

**Monkeypox in Pregnancy – Guidance for Maternity Services**

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**Background**

Monkeypox is a viral zoonotic disease reported in the Central African Republic and in Western Africa. It is caused by monkeypox virus, a member of the Orthopox virus genus, closely related to smallpox. The clinical presentation of monkeypox resembles that of smallpox; however Monkeypox is less contagious than smallpox and causes less severe illness. Human monkeypox was first identified in humans in 1970 in the Democratic Republic of the Congo (DRC).

There are two strains of monkeypox: Central African and West African. The West African lineage is generally associated with milder disease and is responsible for the 2022 outbreak. (1,2)

In May 2022, Monkeypox was reported as an emerging global outbreak. In July 2022, the WHO declared the global monkeypox outbreak a public health emergency of international concern, with (then) more than 16,000 reported cases from 75 countries and territories, and five deaths. The 10 most affected countries globally are: the US, Spain, Germany, the UK, France, Brazil, Canada, Netherlands, Columbia and Peru; these countries account for 88% of the cases reported globally. As of September 7<sup>th</sup> 2022, a total of 54,709 laboratory confirmed cases and 397 probable cases, including 18 deaths, have been reported to the WHO. (3)

Monkeypox is transmitted to humans through close contact with an infected person or animal, or with material contaminated with the virus. Inoculation by infected animal bite is a recognised route. Animal hosts include a range of rodents and non-human primates. Transmission can occur through contact with the virus from an animal or other source e.g. preparation or ingestion of bushmeat or contact with bedding contaminated with the virus. The virus enters the body through broken skin respiratory tract or mucous membranes (eyes, nose, mouth) It usually takes close physical contact with a symptomatic individual for transmission to occur. Faecal viral shedding may represent another mode of transmission. (1,2)

Human-to-human transmission occurs by direct contact with lesion exudate, crust material, lesion scabs, body fluids or contaminated materials such as bedding and clothing, and hand touch surfaces. Person to person transmission may also occur through large respiratory droplets that generally cannot travel more than one or two metres, and this usually requires prolonged face-to-face contact. Close household or sexual contact poses the greatest risk person-to person spread, particularly after direct contact with lesions. Transmission can also occur from mother to fetus, which can lead to congenital monkeypox, and newborn infection by close contact is also possible. (1 2)

In the current global outbreak, 98% cases are male and 91% of transmission events are reported after sexual contact. Cases have been reported in healthcare workers, with at least one occupational exposure. (3)

In Ireland, 160 cases have been notified to the HPSC to date (7<sup>th</sup> September); only one case was female and 17 were hospitalised. The epidemiological picture to date in Ireland is reported to be similar to that seen in other countries. (4)

## Clinical Features

The incubation period of monkeypox is usually from 6 to 13 days but can range from 5 to 21 days. Monkeypox is usually a self-limited disease with the symptoms lasting from 2 to 4 weeks. Severe cases are more common in children and are related to the extent of virus exposure, patient health status, underlying immune deficiencies and nature of any complications. Severe disease includes haemorrhagic disease, sepsis, encephalitis, or other conditions requiring hospitalisation. The WHO reports the case fatality ratio of monkeypox in the current outbreak at around 3–6%. (1, 3)

Symptoms include: fever, which may be absent in mild cases, headache, myalgia, back pain and exhaustion. The rash appears 1-3 days after the fever starts, this is generally seen on face (95% of cases) and extremities (palms and soles; 75%), and spreads to other parts of the body. Also affected are oral mucous membranes (in 70% of cases), genitalia (30%), and conjunctivae (20%), as well as the cornea. It is a maculo-papular rash that evolves into vesicles and pustules, which crust, dry up and fall off. The number of lesions varies from a few to several thousand. A person with monkeypox infection is considered contagious from initial viral prodrome and development of rash until the lesions have fully healed and new skin has formed over the scabs. (1)

The cases of monkeypox described in the current outbreak are reported to have some atypical features. The rash may start in the genital and perianal areas, the rash may not always disseminate to other parts of the body and typical prodromal symptoms may be mild or absent. These features can easily be confused with sexually transmitted infections (STI). (1 2)

## Pregnancy

The possibility of infection in pregnant women, though low, is present due to documented community transmission, the scale of the current global outbreak, and the reopening of borders after the COVID-19 pandemic.

