



Stakeholder meeting report: Chikungunya virus – recent outbreaks, vaccine development and the way forward

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ABSTRACT

The International Vaccine Institute and Gorgas Institute (Gorgas Memorial Institute for Health Studies) organized the first Chikungunya Global Meeting in Panama City, Panama on December 12–13, 2023. Experts represented eight countries: Brazil, Colombia, Dominican Republic, India, Kenya, Panama, Paraguay, and Thailand. The aim of this meeting was for stakeholders to discuss chikungunya disease burden, vaccine deployment strategies, regulatory challenges, and access issues. This meeting highlighted lessons learned from recent chikungunya outbreaks and perspectives on ways forward in chikungunya research. Specifically, the following topics were discussed in the meeting: (i) lessons from recent chikungunya outbreaks and regional perspectives, (ii) chikungunya research priorities, (iii) chikungunya vaccine development, (iv) regulatory approval and pathways, (v) vaccine access, financing, and procurement, (vi) ways forward through a chikungunya vaccine initiative, and (vii) chikungunya research on how to analyse protection and long-term memory. Experts called for investments in vaccine deployment and a better understanding of the long-term economic impacts of chikungunya. Going forward, the experts recommended creation of a global chikungunya vaccine initiative to coordinate research and generate evidence to inform prevention and control programmes of chikungunya outbreaks and introduction of chikungunya vaccination in high-burden settings and regions at risk of chikungunya outbreaks.

1. Introduction

Chikungunya was first detected in 1952 in Tanzania and has expanded to Asian and African countries, and more recently to the Americas [1]. Chikungunya is an arboviral disease, and its primary vectors are *Aedes* mosquitoes such as *Aedes aegypti* or *Aedes albopictus* [2]. Chikungunya has four major lineages, namely Asian Urban (AUL), West African (WA), Indian Ocean (IOL), and East, Central, and South African (ECSA) lineages [3].

Although chikungunya-attributable mortality is less than 1 %, the resulting long-term morbidity can persist for more than few months up to few years and is debilitating with more than 50 % of the symptomatic chikungunya infected individuals experiencing chronic disabilities [2,4]. Chikungunya disease progresses through acute, sub-acute, and chronic stages. The acute phase, lasting less than 14 days, features symptoms such as high fever (over 39 °C), myalgia and arthralgia. The sub-acute phase extends up to 90 days, characterized by inflammatory arthralgia and joint stiffness [5]. The chronic phase persists over three months, potentially lasting several years, with symptoms including persistent articular arthritis, degenerative osteoarthritis, and stiffness. Severe complications such as seizures, stroke, hearing loss, or other neurological disorders predominantly affect neonates, elderly, and individuals with co-morbidities [6].

Despite the disease's severity, awareness and recognition of chikungunya management among clinicians remain limited, with no vaccines or specific antiviral treatments currently employed in public health settings [7]. While several studies on chikungunya burden are available [8–10], global data on the burden of chikungunya is scant [4].

2. Lessons from recent chikungunya outbreaks: regional perspectives

Chikungunya significantly affects children under five years and adults over 60 years more than other age groups, as research in Kenya, Colombia, Paraguay, and Brazil demonstrates. In Kenya, analysis of hospitalized children's blood samples showed a high infection rate among children under five [11]. During the 2014 outbreak in Colombia, children under five years and adults over 60 years accounted for significant infection rates, with neonates often experiencing severe symptoms such as skin lesions and atypical mucocutaneous manifestations [12–14]. In 2023, Paraguay reported that about 4.2 % of chikungunya hospitalizations occurred in neonates, with over 30 % requiring intensive care unit (ICU) care [15]. Brazil similarly recorded higher mortality rates among the children under five and elderly. These findings underscore the vulnerability of these age groups to severe chikungunya infection.

