RAPID RISK ASSESSMENT

Risk assessment for the EU/EEA of the mpox epidemic caused by monkeypox virus clade I in affected African countries

16 August 2024

Summary

Epidemiological situation

The monkeypox virus (MPXV) clade I epidemic that has been affecting the Democratic Republic of the Congo (DRC) since November 2023 has recently spread to several other African countries including Burundi, Rwanda, Uganda and Kenya. The size of these outbreaks could be larger than reported due to under-ascertainment and under-reporting.

On 15 August 2024, one case of MPXV clade Ib was reported in the EU/EEA and more imported MPXV clade I cases will likely occur. It is therefore important for European countries to be prepared to handle such imported cases and prevent secondary transmission.

In countries reporting clade I cases, human-to-human transmission through close physical contact and through both sexual and non-sexual transmission has been documented. Although all age groups are represented among cases infected with MPXV clade I, preliminary data show that infections by clade Ib virus concern mostly the adult population, whereas infections by clade Ia concern mostly children. To date, there are still significant uncertainties about the main transmission routes, transmissibility, severity, and natural disease history, and whether these differ between the two circulating subclades of clade I MPXV.

Mpox symptoms usually appear 6–13 days (up to 21 days) after infection. The clinical manifestation of the disease includes general febrile symptoms, a distinct rash (papules) on the skin and sores on the mucosa, back pain and muscle aches. The rash may spread quickly throughout the body within three days of experiencing the initial symptoms. Most people experience mild to moderate symptoms that usually last two to four weeks, followed by a full recovery.

Risk assessment

In the affected areas in the African continent:

The likelihood of infection with MPXV clade I for EU/EEA citizens travelling to or living in the affected areas and having close contact with affected communities is high, while the likelihood of infection is low when contacts with affected communities are avoided. The severity of the disease is expected to be low. Overall, the risk for these populations is **moderate** and **low**, respectively.

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In the EU/EEA:

The overall risk for the EU/EEA general population is currently assessed as **low**, based on a very low likelihood and a low impact.

The likelihood of infection with MPXV clade I for close contacts of possible or confirmed imported cases is high, yet the severity of the disease is expected to be low. However, in this same group, the severity of the disease is considered moderate amongst those with underlying conditions, particularly individuals who are immunocompromised. Overall, the risk for these populations is **moderate** and **high**, respectively.

The likelihood of infection for people with multiple sexual partners who were not previously infected with MPXV clade IIb or were not vaccinated in the 2022 outbreak is considered moderate. This assessment is based on the difficulty of controlling the spread of infection during the clade II outbreak in 2022/23 in this risk group. Although the severity of the disease would in most instances be low, people who are immunocompromised and those with an untreated HIV infection could experience moderate clinical severity. Overall, the risk for these populations is **moderate**.

Recommendations

To contain any possible outbreak in the EU/EEA, detecting cases and preventing secondary transmission is vital. This can be achieved through:

- Raising awareness among clinicians and other health professionals about possible travel-associated mpox cases caused by MPXV clade I, including the possibility of different clinical presentations, transmission through sexual and non-sexual routes and different groups affected than in previous outbreaks.
- Ensuring effective surveillance, laboratory testing (including molecular clade identification), epidemiological investigation and contact tracing capacities. Importation of MPXV clade I infections, or notable mpox events (outbreaks related to mass gathering events or other specific settings, re-infections among cases, rise in cases among women, children or other risk groups) should be promptly reported via EpiPulse and/or EWRS. All mpox cases should be reported to the European Surveillance System (TESSy).
- Providing advice to travellers to affected areas on national guidance for vaccination against mpox prior to travelling.
- Rapidly isolating any suspected cases until proven negative and, if positive, until symptom resolution.
- Implementing contact tracing and testing close contacts of confirmed cases following ECDC testing protocols.
- Providing travel advice to people visiting or returning from countries with confirmed MPXV clade I outbreaks.
- Continuing risk communication activities and working with civil society organisations to engage population groups at higher risk of infection.

Epidemiological situation

Epidemiological situation in affected African countries

Mpox (formerly monkeypox) is a viral disease caused by the monkeypox virus (MPXV), which is present in the wildlife in several central- and west African countries. In 2022, an outbreak occurred in Europe and globally where the disease was transmitted between humans through mainly sexual contact.

