a start-up delay caused by presidential elections, may also have contributed to a feeling of precariousness. Three facilitators reported that what they liked most about their work was acquiring new knowledge. Continuous capacity building is probably crucial to maintain human resources and sustain their motivation. Furthermore, the feeling of being useful and part of an innovative project which they believed in was an important incentive shared by the vast majority (44).

One principal investigator located in Rio de Janeiro and one coordinator in Oiapoque were responsible for the Brazilian sites. A single person was both coordinator and principal investigator in Suriname. However, these assignments were in addition to their usual work. Due to the distance between the sponsor team in Cayenne and the distribution sites, the presence of a supervisor hierarchically above facilitators in each country was decided, in addition to the regular visits of the sponsor team and the continuous monitoring of data collected by facilitators (see Fig. 4). In the long run, direct interaction between the sponsor team and facilitators on the field on both river borders proved to be more convenient. Indeed, except on two sites, the distance was also an issue for frequent on-site supervising visits. Lack of availability due to lack of time on one side and difficulties to recruit a permanent supervisor on the other side was a reason for poor ongoing training. Nonetheless, the ambiguity of the supervision role of the sponsor team in Cayenne without hierarchical relations was sometimes confusing for facilitators.

Facilitators were provided with “field reports” to counteract distance issues. The purpose was to improve and homogenize practices by capitalizing on field experiences, reminding important points, and formalizing some guidelines. This information was provided digitally on an instant messaging group and on paper. Despite efforts to make the instructions synthetic and palatable with the addition of diagrams and pictures, facilitators showed variable interest in these reports. One-to-one direct debriefings, either in person or via instant messaging, had better impact. Oral culture seemed to prevail over written culture among facilitators.

Content and quality delivery

All tools created for the training were systematically used, except one poster illustrating the effect of the ACT on the malaria over time and the mechanism of resistance (Fig. 5), which was forsaken by some facilitators who found it redundant with the illustration on the kit about the treatment (Fig. 3).

Sometimes, less may be more. The shortcoming encountered, mainly at the beginning, was the surplus of information, or inaccurate information rather than the lack of information given by facilitators to participants. Adding too much detail may dilute the important information, or make it confusing, and eventually become detrimental to the training. For example, one facilitator described the drug primaquine included in the kit as abortifacient, when explaining that it should not be taken by pregnant women, which can lead to misuse for that very purpose. While speaking about risk situations, instead of only explaining the danger of Coartem® in case of heart problems, a facilitator mentioned the risk also for Artecom®, the main antimalarial drug found on the black market. This may confuse the message about avoiding under-the-counter medications. As time went by, the talk was well mastered. The facilitators confirmed that they adapted the time spent explaining, the stress on specific messages, the number of repetitions, and the vocabulary according to the audience and its availability, as the training was highly interactive.

Exposure to the intervention and participants responsiveness

Intervention availability for the study population

Despite a delay in implementation on the Brazilian side due to regulatory issues related to the 2018 context of presidential election, the project was not shortened thanks to the obtaining of funds for a six-month extension. Furthermore, a continuous presence of the facilitators on distribution sites was ensured, with the exception of end-of-year holidays.

While the location of the distribution sites was determined at the beginning of the study, the protocol included the possibility to adapt the strategy according to the mobility of the study population. These *ad hoc* relocations of the intervention to additional resting sites proved to be very effective in reaching the study population but could not be repeated as often as necessary due to insufficient funding and human resources.

Several contextual factors can influence the mobility and thus the frequentation of resting sites. The following are the main ones identified: 1) The French police operations on mining sites in French Guiana, and of the presence of Brazilian army on the Brazilian border; 2) Seasons and periods of the year (for example more movements during end-year holidays); 3) Gold mining activity depending on the location of gold seams and ‘rush’ following rumors of new discoveries (in Portuguese, *fofoca*), and indirectly the presence of armed gangs (*faccções*); 4) Role on gold mines, mobile activity (*e.g.* travelling vendors, transport providers and porters) *versus* non-mobile activity (*e.g.* goldminers, shop owners, machine owners).

