

Supplementary Appendix

Supplement to: Thornhill JP, Barkati S, Walmsley S, et al. Monkeypox virus infection in humans across 16 countries — April–June 2022. *N Engl J Med* 2022;387:679-91. DOI: 10.1056/NEJMoa2207323

This appendix has been provided by the authors to give readers additional information about the work.

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SUPPLEMENTARY APPENDIX

Supplement to: Thornhill J, Barkati S, Walmsley S al. **Human Monkeypox Infection across 16 Countries — April–June 2022**

This appendix has been provided by the authors to give readers additional information about the work.

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SHARE-net writing group

We would like to thank all the individuals with monkeypox infection who contributed their clinical data and images to the case series without whom this work would not be possible. We thank SHARE Collaborative Programme Manager Ms Sadna Ullah for administrative help. We thank the many clinicians in 16 countries who worked so hard to provide us with the data for the case series. They are all listed as investigators below and their contribution was invaluable.

List of SHARE-net investigators
(arranged alphabetically)

Name	Institute/s	Location
Anger, Camille	Clinique médicale du Quartier Latin	Montreal, Quebec, Canada
Antinori, Andrea*	National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS	Roma, Italy
Apea, Vanessa J.*	The Blizard Institute & SHARE Collaboration, Queen Mary University of London; Department of Infection & Immunity, Barts Health NHS Trust	London, United Kingdom
Arenzana, Carmen B.	HIV Unit. Hospital Universitario La Paz CIBERInfec, IdIPaz	Madrid, Spain
Barkati, Sapha*	Department of Medicine, Division of Infectious Diseases, McGill University Health Centre; J.D. MacLean Centre for Tropical Diseases at McGill University Research Institute of the McGill University Health Centre	Montreal, Quebec, Canada
Basgoz, Nesli	Massachusetts General Hospital, Harvard Medical School	Boston, Massachusetts, United States of America
Behr, Marcel	McGill University Health Centre	Montreal, Quebec, Canada
Benomar, Khadija	Clinique Quorum	Montreal, Quebec, Canada
Bérot, Vincent	Department of Infectious Diseases, Pitié-Salpêtrière Hospital, APHP, Sorbonne University	Paris, France
Blais, Antoine	Clinique l'Agora	Montreal, Quebec, Canada
Blanco, Jose Luis*	Infectious Diseases Department, Hospital Clinic-IDIBAPS, University of Barcelona; Centro de Investigación Biomédica en Red de Enfermedades Infecciosas (CIBERINFEC), Instituto de Salud Carlos III	Barcelona, Spain; Madrid, Spain

Bleibtreu, Alexandre	Department of Infectious Diseases, Pitié-Salpêtrière Hospital, APHP, Sorbonne University	Paris, France
Boesecke, Christoph*	Department of Medicine, University Hospital Bonn	Bonn, Germany
Brin, Cécile	Department of Infectious Diseases, Pitié-Salpêtrière Hospital, APHP, Sorbonne University	Paris, France
Broderick, Kaitlyn L.	Hospital of the University of Pennsylvania	Philadelphia, United States of America
Bui-Nguyen, Andrew	Clinique Quorum	Montreal, Quebec, Canada
Burrel, Sonia	Department of Virology, Pitié-Salpêtrière Hospital, APHP, Sorbonne University	Paris, France
Camprubi, Daniel	Infectious Diseases Department, Hospital Clinic-IDIBAPS, University of Barcelona	Barcelona, Spain
Caria, João	Hospital de Curry Cabral – CHULC	Lisboa, Portugal
Castagna, Antonella	Clinic of Infectious Diseases, Vita-Salute San Raffaele University, San Raffaele Scientific Institute	Milan, Italy
Català, Alba	Infectious Diseases Department, Hospital Clinic-IDIBAPS, University of Barcelona	Barcelona, Spain
Catellan, Anna Maria*	Infectious Diseases Division, Department of Medical Sciences, Azienda Ospedale Università'	Padova, Italy
Chakravarti, Arpita	Centre Hospitalier de l'Université de Montréal	Montreal, Quebec, Canada
Coleman, Harry L.	Department of Sexual and Reproductive Health, Guy's & St Thomas' NHS Foundation Trust	London, United Kingdom
Corral-Herrera, Ever Arturo	Médico Residente de Infectología, Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán	Mexico City, Mexico
Coyne, Katherine	Homerton University Hospital NHS Trust	London, United Kingdom
Cuervo, Guillermo	Infectious Diseases Department, Hospital Clinic-IDIBAPS, University of Barcelona	Barcelona, Spain

Dakshina, Subathira	Department of Infection & Immunity, Barts Health NHS Trust	London, United Kingdom
De la Calle-Prieto, Fernando	National Referral Centre for Tropical Diseases, Hospital Universitario La Paz, CIBERInfec, IdIPaz	Madrid, Spain
de Loreda, Nicolas	Infectious Diseases Department, Hospital Clinic-IDIBAPS, University of Barcelona	Barcelona, Spain
De Scheerder, Marie-Angélique	General Internal Medicine, Ghent University Hospital	Ghent, Belgium
de Stoppelaar, Sacha	Amsterdam University Medical Centers, University of Amsterdam	Amsterdam, The Netherlands
Díaz-Menéndez, Marta	National Referral Centre for Tropical Diseases, Hospital Universitario La Paz, CIBERInfec, IdIPaz	Madrid, Spain
Drauz, Daniela	Department of Infectious Diseases, St. Joseph Hospital	Berlin-Tempelhof, Germany
Emilia, Reggio	Clinic of Infectious Diseases, University of Modena	Modena, Italy
Esperti, Sara	Clinic of Infectious Diseases, University of Modena	Modena, Italy
Farooq, Hamzah	The Blizard Institute & SHARE Collaboration, Queen Mary University of London; Department of Infection & Immunity, Barts Health NHS Trust	London, United Kingdom
Florence, Eric*	Institute of Tropical Medicine	Antwerp, Belgium
Friedel, Nadav	Sackler Faculty of Medicine, Tel Aviv University; Department of Infectious Diseases and Infection Control, Tel Aviv Sourasky Medical Center	Tel Aviv, Israel
Fuertes, Irene	Infectious Diseases Department, Hospital Clinic-IDIBAPS, University of Barcelona	Barcelona, Spain
Garbuglia, Anna Rosa	National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS	Roma, Italy
Garcia, David	Infectious Diseases Department, Hospital Clinic-IDIBAPS, University of Barcelona	Barcelona, Spain;
Gavaud, Ariane	Department of Infectious Diseases, Pitié-Salpêtrière Hospital, APHP, Sorbonne University	Paris, France

Gilera, Vanessa	Infectious Diseases Department, Hospital Clinic-IDIBAPS, University of Barcelona	Barcelona, Spain
Girardi, Enrico	National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS	Roma, Italy
Gonzalez-Cordón, Ana	Infectious Diseases Department, Hospital Clinic-IDIBAPS, University of Barcelona	Barcelona, Spain
Goorhuis, Bram*	Amsterdam University Medical Centers, University of Amsterdam	Amsterdam, The Netherlands
Greenaway, Christina	Jewish General Hospital	Montreal, Quebec, Canada
Grunemwald, Thomas	Le 190 Sexual Health Center	Paris, France
Guaraldi, Giovanni	Clinic of Infectious Diseases, University of Modena	Modena, Italy
Habibi, Maximillian S.*	St George's University Hospitals NHS Foundation Trust	London, United Kingdom
Hansen, Anna-Brit E.*	Department of Infectious Diseases, University Hospital of Copenhagen	Hvidovre, Denmark
Harrington, David	Barts Health NHS Trust	London, United Kingdom
Harrison, Luke B.*	Department of Medicine, Division of Infectious Diseases, McGill University	Montreal, Quebec, Canada
Hoffmann, Christian*	ICH Study Center MVZ Stadmitte	Hamburg, Germany
Huchet, Emmanuelle	Clinique l'Agora	Montreal, Quebec, Canada
	Department of Medicine, Division of Infectious Diseases, McGill University Health Centre; Chronic Viral Illness Service, Department of Medicine, McGill University Health Centre;	
Klein, Marina*	Research Institute of the McGill University Health Centre	Montreal, Quebec, Canada
Kronborg, Gitte	Department of Infectious Diseases, University Hospital of Copenhagen	Hvidovre, Denmark
Lascoux-Combe, Caroline	Department of Infectious Diseases, University of Paris Cité, AP-HP, Saint-Louis-Lariboisière Hospital	Paris, France
Lazzarotto, Tiziana	Microbiology Unit, IRCCS Azienda Ospedaliero-Universitaria di Bologna	Bologna, Italy