The chikungunya virus has shown adaptability to local mosquito vectors, mutating, and spreading regionally. Initially identified in Thailand, the Asian genotype was first documented in 1958 [16,17]. The ECSA genotype with the E1-A226V mutation associated with enhanced adaptation to *Aedes albopictus*, triggered an outbreak in southern Thailand in 2008–2009, with mutations later detected in northeastern Thailand in 2013 [18]. In Paraguay, the ECSA genotype expanded rapidly during the 2022–2023 outbreak, causing higher mortality rates than the Asian genotypes found in the 2015 outbreak [19]. These instances indicate the adaptive mutations of chikungunya virus across lineages, emphasizing the importance of further research.

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Despite the virus's potential for causing severe outbreaks, public health concern remains low in at-risk countries compared to other arboviruses like dengue [20]. For instance, in Thailand, focus remains primarily on dengue due to a lack of chikungunya-related fatalities since 2009 and the higher mortality rate of dengue hemorrhagic fever. Similarly, Panama has shown less concern due to a low chikungunya seroprevalence (1.1 %) in areas with high SARS-CoV-2 infection rates.

To manage chikungunya effectively in the Americas, the Pan American Health Organization (PAHO) supports an Integrated Management Strategy for Arboviral Diseases (IMS-Arbovirus). The strategy aims to strengthen case management, standardize laboratory diagnostic algorithms, improve surveillance, and enhance decision-making through technical cooperation. This collaborative approach seeks to improve chikungunya prevention and control and produce data to inform public health strategies [21].

3. Chikungunya vaccine development

Valneva is an integrated vaccine company focused on developing, manufacturing, and commercialising vaccines for infectious diseases. Valneva has a diverse R&D pipeline [7], with the chikungunya vaccine IXCHIQ® standing out as the first approved chikungunya vaccine by the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) in November 2023 and May 2024, respectively [22,23]. This live-attenuated vaccine, based on the La Reunion strain of the ECSA genotype, aims for long-lasting immunity with a single dose. It demonstrated a 99 % sero-response rate in a phase 3 clinical trial in the US, with most adverse events being mild or moderate [24]. Additionally, a long-term follow-up study is underway to assess antibody persistence and safety for 10 years. While adult trials have been completed, phase 2 clinical trial for paediatric studies is planned at three trial sites in the Dominican Republic and Honduras [25]. Valneva is also working on preparing two Phase 4 post-marketing effectiveness studies with the aim to estimate the clinical benefit such as the efficacy of IXCHIQ® in the prevention of symptomatic lab confirmed chikungunya cases after a single vaccination [26]. To accelerate the access of the chikungunya vaccines for low- and middle-income countries (LMICs), Valneva has partnered with Instituto Butantan (IB) and received grants from the Coalition for Epidemic Preparedness Innovations (CEPI) to support the development, manufacturing, and marketing of VLA1553 (IXCHIQ) [27].

The virus like particle (VLP) vaccine candidate from Bavarian Nordic, which does not contain viral RNA, has completed randomised, double-blind phase 3 clinical trials with over 3000 participants [28]. This study yielded a robust sero-response rate of 97.8 % in the vaccinated group and 1.2 % in the placebo group by day 22 [29]. The sero-response remained high at 96 % on day 15 and decreased slightly to 87 % by day 22. Overall, the vaccine met both primary and secondary endpoints, showing good tolerance and a strong immune response in participants aged over 12 years [30].

Bharat Biotech International Limited, based in Hyderabad in India, is developing the BBV87 vaccine candidate for 12 to 65-year-olds. Using an inactivated Indian isolate of the ECSA strain, this vaccine addresses the genetic diversity and serotypes of chikungunya virus. Phase 2 trials have been completed in six countries, with promising safety and immunogenicity results [31]. Phase 3 trials are expected to conclude in 2025.