It is unknown if pregnant women are more susceptible to being infected with monkeypox virus or if the disease is more severe during pregnancy. However, an increased risk of maternal mortality and morbidity has been documented with other poxvirus infections. (5, 6)

Fetal loss following vertical transmission has been reported with smallpox and with other orthopox viruses. (5,6,7)

The effects of Monkeypox on pregnancy and the pregnant woman are not well documented, but there are reports of high fetal loss rates in affected individuals. Preterm delivery and neonatal monkeypox infection have also been reported. The frequency and risk factors for severity and adverse pregnancy outcomes are not known. (5,7)

One paper reported four pregnant women treated in the DRC, from 2007 to July 2011. One was infected at six weeks (miscarriage at 9 weeks), one at 6-7 weeks (miscarriage at 8-9 weeks), one at 14 weeks (livebirth at term), and one at 18 weeks (fetal death at 21 weeks). Monkeypox virus DNA was found in the placenta, umbilical cord, and fetal tissue of the stillborn fetus, demonstrating vertical transmission of the monkeypox virus. A follow up series added a 5<sup>th</sup> case where a late fetal death also occurred. (8, 9)

One case of probable congenital monkeypox in Zaire has been described in the literature. At 24 weeks' gestation, a pregnant woman developed a febrile illness with a rash; monkeypox virus was subsequently isolated from a vesicular lesion. Six weeks later she delivered a 1,500-g female infant with a generalized skin rash resembling monkeypox, who died of malnutrition at 6 weeks of age. (10)

No infected pregnant women were reported in any of the CDC reports of the 2003 United States outbreak of monkeypox. (11) One case of a 26-week fetal loss was reported in Nigeria in 2019. (12)

It is unknown when or how often vertical transmission occurs during pregnancy, nor how infection during pregnancy contributes to stillbirth risk. (5, 6, 7)

In the current global monkeypox outbreak, the WHO's update of 7<sup>th</sup> September 2022 does not include any cases of monkeypox in pregnancy, and none have yet been reported in the published literature. (13)

## Clinical Guidance

While numbers in Ireland are expected to be low, there is a need for guidance and a treatment pathway for affected individuals. This clinical guidance is based on the above literature review (including; 7, 14, 15) and current guidance from various bodies including the HPSC, Ireland (2, 16, 17), SMFM, US (5) the WHO (1,3) and the CDC (18).

Consider Monkeypox as a diagnosis if there is / has been:

- Travel to an affected country where monkeypox is endemic, in the previous 21 days.
- Close contact with a person with confirmed or probable monkeypox infection (co-habiting, sexual contact, contact with bodily fluids or infected bedding)
- Close or intimate in-person contact with individuals in a social network experiencing monkeypox activity
- Contact with a dead or live wild animal or exotic pet that is an African endemic species or used products derived from such animals (e.g., game meat, creams, lotions, powders, etc.)

The signs and symptoms of monkeypox infection in people who are pregnant appear similar to those in non-pregnant people with monkeypox virus infection, including prodromal symptoms and rash.

Rash in a pregnant woman, who has risk factors for monkeypox infection needs to be differentiated from dermatoses of pregnancy, including polymorphic eruption of pregnancy. Those with rashes initially considered characteristic of more common infections (e.g., varicella zoster or STIs like herpes or secondary syphilis) should be carefully evaluated for a characteristic monkeypox rash, and diagnostic testing should be considered, especially if the person has epidemiologic risk factors for monkeypox infection. Co-infections with monkeypox virus and STIs have been reported and the presence of an STI does not rule out monkeypox, so a broad approach to testing is encouraged.