Malakit awareness and participation

From post-intervention surveys sampling gold miners at resting sites - one at the Suriname border and the other at the Brazilian border - the estimated coverage of Malakit participation among persons frequenting resting sites was 29.7% (95%CI [25.7–33.7], n = 147/493) in December 2019 (19). This measure probably overestimates overall coverage because people who participated in the post-intervention survey are likely to take better care of their health and thus have a higher probability of also participating in the Malakit intervention, and because it does not take into account gold miners who stay in the forest for very long periods. However, data collected in a very remote and isolated site one year after the start of distributions (Repentir mission in June 2019) showed satisfactory penetration of the intervention. The representativeness of this sample was low since only 25 people were interviewed with a high proportion of women (64% vs. 34% among Malakit participants). Nonetheless, 28% (95%CI [9.1–46.7]) of the persons met were included in the Malakit study. Finally, for a population of approximately 10,000 gold miners, reaching more than 3,700 people in two years is satisfactory given the challenging context.

Results from both the post-intervention survey and Repentir mission showed that around two thirds had heard about the project (respectively 64.8 %, 95%CI[60.6–69.0] and 60%, 95%CI [39.3–80.6]) and that about half of those who knew about it were participating (respectively 46.1%, 95%CI [40.6–51.6] and 47%, 95%CI [18.1–75.3]). The findings of the qualitative study revealed a good knowledge of Malakit but a probable heterogeneity of the project awareness from one site to another (20).

Opinion on Malakit

The strong acceptance and enthusiasm of project facilitators and participants that emerged from the qualitative study was confirmed by the findings from the post intervention survey and Repentir mission (20). From the former source, 81.5% (95%CI [77.3–85.8]) of the 320 respondents acknowledged either the importance of the strategy for the population or its public health significance. Only four people expressed a negative opinion either because of the perception that the medication of the kit was not effective, the lack of usefulness due to the absence of malaria, or the requirement to prick oneself. Repentir mission revealed that 12 persons out of 15 who knew about the project had very good opinion of Malakit. Only one person had a bad opinion and also thought that Coartem® was ineffective.

"It is useful because we can know what disease it is and which treatment to use."

"It is interesting and useful, my daughter-in-law was able to treat herself"

"It is good", one of the positive pieces of feedback from colleagues that had used it, "good project".

Barriers to participation

The motives for not participating among persons who had heard about the project were documented for 135 people from the post intervention survey (Table 2). Not having the opportunity to go to a distribution site was the main reason (40/135, 29.6%). Lack of access to Malakit sites primarily due to travel cost and time but also sometimes related to the fear of enforcement authorities, was also the main obstacle identified in the qualitative study (20). According to this same source, gold miners acknowledged that time for the training and questionnaire can be disincentive. Facilitators also stressed on the importance of making the process before handing the kit

quick and when asked what could be improved, three of them mentioned the shortening of visits. One suggested to reduce the training part with more videos and one proposed to remove questions to shorten follow-up visits (20,44). The inclusion process lasted between 30 and 45 minutes but the metadata analysis of monitoring questionnaires revealed that the median time spent on electronic data capture was five minutes, after debriefing with the participant, for both types of visits combined (42). Reasons for refusing to be part of the study were collected by Malakit facilitators among people who were approached, in other terms who had the opportunity to go to a distribution site. The data are not exhaustive, come mainly from a specific site and mainly from persons who had started the training (Table 2). Lack of time is once again the main barrier that emerged.

Table 2
Reasons for not participating in the Malakit study (Suriname and Brazil)

Reason	People interviewed during the post-intervention survey	People approached by facilitators during Malakit intervention (several possible answers)	
		Total N = 250 n (%)	People who had started the training N = 140 n (%)
Not having had the opportunity to go to a distribution site	40 (29.6)	i	i
Unawareness of where to get a kit	7 (5.2)	i	i
Having obtained a kit by another mean	6 (4.4)	i	i
Absence of facilitators at the inclusion site	3 (2.2)	i	i
Lack of time	30 (22.2)	144 (57.6)	58 (41.4)
Not interested in the Malakit project or lack of recognition of utility due to perceived absence of malaria	35 (25.9)	86 (34.4)	33 (23.6)
Fear of needles	1 (0.7)	77 (30.8)	66 (47.1%)
Unable to perform the RDT	ii	7 (2.8)	7 (5%)
Refusal to share personal information	2 (1.5)	3 (1.2)	2 (1.4%)
<p>ⁱ These reasons can only concern persons who have not been approached by a facilitator at a distribution site.</p> <p>ⁱⁱ This reason can only concern persons who have been approached by facilitators. The facilitator is the person who assesses if the person is capable of performing a self-RDT.</p>			

The ability and willingness of potential participants to spend their time for Malakit training was more or less pregnant depending on the distribution location (see Table 1). In distribution sites where gold miners were just passing through before final destination (*e.g.*, Albina) and/or where the departure by boat to the gold mining sites could be sudden and thus where gold miners were on the lookout (*e.g.*, Vila Brasil), the time required for inclusion was a barrier, obtaining a malakit not being a priority. On the contrary, participants living at the resting site (Antonio do Brinco, Ilha Bela, Oiapoque) with no “competing activity” showed a much greater engagement in the intervention. Facilitators also reported better availability of participants on transient distribution points, during punctual missions.

