Filovirus collaborative open research consortium research priorities for the ongoing Bundibugyo virus disease outbreak

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Abbreviations and acronyms

BDBV	Bundibugyo virus
BVD	Bundibugyo virus disease
CORC	Collaborative open research consortium
PEP	Post-exposure prophylaxis
WHO	World Health Organization

Background

Bundibugyo virus (BDBV) remains one of the least studied *Orthoebolaviruses*. No licensed vaccine or specific treatment is currently available, and clinical evidence is limited to two documented outbreaks involving approximately 200 confirmed cases, prior to the ongoing outbreak. This limited evidence highlights the urgent need to accelerate the generation of evidence for vaccines, therapeutics, diagnostics and other medical and public health interventions.

Experience from previous Ebola disease outbreaks has also shown that effective outbreak control depends not only on medical countermeasures but also on a better understanding of Bundibugyo virus disease (BVD), transmission and the cross-cutting factors influencing outbreak control.

Given the rarity of BVD outbreaks and the limited opportunities to generate evidence, a prioritization exercise was undertaken to identify the research areas with the greatest potential to inform both the current response and future preparedness. It builds on the collaborative open research consortium (CORC) *Filovirus research and development roadmap (1*), adapted to the specific context of BVD through the methodology described below.

Objectives

Research priorities were developed to guide the generation of actionable evidence for BVD in areas where knowledge gaps currently limit clinical management, outbreak response and preparedness. Their purpose is to help focus research efforts and resources on the questions most relevant to the current outbreak context.

The overall objective of this prioritization exercise is to generate evidence that improves patient outcomes and reduces mortality, strengthens outbreak response and contributes to stopping transmission. More broadly, these priorities also recognize that effective outbreak control depends on community engagement, trust, the acceptability of interventions and the wider social and behavioural conditions that enable an effective and sustainable response.

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AfricaCDC Centres for Disease Control and Prevention
World Health Organization

This agenda is intended to support—not to replace—national and regional priorities, strengthen local research capacity and promote long-term collaboration to ensure that evidence generation addresses the needs of affected populations and informs both the current response and future preparedness.

Methodology and prioritization process

The prioritization process for identifying BVD research priorities followed a stepwise approach built on the CORC *Filovirus research and development roadmap* (*1*), which provided the overarching framework for this work (*2*).

As a first step, the CORC filovirus team and working group leaders reviewed and adapted the roadmap to the specific scientific, clinical, operational and public health challenges related to BVD. The resulting body of evidence and expert input was then used to identify the research areas considered most critical for the current outbreak.

In a second step, the draft priorities were refined through an iterative process informed by seven dedicated scientific consultations and technical expert groups convened throughout the outbreak (*3*). These included CORC consultations on filovirus research, diagnostics, Ervebo cross-protection and research for patients who have recovered from Ebola diseases, the Global Research Collaboration for Infectious Disease Preparedness consultation and research priorities on social and behavioural sciences, together with the World Health Organization (WHO) Technical Advisory Group recommendations on vaccine candidates, therapeutics and host-directed therapies (*4*–*6*).

These consultations systematically brought together international experts with frontline professionals directly involved in outbreak response, including clinicians, laboratory scientists, epidemiologists and public health teams, to ensure that operational experience continuously informed the prioritization process.

As a final step, the resulting priorities were reviewed with WHO, the Africa Centres for Disease Control and Prevention and other international partners to ensure their scientific relevance, operational feasibility and alignment with the needs of the ongoing outbreak response.

Prioritization was guided by the following considerations:

- Expected impact on patient outcomes and virus transmission
- Urgency of collecting data during the current outbreak before the opportunity to generate this evidence is lost
- Potential for research findings to become available in time to inform clinical and public health decision-making considering the expected course of the current outbreak
- Specific relevance to BDBV, particularly where knowledge gaps are greatest
- Cross-cutting value across multiple scientific disciplines and public health domains.

Research implementation principles

Implementation of these priorities should be coordinated through the filovirus CORC, leveraging its scientific convening and knowledge-sharing role, in close collaboration with affected countries, the Africa Centres for Disease Control and Prevention, WHO, research networks and other partners (*4*). Successful implementation of these priorities will ultimately depend on the leadership and ownership of affected countries, supported through equitable partnerships with the international research community.