Levy, Itzhak	Sheba Medical Center, Tel Hashomer	Ramat Gan, Israel
Lezama-Mora, Jezer Ivan*	Condesa Specialized Clinic	Mexico City, Mexico
Libman, Michael	McGill University Health Centre	Montreal, Quebec, Canada
Macpherson, Liana	St George's University Hospitals NHS Foundation Trust	London, United Kingdom
Maggi, Fabrizio*	National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS	Roma, Italy
Makofane, Keletso*	International AIDS Society; Harvard Medical School	Geneva, Switzerland; Boston, Massachusetts, United States of America
Maltez, Fernando*	Hospital de Curry Cabral – CHULC	Lisboa, Portugal
Marcelin, Anne-Geneviève	Department of Virology, Pitié-Salpêtrière Hospital, APHP, Sorbonne University	Paris, France
Marot, Stéphane	Department of Virology, Pitié-Salpêtrière Hospital, APHP, Sorbonne University	Paris, France
Martinez, Mikel	Infectious Diseases Department, Hospital Clinic-IDIBAPS, University of Barcelona	Barcelona, Spain
Masuhr, Anja	Vivantes Auguste-Viktoria-Klinikum	Berlin, Germany
McMahon, James	Department of Infectious Diseases, Alfred Hospital and Monash University; Department of Infectious Diseases, Monash Medical Centre	Melbourne, Australia
Migaud, Pascal*	Department of Infectious Diseases, St. Joseph Hospital	Berlin-Tempelhof, Germany
Mishra, Sharmistha	Division of Infectious Diseases and MAP Centre for Urban Health Solutions, St. Michael's Hospital; Department of Medicine, University of Toronto,	Toronto, Canada
Molina, Jean-Michel	Department of Infectious Diseases, University of Paris Cité, AP-HP, Saint-Louis-Lariboisière Hospital	Paris, France
Monsel, Gentiane	Department of Infectious Diseases, Pitié-Salpêtrière Hospital, APHP, Sorbonne University	Paris, France

Moschese, Davide*	Division of Infectious Disease, Luigi Sacco Hospital, ASST Fatebenefratelli Sacco, Milan Italy	Milan, Italy
Muñoz, José	Infectious Diseases Department, Hospital Clinic-IDIBAPS, University of Barcelona	Barcelona, Spain
Mussini, Cristina*	Clinic of Infectious Diseases, University of Modena	Modena, Italy
Nemeth, Johannes*	Division of Infectious Diseases and Hospital Epidemiology	Zurich, Switzerland
Nicastri, Emanuele	National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS	Roma, Italy
Noe, Sebastian*	MVZ München am Goetheplatz	Munich, Germany
Nori, Achyuta Vithal*	Department of Sexual and Reproductive Health, Guy's & St Thomas' NHS Foundation Trust	London, United Kingdom
Nouchi, Agathe	Department of Infectious Diseases, Pitié-Salpêtrière Hospital, APHP, Sorbonne University	Paris, France
Nozza, Silvia*	Department of Infectious and Tropical Diseases, IRCCS-Ospedale San Raffaele	Milan, Italy
Nutland, Will	London School of Hygiene and Tropical Medicine (LSHTM)	London, United Kingdom
Op De Coul, Eline	Centre for Infectious Disease Control, National Institute for Public Health and the Environment (RIVM), Bilthoven	The Netherlands
Orkin, Chloe*	The Blizard Institute & SHARE Collaboration, Queen Mary University of London; Department of Infection & Immunity, Barts Health NHS Trust	London, United Kingdom
Ostrowski, Mario	Division of Infectious Diseases and MAP Centre for Urban Health Solutions, St. Michael's Hospital; Department of Medicine, University of Toronto	Toronto, Canada
Oughton, Matthew	Jewish General Hospital	Montreal, Quebec, Canada
Palich, Romain*	Department of Infectious Diseases, Pitié-Salpêtrière Hospital, APHP, Sorbonne University	Paris, France

Paran, Yael	Sackler Faculty of Medicine, Tel Aviv University; Department of Infectious Diseases and Infection Control, Tel Aviv Sourasky Medical Center	Tel Aviv, Israel
Pilarski, Robert	Clinique Médicale La Licorne	Montreal, Quebec, Canada
Pintado, Claire*	Department of Infectious Diseases, University of Paris Cité, AP-HP, Saint-Louis-Lariboisière Hospital	Paris, France
Poulin, Sébastien	Clinique I.D.	St-Jérôme, Quebec, Canada
Pourcher, Valérie*	Department of Infectious Diseases, Pitié-Salpêtrière Hospital, APHP, Sorbonne University	Paris, France
Póvoas, Diana	Hospital de Curry Cabral – CHULC	Lisboa, Portugal
Reeves, Iain*	Homerton University Hospital NHS Trust	London, United Kingdom
Richardson, Daniel	University Hospitals Sussex NHS Foundation Trust	Brighton, United Kingdom
Riddell, Anna	Barts Health NHS Trust	London, United Kingdom
Riera, Josep	Infectious Diseases Department, Hospital Clinic-IDIBAPS, University of Barcelona	Barcelona, Spain
Rizzardini, Giuliano	Luigi Sacco Hospital	Milan, Italy
Rockstroh, Jürgen*	Department of Medicine, University Hospital Bonn	Bonn, Germany
Rossini, Giada	Section of Microbiology, Department of Experimental, Diagnostic and Specialty Medicine, University of Bologna	Bologna, Italy
Rubenstein, Emma	Department of Infectious Diseases, University of Paris Cité, AP-HP, Saint-Louis-Lariboisière Hospital	Paris, France
Sandoval, Carolina	Francisco Javier Muñiz Infectious Diseases Hospital	Buenos Aires, Argentina
Schewe, Carl-Knud	MVZ ICH Stadmitte	Hamburg, Germany
Schinkel, Cornelia J.	Amsterdam University Medical Centers, University of Amsterdam	Amsterdam, The Netherlands

Sendagorta, Elena*	Department of Dermatology, University Hospital La Paz, CIBERInfec, IdIPaz	Madrid, Spain
Soni, Suneeta	University Hospitals Sussex NHS Foundation Trust	Brighton, United Kingdom
Valentina Mazzotta	National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS	Roma, Italy
Staehelin, Cornelia	Inselspital University Hospital Bern	Bern, Switzerland
Stocker, Harmut	Department of Infectious Diseases, St. Joseph Hospital	Berlin-Tempelhof, Germany
Szabo, Jason	Clinique Médicale l'Actuel	Montreal, Quebec, Canada
Taggart, Linda	Division of Infectious Diseases and MAP Centre for Urban Health Solutions, St. Michael's Hospital; Department of Medicine, University of Toronto	Toronto, Canada
Tan, Darrell*	Division of Infectious Diseases and MAP Centre for Urban Health Solutions, St. Michael's Hospital; Department of Medicine, University of Toronto,	Toronto, Canada
Thomas, Réjean	Clinique Médicale l'Actuel	Montreal, Quebec, Canada
Thornhill, John P*	The Blizzard Institute & SHARE Collaboration, Queen Mary University of London; Department of Infection & Immunity, Barts Health NHS Trust	London, United Kingdom
Trottier, Benoît	Clinique médicale du Quartier Latin	Montreal, Quebec, Canada
Vaia, Francesco	National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS	Roma, Italy
Vandekerckhove, Linos*	HIV Cure Research Center, Department of Internal Medicine and Paediatrics, Faculty of Medicine and Health Sciences, Ghent University; Ghent University Hospital	Ghent, Belgium

Vinh, Donald	McGill University Health Centre	Montreal, Quebec, Canada
Wakim, Yara	Department of Infectious Diseases, Pitié-Salpêtrière Hospital, APHP, Sorbonne University	Paris, France
Walmsley, Sharon*	University Health Network, University of Toronto	Toronto, Canada
Wendtner, Clemens	MVZ München am Goetheplatz	Munich, Germany
Wieder, Anat	Sheba Medical Center, Tel Hashomer	Ramat Gan, Israel
Yakubovsky, Michal*	Sackler Faculty of Medicine, Tel Aviv University; Department of Infectious Diseases and Infection Control, Tel Aviv Sourasky Medical Center	Tel Aviv, Israel
Zaharatos, Gerasimos J.	Jewish General Hospital,	Montreal, Quebec, Canada

**Author on main manuscript*

Authorship contributions

Contributions to the Design, Conduct and Reporting of the Case Series

Prof Chloe Orkin (CMO) initiated and lead the collaboration on behalf of the SHARE-net group. CMO and John Thornhill (JPT) developed the Case Report Spreadsheet (CRS), RP, PM, MBK, VA and SW provided clinical input. JPT and CMO gathered the data and assure the quality of the data collected from the participating sites. JPT performed the analysis. The first draft was jointly written by CMO and JPT. All subsequent drafts were written and edited by CMO, JPT, MBK, SW, AA, JR, SB et al and approved by the main authors. The Image library curation was led by SB. CMO, JPT, SB, JN developed the slide template for uniform presentation of image chronologies. Main authors MY, JN, JL, AB, AC, CB, SN, DM, PM, AH, DT, CP, SW curated images. Investigators Cornelia Staehlin and Suneeta Soni also submitted images. The map of clinical sites was created by SN and CMO. The table on seminal fluid was created by AA, FM and JPT. The decision to publish these results and images was agreed by all authors. The writing group vouches for and the data, the analysis and the content of the manuscript.