Overall the fear of pricking oneself was occasional and some facilitators reported efficacious strategies to overcome this (see Additional file 1 and Table 2) (20). All the sources of information revealed that the inability to perform a self-test - excluding the fear of needles - and the reluctance to share personal data, - which were anticipated as potential barriers - were anecdotal. Facilitators confirmed that distrust was generally overcome and tended to decrease over the course of the project (20).

Unexpected mechanisms and consequences

Influence of the research context

Measurement may disturb the object measured. Although the degree of pragmatism is high on the pragmatic-explanatory continuum, the intervention was not implemented in fully “real-world” settings (9).

For example, the instruction given to facilitators not to judge participants misusing kits, like sharing kits, in order to encourage participants to tell the truth about practices may have led to a feeling from the participants that the sharing of the kit was acceptable. Moreover, the continuous and longitudinal collection of data carried out by the facilitators as part of a research project was more extensive than it would be for monitoring a public health intervention. Despite efforts to limit the number of questions and to avoid sensitive questions (*e.g.* questions on past whereabouts only, not on future destinations), the questionnaires may have been a source of suspicion for a community constantly on guard due to their illegal and clandestine status. Conversely, the multitude of partners from different countries (45) and the logos of which were displayed on easels and facilitators’ vests, were a source of trust from the participants.

Diagnosis discrepancies

The difference of diagnostic method between Malakit; *i.e.* CareStart™ Malaria (Pan) and those provided at malaria clinic in Suriname, *i.e.* SD BIOLINE Malaria Antigen P.f/P.f/P.v® and microscopy, and Brazil, *i.e.* microscopy, sometimes led to divergent results. Because of the large number of persons tested, mostly asymptomatic, the frequency of such discordant diagnoses seemed high. An investigation using PCR as a gold standard found a false-positive proportion of 1.72%, consistent with an expected false positive rate of 2.4% for a reported specificity of 97.6% and in a low prevalence setting, and a Positive Predictive Value of 40%, consistent with the low PCR prevalence of 5.3% measured during the post-intervention survey (19). Routine diagnosis was performed on Malakit participants only in case of symptoms or positive Malakit RDT on the Surinamese side and systematically on the Brazilian side. Despite an agreed common procedure between concerned stakeholders to address this problem, confusion among participants and decreased confidence in the Malakit RDT or in routine care were observed anecdotally. Moreover, the success of the intervention may have competed with the malaria

routine care despite the complementarity of the two. A feeling of competition has been expressed by some healthcare workers, which was then dissipated with improvements in the communication.

Risk related to the kit value

The relatively high market value of the kit itself (more than two grams of gold *i.e.* about 50 USD according to gold miners' testimony) represented several risks. Despite close verification of stock flows, the discontinuous presence of supervisors on the field did not allow guaranteeing the absence of kits resale by facilitators.

Epidemiological evolution

During the project period, the incidence of malaria decreased at the gold mining sites and in the region. Preliminary modeling work estimated that the intervention itself helped avert 43% of the new malaria cases predicted in the absence of Malakit between April 2018 and March 2020 (19). This diminution can lead to the perception that malaria does not exist anymore and then to a diminished interest in the malakit. Towards the end of the project, facilitators of one particular site reported several cases of people not feeling concerned in the kit, because they considered malaria not to be present on their worksite anymore.

Discussion

Feedback from players who were engaged in the protocol (intervention design and evaluation) and tools development, training and close field supervision can constitute valuable information to complete "impact results".

The distinction of the "core components" and the adaptable elements related to an intervention can only be discerned through practice and mispractice over time as the intervention is more widely deployed and replicated in other contexts, as explained in the Consolidated Framework of Implementation Research (46). As an innovative strategy, several choices and adaptations were made during the implementation itself. Thus, the objective of this article was not to create fidelity measures to assess an evidence-based intervention but to capitalize on this unprecedented field experiment to contribute to future process evaluation or implementation research on the strategy. Workshop bringing together all facilitators and supervisors animated by an external assessor was planned in April 2020 but was cancelled due to the COVID-19 pandemic. While the main defect of the present assessment is the absence of quantitative indicators for content adherence, the main strength is the regularity of missions throughout the project and not only at specific periods, and in-depth feedback from the players.

Anyway, it is possible to affirm from observation data that the content of the messages and the way to transmit them were satisfactorily conforming to what was planned even if rectifications were necessary at the beginning. Dane and Schneider suggest (47) that lack of confidence, experience, as well as not being professional – *i.e.* paraprofessional or lay persons – were predictors of poor program integrity in preventive interventions research. On the contrary, in a study assessing the fidelity of implementation of malaria care for children by CHWs in Nigeria, adherence to the diagnostic, treatment and counseling protocol by CHWs was found to be equal or higher to that of the medical staff who served as gold-standard comparators, and not related to age, level of education or primary occupation (48). In the Malakit intervention, previous experience in health care or health mediation did not seem to be an asset – also because compared to other interventions no clinical evaluation was performed – and excess of confidence was rather a barrier to compliance with what was planned, to the point of having to replace facilitators (see Additional file 1, "Terms and conditions to be included"). This is consistent with WHO's

finding that CHWs may be men or women, young or old, literate or illiterate, as long as they blend into the culture of the community and ensure their acceptance (43). The geographical distance issues identified here as a main constraint in the implementation and monitoring, may be encountered in other contexts involving several countries and should be addressed. Field supervision and refresher trainings, very time-consuming when two days are needed to go to one place, should be assigned to someone dedicated to these tasks only; this person should actively collaborate to the elaboration and design of the training contents and data collection tools with the principal investigators. The development of refresher training tools for facilitators with a participatory approach – as used for participants training tools – to adapt to their literacy and needs, could also alleviate distance issues. Constant and long-term efforts to maintain quality are essential to adapt to evolving contexts, including beyond scale-up. Indeed, while resources allocated for research are sufficient to ensure integrity, for example through continuous in-person and distance supervision, decrease in fidelity is more likely when interventions are adopted and sustained (47). Indeed, although ongoing training in any form, including supportive supervision, is a recommended practice, some negative outcomes associated to it have been reported and linked with dissatisfaction (49). Facilitators did not express such discontent despite all opportunities to do so. Using mobile technologies in particular was rather well accepted (42). In low and middle income countries, it is increasingly seen as an opportunity to better train and improve performance of workers remotely (50,51). This approach, also named “Mobile Learning for Development”, is the subject of recent studies concluding in the need for further research to better assess and adapt the approaches (52,53). In Kenya, in a very similar manner to the Malakit intervention, an intervention included a WhatsApp group to strengthen “supervision, professional development and team building”, and found also an interest in quality assurance, information sharing, and the creation of a supportive environment (54). More broadly, social interaction and peer assessment has been found to be associated with better guideline implementation and clinical practice change (55,56). In the present project, the peer-to-peer form of supervision within the WhatsApp group was not observed. Facilitators of the two countries knew each other little or not at all due to few joint trainings or meetings (all of them needing visa to come to French Guiana). That is why they may not have felt comfortable enough to ask questions and share difficulties, and tended to rather share success. In-person peer supervision, at some point considered, which may be a mean to further foster performance, could not be implemented.

Although quite satisfactory after two years of intervention, coverage could be improved by a better planning of funds and resources for adapting to the gold miners’ mobility in a timely manner, especially with an increasing heterogeneity of malaria transmission among gold mining regions. The findings underline the importance of the factors contributing to the trust of the population towards the project, especially with wary communities. Research requirements namely, represent constraints regarding the perception of the community that should not be underestimated. Although still experimental, articulation with existing care services should have been further developed to avoid potential competition felt instead of complementarity. Nonetheless, the excellent appropriateness – as “perceived fit of the innovation to address a particular problem”- and good adoption from the study population are definitely not a barrier to the reach although it may become one with diminution of malaria prevalence (38). Maintaining community uptake may be achieved by expanding services offered by facilitators, as seen in Myanmar, where the management of non-malaria febrile illnesses and the referral of severely ill patients complemented “malaria only” CHW prerogatives (57). Participants acceptability and engagement were also very good despite the deterrent factor of time availability in some places (38).

Conclusion

These feedbacks reveal information that can improve the validity of the research project because the main results can now be interpreted in light of what was actually implemented (19). The satisfactory compliance with what was planned, the improvements to be done to reach the population and the good responsiveness of the participants are the main points observed. In addition, the confrontation of the protocol with reality highlights considerations that will be essential for the sustainability, applicability and transferability of the strategy in other contexts. (58–60)

Declarations

Ethics approval and consent to participate

The research study obtained all competent ethical approval required according to the respective regulations in Brazil and Suriname. Written consent was obtained from all participants.