The following implementation principles define the framework for maximizing the impact of research during the current outbreak and strengthening preparedness for future outbreaks:

- Research should be embedded within outbreak response while contributing to the maintenance of preparedness capacities between epidemics and strengthening long-term research readiness.
- Implementation should remain feasible and generate meaningful evidence under emergency conditions; research activities should be designed with the operational realities of outbreak settings in mind, including laboratory capacity, logistics, staffing, security constraints and access to affected communities.
- Whenever possible, studies should build on and rapidly adapt existing filovirus research platforms, harmonized protocols, shared data systems and collaborative networks. This includes maintaining ready-to-deploy ("sleeping") protocols, pre-identified investigators and trained research teams, together with sustainable laboratory and research capacities that can be rapidly activated.
- Leveraging pre-approved ethical and regulatory protocols, together with established operational frameworks, will accelerate research activation and maximize evidence generation during the limited window of opportunity provided by a BVD outbreak.
- Research should be designed to ensure the meaningful inclusion of groups requiring specific clinical and research considerations, such as pregnant women, lactating women and children, as well as other underrepresented groups. Such an approach will ensure that the evidence generated is representative, equitable and directly relevant to those affected by BVD outbreaks.
- Research should adopt a One Health approach by integrating human, animal and environmental health perspectives whenever relevant, strengthening multidisciplinary collaboration to improve understanding of pathogen emergence, transmission dynamics, spillover events and future outbreak preparedness.
- Evidence on the needs, preferences and experiences of health care workers and patients should inform the development and evaluation of target product profiles and guide the design of acceptable, feasible and scalable medical countermeasures.

Ten research priorities for the ongoing BVD outbreak

1. Improve knowledge of BVD natural history, disease pathogenesis and transmission dynamics

Research should characterize clinical presentations, determinants of disease progression, severe outcomes and mortality, while improving understanding of the biological mechanisms underlying acute infection. Studies should investigate host immune responses and immunopathological pathways associated with disease severity, identify biomarkers of prognosis and clinical outcomes and assess the role of co-infections, host factors and pre-existing or cross-reactive immunity in shaping disease trajectories.

Experimental animal models should complement human studies by generating data on pathogenesis and mechanisms of severe disease that cannot easily be obtained in outbreak settings.

In parallel, research should characterize transmission chains, contact networks, the burden of asymptomatic or minimally symptomatic infections, and the epidemiological parameters needed for predictive modelling and operational planning. Population movement, cross-border exchanges, health care-associated transmission and social interactions may all influence outbreak dynamics and should be better documented through integrated clinical, epidemiological, laboratory, and social science approaches.

2. Interrupt community transmission through social and behavioural research, community engagement and trust-building

Social and behavioural research produces scientific evidence that helps public health responders understand and stop community transmission and implement lifesaving public health interventions. Rapid, iterative social and behavioural research should be conducted throughout the outbreak to identify emerging community concerns and priorities, enabling continuous adaptation of community engagement and risk communication strategies. Longitudinal research should also examine how stigma, social cohesion, community resilience and socioeconomic impacts evolve beyond the acute outbreak phase.

The success of outbreak response depends on community trust and the acceptability of public health measures. In the context of insecurity, population displacement and recurrence of Ebola disease and other emergencies, social and behavioural dimensions strongly influence case detection, contact tracing and adherence to recommended infection prevention measures and care. Particular attention should be given to high-risk community settings, including cross-border markets, religious gatherings, funerals and other mass gatherings where culturally appropriate engagement and communication strategies are essential. In addition, funeral practices and the cultural meanings attached to death are particularly sensitive issues and tensions surrounding safe and dignified burials have repeatedly fueled suspicion and transmission during previous outbreaks.

Risk communication and community engagement aim to build trust and community support but must be informed by social and behavioural research into the specific dynamics and priorities facing populations during the outbreak, including stigma and misinformation, which may vary between groups, across locations and over time. Findings of such research must feed back into the reshaping of the wider response, including clinical care, family engagement and safe and dignified burials, as well as addressing rumors transparently. This will strengthen trust and local ownership of the response.

Social and behavioural research is also needed to optimize community engagement, inform the design and implementation of clinical trials, and better understand the experience of frontline teams delivering research during outbreaks. Engagement is strongest when research is clearly connected to improved patient care and access to treatment, particularly when studies are embedded within the routine health care delivery of health care. Patients and communities are more willing to participate when they perceive a direct benefit for those affected by the disease.

3. Strengthen diagnostic innovation, genomic surveillance and integrated data systems

The current outbreak offers a unique opportunity to evaluate diagnostic tools under real-world field conditions. Research is needed to develop and evaluate innovative diagnostic tools and sampling approaches that facilitate safe, rapid and close to patient testing, while supporting the development and validation of BDBV-specific as well as pan-filovirus diagnostic tests. This may include rapid molecular and antigen-based assays, as well as minimally invasive strategies such as saliva-based diagnostics, self-sampling devices and skin-patch technologies.

Studies should also optimize genomic surveillance and explore the integration of diagnostic, sequencing and epidemiological data to better characterize pathogen evolution and transmission patterns. Research should support the development of harmonized biobanks, multiplex diagnostic platforms and interoperable data systems to improve early detection, enable accurate differential diagnosis and enhance preparedness for future outbreaks.

4. Optimize supportive care and clinical management

In the absence of licensed BDBV-specific vaccines or treatments, supportive care remains one of the most immediately actionable interventions for reducing mortality and improving patient outcomes.

Research should identify the components of supportive and critical care that are most strongly associated with survival, define optimal clinical management strategies and determine how they can be standardized and safely implemented across different care settings. Particular attention should be given to the role and timing of and indications for advanced supportive interventions, including fluid resuscitation, haemodynamic support with vasoactive agents, mechanical ventilation, renal replacement therapy, extracorporeal membrane oxygenation, and other organ-support strategies.

In parallel, research should examine how models of care delivery influence outcomes, including referral pathways, centralized versus decentralized care, post-discharge management and the infrastructure required to support optimized patient management. This includes treatment centre organization, patient flow, staffing, monitoring capacity, and the practical conditions needed to deliver high-quality care while maintaining infection prevention and control standards.

5. Evaluate and optimize monoclonal antibody therapies for BVD

Research should evaluate the therapeutic potential of monoclonal antibodies developed against other *Orthoebolaviruses*, particularly broadly neutralizing antibodies such as MBP134, while optimizing their use for BDBV infection. Preclinical data suggest particular interest in broad-spectrum antibodies, such as MBP134, which are capable of neutralizing several filovirus species. However, no clinical data specific to BVD are currently available, which limits the ability to anticipate real-world efficacy.

Given high production costs, logistical constraints and the limited availability of monoclonal antibodies, it is essential to diversify the therapeutic portfolio and avoid relying exclusively on this class of products. Considerations regarding availability, manufacturing, and scale-up capacity must be integrated early to ensure accessibility during emergencies.

The absence of virological and immunological correlates of progression, recovery and therapeutic response remains a major barrier to evaluating monoclonal antibodies and defining optimal therapeutic windows. Research should therefore explore and validate biomarkers associated with treatment response, with the aim of optimizing patient selection, treatment timing and the evaluation of therapeutic candidates.

6. Develop broad-spectrum antivirals and innovative therapeutic strategies for treating BVD

Clinical data on the effectiveness of broad-spectrum **antivirals** (remdesivir, obeldesivir) against BDBV infection are insufficient, and determinants of severity — including the role of co - infections such as malaria or HIV —remain poorly documented. Additional studies are needed to document antiviral activity, pharmacokinetics, tolerance and efficacy. These molecules have the advantage of being easier to produce, store and deploy, making them particularly suitable for resource-limited settings.

Novel therapeutic strategies for treating BVD should be explored and evaluated, including immunomodulatory and other host-directed therapies with evidence of benefit in severe viral infections. Research should investigate their mechanisms of action and therapeutic potential in animal models, while identifying biomarkers and immunophenotypic profiles associated with treatment response.

Research should also assess the role of viral persistence in immune-privileged sites in shaping therapeutic efficacy and explore the potential contribution of convalescent plasma where appropriate.

High-quality data on the natural history of BDBV infections will be essential to define the optimal timing, patient selection, and safety and efficacy of these approaches and to support the design of future clinical trials.

Combinations of monoclonal antibodies and antiviral agents should be explored. Evidence from other filoviruses and viral infections shows that combination therapies can enhance efficacy, reduce required doses, limit the emergence of resistance and improve survival.

7. Develop and evaluate post-exposure prophylaxis strategies for BDBV

Research should compare the effectiveness of post-exposure prophylaxis (PEP) regimens based on different candidate molecules across different exposure categories and epidemiological contexts, while assessing their operational feasibility, including adherence, tolerability and acceptability. Particular attention should be given to evaluating the respective roles of intravenous remdesivir and orally administered obeldesivir, the ease of deployment of which could represent a major advantage for community-based PEP.

Harmonized sampling across sites should support the characterization of immune and virological markers associated with protection or breakthrough infection, while evidence from therapeutics and animal models should inform the development of alternative formulations and combination approaches. The possibility of prolonged viral persistence and sexual transmission further underscores the need for early, scalable and easily deployable PEP strategies.

Research should also identify the populations most likely to benefit from PEP by refining exposure-risk classification and eligibility criteria according to the epidemiological characteristics of BVD. A better understanding of transmission dynamics will be essential to optimize the targeting and implementation of PEP during future outbreaks.

8. Accelerate the development, evaluation and deployment of vaccines against BDBV

Research should accelerate the development and evaluation of these vaccine candidates by strengthening animal models of BVD, harmonizing immunological assays and generating robust data on vaccine immunogenicity, durability and cross-protective immune responses.

Priority should be given to identifying immune correlates of protection and validating immunobridging approaches, thereby reducing reliance on conventional efficacy trials that are difficult to conduct during rare outbreaks.

Existing BDBV-specific (rVSV BDBV, HPIV3 BDBV, ChAdOx1 BDBV, mRNA BDBV) and pan-filovirus vaccine candidates represent the most promising long-term strategy for preventing BVD, but major scientific and operational challenges remain before they can be deployed.

Finally, research should generate the evidence needed to optimize vaccination strategies in outbreak settings, including ring vaccination, prioritization of health care workers and other high-risk groups, and vaccination of underrepresented populations such as children, pregnant women and other vulnerable individuals. Defining optimal vaccination strategies will require a better understanding of BDBV transmission dynamics and the operational feasibility, effectiveness and acceptability of different deployment approaches.

9. Advance research on viral persistence, long-term sequelae and immunity through longitudinal cohorts of recovered patients

Establishing longitudinal cohorts of recovered patients, also called “survivors”, must begin during the current outbreak, as many critical virological, immunological and clinical data cannot be collected retrospectively once the outbreak has ended.

Recovered patients represent both a vulnerable population and a unique research platform to advance understanding of BVD and evaluate the long-term impact of medical countermeasures. Unlike Ebola virus and Sudan virus, for which longitudinal cohorts have provided critical insights into viral persistence, immune responses and long-term sequelae, post-infection trajectories following BVD remain largely unknown.

Longitudinal cohort studies are needed to investigate viral persistence in immune-privileged compartments and to assess its implications for recrudescence risk. They should characterize immune responses through integrated immunophenotyping and clinical follow-up, identify predictive biomarkers of viral persistence, protective immunity and long-term clinical outcomes and document the full spectrum of sequelae, including ocular, neurological and psychiatric complications. Research should also examine the social trajectories of recovered patients, including stigma, health care-seeking behaviours, social reintegration and quality of life, while paying particular attention to children, pregnant women and other vulnerable populations.

Beyond improving understanding of post-BVD outcomes, harmonized survivor cohorts will provide an essential platform for evaluation of the impact of acute-phase treatments, PEP and other medical countermeasures on viral clearance, persistence in immune-privileged sites, protection against reinfection and the durability of immune responses. They will also support the identification of subgroups that require enhanced follow-up and will contribute to the development of clinically relevant endpoints, biomarkers and correlates of protection to inform future vaccine and therapeutic trials.

10. Generate evidence on infection prevention and operational bottlenecks in outbreak response

Rapid operational evidence is needed to improve the effectiveness of outbreak control and care delivery. Research should assess infection prevention and control strategies both in and outside of health care settings, including exposure risks, adherence barriers, effectiveness and acceptability of personal protective equipment and practical adaptations for complex humanitarian or insecure environments.