Hilleman Labs in Singapore in collaboration with Institute Pasteur Paris has developed MV-CHIK, a live-attenuated recombinant vaccine candidate using the measles vaccine Schwartz strain. Targeting heterologous chikungunya lineages, it is designed for individuals aged 6 months and older, with a two-dose regimen ensuring at least five years of durability. The vaccine has demonstrated immunogenicity and efficacy in animal studies and has shown protective efficacy in animal models, including mice and cynomolgus monkeys [32]. The safety of the vaccine was confirmed in Good Laboratory Practice (GLP) compliant

repeated dose toxicity studies. Six human Phase 1 and Phase 2 studies have been completed confirming the safety and immunogenicity in human subjects. Future plans include pivotal Phase 3 trials, lot-to-lot consistency, paediatric studies, process development finalisation, technology transfer, post-approval effectiveness studies, and regulatory filings.

These four companies are at different stages of vaccine trials, each contributing uniquely to vaccine development against chikungunya. Their efforts represent a significant stride in managing this disease globally, especially in regions most affected by chikungunya outbreaks.

4. Regulatory approval and pathways

Chikungunya outbreaks are sporadic, making the size and timing of these outbreaks unpredictable. This unpredictability complicates the process of conducting traditional randomised clinical trials (RCTs) to evaluate vaccine efficacy, as it is challenging to obtain an adequate sample size. Therefore, surrogate endpoints are often used instead of classical vaccine efficacy data [33]. Identifying correlates of protection (CoP) is crucial for chikungunya vaccines, especially since human challenge trials are not feasible due to ethical considerations. To respond to the challenges presented by the sporadic nature of chikungunya outbreaks, Virus Neutralising Antibody levels in human plasma have been demonstrated to be a reliable CoP against chikungunya and are being used for vaccine licensing approval. The Medicines and Healthcare Products Regulatory Agency (MHRA) is currently conducting a program to identify these CoP using animal models, especially a non-human primate (NHP) model.

The US FDA has also recognised the challenges in vaccine efficacy trials for the chikungunya vaccine. It has declared that a surrogate endpoint is reasonably likely to predict clinical benefit and is acceptable for chikungunya vaccine approval [34]. For US FDA approval, sero-epidemiological studies, an NHP model, and the passive transfer of vaccinee sera to NHPs were used to identify immune markers for the chikungunya vaccine.

In India, there is an expedited process for granting approval to new drugs or vaccines, considering the severity, rarity, and prevalence of the disease. In this context, the approval may be based on data generated in clinical trials where a surrogate endpoint, applicable for chikungunya vaccine approval, is considered. Central America is currently in the development phase of a joint evaluation. So far, synthesised molecules have undergone this process to validate the procedure. It is anticipated that this approach could later become a regional strategy to improve timely access to vaccines. This process involves technical expertise from different countries to review and evaluate the technical aspects of vaccine approval. The goal is to strengthen safety and improve the region's access to better healthcare products.

In Brazil, the approval process involves assessing whether it is acceptable to use immunogenicity as a primary endpoint without conducting efficacy trials. For the chikungunya vaccine, the use of validated surrogate endpoints and the demonstration of neutralising activity against heterologous virus lineages were crucial to accelerate availability of an approved vaccine (US FDA approval for IXCHIQ). Additionally, a post-approval monitoring process should also be considered [35].

In the Americas, possible major challenges include the interpretation of legislation regarding vaccine approval using CoP as an alternate to efficacy trial. Collaboration between agencies could facilitate harmonising regulations across American countries to ensure inclusive and equitable access to chikungunya vaccines for at-risk populations.

Regulators recognise that a primary obstacle in the development of a chikungunya vaccine lies in conducting traditional clinical trials to determine efficacy endpoints. However, efficacy can be inferred through validated surrogate endpoints, though these may vary depending on the vaccine platform.

During the meeting, participants agreed it is crucial to emphasise

that analyses will be carried out on a case-by-case basis. To achieve this, benefit-risk and risk management plans must consider local and regional epidemiological data, with a recommendation for supplementation with additional information. For example, demonstrating neutralising activity against heterologous virus lineages is essential. The pivotal clinical trial population should accurately reflect chikungunya epidemiology in the country of study, considering variations in seronegative and seropositive rates, as well as age ranges. Collecting effectiveness and safety data from endemic areas is crucial, although legislative requirements may necessitate local or in-country data. Furthermore, post-approval monitoring of both efficacy and safety is a critical element in the comprehensive evaluation of chikungunya vaccines.