Ethical committee of the FUNDAÇÃO OSWALDO CRUZ : CAAE: 89482118.0.0000.5248 ; Approval No: 2.831.534.

Ethical committee in Suriname for the Malakit study: CMWO. Approval No : VG 25-17.

Ethical committee in Suriname for the post intervention survey (short title: Orpal-2): CMWO. Approval No : DVG 738.

Ethical committee of the University of Montréal, “Comité d’éthique de la recherche– Société et culture (CER-SC)” for the qualitative study “Malakit Project: a complementary case study”: Project CERSC-2019-083-D.

Consent for publication

“Not applicable”

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

Funding

The CHC, as sponsor, directly managed most of the project funds. Half of the funding was by the European Regional Development Fund (FEDER) via the Interregional Amazon Cooperation Program (IACP) 2014-2020 (N° Synergy 3949), supplemented with self-funding from the CHC, funds from the French Guiana Health Regional Agency, the European Horizon 2020 Program and contributions in kind from the Surinamese Ministry of Health, as beneficiary of the GF (Global Fund to Fight AIDs, Tuberculosis and Malaria); the Ministry of Health of Brazil;

the PAHO/WHO ECC (Pan-American Health Organization/World Health Organisation for Eastern Caribbean Countries) ; and the French Development Agency (Agence Française de Développement AFD).

The funding bodies have no role in the implementation and analysis of the project.

Authors' contributions

MSG, YL, LG, MSM, SV, MN, AA, HH, CP, AS and MD conceived the study and wrote the protocol. MSG, YL, LG, MSM, LM, SV, JBM, JHG, HC and MD implemented the study. MSG, LM, YL and MD performed the analysis. MSG, YL and MD wrote the first draft. All authors read and approved the final manuscript.

The authors confirm they had full access to the data in the study and accept responsibility to submit for publication.

Acknowledgements

The authors thank all facilitators from the Malakit Project. In Suriname: Breno Otavio Barbosa, Isadora Batista dos Santos, Astrid Huur, Carla Pereira de Paulo, Fernando Silva Rodrigues Barbosa, Nicholas Valente Ferreira. In Brazil: Samanta Braga, Salomao Brito, Alejandro Chavarro, André Da Silva Alancantara, Ronnie Edison and Leonardo Villalba-Bassulto.

Hélène Hilderl, Sam Trinh, Amandine Duclau, Nicolas Vigner and Cécile Longchamps (Hospital of Cayenne).

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Figures

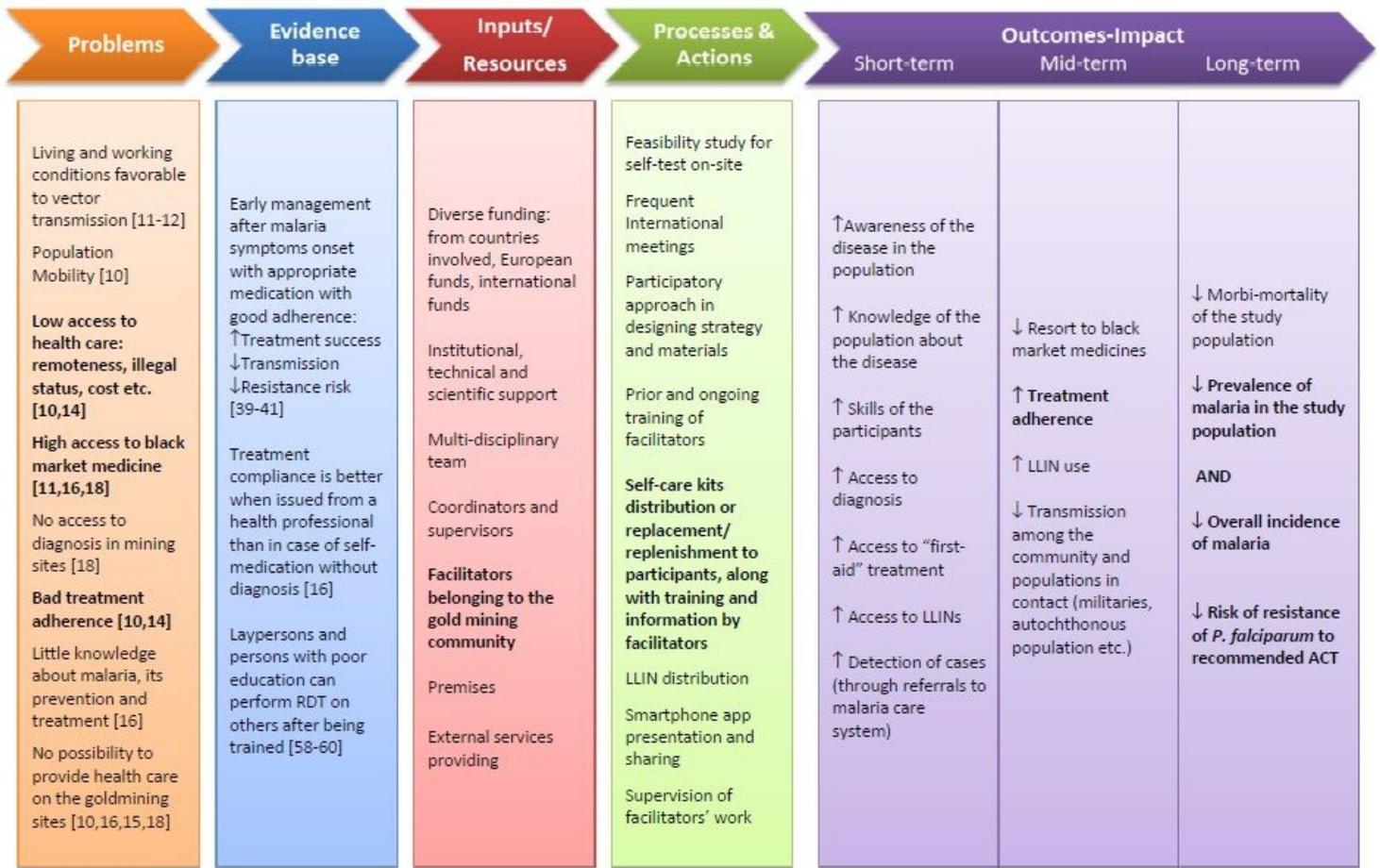


Figure 1

Logic model of the Malakit intervention before the start of the Malakit study

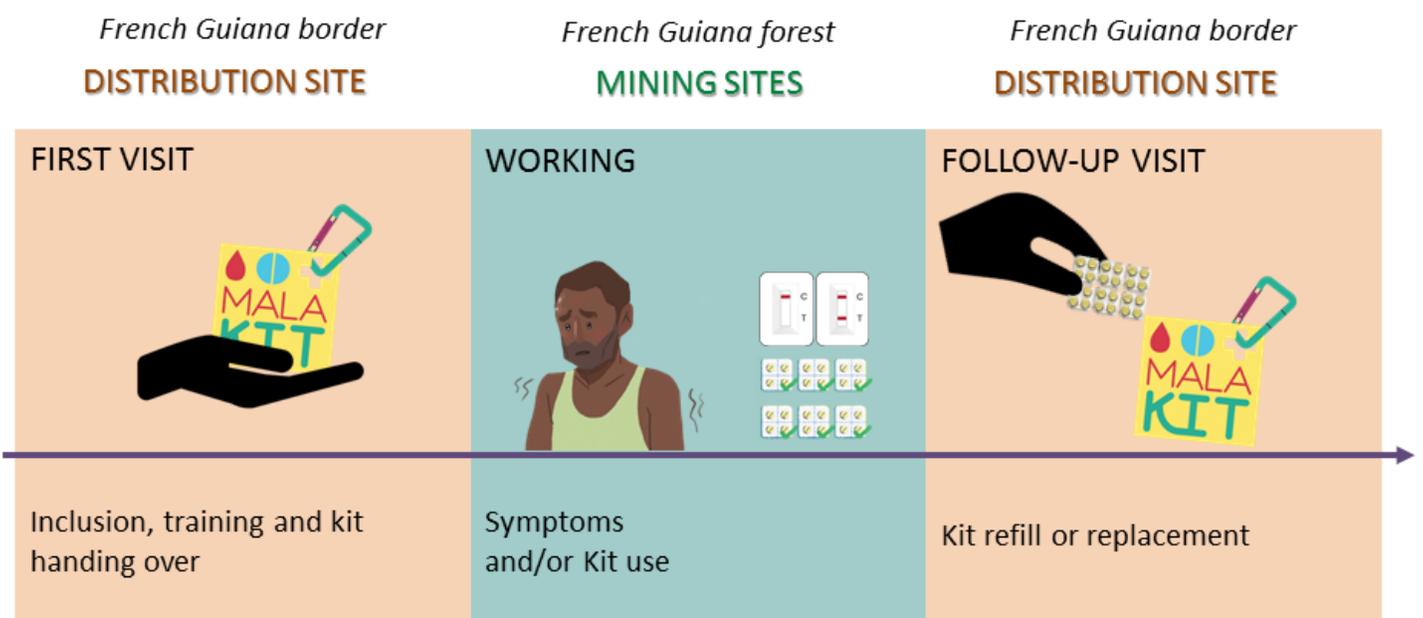


Figure 2

Principle of the Malakit intervention in Suriname and Brazil (April 2018-March 2020)