This priority should also address how care is organized in practice. Studies should evaluate centralized and decentralized treatment models, patient pathways, referral systems, treatment center layout, and the broader organization of services needed to maintain safe and effective care during outbreaks. The design and functioning of health care facilities can directly influence both caregiver safety and quality of care.

Operational research should further document bottlenecks across the response, including diagnostic delays, disruptions to routine health services, contact tracing performance, workforce constraints and the impact of outbreaks on health care workers' well-being and safety. Such evidence is essential for adapting response strategies in real time and for informing future preparedness.

Implementation framework

Phase I: Immediate outbreak response (0–6 months)

The immediate priority is to rapidly activate research activities and generate critical evidence that can be collected only during the acute phase of the outbreak, while directly supporting clinical management and public health response.

Focus areas

- Activate harmonized outbreak research protocols
- Characterize BVD clinical spectrum and transmission
- Strengthen diagnostics, sequencing and interoperable data systems
- Optimize supportive care
- Establish longitudinal cohorts of recovered patients
- Launch community engagement and social science studies
- Generate operational evidence to improve outbreak response
- Establish harmonized biobanks and integrated clinical, laboratory and epidemiological data systems
- Characterize transmission including through contact networks and cross-border transmission
- Evaluate innovative and close to patient diagnostic approaches
- Launch predictive modelling activities
- Optimize and expand animal models

Expected deliverables

- Harmonized clinical, laboratory and epidemiological datasets
- Biobanks established
- Diagnostic evaluation studies initiated
- Candidate vaccines, PEP and therapeutics studies activated
- Longitudinal cohort enrolment initiated
- Social and behavioural research embedded within response
- Rapid evidence informing clinical and public health decisions
- Initial transmission models and epidemiological parameters
- Harmonized genomic surveillance datasets
- Validated field and multiplex diagnostic platforms
- Validated preclinical models supporting medical countermeasure development

Phase II: Ongoing outbreak (>6 months through the end of the outbreak)

Efforts should focus on evaluating and optimizing medical and non-medical countermeasures while continuing to generate outbreak-specific evidence to inform clinical and public health decision-making.

Focus areas

- Evaluate vaccine candidates, cross-protection, immune correlates and vaccination strategies
- Evaluate and optimize PEP strategies and candidate regimens
- Evaluate and optimize monoclonal antibody therapies

- Evaluate broad-spectrum antivirals and innovative therapeutic strategies
- Optimize supportive care, clinical management and models of care delivery
- Expand and harmonize longitudinal follow-up of recovered patients
- Evaluate and optimize diagnostic platforms, genomic surveillance and integrated data systems
- Evaluate and adapt strategies for community engagement, trust and social acceptability
- Generate operational evidence to optimize infection prevention and outbreak response

Expected deliverables

- Vaccine immunogenicity and cross-protection data
- Evidence-based vaccination strategies
- Therapeutic safety and efficacy data
- PEP effectiveness and implementation data
- Validated biomarkers of protection, treatment response and patient stratification
- Optimized standards of care and clinical care algorithms
- Longitudinal cohort data on viral persistence, immunity and long-term sequelae
- Evidence supporting combination therapeutic strategies
- Evidence informing community engagement and risk communication strategies
- Evidence informing infection prevention and operational response strategies

Phase III: Post-outbreak

As the outbreak evolves, research should consolidate the evidence generated, complete longitudinal studies, and translate findings into recommendations to strengthen patient care, outbreak response and future preparedness.

Focus areas

- Complete longitudinal follow-up of recovered patients
- Characterize viral persistence, long-term immunity and clinical sequelae
- Assess social trajectories and long-term quality of life
- Evaluate the long-term impact of medical countermeasures
- Validate biomarkers, correlates of protection and clinical endpoints for future trials
- Integrate longitudinal clinical, laboratory and immunological datasets
- Translate evidence into recommendations for future clinical trials and outbreak preparedness

Expected deliverables

- Evidence on viral persistence, long-term immunity and clinical sequelae
- Evidence on the long-term effectiveness of medical countermeasures
- Final recommendations for vaccination strategies
- Validated biomarkers, correlates of protection and clinical trial endpoints
- Evidence-based recommendations for clinical management and medical countermeasures
- Long-term follow-up recommendations
- Longitudinal clinical, laboratory and immunological datasets
- Updated target product profiles
- Evidence on social recovery, stigma, health care-seeking behaviours and community resilience

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