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Understanding the human, animal and environmental interface of monkeypox transmission in Nigeria

Submission date
03/04/2024

Recruitment status
No longer recruiting

Registration date
11/04/2024

Overall study status
Completed

Last Edited
01/04/2026

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Mpox virus, previously known as Monkeypox, poses a significant global health threat since its re-emergence in Nigeria in 2017, with increasing cases annually. In 2022, a global outbreak coincided with Nigeria's largest outbreak yet. Despite improved surveillance, key knowledge gaps persist, including the effectiveness of historical smallpox vaccination and the virus's transmission dynamics. To address these, a collaborative effort involving Nigerian and international institutions was initiated before the 2022 outbreak. The project aims to enhance understanding of Mpox transmission pathways through a One Health Study and to fill clinical knowledge gaps with a separate Clinical Characterization Study. This research aims to bolster prevention, response, and control measures in Nigeria and similar endemic areas. It is comprised of two linked studies: the One Health Study (this study) which aims to increase understanding of the spread of mpox infection (i.e. human-to-human, animal-to-human, environment-to-human) in Nigeria, and the Clinical Characterisation Study which will address knowledge gaps in the clinical understanding of the virus and the natural history of infection. The Clinical Study is registered separately and further details can be accessed here (https://www.isrctn.com/ISRCTN13739887)

Who can participate?
The Mpox One Health Study focuses on the households and other close (including intimate) contacts of confirmed cases as these people would have been exposed to mpox infection. The One Health Study will recruit participants by approaching cases identified by the Clinical Study and asking their permission to contact their household and other close contacts.

What does the study involve?
For participants, the study has several elements: blood sampling to identify undiagnosed, mild or asymptomatic mpox infection, a questionnaire about their exposure to the case and other risk factors and, in the follow-up visit 28 days later, participation in an interview where they will be asked to share their experiences of having mpox in their household/community. Households will be asked to give their permission for the One Health Study animal team to set traps to capture wild rodents and other small mammals in the vicinity of their household, and for their pets to be sampled to see if they are or have been infected with mpox. Finally, households will be asked to

give permission for hard surfaces in their home to be swabbed, to see if mpox virus can be identified, and if so, whether it is capable of transmitting infection.

What are the possible benefits and risks of participating?
Participants' data are pseudonymized and treated as confidential and all records and data are maintained securely. There are no direct benefits for an individual participant of this study but we believe the information gained from participants will help improve national the response to mpox as well as contribute to increasing global knowledge about mpox and its effects on human health.

Where is the study run from?
The Mpox One Health Study is run jointly by the Nigeria Centre for Disease Control and Prevention (NCDC), National Veterinary Research Institute (NVRI), and the UK Public Health Rapid Support Team. The study is sponsored by the London School of Hygiene and Tropical Medicine, London, UK.

When is the study starting and how long is it expected to run for?
August 2022 to March 2026

Who is funding the study?
UK Government ODA, via UK Public Health Rapid Support Team

Who is the main contact?
Dr Chioma Achi (Mpox Study Coordinator, UK-PHRST), ritahalichi@yahoo.com, Chioma.achi@lshtm.ac.uk

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Additional identifiers

Protocol serial number
UKPHRST_NMOHS_1.0

Study information

Scientific Title
Nigeria Mpox One Health Study

Acronym
NMOHS

Study objectives
The Mpox One Health Study is one of two linked studies that aim to address a number of questions about the natural history and transmission of mpox virus in Nigeria. The One Health study focuses on establishing epidemiological parameters and transmission factors among case-household and proximate animals in Nigeria. The linked study, entitled the Nigeria Mpox Clinical Characterization Study [registration no. ISRCTN13739887], focusses on the clinical, immunological and virological features of the disease in confirmed cases and will be the source of the confirmed cases for the One Health Study.

The study hypothesizes that establishing key epidemiological parameters (such as incidence, range of severity, rate of secondary transmission and risk factors for infection) and the relative importance of different routes of transmission (including animal-to-human and human-to-human) in case households and among close contacts will assist public health decision-makers in Nigeria and elsewhere to improve prevention and response activities. The study will also gather information on past and present mpox infection in rodents, domesticated and 'bush' animals in the vicinity of case-households and the role of surface contamination in household transmission.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 06/09/2023, National Health Research Ethics Committee of Nigeria (NHREC) (Department of Health Planning, Research & Statistics, Federal Ministry of Health, 11th Floor, Federal Secretariat Complex Phase III, Ahmadu Bello Way, Abuja, 900211, Nigeria; +234-09-523-8367; secretary@nhrec.net), ref: NHREC/01/01/2007-06/09/2023

2. approved 16/10/2023, London School of Hygiene and Tropical Medicine Observational /Interventions Research Ethics Committee (Keppel Street, London, WC!E 7HT, United Kingdom; +44 20 7636 8636; ethics@lshtm.ac.uk), ref: 28801

3. approved 30/10/2023, Government of Rivers State of Nigeria Health Research Ethics Committee (Rivers State Hospitals Management Board, 26 Okoroma Street, Port Harcourt, PMB 6083, Nigeria; +234-084-230828; rshmbph@yahoo.com), ref: RSHMB/RSHREC/2023/052