Monkeypox can have considerable risks to the fetus, so testing asymptomatic pregnant women with significant monkeypox virus exposure is suggested, to identify those who will require monitoring and ongoing fetal surveillance.

### Care of the pregnant woman

As per the HPSC guidance (16<sup>1</sup>) if there is a suspicion of monkeypox infection:

- all recommended infection protection control (IPC) precautions should be implemented
- all healthcare staff/visitors/ patients who have contact with the woman should be documented
- referral to Public Health should be made – this is a notifiable disease

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<sup>1</sup> Assessment and testing pathway for use in acute settings: [https://www.hpsc.ie/a-z/zoootic/monkeypox/guidance/Monkey%20Pox%20Assessment%20and%20testing%20pathway\\_Acute%20Settings.pdf](https://www.hpsc.ie/a-z/zoootic/monkeypox/guidance/Monkey%20Pox%20Assessment%20and%20testing%20pathway_Acute%20Settings.pdf)

- testing should follow the process outlined in the (HPSC) laboratory transportation plan (17)
- cases should, following an individual health risk assessment for severity and risk factors, be clinically categorised as either requiring inpatient care, or being fit for home isolation.

#### Testing for Monkeypox:

- One standard viral swab in viral transport medium.
- Swab taken from a cutaneous lesion either ulcer or vesicular fluid if present.
- The sample will be tested for MPX DNA at NVRL with the aim to test concurrently for VZV DNA and HSV 1 and 2 DNA.
- If there are concerns that patient is presenting during the prodromal stage and there are no cutaneous lesions, a throat swab may be taken instead.
- A negative result for the throat swab does not rule out infection and clinical correlation is advised, with a follow up swab sample is required if lesions develop

#### For Asymptomatic exposure:

- Test for Monkeypox infection
- Isolate at home while waiting for test result
- If negative test – stop monitoring and consider post-exposure vaccination. This advice may vary depending on the level / significance of exposure
- If positive test – isolation at home for 21 days, with clinical self-monitoring (temperature and rash)

#### For Symptomatic cases:

- Test for Monkeypox infection
- Isolate at home while waiting for test result
- If negative test – isolation at home for 21 days, with clinical self-monitoring, and retest if symptoms persist
- If positive test – hospitalise in a tertiary hospital or designated centre (e.g. Mater/ SJH / CUMH)

Due to the low anticipated numbers, it is important that women are cared for in a unit with:

- Infectious disease expertise available
- Maternal fetal medicine expertise on site

Pregnant women should be prioritized for medical treatment. This is because of the probable increased risk of severe disease during pregnancy, risk of transmission to the fetus during pregnancy or to the newborn by close contact during and after birth, and risk of severe infection in newborns.

Treatment for monkeypox virus should therefore be offered to pregnant women, and the risks and benefits of treatment should be discussed. Close monitoring for severe disease and pregnancy complications is important.

Visitors to pregnant or postpartum women with monkeypox (home or hospital) should be limited to those essential for the patient's care and wellbeing.

#### Treatment – pregnant women

There is no specific treatment for monkeypox infection, nor is there a specific vaccine that is fully protective against monkeypox virus infection. (1, 2, 5, 18)

Antiviral therapy should be initiated in consultation with an infectious diseases physician.

Tecovirimat should be considered the first-line antiviral for pregnant or post-partum women. Tecovirimat (also known as TPOXX or ST-246) is an antiviral medication approved for the treatment of smallpox in adults and children, and it is expected to have antiviral activity against monkeypox virus. The usual course is 14 days. There are no data on its use in pregnancy. (5, 18, 19)

Although cidofovir and brincidofovir have been considered as alternative antiviral therapies to treat monkeypox infection, animal studies showed evidence of teratogenicity. As such, these medications should not be used to treat monkeypox infection in those who are in the first trimester of pregnancy or breastfeeding. (18, 19)

Animal reproduction studies have not been conducted with vaccinia immune globulin (VIGIV); therefore, it is not known whether it can cause fetal harm when administered during pregnancy or whether it can affect future fertility. However, immune globulins have been widely used during pregnancy for many years without any apparent negative reproductive effects. The risks and benefits of VIGIV administration should be assessed for each individual patient. If tecovirimat is unavailable, VIG is the next preferred option, and in pregnant patients, VIGIV may be preferred over tecovirimat (presuming VIG is available). (5, 14, 18, 19)

Secondary bacterial skin infection is common in monkeypox infection and requires early intervention; antibiotics may be required.