Figures

Figure S1 Case Report Form – World Health Organisation



Global Clinical Data Platform

Monkeypox CASE REPORT FORM (CRF)

INTRODUCTION

The Rapid Core CRF is designed to collect data obtained through examination, interview and review of hospital or clinic notes of patients with suspected, probable, or confirmed monkeypox infection. Data may be collected prospectively or retrospectively. The data collection period is defined as the period from hospital admission or first clinic visit to discharge from care, transfer, death, or continued hospitalization without possibility of continued data collection.

This CRF has three modules:

- Module 1:** To be completed on the first day of presentation or admission to the health centre.
- Module 2:** To be completed daily during hospital stay for as many days as resources allow, or on follow-up visits to health centre.
- Module 3:** To be completed at last visit, either hospital discharge or last follow-up.
- Pregnancy module:** To be completed if currently pregnant or recently pregnant ≤ 21 days.

GENERAL GUIDANCE

Participant identification numbers consist of a site code and a participant number. You can register on the data management system by monkeypox_clinicaldatapatform@who.int and our data management team will contact you with instructions for data entry and will assign you a 5-digit site code at that time. Please contact us at monkeypox_clinicaldatapatform@who.int for any information.

MODULE 1. Complete on hospital admission (within 24 hrs from admission) or first visit to outpatients

Facility/clinic name _____

Country _____

Date of enrolment [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []

1a. DEMOGRAPHICS

Sex at birth Male Female Not specified Date of birth [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []
 If date of birth is Unknown, record: Age [] [] [] years OR [] [] months OR [] [] days
 Health care worker? Yes No Unknown Laboratory worker? Yes No Unknown
 If yes: not wearing all recommended PPE wearing all recommended PPE other specify _____
 Race/ethnicity (tick all that apply) Asian African/Black Caucasian/White
 Hispanic/Latino Other Unknown
 History of smallpox vaccination Yes No Unknown
 History of tetanus vaccination Yes No Unknown
 Pregnant? Yes No Unknown N/A If yes: Gestational weeks assessment [] [] weeks
 If No, was person recently pregnant: within ≤ 21 days? Yes No Unknown.
 If Yes, also complete Pregnancy Module

1b. DATE OF ONSET AND ADMISSION VITAL SIGNS (first available data at presentation/admission)

Symptom onset (date of first/earliest symptom) [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []
 First described symptoms: _____

 Admission or visit date at this facility [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []
 Temperature [] [] [] °C
 Heart rate [] [] [] beats/min Respiratory rate [] [] breaths/min
 BP [] [] [] (systolic) [] [] [] (diastolic) mmHg Severe dehydration Yes No Unknown
 Alert Voice Pain Unresponsive (circle one)
 Height [] [] [] cm Weight [] [] [] kg

1c. CO-MORBIDITIES (existing at admission or initial visit)

Chronic cardiac disease (not hypertension) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Diabetes <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Hypertension <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Current smoking <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Chronic pulmonary disease <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Tuberculosis (active) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Asthma <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Tuberculosis (previous) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Chronic kidney disease <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Asplenia <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Chronic liver disease <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Malignant neoplasm <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Chronic neurological disorder <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	If yes, on therapy for neoplasm at present? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Current alcohol use <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	On immunosuppressants <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Known current sexually transmitted infection <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	If yes, specify _____
If yes, specify: _____	Immunosuppressive condition <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
	If yes, specify: _____
HIV <input type="checkbox"/> Yes (on ART) <input type="checkbox"/> Yes (not on ART) <input type="checkbox"/> No <input type="checkbox"/> Unknown	
ART regimen _____	
Most recent CD4: [] [] []	

1d. SIGNS AND SYMPTOMS ON ADMISSION

Number of lesions on the entire body that are NOT resolved (resolved = scabbed and desquamated):

0 1–5 6–25 26–100 > 100 > 250

Number of lesions on the right leg (to the hip crease, including front and back of foot and leg): [] [] [] []
 Number of lesions on the right arm (including hand and shoulder): [] [] [] []
 Number of lesions on the left leg (to the hip crease, including front and back of foot and leg): [] [] [] []
 Number of lesions on the left arm (including hand and shoulder): [] [] [] []
 Number of lesions on the genitals (from hip crease to hip crease): [] [] [] []

Does the patient have active lesions in the following areas:

Face	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Palms of hands	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Nose	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Arms	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Mouth	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Forearms	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Chest	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Thighs	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Abdomen	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Legs	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Back	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Soles of feet	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Perianal	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Other	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Genitals	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Specify where:	_____

Types of lesions on the body:

Macule	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Umbilicated pustule	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Papule	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Ulcerated lesion	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Early vesicle	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Crusting of a mature lesion	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Small pustule	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Partially removed scab	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

Pain at any lesion site: YES NO If yes, pain score (0–10; 0 is no pain, 10 is worst imaginable pain): [] []

1e. SIGNS AND SYMPTOMS ON ADMISSION

Sore throat	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Chest pain	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Muscle aches (myalgia)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Joint pain (arthralgia)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Headache	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Fatigue/malaise	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Visual symptoms/Keratitis	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Psychological disturbance	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Vomiting/nausea	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Diarrhoea	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Genital ulcers	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Dizziness	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Anal ulcers	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Decreased urine output	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Lymphadenopathy			
If yes,			
Axillary	<input type="checkbox"/> Yes, painful <input type="checkbox"/> Yes, not painful <input type="checkbox"/> NO		
Cervical	<input type="checkbox"/> Yes, painful <input type="checkbox"/> Yes, not painful <input type="checkbox"/> NO		
Inguinal	<input type="checkbox"/> Yes, painful <input type="checkbox"/> Yes, not painful <input type="checkbox"/> NO		
Other	<input type="checkbox"/> Yes, painful <input type="checkbox"/> Yes, not painful <input type="checkbox"/> NO		
Specify _____			

MPSI CASE REPORT FORM 14 June 2022
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MODULE 3. Complete at discharge/death/last follow up

3a. DIAGNOSTIC PATHOGEN TESTING please list all diagnostic tests for pathogens			
Date	Specimen type	Test performed	Result
____/____/____	<input type="checkbox"/> Nasal/NP swab <input type="checkbox"/> Throat swab <input type="checkbox"/> Combined nasal/NP + throat swab <input type="checkbox"/> Sputum: <input type="checkbox"/> BAL, <input type="checkbox"/> OCTA <input type="checkbox"/> Lesion/crust swab <input type="checkbox"/> Urine <input type="checkbox"/> Oropharyngeal swab <input type="checkbox"/> Blood <input type="checkbox"/> Other, specify: _____	<input type="checkbox"/> Monkeypox PCR <input type="checkbox"/> Orthopoxvirus PCR <input type="checkbox"/> Other: _____	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown
____/____/____	<input type="checkbox"/> Nasal/NP swab <input type="checkbox"/> Throat swab <input type="checkbox"/> Combined nasal/NP + throat swab <input type="checkbox"/> Sputum: <input type="checkbox"/> BAL, <input type="checkbox"/> OCTA <input type="checkbox"/> Lesion/crust swab <input type="checkbox"/> Urine <input type="checkbox"/> Oropharyngeal swab <input type="checkbox"/> Blood <input type="checkbox"/> Other, specify: _____	<input type="checkbox"/> Monkeypox PCR <input type="checkbox"/> Orthopoxvirus PCR <input type="checkbox"/> Other: _____	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown
____/____/____	<input type="checkbox"/> Nasal/NP swab <input type="checkbox"/> Throat swab <input type="checkbox"/> Combined nasal/NP + throat swab <input type="checkbox"/> Sputum: <input type="checkbox"/> BAL, <input type="checkbox"/> OCTA <input type="checkbox"/> Lesion/crust swab <input type="checkbox"/> Urine <input type="checkbox"/> Oropharyngeal swab <input type="checkbox"/> Blood <input type="checkbox"/> Other, specify: _____	<input type="checkbox"/> Monkeypox PCR <input type="checkbox"/> Orthopoxvirus PCR <input type="checkbox"/> Other: _____	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown
____/____/____	<input type="checkbox"/> Nasal/NP swab <input type="checkbox"/> Throat swab <input type="checkbox"/> Combined nasal/NP + throat swab <input type="checkbox"/> Sputum: <input type="checkbox"/> BAL, <input type="checkbox"/> OCTA <input type="checkbox"/> Lesion/crust swab <input type="checkbox"/> Urine <input type="checkbox"/> Oropharyngeal swab <input type="checkbox"/> Blood <input type="checkbox"/> Other, specify: _____	<input type="checkbox"/> Other: _____	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown
____/____/____	<input type="checkbox"/> Nasal/NP swab <input type="checkbox"/> Throat swab <input type="checkbox"/> Combined nasal/NP + throat swab <input type="checkbox"/> Sputum: <input type="checkbox"/> BAL, <input type="checkbox"/> OCTA <input type="checkbox"/> Lesion/crust swab <input type="checkbox"/> Urine <input type="checkbox"/> Oropharyngeal swab <input type="checkbox"/> Blood <input type="checkbox"/> Other, specify: _____	<input type="checkbox"/> Other: _____	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown
____/____/____	<input type="checkbox"/> Nasal/NP swab <input type="checkbox"/> Throat swab <input type="checkbox"/> Combined nasal/NP + throat swab <input type="checkbox"/> Sputum: <input type="checkbox"/> BAL, <input type="checkbox"/> OCTA <input type="checkbox"/> Lesion/crust swab <input type="checkbox"/> Urine <input type="checkbox"/> Oropharyngeal swab <input type="checkbox"/> Blood <input type="checkbox"/> Other, specify: _____	<input type="checkbox"/> Other: _____	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unknown