5. Vaccine access through policy, financing, and procurement

In November 2023, the US FDA approved IXCHIQ, the first chikungunya vaccine developed by Valneva. To navigate the complexities of introducing this vaccine, stakeholder engagement is crucial for devising effective vaccination strategies, deciding on the optimal timing for vaccination, establishing vaccine stockpiles, and pinpointing target populations. A stakeholder evaluation study, guided by Evidence to Recommendation (EtR) criteria used by national immunisation technical advisory groups, engaged national and subnational stakeholders through purposive and snowball sampling from December 2022 to May 2023 [20]. This engagement spanned four global regions at risk of chikungunya outbreaks and involved 18 stakeholders. The study identified gaps in EtR criteria around unknown disease burden, stemming from diagnostic challenges, the unpredictable nature of outbreaks and lack of disease specific passive surveillance. Stakeholders also grappled with the disease's high morbidity yet lower mortality, which complicates disease prioritisation amidst competing health threats, like dengue and other febrile illnesses. Many stakeholders advocated for improved chikungunya awareness within the community, citing limited community engagement as a current obstacle and another gap in EtR criteria. Furthermore, there is ambiguity surrounding the target population for the vaccine, with logistical challenges in rollout, uncertainty about age-specific targeting, and deployment strategies, further exacerbated by socioeconomic factors of populations most at risk of chikungunya infection. In the future, the implications of climate change on vector viability introduce another layer of complexity, necessitating considerations of specific climate or vector factors in chikungunya vaccine planning.

While this stakeholder analysis focused on perspectives in regions at current risk of chikungunya outbreaks and excluded Europe, the rising concern of transmission-competent mosquito populations in Europe highlights just one aspect of how changing climate patterns can shift the future epidemiology of chikungunya outbreaks [36]. To address these evolving patterns, the involvement of stakeholders in all phases of vaccine development and rollout alongside risk assessment and climate sensitivity of chikungunya will be crucial to uncover challenges and gaps to be addressed in the future. It is also crucial to fill the key data gaps in evidence regarding chikungunya disease burden. Currently, the chikungunya burden is not systematically estimated at global or regional levels. There are few studies estimating the chikungunya burden at the country level, such as in Colombia [37] and at the global and regional levels, like the systematic review by Puntasecca and colleagues [38]. However, these studies did not estimate the chikungunya burden by age or sub-national regions, which are key parameters for vaccine implementation. Due to the lack of robust global burden estimates, policy-makers are unable to make informed decisions regarding vaccine use.

6. Ways forward through a chikungunya vaccine initiative

We recommend a global chikungunya vaccine initiative to coordinate research and generate evidence to inform prevention and control programmes of chikungunya outbreaks and introduction of

chikungunya vaccination in high-burden settings and regions at risk of chikungunya outbreaks. Other vaccine initiatives against polio and measles have achieved global success through globally coordinated vaccination strategies and international cooperation [39,40].

Vaccine discovery, development, and delivery is a complex and time-consuming process, necessitating meticulous planning, adequate resources, and close cooperation among stakeholders. Developing the chikungunya vaccine initiative is a multifaceted endeavour that requires collaboration across disciplines and adherence to regulatory guidelines. For example, the Global Polio Eradication Initiative (GPEI), is a long-standing vaccine initiative launched in 1988, which aimed to eradicate polio through mass vaccination campaigns. The initiative has reduced polio cases by over 99 %, with only two countries (Afghanistan and Pakistan) still reporting cases of wild poliovirus. Key success factors include high global coordination, strong funding, and effective surveillance. The Measles & Rubella Initiative started in 2001 and seeks to reduce and eliminate measles and rubella through vaccination campaigns [41]. Led by organizations like the WHO and UNICEF, it has helped reduce global measles deaths by 73 % between 2000 and 2018. Key success factors for this initiative include mass vaccination campaigns, integration with routine immunisation programs, and rapid outbreak response teams.