Figure 3

Illustrated instructions printed on the kits distributed during the Malakit study in Suriname and Brazil

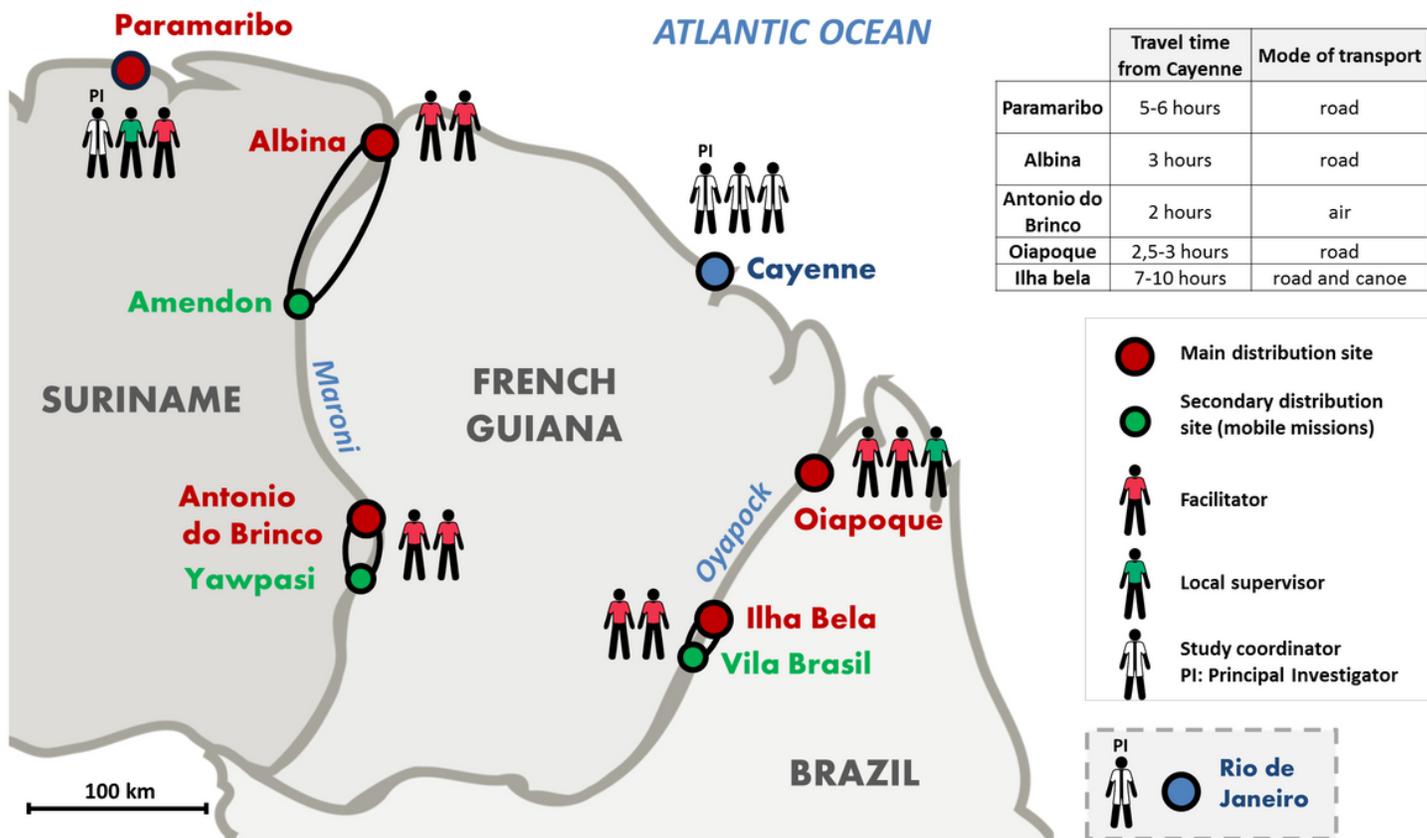


Figure 4

Map of the distribution sites of the Malakit intervention in Suriname and Brazil (April 2018-March 2020)

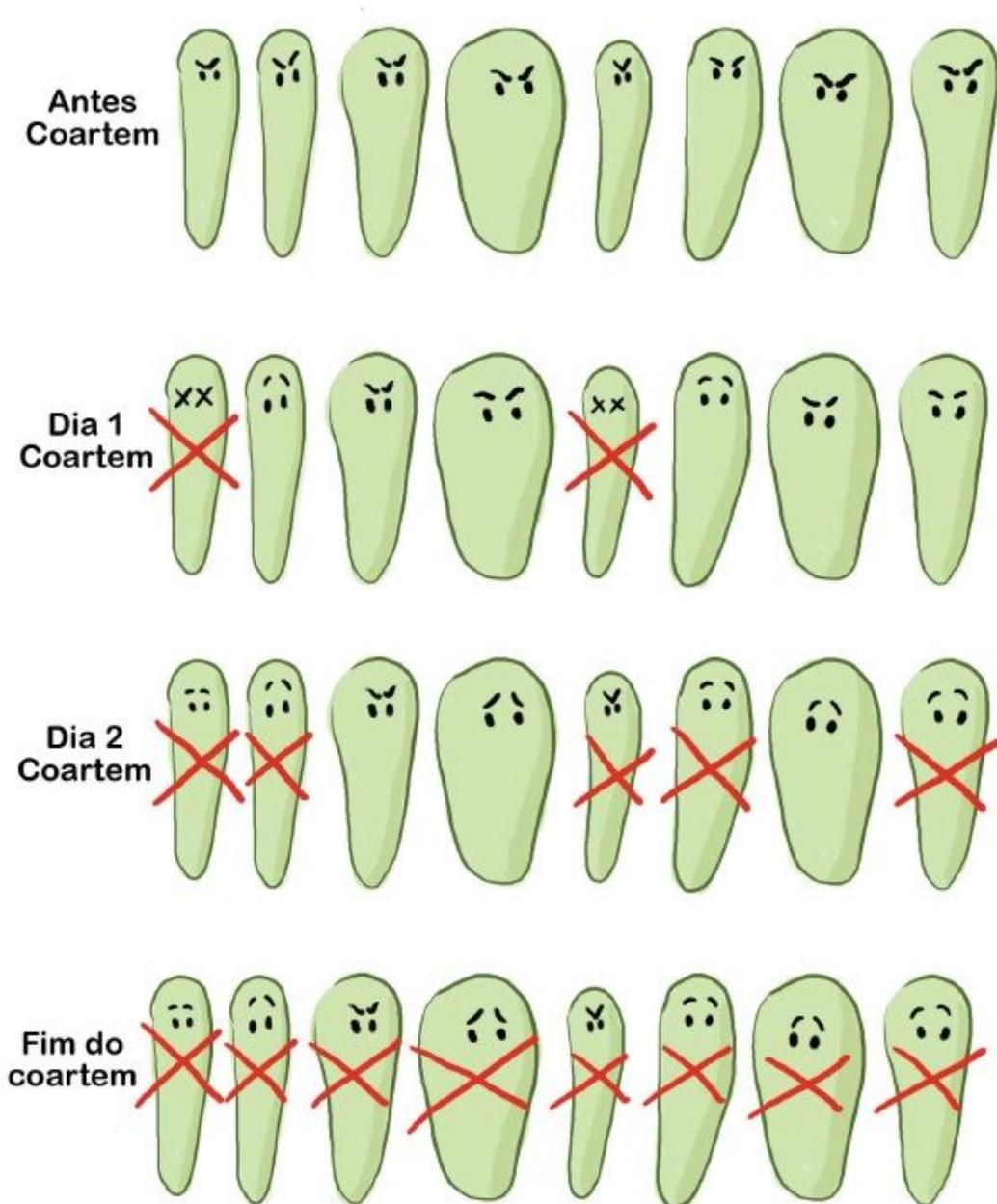


Figure 5

Poster illustrating the effect of the ACT on the malaria over time and the mechanism of resistance, material used during the training of participants of the Malakit intervention in Suriname and Brazil (April 2018-March 2020)

Supplementary Files

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