WHO CASE REPORT FORM (CRF) v. 2021
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3b. COMPLICATIONS if hospitalized, at any time during hospitalization, did the patient experience:					
Shock	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Bacteraemia	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Seizure	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Bacterial super-infection	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Meningitis/encephalitis	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Bleeding	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Anaemia	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Abcess	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Cardiac arrhythmia	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Myocarditis/pericarditis	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Cardiac arrest	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Acute renal injury	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Pneumonia	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Pancreatitis	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Cellulitis	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Liver dysfunction	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Acute respiratory distress syndrome (ARDS)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Cardiomyopathy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Stroke: ischaemic stroke	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Ocular infection	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Necrotizing infection	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	Other if yes, specify _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

3c. MEDICATION while hospitalized or at discharge, were any of the following administered:	
Oral/orogastric fluids?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Intravenous fluids?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Experimental orthopox antiviral?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If yes: <input type="checkbox"/> Brincidofovir <input type="checkbox"/> Cidofovir <input type="checkbox"/> Tecovirimat	
<input type="checkbox"/> Other, specify: _____	
If yes: side effect reported? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
If yes, specify: _____	
Antibiotic?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If yes, specify: <input type="checkbox"/> Ceftriaxone <input type="checkbox"/> Doxycycline <input type="checkbox"/> Amoxicillin-clavulanate <input type="checkbox"/> Other _____	
Antifungal agent?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Other	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Other experimental agent?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If yes, specify: _____	

Figure S2 Case Report Spreadsheet (CRS)

Instructions for completion

Thank you for taking the time to completing this datasheet

There are **two data sheets for completion** on separate tabs **PLEASE COMPLETE THIS_SITE DATA** and **PLEASE COMPLETE THIS_CASE DATA**

We aim to collect data on both **confirmed monkey pox cases** and **those not yet confirmed but with a high clinical suspicion**, please enter data for all cases

Where possible please use the dropdown menus for completion

Each site is given a list of unique identifiers labelled as study number, please use the study number provided to identify cases should we have any data queries

Please only include consented cases and store the consent at your clinical site with the patient record

To ensure secure data transfer may I ask you to send your completed spreadsheet with anonymised data using egress.

Egress is a secure file sharing email platform.

<https://switch.egress.com/ui/signin.aspx>

A key for the data requested is below, if you have any questions please call or email me, thank you John

Variable Key

Study Number	Unique study identifier provided on blank template,
Site	Please select your site or country from the dropdown list
Age	Please input age in whole numbers
Gender Identity	Please select gender identity from dropdown list
Ethnicity	Please select ethnicity from dropdown list
Ethnicity - other	If ethnicity not listed, please use freetext
Sexual Orientation	Please select sexual orientation from dropdown list
HIV status	What is the persons HIV status, select from dropdown list
Date of last CD4	If the person is living with HIV, what was the date of last CD4 count in format dd/mm/yyyy
Last CD4Count	If the person is living with HIV, what was the absolute CD4 count
Date of last HIV viral load	If the person is living with HIV, what was the date of last HIV VL in format dd/mm/yyyy
Last VL (cpm)	If the person is living with HIV, what was the last HIV viral in CPM
On ART	If the person is living with HIV, Is the Patient currently taking ART
ART Regimen	
TDF/TAF or ABC or 2DR	If on ART select from dropdown
3TC or FTC	If on ART select from dropdown
3rd Agent	If on ART select from dropdown
Comments or other regimens	If on ART but drug not in dropdown please add in freetext
Transmission Route	What was the suspected route of transmission
Contact	Was the individual in contact with a known case of Monkey Pox
Recent Travel 1/12	Did the individual travel abroad in the previous month before their diagnosis
If Travel, list country of travel	If abroad which country was visited
Sex on Site Venue	Did the individual attend a sex on site venue in the previous month before their diagnosis
Festival or Large Event	Did the individual attend a festival or large party (with more than 30 people) in the previous month before their diagnosis
If yes, name of event	If yes, please specify event or party
ChemSex	Did the individual report any chemsex use in the month before their diagnosis
Initial presenting complaint to department	What was the individual's initial reason for seeking medical attention
Department Presenting to	What was the initial healthcare setting attended, please select from dropdown
Date of Presentation	what was the date of presentation in dd/mm/yyyy
Fever Y/N	Did the individual have a fever (>37.8C)
Lethargy/Exhaustion Y/N	Did the individual report lethargy or exhaustion
Headache Y/N	Did the individual report headache

Sore Throat / Pharyngitis	Did the individual report sore throat or pharyngitis
Lymphadenopathy Y/N	Did the individual have lymphadenopathy
Low mood Y/N	Did the individual report low mood
Myalgia Y/N	Did the individual report muscle aches or myalgia
Rash (Y/N)	Did the individual have a rash
Type of rash	Please select the type of rash from the dropdown menu or describe later in freetext
Face, body, genitals, Palms or soles	Please select where the rash was present, if multiple sites please specify in the next column
If multiple sites please specify	If rash is present in different sites, please list these
Number of lesions	Select from dropdown list the number of lesions present
Mucosal Lesion Y/N	Were mucosal lesions present, if so, describe in the next column
Please describe the mucosal lesions	Please describe the location and frequency of the lesions
Any Other Clinical Features	Please add any other clinic feature to this freetext box
Sexual History	Please enter the number of sexual partners in the previous three months
PrEP	Please indicate if the individual used PrEP in the month prior to MPXV
Concurrent STI	Where there concurrent STIs diagnosed
If yes, which one(s)	If yes select which one from the dropdown list
Gonorrhoea	Was gonorrhoea suspected or diagnosed
Site of Gonorrhoea	what site was gonorrhoea diagnosed from
Chlamydia	Was chlamydia suspected or diagnosed
Site of Chlamydia	what site was chlamydia diagnosed from
Syphilis	Was syphilis diagnosed
HIV	If HIV status was reported as negative or unknown, was a repeat HIV test taken at time of M Pox diagnosis
MPV Diagnosis	At the time of data collection was the diagnosis of M Pox confirmed by PCR or a high clinical suspicion with PCR awaited
Monkeypox viral DNA detected via PCR	Was a M Pox PCR taken from a Skin/Rash/Lesion
	Was a M Pox PCR or serology taken from Blood
	Was a M Pox PCR taken from a Nose or Throat swab
	Was a M Pox PCR taken from a Urine sample
Treated as?	Was the individual treated as an inpatient or an outpatient
M Pox Treatment	Did the individual receive a treatment for M Pox
Which Treatment	If treatment other than supportive was given, which treatment was given, select from dropdown
Smallpox vaccination	Does the individual have a history of small pox vaccination
Hepatitis B Surface Antigen	Is the HBsAg status positive, negative or unknown
Hepatitis C antibody	Is the HCV Ab positive, negative or unknown
Hepatitis C PCR	Is the HCV PCR undetectable or unknown
Any other information	Any comments or other relevant information

Sample of Case Report Spreadsheet

Study Number	Consented	Site	Age	Gender Identity	Ethnicity
Each Site is given 20 unique numbers	Has the Case Consented Yes/No			Male Female Trans Man Trans Woman Non-Binary Other	White Black Asian Mixed First Nation, Inuit, Métis LatinX Other - please specify
<i>ID</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>Number</i>	<i>Dropdown</i>	<i>Dropdown</i>

Ethnicity	Sexual Orientation	MSM
Other - please specify	Heterosexual Homosexual Bisexual Pansexual Other	Yes/No
<i>freetext</i>	<i>Dropdown</i>	<i>Dropdown</i>

HIV status	If PLHIV:				
positive negative unknown	Last CD4 date	Last CD4Count	HIV VL Date	Last VL (cpm)	On ARVs
<i>Dropdown</i>	<i>date</i>	<i>number</i>	<i>date</i>	<i>number</i>	<i>Dropdown</i>

ART Regimen			
tenofovir (TDF/TAF) or abacavir or 2DR	lamivudine or emtricitabine	3rd Agent dolutegravir bictegravir raltegravir elvitegravir/c DRV/c or DRV/r ATV/c or ATV/r doravirine rilpivirine efavirenz nevirapine	Comments or other regimen
<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>freetext</i>

Transmission Route	Contact	Recent Travel 1/12	list country of travel
Sexual Household Non-sexual close contact Healthcare worker Unknown	Contact of another case	Y/N	
<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>

Sex on Site Venue	Festival or Large Event	If yes, name of event
Did the person attend a sex on site venue or party in the month before M Pox diagnosis	Did the person attend a large gathering or party (>30 people) in the month before M Pox diagnosis	
<i>Dropdown</i>	<i>Dropdown</i>	<i>freetext</i>

ChemSex	Initial presenting complaint to department	Department Presenting to
Any Chemsex use reported in the 1 month before M Pox Diagnosis	Were Monkey Pox symptoms the reason the person attended, please describe	Sexual health clinic Emergency department Primary care/GP Dermatology HIV clinic Other Hospital Clinic Other
<i>Dropdown</i>	<i>free text</i>	<i>Dropdown</i>

Date of Presentation	M Pox Clinical Features						
dd/mm/yy	Fever (Yes/No)	Lethargy Exhaustion (Yes/No)	Headache (Yes/No)	Sore Throat / Pharyngitis (Yes/No)	Lymph-adenopathy (Yes/No)	Low Mood (Yes/No)	Myalgia (Yes/No)
<i>date</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>

M Pox Clinical Features							
Rash (Y/N)	Type of rash Vesicular-pustular rash Macular Single ulcer Multiple ulcers Other	Location Face Body, Genitals Palms or Soles Other	If multiple sites please specify	Number of lesions <5 5 to 10 11 to 20 >20	Mucosal Lesions Yes No Not known	Please describe Mucosal lesions	Any Other Clinical Features
<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>free text</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>freetext</i>	<i>freetext</i>

Sexual History	PrEP	Concurrent STI	If yes, which one(s)
Number of sexual partners in previous 3 months	PrEP us in the previous 3months Yes No Not Known	Yes/No	Choose from dropdown Chlamydia Gonorrhoea Syphilis Warts (HPV) Molluscum Contagiosum Herpes (HSV) NSU LGV Shigella Other
<i>freetext</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>

Gonorrhoea	Site of Gonorrhoea	Chlamydia	Site of Chlamydia	Syphilis	HIV
Y/N	1=Pharyngeal, 2= Rectal, 3= Vaginal, 4= Penile	Y/N	1=Pharyngeal, 2= Rectal, 3= Vaginal, 4= Penile	Y/N	If HIV status was reported as negative or unknown, was a repeat HIV test taken at time of M Pox diagnosis
<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>

MPV Diagnosis	Monkeypox viral DNA detected via PCR			
Confirmed MPV	Skin/Rash/Lesion (Y/N)	Blood (Y/N)	Nose or Throat swab (Y/N)	Urine (Y/N)
<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>

Treated as?	M Pox Treatment	Which Treatment	Smallpox vaccination history
1= Inpatient, 2= Outpatient	Was M Pox treatment, other than supportive treatment given Yes/No	Which M Pox Treatment was Used Smallpox vaccine Cidofovir Tecovirimat Vaccinia immune globulin (VIG) Other	Yes/No/Unknown
<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>

Hepatitis B Surface Antigen	Hepatitis C antibody	Hepatitis C RNA
Positive/Negative or unknown	Positive/Negative or unknown	Is the HCV PCR positive, negative (i.e. undetectable) or unknown
<i>Dropdown</i>	<i>Dropdown</i>	<i>Dropdown</i>

Any other information
Comments
<i>Free text</i>

Sample of Clinical Site Information Form

	Please add information below
Name of Clinic	
Country of Site	
Type of clinic e.g., sexual health only, HIV only, infectious diseases	
No of PWH attending clinic	
Total number of confirmed monkeypox cases	
Site PI (name)	
Person completing this form (name)	
Contact details of Site PI	
Contact details of person completing this form	

Tables

Table S1: International Clinical Case Definition

Currently used monkeypox case definitions (as of 27th of June 2022)

	<i>World Health Organisation (WHO)</i>	<i>European Centre for Disease Prevention and Control (ECDC)</i>	<i>Centers for Disease Control and Prevention (CDC)</i>	<i>UK Health Security Agency (UKHSA)</i>	<i>Public Health Agency of Canada (PHAC)</i>
Rash description	An unexplained acute rash or one or more acute skin lesions	An unexplained rash on any part of the body	A deep-seated and well-circumscribed lesion, often with central umbilication; and lesion progression through specific sequential stages— macules, papules, vesicles, pustules, and scabs	An unexplained rash on any part of their body	An unexplained acute rash
Fever	>38.3°C (101°F)	Fever (usually > 38.5°C)	Not mentioned	>38.5°C	>38.5°C
Lymphadenopathy	Lymphadenopathy	Generalised or localised	Not mentioned	Lymphadenopathy	Lymphadenopathy
Mucosal lesions	Not mentioned	Not specifically mentioned	Not mentioned	Not mentioned	An unexplained acute genital, perianal or oral lesion (s)
Other symptoms	intense headache, back pain, myalgia and intense asthenia	headache, backache, and fatigue	Not mentioned	chills, headache, exhaustion, Myalgia (muscle and body aches) Back pain Asthenia (profound weakness)	Headache, myalgia, back pain, asthenia

<https://www.gov.uk/guidance/monkeypox-case-definitions>

<https://www.cdc.gov/poxvirus/monkeypox/clinicians/case-definition.html>

<https://www.who.int/publications/i/item/WHO-MPX-Surveillance-2022.2>

<https://www.canada.ca/en/public-health/services/diseases/monkeypox/health-professionals/national-case-definition.html>

<https://www.ecdc.europa.eu/en/news-events/epidemiological-update-monkeypox-multi-country-outbreak-15-june>

Table S2 “Demographics and clinical presentation of Human Monkeypox Virus infection in people with and without HIV”

Demographics and clinical presentation of Human Monkeypox Virus infection in people with and without HIV

	<i>HIV status negative or unknown HIV Status</i>	<i>People with HIV</i>
	<i>N=310 (59%)</i>	<i>N=218 (41%)</i>
Age, years		
Median (range)	36 (18-68)	39 (21,62)
Gender, n (%)		
Male	309 (>99)	218 (100)
Female	0	0
Trans or non-binary	1 (<1)	0
Sexual Orientation, n (%)		
Heterosexual	7 (2)	2 (1)
Homosexual	297 (96)	212 (97)
Bisexual	6 (2)	4 (2)
Ethnicity, n (%)		
White	240 (77)	158 (73)
Black	14 (5)	10 (5)
Mixed	12 (4)	7 (3)
Latin X	30 (10)	37 (17)
Other	14 (4)	6 (2)
Medical setting of presentation, n (%)		
Sexual Health Clinic	82 (26)	38 (17)
Emergency Department	77 (25)	29 (13)
Primary Care	14 (5)	6 (3)
Dermatology	20 (6)	18 (8)
HIV Clinic	59 (19)	95 (44)
Other Hospital Clinic	15 (5)	15 (7)
Private hospital / Other	43 (14)	17 (8)
Suspected route of transmission		
Sexual Close Contact	298 (96)	206 (95)
Non-Sexual Close Contact	2(<1)	2 (1)
Household Contact	2 (<1)	1 (1)
Other/unknown	8 (3)	9 (3)
Clinical features, n (%)		
Rash	298 (96)	202 (93)
Fever	194 (62)	136 (62)
Headache	84 (27)	61 (28)
Myalgia	102 (33)	63 (29)
Lethargy/Exhaustion	134 (43)	82 (38)
Lymphadenopathy	183 (59)	112 (51)
Pharyngitis	60 (19)	53 (24)

Proctitis	45 (15)	30 (14)
Low Mood	27 (9)	27 (12)
Site of positive monkeypox virus PCR†, n (%)		
Skin lesion	304 (98)	208 (98)
Nose or throat swab	73 (24)	65 (30)
Urine	7 (2)	7 (3)
Blood	15 (5)	20 (9)
Semen	14 (5)	15 (7)
Description of rash, n (%)		
Vesicular- Pustular	178/298 (60)	113/202 (56)
Macular	10/298 (3)	9/202 (5)
Single ulcer	32/298 (11)	22/202 (11)
Multiple ulcers	56/298 (19)	39/202 (19)
Other	22/298 (7)	19/202 (9)
Number of skin lesions, n (%)		
<5	123 (40)	84 (39)
5-10	77 (25)	54 (25)
11-20	68 (22)	44 (20)
>20	25 (8)	31 (14)
No Lesions or missing data, n	17	5
Site(s) of Rash*,n (%)		
Genital	235 (76)	149 (68)
Face	75 (24)	60 (28)
Body	175 (56)	116 (53)
Palms or soles	26 (8)	25 (12)
Mucosal lesions Present, n (%)	122 (39)	95 (44)
Location of Mucosal lesions		
Anogenital only	83/122 (68)	64/95 (68)
Oral Only	27/122 (22)	24/95 (25)
Anogenital & Oral	9/122 (7)	7/95 (7)
Nasal and/or eye	3/122 (3)	0
STI testing performed, n (%)		
Presence of concomitant STI in those tested	208/310 (67)	169/218 (78)
	56 /208 (27)	53/169 (31)
Management setting, n (%)		
Inpatient	39 (13)	31 (14)
Outpatient	271 (87)	187 (86)
Monkeypox specific treatment given, n (%)	12 (4)	13 (6)
Monkeypox treatment used, n (%)		
Cidofovir	7 (2)	5 (2)
Tecovirimat	3 (1)	5 (2)
Vaccina IG	0	1 (<1)
Other	2 (<1)	0