4. approved 31/07/2023, National Veterinary Research Institute (NVRI), Vom, Nigeria Animal Ethics Committee (Vom, Plateau State, Jos, P.M.B 01, Nigeria; +234 8111118533; edvr@nvri.gov.ng), ref: NVRI/AEC/03/136/2

5. approved 18/03/2024, London School of Hygiene & Tropical Medicine Animal Welfare and Ethical Review Board (Keppel Street, London, WC1E 7HT, United Kingdom; +44 20 7636 8636; ethics@lshtm.ac.uk), ref: 2023-08

6. approved 22/11/2023, Lagos State Government Social Approval (Block 4, The Secretariat, Alausa, Ikeja, P.M.B 210007, Nigeria; +234-1-4969061; joywenuga@lagosstate.gov.ng), ref: LSMH /4773/1/78

7. submitted 18/03/2024, Government of Ogun State Health Research Ethics Committee (Ogun State Hospitals' Management Board) (BLOCK A, STATE SECECRETARIAT COMPEX, OKE-MOSAN, Abeokuta, P.M.B 2226, Nigeria; +234 803 681 0362; info@ogunhmb.com.ng), ref: -

Study design
Multicentre mixed-methods observational cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Monkeypox

Interventions
Multicentre mixed-methods observational cohort study of case households and non-household contacts using paired serology, exposure data and perception interviews, and cross-sectional animal and environmental sampling

Demographic and exposure data will be collected at recruitment and at follow-up visits, using a structured questionnaire. Blood samples will be taken at recruitment and follow-up visits, for serological analyses of anti-orthopox antibodies. Biological samples of wild rodents/small mammals and domestic animals will be collected for laboratory analysis to identify presence of the mpox virus and anti-orthopox antibodies. Pets will be sampled after appropriate non-harmful restraint including blood and oral, nasal, and skin scab swabs. Wild rodents and small mammals will be collected in traps placed near targeted households. They will be anesthetized prior to blood sampling and euthanized prior to tissue sampling. Environmental samples will be collected for laboratory analysis and where possible cultured to identify whether any virus found is infection-competent. There are no pharmaceutical interventions in this study.

Intervention Type
Other

Primary outcome(s)
1. Household incidence and secondary transmission estimated by qPCR (cases) and orthopox serology (asymptomatic or un-diagnosed contacts) at baseline and day 28 following household enrolment, taking into account previous smallpox vaccination.
2. Symptomatic, pauci-symptomatic and asymptomatic fractions of mpox infection based on orthopox serology and symptom questionnaires, at baseline and day 28 following household enrolment.
3. Identification of key risk factors and drivers of human mpox infection using risk ratios derived

from individual exposure questionnaires in cases, household members and non-household close contacts carried out at baseline and covering a period of 1 month prior to household enrolment, and at day 28 following household enrolment covering the period since enrolment in the study.
4. Evidence of active and past infection in animals in the vicinity of a case household identified using PCR and serology on blood, tissue and swab samples at the time point of sampling.
5. Evidence of extent of surface contamination in case households using qPCR on samples taken on day 1 and day 3 after household enrolment. Cultures will be done on the same samples if resources allow.

Key secondary outcome(s))
1. Identification of barriers to and enablers for mpox prevention and control using themes derived from qualitative information gained using semi-structured household interviews on day 28 following household enrolment and covering the period since the household became aware of mpox. The period will vary depending on household experience.
2. Description of case household knowledge, experience and perceptions of mpox from qualitative information gained using semi-structured household interviews on day 28 following household enrolment and covering the period since the household became aware of mpox. The period will vary depending on household experience.
3. Identification of possible reservoirs of mpox virus using serology results by species derived from samples taken at one time point.

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Confirmed mpox cases and all their household members (defined as people living together within the same residential structure and sharing meals) and up to five non-household close contacts will be invited to take part regardless of age, sex, pregnancy, smallpox vaccine status, language, or any other variable.
2. Wild rodents/small mammals in and around the case household will be trapped for sampling (unless pregnant or lactating). Cats and dogs in the case household and neighbouring households will also be sampled. All animal trapping and sampling will be done with relevant household consent.

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
1017

Key exclusion criteria
There are no exclusion criteria

Date of first enrolment
05/02/2024

Date of final enrolment
30/11/2025

Locations

Countries of recruitment
Nigeria

Study participating centre
Rivers State
Nigeria
500001

Study participating centre
Ogun State
Nigeria
110271

Study participating centre
Lagos State (to be confirmed)
Nigeria
100001

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
UK Government ODA, via UK Public Health Rapid Support Team

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study will be stored in a non-publicly available repository maintained by NCDC. All individual participant stored data will be pseudonymised, so individuals cannot be identified by those accessing the data. Use of any stored data or residual biological samples by other researchers will be controlled by a data and materials access committee. The committee will have scientist members and advisers from Nigeria and the UK, and processes will be in place for making requests to access data or materials, and for reviewing and approving or rejecting requests.

IPD sharing plan summary
Available on request, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		03/10/2023	09/04/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes