

# Exhibit 405

## WHO Issues Warning on “Unusual” Surge of Severe Myocarditis Cases in Newborns and Infants

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# WHO Issues Warning on “Unusual” Surge of Severe Myocarditis Cases in Newborns and Infants

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The World Health Organization (WHO) has sounded the alarm over a significant increase in cases of “severe myocarditis” among newborns and infants in Wales and England.

The WHO issued a warning on Tuesday, drawing attention to a worrying increase in these severe cases of myocarditis between June 2022 and March 2023 and recommending increased awareness and further investigation into the underlying causes.

“On 5 April 2023, the National IHR Focal Point for the United Kingdom informed WHO of an increase in severe myocarditis in neonates associated with enterovirus infection in Wales,” according to the [news release](#).

There were ten newborns hospitalized with myocarditis, and one of them died.

“Between June 2022 and April 2023, ten hospitalized neonates with a positive enterovirus Polymerase Chain Reaction (PCR) test were found to have myocarditis. Seven of the ten cases had further subtyping, with either coxsackie B3 or coxsackie B4 identified. As of 5 May

2023, one patient was still hospitalized, and one had died.”

According to a UK Health Security Agency (UKHSA) representative who spoke with [The Epoch Times](#), there were also five cases of myocarditis in England.

Myocarditis, an inflammation of the heart muscle, can lead to significant complications and, in severe cases, even result in heart failure. Typically, enterovirus infections in neonates and young infants tend to be mild and self-limiting. However, the recent surge in severe myocarditis cases with adverse outcomes in this population is highly unusual and warrants immediate attention.

“Although enterovirus infections are common in neonates and young infants, the reported increase in myocarditis with severe outcomes in neonates and infants associated with enterovirus infection is unusual,” said WHO.

WHO added that epidemiological investigations are ongoing.

More from the WHO’s [news release](#):

On 5 April 2023, the National IHR Focal Point for the United Kingdom informed WHO of an increase in severe myocarditis in neonates and infants associated with enterovirus infection in Wales.

Between June 2022 and April 2023, ten neonates, under 28 days of age, presented with a picture consistent with myocarditis and a positive enterovirus PCR. Seven cases were treated in intensive care, and one case died before transfer to tertiary care. Cases presented with features of sepsis, myocarditis, or in cardiorespiratory arrest. The peak incidence of cases was in November 2022, with sporadic cases in other months.

Enterovirus PCR testing of all ten cases (with either blood, throat swab, nose swab, nasopharyngeal aspirate or cerebrospinal fluid samples) confirmed the presence of an enterovirus, subtyping (where available) to either coxsackie B3 or coxsackie B4.

Critical care support including intubation, ventilation and circulatory support was given to the patients who went to intensive care.

As of 5 May 2023, one patient was still hospitalised and one had died.

The reported increase in severe myocarditis in neonates and infants associated with enterovirus infection is unusual. In the tertiary hospital covering the South Wales region, two other similar cases have been identified in the 6 years prior to June 2022.

A further five cases have been identified over the same period in the Southwest of England. No additional information is currently available about these cases. Details of five of the cases from South Wales and three of the additional cases from Southwest England have recently been published (Ng et al., 2023).



# Myocarditis - United Kingdom of Great Britain and Northern Ireland

17 May 2023

*This Disease Outbreak News was first published on 16 May 2023 and later updated on 17 May 2023 to correct the number of cases, deaths, and the number of cases with PCR testing.*

## Situation at a glance

On 5 April 2023, the National IHR Focal Point for the United Kingdom informed WHO of an increase in severe myocarditis in neonates associated with enterovirus infection in Wales. Between June 2022 and April 2023, ten hospitalised neonates with a positive enterovirus Polymerase Chain Reaction (PCR) test were found to have myocarditis. Seven of the ten cases had further subtyping, with either coxsackie B3 or coxsackie B4 identified. As of 5 May 2023, one patient was still hospitalised, and one had died.

Although enterovirus infections are common in neonates and young infants, the reported increase in myocarditis with severe outcomes in neonates and infants associated with enterovirus infection is unusual.

## Description of the situation

On 5 April 2023, the National IHR Focal Point for the United Kingdom informed WHO of an increase in severe myocarditis in neonates and infants associated with enterovirus infection in Wales.

Between June 2022 and April 2023, ten neonates, under 28 days of age, presented with a picture consistent with myocarditis and a positive enterovirus PCR. Seven cases were treated in intensive care, and one case died before transfer to tertiary care. Cases presented with features of sepsis,

myocarditis, or in cardiorespiratory arrest. The peak incidence of cases was in November 2022, with sporadic cases in other months.

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The reported increase in severe myocarditis in neonates and infants associated with enterovirus infection is unusual. In the tertiary hospital covering the South Wales region, two other similar cases have been identified in the 6 years prior to June 2022.

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### **Epidemiology of Myocarditis (acute infective)**

Myocarditis is an inflammation of the heart muscle (myocardium). The most common cause of myocarditis is viral infection (e.g., Enteroviruses), but it can also be caused by a bacterial infection, a reaction to a drug or an autoimmune disease. Myocarditis symptoms include new and persistent chest pain, shortness of breath and heart palpitations (racing or pounding heartbeat).

Enteroviruses can cause a number of infectious illnesses and are responsible for annual epidemics. These are usually mild but have been found to affect neonates differently, and often more severely, than older children. There are multiple transmission routes, particularly in the neonatal period. The reported incident represents an increase in both the number and severity of enterovirus (coxsackieviruses) infections in infants under the age of one month. There is increased morbidity and mortality associated with the current incident.

## **Public health response**

On 28 February 2023, pediatricians in the South Wales region were alerted about the recent cases, with advice to consider myocarditis in infants and neonates presenting in shock. A briefing note to clinicians, microbiologists, health boards and public health teams was sent from Public Health Wales

on 3 May 2023, following an incident meeting in Wales on 26 April 2023.

An Incident Management Team set up by the United Kingdom authorities are reviewing the evidence from all English Regions and United Kingdom countries and agree on the next steps for response. Epidemiological investigations are ongoing.

## WHO risk assessment

According to the authorities of the United Kingdom, a review of past data from the previous six years from the same tertiary care centre in Wales, United Kingdom, has identified only two similar cases prior to June 2022 (which may or may not be linked to the current incident).

Based on the limited information available at this point, WHO assesses the public health risk for the general population to be low. However, asymptomatic carriage and shedding of infectious virus is a feature of enterovirus infection and there was little evidence in this case series of maternal infection prior to or during delivery. As enterovirus infection is often not among the notifiable diseases in Member States, additional cases of severe, neonatal enterovirus infections might have gone undiagnosed and/or unreported elsewhere.

## WHO advice

Non-polio enteroviruses are common and distributed worldwide. Although infections often are asymptomatic, others present with mild to moderate respiratory tract infections. Symptoms include fever, runny nose and body weakness. These viruses are also associated with occasional outbreaks in which an unusually high proportion of patients develop clinical disease, sometimes with serious and fatal consequences – in this instance myocarditis. Clinicians seeing infants and neonates presenting in shock may consider a diagnosis of myocarditis and consider testing for enteroviruses.

No specific antiviral therapy is available, and treatment focuses on prevention of complications. As there is no vaccine for this virus, control measures during outbreaks are focused on classical hygiene measures including frequent handwashing and disinfection of soiled clothing and surfaces. In certain situations, it may be advisable to close child-care facilities and schools to reduce the intensity of transmission.

WHO does not recommend any travel and/or trade restrictions to United Kingdom based on the information available for this event.

## Further information

- World Health Organization, Health topics, Enterovirus 71, available at <https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/vaccine-standardization/enterovirus-71>
- UK Health Security Agency, Enterovirus: summary of strain characterisation available at: <https://www.gov.uk/government/publications/enterovirus-strain-characterisation/enterovirus-summary-of-strain-characterisation> [accessed 20 April 2023]
- Ng KF, Gibb J, Struik S Neonatal Enteroviral Myocarditis Consortium, et al. Remember the heart: neonatal myocarditis Archives of Disease in Childhood 2023;108:417-419. Available at: <http://dx.doi.org/10.1136/archdischild-2023-325316>

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