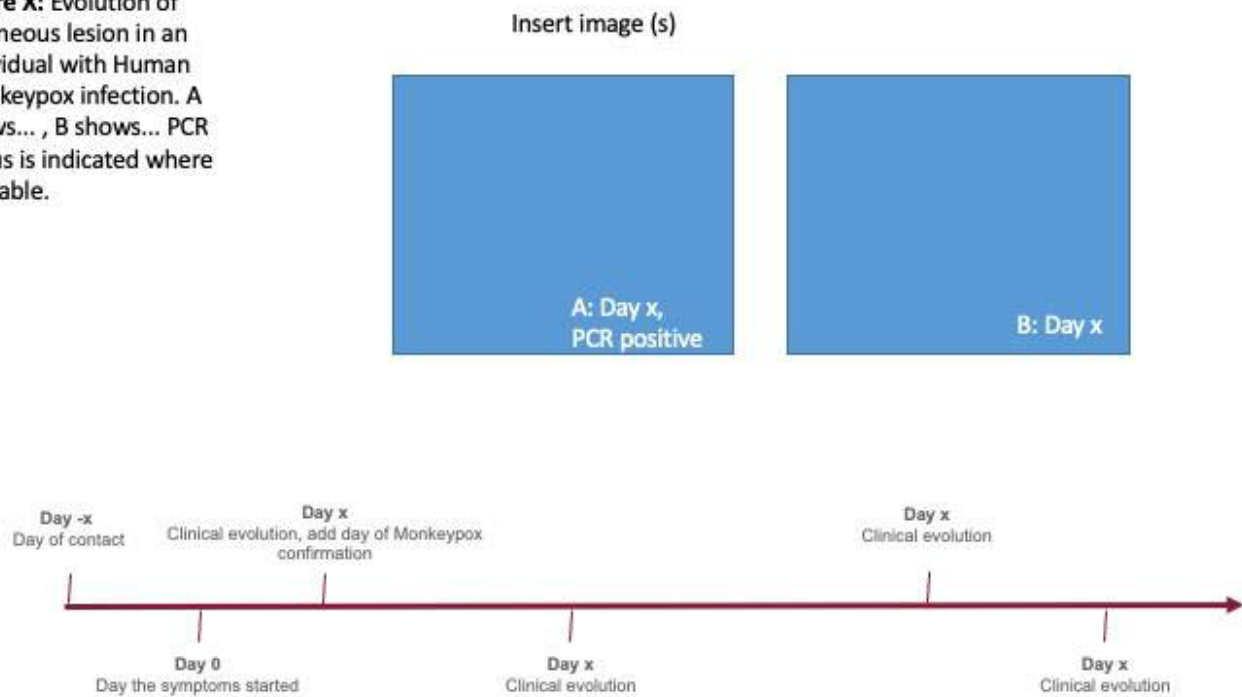
Values given represent (%) for categorical variables and median (interquartile range or range) for continuous variables. Abbreviations: Latin X, Latin American origin or descent; PCR, polymerase chain reaction; PrEP, Pre-exposure prophylaxis.

*may be present in more than one site

†not all sites were tested in all individuals

Table S3 Image presentation template

Figure X: Evolution of cutaneous lesion in an individual with Human Monkeypox infection. A shows... , B shows... PCR status is indicated where available.



Statistical Analysis Plan (SAP)

Statistical Analysis Plan (SAP) - Human Monkeypox Infection across 16 Countries — April–June 2022

Remit of SAP

The purpose of this document is to provide details of the statistical analyses and presentation of results to be reported within the principal paper(s) of the “Viruses know no borders – a global human monkeypox infection cases series”.

Case series title Human Monkeypox Infection across 16 Countries — April–June 2022

Objective Primary objective:

- To describe the clinical presentation, routes of transmission, diagnosis and initial management of the current (May – June 2022) human monkeypox epidemic outside of endemic areas so as to inform current international case definitions and to allow early identification and support clinical management

Case series description: This is a retrospective convenience sample case series, cases were identified through existing clinical and research networks. A new global collaborative group (SHARE-net) was led by the SHARE Collaborative at Queen Mary University of London and formed to support data collection and inform the monkeypox clinical response.

Setting Data were collected from 43 clinical site in 16 countries presenting over a two-month period. Cases were submitted from 4 continents (Europe, North America, South America and Australia).

Case Definition We used the UK Health Security Agency (UKHSA) definition of a confirmed case - a laboratory-confirmed monkeypox infection defined by a positive monkeypox virus PCR from any anatomical site. The PCR platform was locally determined as per availability and guidelines.

Data Collection	Each contributing centre completed a de-identified structured case report spreadsheet (CRS) developed on May 31, 2022 (Supplemental Figure S2). Dropdown menus and free text fields were used. The CRS captured clinical data and demographic data and was not part of a research protocol. Variables of interest were derived from case definitions that preceded this outbreak, and evolving international case definitions (Supplemental Figure 1 and Table S1). The CRS was iteratively refined from the growing clinical experience within our network. Confirmed monkeypox virus infections diagnosed since April 27th 2022 were submitted between June 1st - 24th 2022. Templates were provided for uniform presentation of the clinical image web library. (Supplemental Figure S2 and web library SX).
Data Sharing	De-identified data from consented individuals was securely transferred to the coordinating site and stored and analysed within the Queen Mary University of London Barts Cancer Institute data safe haven. A secure email data transfer platform (Egress) was used to transfer anonymised data.
Analysis Methods:	This analysis is a descriptive report of cases collected. Frequencies of categorical data and binary outcomes such as clinical, characteristics and demographics were presented as proportions and percentages. For continuous variables the median and range or first and third quartiles were reported. For a variable, where the frequency of missing data is greater than 5 cases this is indicated in the tables. It is not indicated where the data was reported as “No or Unknown” as was the case for specific clinical characteristics. Data analysis was performed using IBM SPSS Statistics Version 28.0.0.0 (190).
Statistical tests	As this is a descriptive analysis, p-values were not reported for the differences between groups.

Web gallery

Viruses without Borders-
Image Library

1

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Figure 1: Evolution of cutaneous lesions in an individual with Human Monkeypox infection first presented with several penile lesions. A shows penile lesions, B1-B2 show evolution of penile lesions after diagnosis. PCR status is indicated where available.

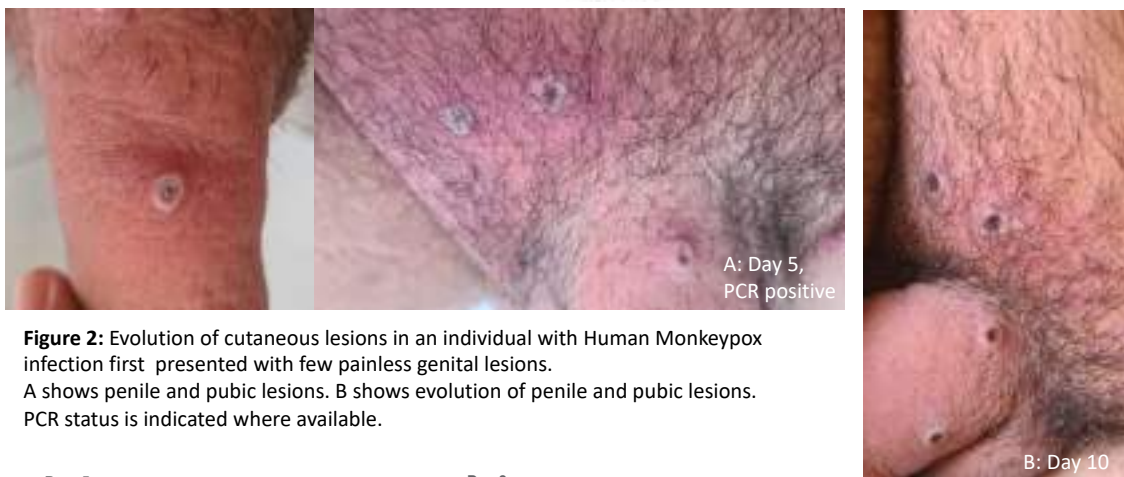


Figure 2: Evolution of cutaneous lesions in an individual with Human Monkeypox infection first presented with few painless genital lesions. A shows penile and pubic lesions. B shows evolution of penile and pubic lesions. PCR status is indicated where available.