#### Fetal monitoring and delivery

As data on monkeypox infection in pregnancy are limited, the risk to the fetus is currently unquantifiable; however, it appears that vertical transmission and fetal demise are possible. Therefore, a cautious approach is advised.

This includes regular fetal monitoring by cardiotocography, if the gestational age is  $\geq 26$  weeks and/or if the mother is unwell. Ultrasound assessment of the fetus and placental function should be performed regularly during the acute infection.

Antenatal corticosteroids should be administered for fetal lung maturation depending on gestation and on the maternal condition, and if delivery is imminent.

There is no evidence around the optimal mode of delivery in a pregnant woman with active monkeypox infection. The relationship between the timing of infection, risk for congenital infection, and transplacental or intrapartum transmission is unknown. (5)

In general, maternal monkeypox infection *per se* is not an indication to expedite delivery, as most cases are not serious and are self-limiting, particularly those caused by the west African strain of the virus responsible for the current outbreak. Deferring delivery might also permit the transplacental transfer of maternal IgG antibodies against monkeypox.

If at any stage there is evidence of fetal compromise, or if the life of the mother is at risk, consideration should be given to delivering the baby, taking into account the gestational age, estimated fetal weight, condition of the fetus, and whether the mother is likely to benefit from, or be further compromised by, the birth. (7, 14)

It is likely that vertical transmission is possible, in which case Caesarean section may be of no benefit. As the virus can be transmitted via contact with open monkeypox lesions, it is likely, labour and/or vaginal birth in a woman with genital lesions may lead to neonatal infection. However there has been no clear

evidence of transmission through vaginal fluids. Caesarean section can be considered if there are genital or perineal viral lesions to reduce the risk of neonatal contact during delivery, and to prevent neonatal infection. (7, 14, 18)

### Care of the newborn

The mother should be counselled about the risk of transmission and the potential for severe disease in newborns. Infants born to a mother with confirmed monkeypox infection should be isolated separately from the mother to reduce the risk of transmission. If a baby subsequently tests positive for monkeypox infection, they can be reunited with the mother. (5, 18)

The baby should be carefully monitored for signs of compromise or monkeypox infection. Apart from macroscopic examination of lesions the baby should undergo viral PCR testing either by throat swab or any lesions that are present. Due to the increased risks in this age group, there is a low threshold for antiviral treatment if the baby contracts monkeypox. Consideration should be given to post exposure vaccination if viral testing is negative. The baby will require 3 weeks of isolation as a close contact if tests are negative and they remain asymptomatic. (5, 14, 15, 18)

Full PPE should be worn by the maternity and neonatal staff caring for the mother and baby.

All cases of monkeypox-exposed infants should be discussed with the Paediatric Infectious Disease Consultant on call at Children's Health Ireland. (1, 16)

### Breastfeeding

Breast milk is the best source of nutrition for most newborns, and it provides protection against many illnesses. It is unknown if Monkeypox virus is present in breast milk. However, given that Monkeypox virus is spread by close contact and neonatal monkeypox infection may be severe, the proposed strategy for neonatal care would preclude women with active monkeypox infection from breastfeeding or expressing milk for their newborn. (5, 18)

Consideration may be given to using the vaccine (Imvanex®; see below) for those at increased risk who are breastfeeding following individual benefit risk assessment.