There are two genetically distinct clades for MPXV: clade I, with sub-clades Ia and Ib [1], and clade II, with sub-clades IIa and IIb [2]. Sub-clade Ia is often referred to simply as clade I [3].

MPXV clade I has been reported in the past as associated with severe clinical symptoms and higher mortality compared to clade II [4,5] until the 2022 global outbreak, which was instead driven by MPXV clade IIb [6]. Clade IIb is characterised by less severe illness and lower mortality.

Although both MPXV clades I and II are circulating in different countries in the African continent, since the end of 2023, a large outbreak of mpox has been affecting the Democratic Republic of the Congo (DRC), with recent geographical expansion to other African countries. The rapid rise and spread of MPXV clade Ia and Ib has raised concerns at the global level.

Since the beginning of the global mpox outbreak in 2022 and until the end of July 2024, 99 176 confirmed cases of mpox, including 208 deaths, had been reported by 116 countries [7]. In 2024, 14 719 suspected and 2 822 confirmed mpox cases (total 17 541) have been reported in the African continent, including 517 deaths (case fatality 3%), according to the Africa Centres for Disease Control and Prevention (Africa CDC) [8]. The 13 African Union Member States with reported cases in 2024 are Burundi, Cameroon, Central African Republic, Republic of the Congo (hereafter referred to as Congo), Côte d'Ivoire, DRC, Ghana, Liberia, Kenya, Nigeria, Rwanda, South Africa and Uganda [8].

In 2024, **DRC** has reported 16 789 cases (14 151 suspected and 2 638 confirmed) including 511 deaths (case fatality 3%) from all of the country's provinces [8], representing the highest number of cases due to clade I in Africa [9].

Confirmed mpox cases have also been reported in five of the eight neighbouring countries to DRC in 2024, i.e. **Burundi** (61 confirmed, 165 suspected), **Central African Republic** (35 confirmed, 223 suspected), **Congo** (19 confirmed, 150 suspected)**, Rwanda** (four confirmed), and **Uganda** (two confirmed) [8,10]. Additionally, suspected cases were investigated in South Sudan, according to media reports [11]. Out of the eight neighbouring countries to DRC, only the Central African Republic and Congo reported cases in 2023 [8]. Burundi, Uganda and Rwanda reported their first mpox cases at the end of July 2024 with Burundi reporting the most cases indicating community transmission in the country [10]. Besides the neighbouring countries to DRC, **Kenya** reported its first confirmed mpox case at the end of July 2024 [12]. MPXV clade Ia has been isolated from cases in Central African Republic and Congo [9,13,14]. MPVX clade Ib, which was detected first in DRC and reported in April 2024, was also detected in confirmed cases in Burundi, Rwanda, Uganda and Kenya [10,13].

Although the degree of under-ascertainment and under-reporting of cases in affected countries is unknown, it is presumed to be substantial. Thus, the number of reported cases is likely an underestimation of the true number of infections and the case fatality is likely overestimated. Furthermore, it can be assumed that community transmission is taking place in several African countries due to the widespread geographical distribution of reported cases and the wide age ranges represented.

Multiple modes of transmission have been documented in DRC including human-to-human transmission through close contact (e.g. sexual transmission, household transmission), and in some settings, zoonotic transmission. Epidemiological links between confirmed cases in other countries and DRC have also been documented [9,10,15]. Sustained human-to-human transmission including through sexual contact has been shown to contribute to the spread of MPXV clade Ib (e.g., in eastern DRC and neighbouring countries), as previously shown in the global outbreak of MPXV clade IIb [10,14]. An observational study conducted in Kamituga (South Kivu province) in April 2024 showed that among cases infected with sub-clade Ib, 29% reported involvement in sex work [1]. In another study conducted in the same area and published in May 2024, 88% of 371 hospitalised patients reported being involved in transactional sex [16]. Besides sexual contact, non-sexual contact, household and healthcare facility contacts have been reported by cases in DRC [17]. In areas where MPXV clade Ia (which is endemic in DRC) circulates, multiple modes of transmission have been documented [10].

Overall, according to the World Health Organization External Situation Report published on 12 August 2024, adults are the most affected in eastern areas of DRC and neighbouring countries where clade Ib circulates. In areas where clade Ia circulates (e.g. endemic MPXV in DRC, Congo, Central African Republic) children are mostly affected [10].

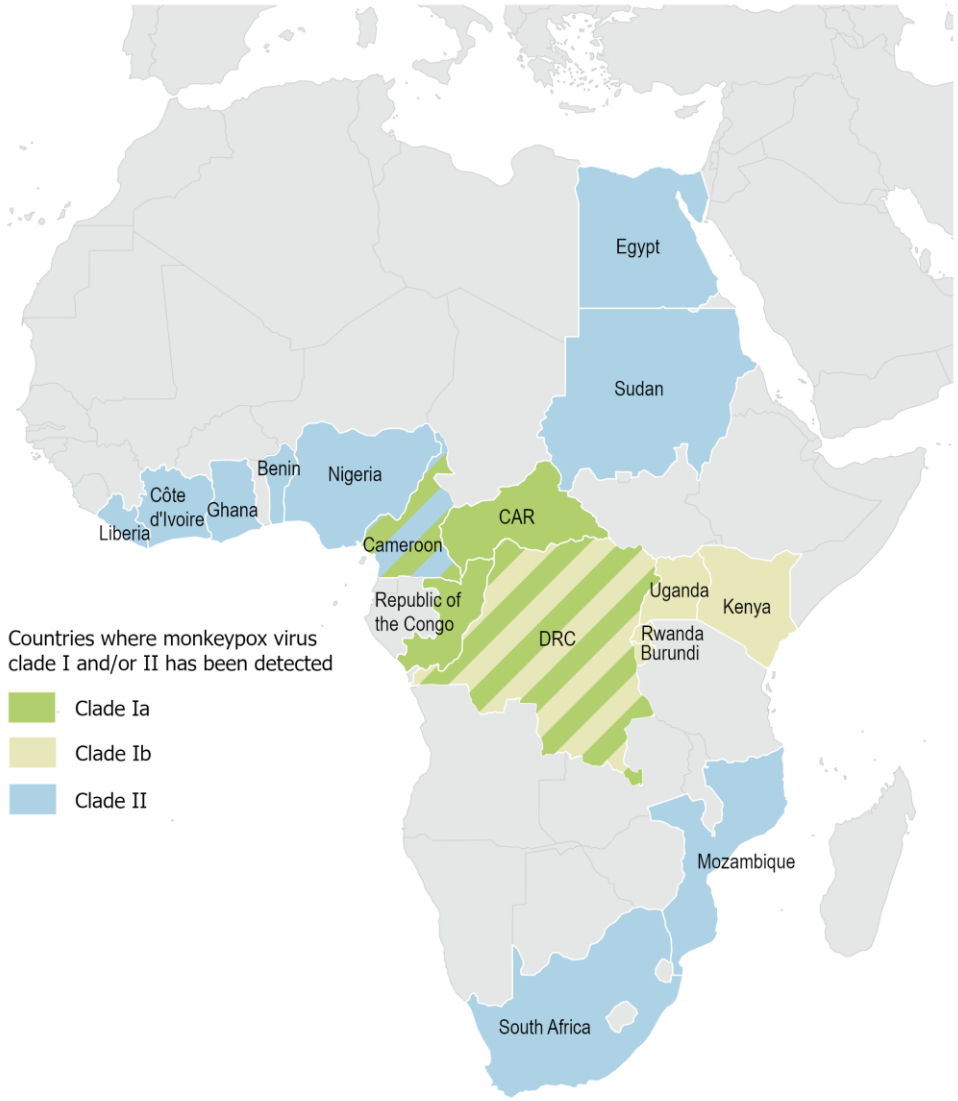
In DRC, most cases and deaths reported are among <15-year-olds, representing 66% of the total cases and 82% of the total deaths. Males account for 73% of the cases in DRC [8]. In Congo, based on information provided by Africa CDC, most confirmed cases (56%) were children <15-years-old and 58% were males; similarly, in the Central African Republic, 43% of the confirmed cases were <15-year-olds and 62% males [9]. Moreover, within the Central African Republic, until 30 July 2024, cases were reported from 14 out of the 35 districts [9,18], including the capital city of Bangui [19]. In Burundi, where cases have been reported from 22 of 48 health districts (data published 9 August), 30% were in 0-5-year-olds and 52% of the confirmed cases were males [8].

While information from surveillance on the clinical presentation of cases reported by DRC and its neighbouring countries is lacking [10], reports mention the presence of rash and in some cases fever and lymphadenopathy [1,16,17].

Further to the countries with reports of MPXV clade I circulation, additional African countries have reported cases of clade II including South Africa and Côte d'Ivoire [10]. As of 5 August 2024, **South Africa** has reported 24 mpox cases and three deaths. Twenty-two of the 24 cases were reported between 8 May and 6 July 2024 [20]. Cases reported by South Africa have a similar epidemiological profile to those reported in the global MPXV clade II outbreak i.e. most commonly in young males [21]. Six confirmed mpox cases have been reported in **Côte d'Ivoire** [22], with the first two confirmed cases reported in the Abidjan region [18].

On 13 August 2024, Africa CDC officially declared mpox a Public Health Emergency of Continental Security (PHECS), marking the first such declaration by the agency since its inception in 2017. The declaration will enable the mobilisation of resources across affected countries, unlocking essential funding, strengthening risk communication and community engagement, boosting surveillance and laboratory testing efforts, and enhancing human resource capacities to respond effectively to the outbreak [23]. On 14 August 2024, the Director General of the World Health Organization declared the outbreak a public health emergency of international concern (PHEIC) [24].

Figure 1. Countries where monkeypox virus clade I and/or clade II have been detected [9,10]



Map produced on: 14 Aug 2024. Source: Africa CDC and WHO. Administrative boundaries: © EuroGeographics © UN–FAO © Turkstat.The boundaries and names shown on this map do not imply official endorsement or acceptance by the European Union.

CAR: Central African Republic; DRC: Democratic Republic of Congo [9,10]

Epidemiological situation in the EU/EEA

On 15 August 2024, Sweden reported one imported case of mpox due to MPXV clade Ib [25]. The case is an adult who returned from an African country where MPXV clade Ib transmission has been reported. The mode of transmission is under investigation. Contacts of the case have been informed and are being monitored.

Previously, and as of 8 August 2024, 22 662 confirmed mpox cases have been reported by 29 countries in the EU/EEA via The European Surveillance System (TESSy) as part of the outbreak driven by clade IIb. Most cases (93%) were reported during an intense period of circulation in 2022. In 2023, 860 cases were reported in 21 EU/EEA countries while so far in 2024, 685 cases have been reported by 20 EU/EEA countries. This indicates continued circulation of MPXV in the EU/EEA, but at very low levels. Information on the virus clade was reported for very few (2.1%) of all mpox cases reported to TESSy since 2022. All cases reported to TESSy as of 8 August 2024 were from clade II.

As of 15 August, 29 genome sequences from samples collected in 2024 in the EU/EEA (from Austria, Germany, Netherlands, and Portugal) and 37 genome sequences from Africa (from DRC, Kenya, and Uganda) were deposited in GISAID EpiPox [26],[27]. All of the sequences from the EU/EEA belong to clade II, while all sequences from Africa belong to clade I.

Between 2022 and 2024, the profile and severity of mpox cases diagnosed in the EU/EEA has remained stable: 98% of mpox cases are males and 39% of cases are in 31-40 years-old, while <0.1% of cases reported are in children <15 years of age. Of the 10 860 cases with data reported on sexual orientation, 95% self-identified as men who have sex with men (MSM). Among cases with known HIV status, 38% (4 308/11 328) were HIV-positive. The cases reported to date in the EU/EEA have been mostly mild, with 10 deaths (10/18 183, case fatality 0.1%) among all reported cases and a low proportion of hospitalised cases (867/12 924, 7%).

ECDC risk assessment

This rapid risk assessment has been developed based on the currently available data at the time of publication and follows the ECDC rapid risk assessment methodology, where the overall risk is determined by a combination of the likelihood of infection and its impact (estimated disease severity) [28]. The likelihood of infection and the impact of the disease are assessed at the time of an emerging health threat, considering characteristics of place (country or countries where occurring) and person (prevalence of risk groups in EU/EEA population).

This assessment draws on historical and emerging data from the MPXV clade I epidemic in DRC and other countries in Africa, and the recent global MPXV clade IIb outbreak. However, solid evidence is lacking on transmission routes, transmissibility, clinical outcomes, risk factors for severity, and whether these differ between MPXV clade Ia and Ib.

Table 1. Summary of the risk due to MPXV clade I for the populations under assessment

	Likelihood of infection	Impact	Overall risk for the assessed population
In the affected countries			
EU/EEA citizens travelling to the affected countries and having close contact (healthcare workers, household or other close contact and/or multiple sexual contacts) with affected communities or living in the affected countries	High	Low	Moderate
EU/EEA citizens travelling to the affected countries, but not having close contact with affected communities	Low	Low	Low
In the EU/EEA			
Close contacts of possible or confirmed imported cases	High	Low	Moderate
Close contacts of possible or confirmed imported cases with underlying immunocompromising conditions and those with an untreated HIV infection	High	Moderate	High
EU/EEA general population	Very low	Low	Low

What is the overall risk due to MPXV clade I circulation for EU/EEA citizens travelling to or living in the affected African countries?

Given the uncertainties on the extent of community transmission in the affected areas and the lack of conclusive evidence on the relative efficiency of different routes of transmission, EU/EEA citizens visiting affected countries and engaging in activities that involve close contact with affected local communities are considered at **high** likelihood of infection. The same applies to EU/EEA citizens living permanently in these countries. Preliminary data from the field show that close contacts are contributing to sustaining the epidemic in Africa.

On the other hand, EU/EEA citizens travelling to the affected countries who do not have close contact with the affected communities have a **low** likelihood of infection.

While the morbidity and case fatality for clade I has been reported in the past as higher than that for clade II [29], current preliminary data from Africa are not showing higher clinical severity in confirmed cases. Based on this assumption and considering the relatively few number of EU/EEA citizens potentially affected, the impact of mpox on EU/EEA citizens visiting or living in the areas affected by the current epidemic is considered **low**.

Based on these levels of likelihood and impact, the risk for EU/EEA citizens travelling to the affected countries and having close contact (healthcare workers, household or other close contact and/or multiple sexual contacts) with affected communities or living in the affected countries is assessed as **moderate**.

Conversely, the risk for EU/EEA citizens travelling to the affected countries who do not have close contact with the local community is assessed as **low**.

What is the overall risk due to MPXV clade I in the EU/EEA?

The increase in the number of mpox cases due to MPXV clade I and the geographical expansion in newly-affected African countries increases the chance of sporadic case introductions into the EU/EEA. On 15 August 2024, one case of MPXV clade I was reported in the EU/EEA.

In the event of more sporadic importations of the MPXV clade I in the EU/EEA, the likelihood of infection for close contacts of possible or confirmed imported cases is assessed **high**. The likelihood of infection is much lower for contacts that have been vaccinated or have a history of previous infection with MPXV clade IIb.

The likelihood of infection in the general population in the EU/EEA is assessed as **very low**, provided that imported cases are diagnosed promptly and control measures are implemented.

Severe disease is more likely for people with underlying immunocompromising conditions and those with an untreated HIV infection (as was the case for clade IIb). Based on these factors, the impact of the disease is assessed as **moderate** for this group, and **low** for the general population.

Therefore, the level of risk is assessed as **high** for close contacts with underlying immunocompromising conditions and those with an untreated HIV infection, **moderate** for healthy close contacts, and **low** for the remaining general EU/EEA population.

If sustained transmission of MPXV clade I is established in the EU/EEA, people with multiple sexual partners are at a higher likelihood of infection. Within this group, unvaccinated, immunocompromised individuals, and those who do not have a history of previous infection with MPXV clade IIb are at higher risk of more severe illness.

After the outbreak of MPXV clade II in the EU in 2022, Tecovirimat and Imvanex were included are part of the rescEU stockpile of medical countermeasures (MCM) against CBRN events. Additionally, several EU Member States have established national stockpiles of Imvanex under their national preparedness plan against smallpox. Finally, in 2022, the Commission has organised joint procurements and signed framework contracts with the producers to ensure availability of both products. As a result of these measures, the Health Emergency Preparedness and Response Authority of the European Commission expects that these medical countermeasures will be available to address immediate needs to respond to the first cases of infection by Clade Ib.

ECDC recommendations

ECDC issues the following recommendations targeted for specific stakeholders, which are summarised in the table below and detailed in the following paragraphs.