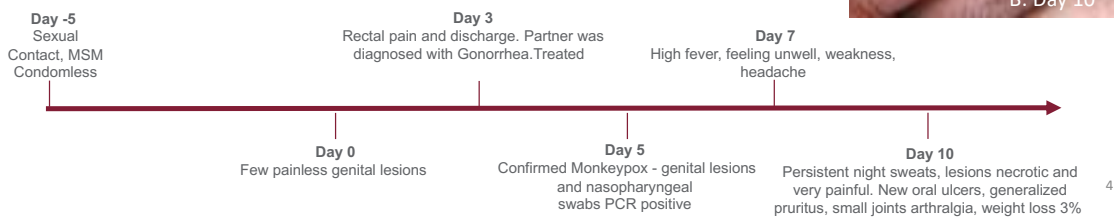
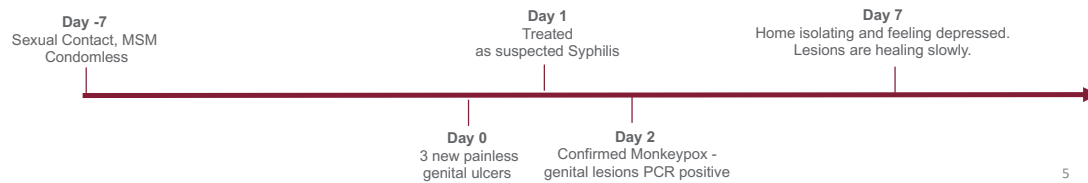


Figure 3: Cutaneous lesions in an individual with Human Monkeypox infection first presented with 3 genital lesions, well controlled HIV infection. A shows penile lesions, PCR positive



A: Day 2, PCR positive



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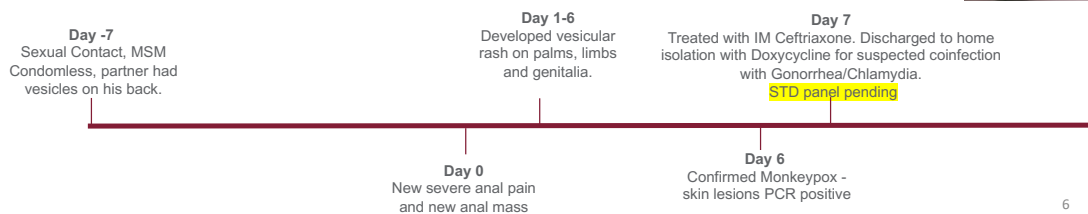
Figure 4: Cutaneous lesions and anal mass in an individual with Human Monkeypox infection first presented with severe anal pain. A shows anal mass. B shows lesions on palm, lower and upper extremities. PCR status is indicated where available.



A: Day 0



B: Day 1-6, PCR positive



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Figure 6: Anal/perianal and cutaneous lesions in an individual with Human Monkeypox infection first presented with fever and one perianal lesion. A shows Anal/perianal lesions. B1-B3 show cutaneous lesions of the scalp arm and leg respectively.

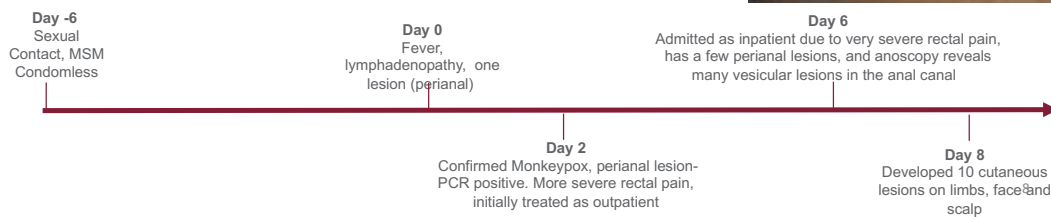
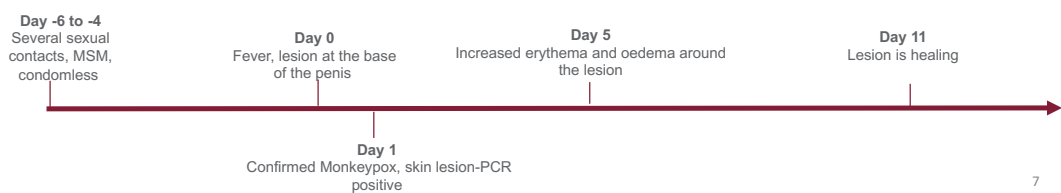


Figure 5: Evolution of cutaneous lesion in an individual with Human Monkeypox infection first presented with a single genital lesion. A shows the lesion at the base of the penis. B shows the evolution of the lesion. PCR status is indicated where available.



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Figure 7: Evolution of cutaneous lesions in an individual with Human Monkeypox infection first presented with a single anal lesion. A1-A3 show evolution of the anal lesions. PCR status is indicated where available.

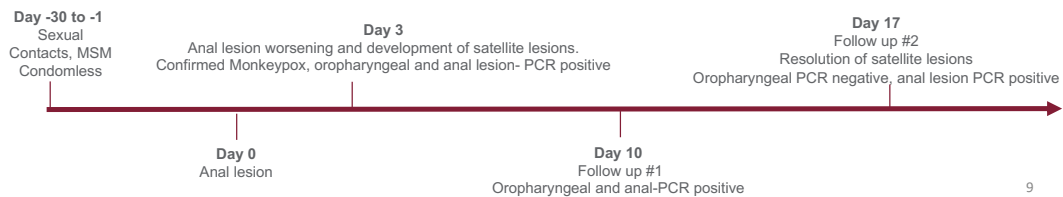


Figure 8: Evolution of cutaneous and pharyngeal lesions in an individual with Human Monkeypox infection. A1-A3 show pharyngeal lesions, B1-2 show truncal rash, C1-2 show lower limb rash. PCR status is indicated where available.

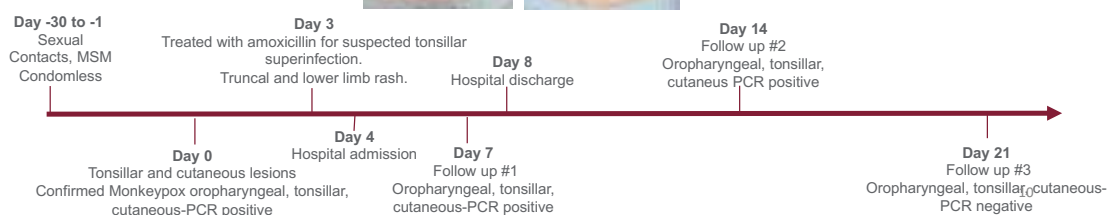


Figure 9: Evolution of genital lesions in an individual with Human Monkeypox infection. A1-A3 show genital lesions. PCR status is indicated where available.

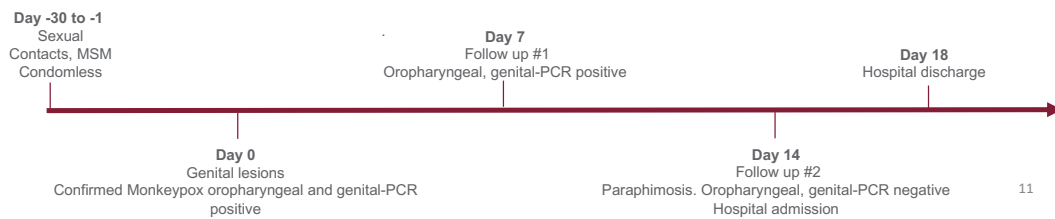
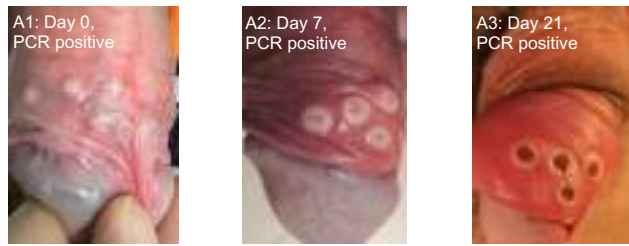


Figure 10: Evolution of perianal lesions in an individual with Human Monkeypox infection. A1-A3 show evolution of the perianal lesions. PCR status is indicated where available.

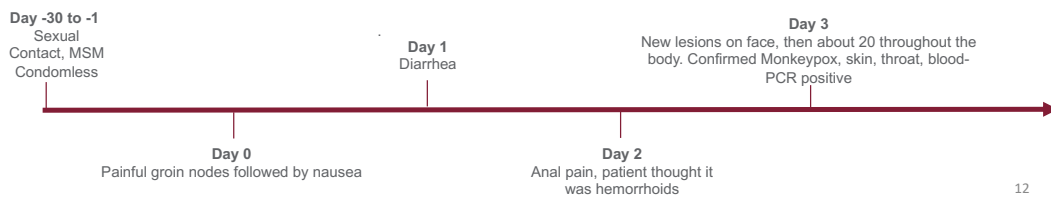
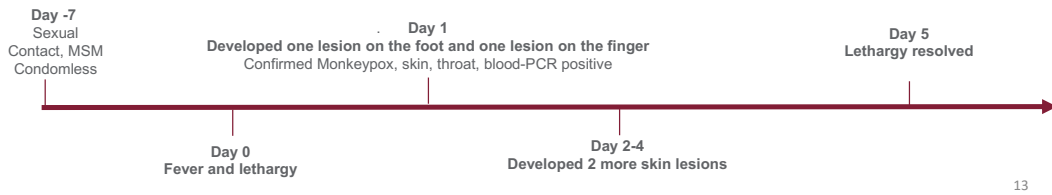


Figure 11: Evolution of cutaneous lesions in an individual with Human Monkeypox infection first presented with foot and hand lesions, HIV well controlled. A1-A3 show evolution of foot lesion. B1-B3 show evolution of finger lesion. PCR status is indicated where available.