### Vaccination in pregnancy

This guidance on vaccination is based on the current guidance from various bodies including the HPSC, Ireland (16), SMFM, US (5), the EMA (20) and the CDC (18, 21, 22). The National Immunisation Advisory Committee, Ireland (NIAC) has published and updated recommendations on vaccination against monkeypox throughout 2022 (23, 24).

Smallpox (vaccinia) vaccination is effective against monkeypox. Previous smallpox vaccines have been shown to be 85% effective in preventing monkeypox in close contacts.

Imvanex® (Imvamune® or MVA-BN) is the only smallpox vaccine authorised by the EMA for active immunisation against smallpox in adults. This vaccine is authorised in the US (as JYNNEOS) and in Canada (as Imvamune®) for the prevention of smallpox and monkeypox disease in adults aged >18 years. The vaccine contains a live non-replicating form of vaccinia. Two doses are administered 28 days apart for maximum effectiveness. (20, 21)

Available human data on this vaccine administered to pregnant women are reported as insufficient to determine if there are any vaccine-associated risks in pregnancy. Studies of the vaccine in animals have shown no evidence of harm to a developing fetus. (5, 20, 21)

There is no theoretical reason for concerns in pregnancy and the adverse events profile is expected to be similar to that in non-pregnant vaccinees. Consideration may be given to using the vaccine in pregnancy for those at increased risk following individual benefit risk assessment. (23, 25) Vaccine recipients should be given comprehensive information about the disease, the risks of contracting it, and the benefits and risks of the vaccine. They should be informed that they may develop adverse reactions similar to the prodromal symptoms of monkeypox infection during the first 48 hours after vaccination. (23)

When vaccination is indicated for a person who is pregnant, breastfeeding, or trying to become pregnant, Imvanex® is the vaccine of choice because it is non-replication competent. (18, 21, 23)

ACAM2000 is a live replicating vaccine licensed for prevention of smallpox. Vaccination with ACAM2000 is contraindicated in those who are pregnant or breastfeeding, due to the risk of pregnancy or fetal loss, congenital defects, and vaccinia virus infection in fetuses and newborns, as well as the availability of a non-replicating viral vaccine (Imvanex®). Vaccinia virus infection following vaccination with replication-competent smallpox vaccines have been reported in fetuses and newborns. (18, 20, 21, 23)

If an individual is vaccinated with ACAM2000, they should be counselled to avoid becoming pregnant (or getting their partner pregnant) for 4 weeks after vaccination, and until the vaccination site has healed, the scabs have fallen off, and a fresh layer of intact skin has formed. (18, 20, 21)

#### Pre exposure prophylaxis for healthcare workers

All healthcare workers should follow recommended infection prevention and control (IPC) measures.

Where possible, healthcare workers who are immunocompromised or pregnant should not directly care for suspected or confirmed monkeypox cases.

Consideration may be given to vaccination, for those at increased risk following an individual benefit-risk assessment. Imvanex® has been used in Europe for pre and post exposure prophylaxis against monkeypox. The vaccine can prevent the onset of symptoms if given within four days of exposure. If given between 5-14 days after the date of exposure, it may reduce the symptoms but may not prevent the disease.(20, 23)

While the priority is to ensure appropriate IPC measures are followed, vaccination may provide additional protection depending on the nature and timing of exposure risk. Designated healthcare and laboratory staff (including domestic staff etc.) who will be involved in the management of monkeypox cases, or their samples, should be offered two doses 28 days apart. (23, 24)

#### Post exposure prophylaxis for contacts

High and intermediate risk contacts within four days of last exposure to a laboratory confirmed case should be offered one 0.5 ml dose of the vaccine (Imvanex®). This may include healthcare workers (including domestic staff, etc.) caring for the case, and other contacts who have not previously been vaccinated. If there is a likelihood of ongoing exposure, a second dose should be given at least 28 days after the first. The vaccine can prevent the onset of symptoms if given within 4 days of known exposure. If given within five to 14 days after the date of last exposure, it may reduce the symptoms but not prevent the disease. (20, 21, 23)

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