For chikungunya, the key to establishing a successful vaccine initiative will involve vaccine development, surveillance, public health infrastructure, funding, and community engagement. With the right support, a chikungunya vaccine initiative could help control outbreaks and reduce the disease burden in affected regions. Integrating chikungunya vaccination with other vaccine initiatives (e.g., dengue or yellow fever campaigns) will maximize coverage and resource use.

Engaging with experts and seeking guidance from regulatory authorities are crucial aspects of the initiative. One suggested step involves supporting chikungunya surveillance and prevalence observational studies. These studies play a pivotal role in public health by providing valuable insights into chikungunya dynamics and vaccination impact upon vaccine introduction.

Surveillance efforts help in understanding the geographical spread of chikungunya, identifying high-risk areas, and assessing the effectiveness of preventive measures. Additionally, observational studies contribute to a deeper understanding of the clinical manifestations of chikungunya, transmission patterns, and long-term consequences. This information is vital for developing strategies for prevention, treatment, and public health preparedness. These studies are essential because the epidemiology of chikungunya disease is characterized by explosive, unpredictable, and rapidly spreading outbreaks. This makes it difficult to predict the size and timing of future outbreaks. Determining the regions that are endemic or experiencing epidemics is also challenging due to limited serological survey data, which provides valuable information on the force of infection, which refers to the rate at which susceptible individuals acquire an infection. This data helps identify the level of endemicity in regions affected by chikungunya. To improve chikungunya diagnosis, it is important to encourage the development of rapid diagnostic methods. Ideally, new tests should be developed that can simultaneously detect chikungunya, dengue, and Zika.

Establishing a research team is another essential component of the initiative. It is crucial to assemble a multidisciplinary team that includes scientists, immunologists, virologists, entomologists, epidemiologists, clinical researchers and infectious diseases specialists, local hospitals, regulatory bodies, and experts in vaccine development and delivery. Collaboration between researchers and institutions with relevant experience in the field is also important. This includes working closely with researchers who have conducted chikungunya observational and interventional studies. Additionally, experts in vaccination programs should be included to help identify the best strategies for delivering chikungunya vaccines. They can provide insights on who should be vaccinated, whether the vaccine should be introduced all at once or in phases, and which other vaccines can be administered concurrently.

Assessing the immunogenicity and safety of different vaccine candidates is a critical step in the development process. This can involve aggregating data from ongoing clinical trials conducted by various developers and facilitating collaborative analysis to gain a comprehensive understanding of the candidates' performance. Preclinical studies, including NHP studies, are also crucial for comprehending the CoP and optimizing vaccine efficacy. Securing funding from government agencies, private organizations, and international health bodies is essential to support research and development efforts. Forming partnerships with pharmaceutical companies, research institutions, and non-profit organizations can also facilitate progress in vaccine development.

Navigating regulatory processes, including progressing to phase 2 and phase 3 clinical trials and collaborating with international partners, is necessary to ensure compliance and accelerate the development process. Community engagement and advocacy efforts are vital for building awareness, garnering support, acceptance and trust from the population, and ensuring equitable access to the vaccine once it is approved. Planning for manufacturing, distribution, and post-market surveillance is crucial to ensure the vaccine's global accessibility and long-term safety and effectiveness. Continued investment in research and development is necessary to improve efficacy, address emerging strains, and explore potential booster doses.

7. Conclusion

We have summarised the presentations, discussions, and insights from the participants of the first Chikungunya Global Meeting in Panama City, Panama on December 12–13, 2023. We have consolidated the perspectives shared at this meeting, covering lessons learned from recent chikungunya outbreaks, research priorities, vaccine development and approval, and strategies for access and financing. Going forward, we recommend a global chikungunya vaccine initiative to coordinate research and generate evidence to inform prevention and control programmes of chikungunya outbreaks and the introduction of chikungunya vaccination in high-burden settings and regions at risk of chikungunya outbreaks.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Data availability

No data was used for the research described in the article.

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