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Figure 12: Cutaneous lesions in an individual with Human Monkeypox infection first presented with single painful perianal ulcer in a HIV-positive individual. A shows a single perianal ulcer. PCR status is indicated where available.

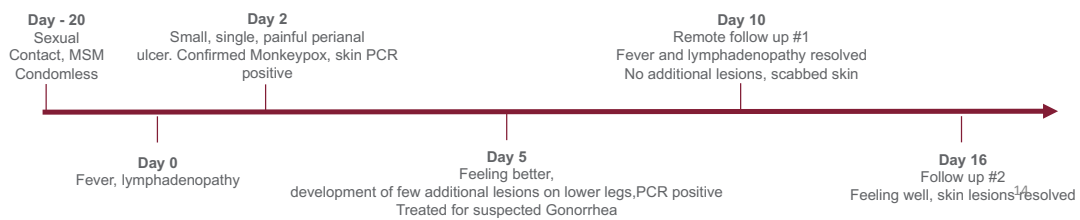


Figure 13: Evolution of clinical signs in a HIV-positive individual with Human Monkeypox infection. A shows a single oral lesion. B shows additional skin lesions and the first dose of tecovirimat. PCR status is indicated where available.

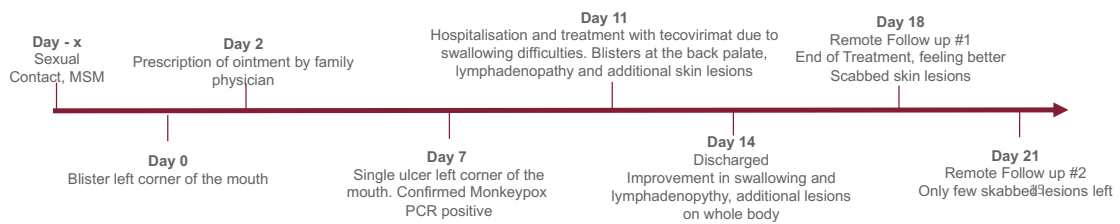


Figure 14: Evolution of clinical signs in a single individual with Human Monkeypox infection. A shows a CT scan of a severe MPX-related proctitis. B and C show additional skin lesions. PCR status is indicated where available.

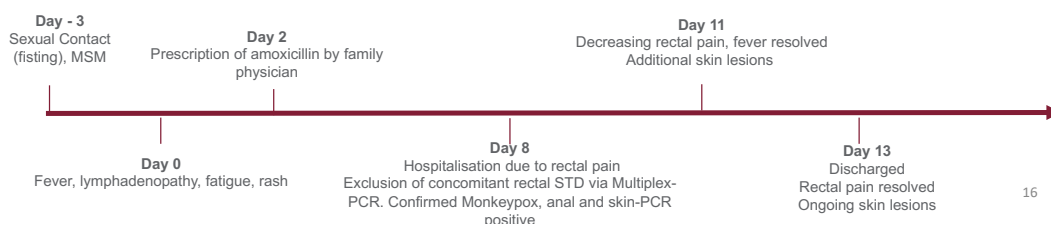
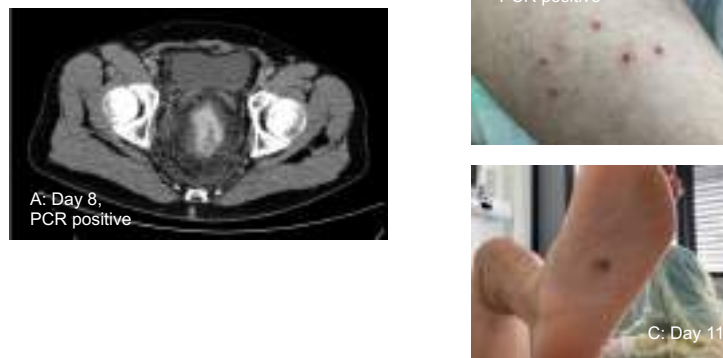
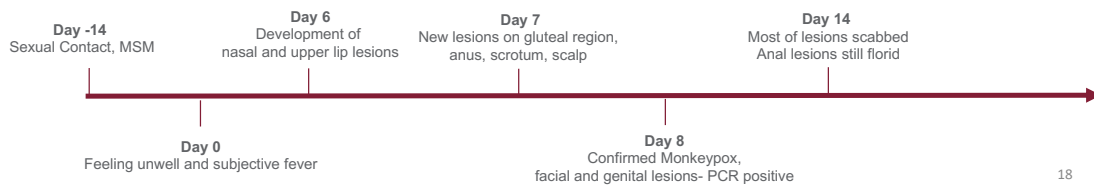
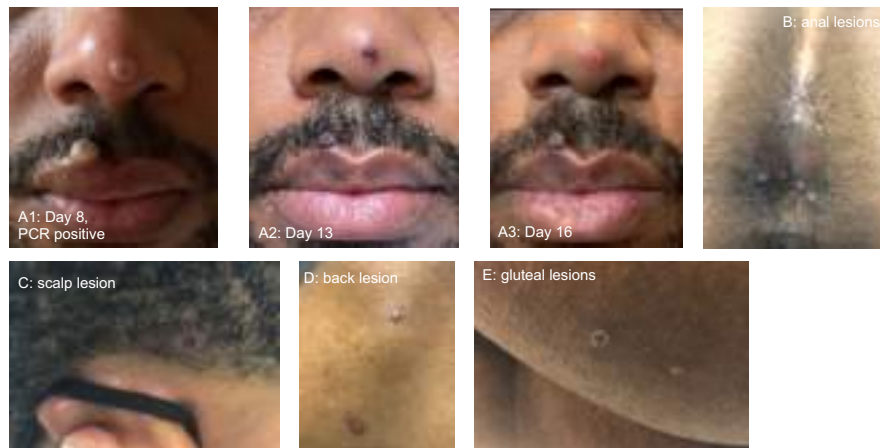


Figure 15: Evolution of nasal lesions in an individual with Human Monkeypox infection first presented with a single nasal lesion. A1-A5 show evolution of a nasal lesion, B shows a single forearm lesion. PCR status is indicated where available.



Figure 16: Evolution of cutaneous lesions in an individual with Human Monkeypox infection. A1-A3 show facial lesions, B shows anal lesions, C shows a lesion on the scalp, D and E shows back and gluteal lesions, respectively. PCR status is indicated where available.



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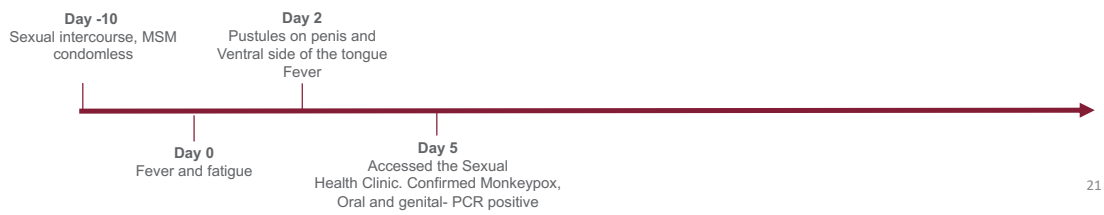
Figure 17: Evolution of cutaneous lesions in an individual with Human Monkeypox infection. A1-A7 show evolution of lesions of the penis. PCR status is indicated where available.



Figure 18: Evolution of cutaneous lesions in an individual with Human Monkeypox infection affected by vitiligo (off therapy). A and B show lesions of the hands, C1-2 show evolution of a chest lesion, D1-2 show evolution of a penile lesion, E shows a gluteal lesion and F shows perianal lesions. PCR status is indicated where available.

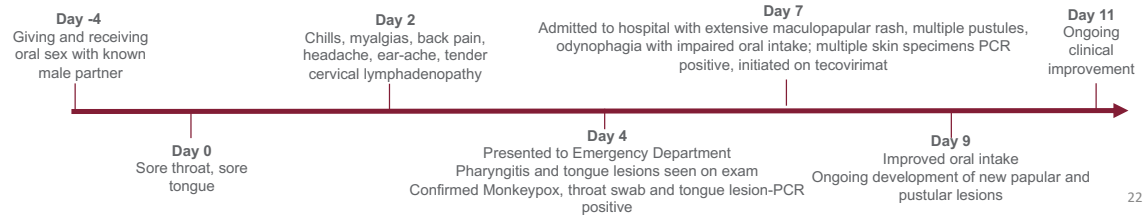


Figure 19: Evolution of oral and genital lesions in an HIV-positive individual with Human Monkeypox infection. A shows tongue lesions and B show lesions of the penis. PCR status is indicated where available.



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Figure 20: Rapid development and evolution of extensive skin lesions in an individual with Human Monkeypox infection. A1-A4 show evolution of forehead lesions and B1-B2 show evolution of tongue lesion on tecovirimat; C shows maculopapular rash with isolated pustules on the groin; D shows sole of foot.



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Figure 21: Genital lesions in individuals with Human Monkeypox infection.



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Figure 22: Genital lesions in individuals with Human Monkeypox infection.



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Figure 23: Skin lesions in individuals with Human Monkeypox infection.



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Figure 24: Skin lesions in individuals with Human Monkeypox infection.



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