Stakeholders	Recommendations
Public health authorities	• Follow ECDC guidelines for case detection and investigation; • Investigate every case and report any significant increases in case numbers or changes in epidemiology (increased severity, detections of MPXV clade I, outbreaks related to mass gathering events, re-infections among cases, rise in cases among women, children or other risk groups); • Implement effective surveillance, ensuring that the system is sensitive enough to ensure prompt response to possible cases; • Rapidly isolate any suspected cases until proven negative and, if positive, until symptom resolution; • Implement contact tracing and testing of close contacts of confirmed cases following the ECDC testing protocols; • Develop information material for clinicians; • Map laboratory capacity; • In the event of a MPXV clade I outbreak in the EU/EEA, identify and offer vaccination to eligible unvaccinated high-risk individuals for sexual transmission. If feasible, post-exposure vaccination of cases with the available third-generation smallpox vaccine can be offered as one of the response options.
People planning to travel to the affected countries in Africa	• Consult guidance from your national health authorities, ECDC guidance and epidemiological information; • Avoid contact with wild animals; • Refrain from sexual or other close contact with individuals with possible or known mpox infection and those with visible lesions or other mpox compatible symptoms. • Consult national guidelines on vaccination against mpox before travel
People living in the EU/EEA	• No special recommendations are issued at this stage for the general public

Surveillance

National mpox surveillance

EU/EEA countries should maintain their mpox event-based and indicator-based surveillance and testing capacity to enable prompt identification of cases and clusters, monitor their epidemiological characteristics, including affected population sub-groups, and rapidly detect changes in disease trends. In this regard, EU/EEA countries are also encouraged to define mpox as a nationally notifiable disease.

To meet these objectives, surveillance systems should be sensitive enough to prompt a thorough investigation of each suspected case as recommended by ECDC.

The ECDC interim indications for testing are:

- Individuals returning from an affected area and reporting any of the symptoms (including prodromal symptoms or lymphadenopathy) described in this document;
- Close contacts of confirmed cases in the EU/EEA reporting any of the symptoms (including prodromal symptoms or lymphadenopathy) described in this document (regardless of type of contact);
- Individuals presenting with mpox compatible lesions or any other typical symptoms, including isolated genital lesions.

EU/EEA mpox surveillance

EU/EEA level surveillance by ECDC is based on indicator-based data collection through TESSy, complemented by event-based surveillance with reporting through EpiPulse (and/or ECDC's Early Warning Response System (EWRS) depending on the event).

National EU/EEA public health authorities should report all mpox cases every month to TESSy. Information about the clade should be included. Case records can be reported in TESSy as soon as information becomes available.

Any significant increases in case numbers or changes in epidemiology, such as increased severity, detections of MPXV clade I, outbreaks related to mass gathering events or other specific settings, re-infections among cases, rise in cases among women, children or other risk groups (e.g., sex workers) should be reported through event-based surveillance as a new event on EpiPulse and/or EWRS.

According to a survey by the European Commission Joint Research Centre in August 2024, MPXV is not systematically included in the list of pathogens monitored in wastewater in EU Member States. Of the 16 countries who responded, only four monitor MPXV in wastewater (two in both community and airport wastewater, and two only in community wastewater This exercise, supported by DG HERA in collaboration with the JRC, will take place in the week of 23 September 2024 and is dedicated to the synchronised collection and coordinated examination of wastewater samples originating from aircraft at a variety of global airports, including in Africa.

Genomic surveillance

Sequencing MPXV contributes to understanding viral evolution, transmission chains and patterns of spread. Countries are encouraged to comprehensively sequence all positive mpox specimens and share sequences in publicly available sequence repositories. Sequencing would be of even greater relevance when sudden clinical and/or epidemiological changes are observed. Such changes may include, but are not limited to, increases in virulence, changes in clinical disease presentation, and changes in the performance of laboratory diagnostics

Laboratory testing

The laboratory diagnosis of mpox is predominantly based on the direct demonstration of the *Orthopoxvirus monkeypox* (MPXV) in a clinical specimen. Real-time polymerase chain reaction (real-time PCR) on skin lesion materials (e.g. swabs, exudate, or lesion crusts) are used most frequently. Viral throat swabs can be used for high-risk contacts of confirmed or high-probable cases who have developed systemic symptoms but do not have a rash or lesions that can be sampled [30]. Several real-time PCR assays for the specific detection of MPXV, or for generic orthopoxvirus detection are available [31-36]. Over 80 MPXV laboratory tests are CE-validated, mostly based on PCR [31-36]. Mpox laboratory diagnostics are well established in several laboratories in Europe (see Emerging Viral Diseases-Expert Laboratory Network – EVD-LabNet [37]).

Identification of the genetic clade of MPXV is mainly based on the determination and analysis of the partial genome sequences of the detected virus; however, clade-specific real-time PCR assays are also used for this purpose in some laboratories. Recent studies revealed that a novel clade I MPXV which was detected in the current mpox outbreak in DRC has a deletion in and surrounding the OPG032 gene. This mutation may result in false negative test results for certain real-time PCR assays to discriminate between clade I and clade II MPXV strains [38,39]. However, validated assays are available for the detection of the new clade Ib variant [40].

Mpox diagnostic laboratories in the EU/EEA have been alerted through the EVD-LabNet about this finding and were advised to use molecular assays which are able to detect this mutant strain. The timely detection of the potential emergence of clade I MPXV in the EU/EEA requires molecular identification of viruses detected in diagnostic specimens. Therefore, nucleotide sequencing and sharing sequence information through public databases (e.g., GISAID) remains an essential component to monitor the mpox epidemiological situation in Europe and globally.

Raising awareness among clinicians and laboratories

Given that case numbers of mpox have declined substantially since the summer 2022, there might be a need to remind clinicians – especially those who do not work directly in STI clinics or with MSM – of mpox symptoms and the possibility that cases may reappear.

Clinicians and laboratories should be aware of how to rapidly report cases of mpox to public health authorities to ensure that a potential increase in transmission is rapidly detected. Similarly, rapid reporting to partner notification or contact tracing services can ensure that potential contacts are notified as quickly as possible.

Awareness should be maintained or raised among clinicians and other health professionals in EU/EEA countries of the ongoing possibility of introduction of clade I or increased circulation of clade II in new risk groups, and the recommendation to promptly test all suspected cases and inform public health authorities even before test results are available. This includes clinicians at sexual health clinics serving MSM and other populations with multiple sexual partners, but also clinicians serving the general population (dermatologists, paediatricians, primary care providers). Clinicians should also be made aware of the possibility of seeing more severe cases due to infection with MPXV clade I. Such patients, as was observed in the outbreak of MPXV clade II, require prompt initiation of supportive and antiviral treatment and/or post-exposure vaccination.

In case of emergence of MPXV clade I in Europe, public health authorities should be ready to perform comprehensive contact tracing with thorough interview of cases to collect essential epidemiological data, such as travel history, list of contacts and type of contact, behavioural risk factors, underlying conditions, vaccination status for previous mpox and/or smallpox vaccination and date of last vaccination.

Travellers to areas where MPXV clade I outbreaks are ongoing should receive pre- and post-travel advice. Hence, travel medicine clinics should be aware of the ongoing outbreaks and familiar with the available preventive and control methods.

Vaccination

ECDC recommends travellers to epidemic areas consult their national guidance on vaccination against mpox before travel. The US CDC has issued recommendations for vaccination which may be useful for Member States to consider until specific guidance from ECDC is available [41,42].

Since people with multiple sexual partners remains at higher risk if infection also with MPVX clade I, ECDC recommends EU/EEA countries to identify and offer vaccination to eligible unvaccinated high-risk individuals. If feasible, post-exposure vaccination of cases with the available third-generation smallpox vaccine can be offered as one of the response options, considering that MPXV clade II is still circulating, albeit at low level. This can be complemented by the vaccination programmes (pre-exposure vaccination for at-risk groups) that have been in place in the EU/EEA since the MPXV clade II outbreak in 2022.

Vaccination campaigns in the EU/EEA and other countries were implemented to control the outbreak of clade IIb MPXV in 2022, with a third-generation non-replicating smallpox vaccine authorised by the European Medicines Agency (EMA) for protection against mpox in adults [43,44]. The vaccine effectiveness of two pre-exposure vaccine (PPV) doses is estimated as 82% (95% CI: 72-92), while even one PPV dose provides effectiveness of 76% (95% CI: 64-88) [45]. For post-exposure vaccination (PEPV) the vaccine effectiveness was estimated at 20% (95%CI: -24-65) [45]. In individuals who experienced infection after being vaccinated, the disease was less severe compared to unvaccinated individuals [46]. The third-generation smallpox vaccine is expected to have similar vaccine effectiveness against MPXV clade I, although clade-specific vaccine effectiveness evidence is currently lacking [47,48].

Reaching the target population for vaccination also presents challenges, although in the first months of the multi-country mpox outbreak in 2022, the number of countries administering this vaccine, and the number of doses administered, increased rapidly. Pop-up vaccination clinics with extended working hours, as well as vaccination in the context of mass gathering events frequented by groups at high risk was effective [49,50].

A survey based on a convenience sample of more than 15 000 MSM at higher risk of HIV infection conducted from October 2023 to April 2024 in 20 countries in Europe found self-reported receipt of at least one dose of the mpox vaccine to be 39%, with wide variation between countries ranging from 51% of the sample in France to <10% of the sample in Poland and Greece [51]. In another exercise to estimate mpox vaccination coverage among MSM with multiple sexual partners using general population data, EMIS-2017 data, and mpox doses reported to ECDC by European countries (as of March 2023), receipt of two doses of the mpox vaccine was estimated to be much lower, ranging from <1% to 12% in EU/EEA countries [52].

Tailored interventions are needed to increase confidence in the vaccine, maximise uptake, and increase vaccine access, especially among key populations residing in regions with low rates of acceptance and uptake [53].

Risk communication and community engagement

Close collaboration with community-based organisations that work with MSM or other groups at high risk is essential to reach target groups. Public health authorities can use guidance and good examples of risk communication and community engagement developed during the 2022-23 mpox outbreak which is available on the ECDC website [54]. Key messages include awareness of symptoms, seeking testing and avoiding sex and close contacts until symptoms resolve, and to seek vaccination if available. Risk communication in the general population if there is increased community circulation in the EU/EEA, should include the risk of exposure to mpox through sex. Anyone presenting with symptoms compatible with mpox should be advised to seek medical care and abstain from sex and close contact with others until a diagnosis is made or until symptoms resolve if infected.

Infection prevention and control

As there is uncertainty around the different routes of transmission in the current outbreak of MPXV clade I, including the role played by respiratory droplets and aerosols, and the possible increased risk to healthcare workers posed by this clade, it is best to apply the precautionary principle when performing at-risk activities (i.e., any procedures likely to spread oral secretions). Further information can be found on the CDC webpage on Infection Prevention and Control of Mpox in Healthcare Settings.

Global efforts to control the outbreak in the affected African countries could reduce geographical spread

The control of the ongoing outbreak in DRC and other affected countries on the African continent would, apart from directly benefiting the affected population, also reduce the likelihood of geographical spread of MPXV clade I within Africa and to the EU/EEA and globally. Building capacity for contact tracing, diagnosis and sequencing, and the provision of vaccines to affected communities are essential to support public health authorities' control efforts. To this end, the Health Emergency Preparedness and Response Authority, Africa CDC and Bavarian Nordic (BN) signed a tripartite agreement on 14 August 2024 to secure 215 000 doses of mpox vaccines for delivery in September 2024 to the most affected African countries where the BN vaccine is authorised[55].

WHO has issued on 21 august 2023 Standing recommendations against mpox, now prolonged by the Director General until 20 August 2025. They are directed to all WHO Member States and cover several aspects, including national action plans, diagnostic capacity, surveillance, risk communication, research, international travel, clinical care and access to vaccines.

ECDC is supporting the GOARN efforts in response to the mpox outbreak in DRC by deploying ECDC experts. Further deployments are planned if needed.

Limitations

This assessment is based on historical data on MPXV clade I, on data from the ongoing epidemic in DRC, and on data from the recent MPXV clade IIb outbreak. Many elements on which this assessment is based on contain a significant level of uncertainty.

The number of reported outbreaks of mpox and the number of cases in Africa within the past year are unprecedented, and the ecological and epidemiological drivers are poorly identified. The sustained transmission chains in the communities and household transmissions may indicate changes in mpox epidemiology, but detailed data on secondary attack rates, basic reproduction numbers and transmission routes, particularly when stratified by clade Ia, Ib and II are not currently available. Altered transmission modes (e.g., through direct vs. indirect contact) may influence the probability of infection of EU/EEA travellers to affected areas in Africa.

Until 15 August 2024, mpox outbreaks reported outside of Africa have been caused by MPXV clade IIb exclusively. These outbreaks predominantly affected MSM in the EU/EEA, with transmission mainly attributed to sexual contact, and the resulting symptoms in those infected were typically mild.

On 15 August 2024, one case of MPXV clade I was reported in the EU/EEA. It is unknown whether the same risk groups will be affected, and whether the severity of the disease will be similar to or higher than observed in mpox cases caused by MPXV clade IIb.

Although vaccines and antivirals used against MPXV clade II should also work for MPXV clade I, there is limited scientific data from real-world settings to confirm this.

When there is relevant new information about transmission modes, disease severity and the effectiveness of preventive and treatment methods, this risk assessment will be updated.

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