



CEPI | Brighton Collaboration

# APPENDIX 1: MPOX ADVERSE EVENTS OF SPECIAL INTEREST

Work Package: [WP10]

V 1.0 [Draft] - [17/09/2024]

Author(s): Barbara Law, Flor Munoz, Manu Chaudhary, Krutika Kuppalli, Eileen Farnon, Shelly Karuna

Nature: [List] | Diss. level: [Public]

## DOCUMENT INFORMATION

Master Service Agreement	SPEAC 2.0	Service order	SO1
Project acronym	SPEAC	Full project title	Safety Platform for Emergency Vaccines
CEPI Project Lead	Rebecca Chandler		
CEPI Project Manager	Thomas Cole		
CEPI Contract Manager	Dorota Zdanekwicz		

Status	Draft <input checked="" type="checkbox"/> Final <input type="checkbox"/>	Version	[1.0]
Nature	Report <input type="checkbox"/> Toolbox <input type="checkbox"/> List <input checked="" type="checkbox"/> Template <input type="checkbox"/> Guidance <input type="checkbox"/> Handbook <input type="checkbox"/> Questionnaire <input type="checkbox"/>		
Dissemination Level	Public <input checked="" type="checkbox"/> Confidential <input type="checkbox"/>		

SPEAC Project Lead	Robert Chen	E-mail: <a href="mailto:robert.chen@speac.cepi.net">robert.chen@speac.cepi.net</a>
Scientific Coordinator	Miriam Sturkenboom	E-mail: <a href="mailto:miriam.sturkenboom@speac.cepi.net">miriam.sturkenboom@speac.cepi.net</a>

Main Author(s)	Barbara Law	E-mail: <a href="mailto:barblaw2015@gmail.com">barblaw2015@gmail.com</a>
	Flor Munoz	E-mail: <a href="mailto:florm@bcm.edu">florm@bcm.edu</a>
	Manu Chaudhary	E-mail: <a href="mailto:manuchaudhary.delhi@gmail.com">manuchaudhary.delhi@gmail.com</a>
	Krutika Kuppalli	E-mail: <a href="mailto:krutika.kuppalli@gmail.com">krutika.kuppalli@gmail.com</a>
	Eileen Farnon	E-mail: <a href="mailto:efarnon@taskforce.org">efarnon@taskforce.org</a>
	Shelly Karuna	E-mail: <a href="mailto:shellykaruna78@gmail.com">shellykaruna78@gmail.com</a>

## DOCUMENT HISTORY

NAME OF DOCUMENT	DATE	VERSION	CONTRIBUTOR(S)	DESCRIPTION
Mpox AESI List	23-Aug-2024	V1.0	SPEAC Executive Board	Creation of the document
Mpox AESI List	17-Sept-2024	V1.0	SPEAC Executive Board	Edition and share

## 1. Mpox AESI List

---

Based on SPEAC Mpox AESI list, v1.1, 17 September 2024 (<https://speacsafety.net/tools/aesi-lists/mpox/>).

This list of potential Adverse Events of Special Interest (AESI) that could follow vaccines to prevent Mpox was developed based on criteria established by the Safety Platform for Emergency Vaccines (SPEAC), which include:

1. A known association with immunization or a specific vaccine platform.
2. The occurrence during wild-type disease due to viral replication and/or immunopathogenesis.
3. A theoretical association derived from animal models.

Special populations, including pregnant women, children, adolescents, and immunosuppressed individuals, may experience an increased frequency and severity of any of the AESIs listed as relevant to all populations. There are also specific AESI that are of particular relevance to special populations, and these are listed according to the population. It is important to note that children, pregnant women and immunocompromised individuals may also have increased severity of expected local and systemic reactogenicity, as well as unexpected autoimmune conditions.

This list is based on the available data for mpox vaccines, which are to be used in response to the 2024 Public Health Emergency of International Concern (PHEIC) for mpox in Africa.

Safety Platform for Emergency vACcines

Body System	Possible AESI	Specific to mpox disease	Specific to vaccine platform	Published BC Case Definition	Completed Companion Guide	Simplified Data form ('RedCap ready')
Relevant to all populations						
Cardiac	Myocarditis/pericarditis	X	MVA-BN, LC16m8	YES	YES	YES
Dermatologic	Rash	X		YES	YES	YES
	Robust take		LC16m8	YES	YES	YES
	Generalized vaccinia		LC16m8	YES	YES	YES
	Eczema vaccinatum		LC16m8	YES	YES	YES
Dermatologic, Mucosal, and Ophthalmologic	Inadvertent inoculation (including ocular vaccinal infections)	X	LC16m8	YES	YES	YES
Dermatologic and Systemic	Secondary infections (bacterial)*	X	LC16m8	NO	NO	NO
Hematologic	Thrombocytopenia		any vaccine	YES	YES	YES
Immunologic	Anaphylaxis		any vaccine	YES	YES	YES
Neurologic	Encephalitis	X	LC16m8	YES	YES	YES
	Generalized convulsive seizure	X	any vaccine	YES	YES	YES
Ophthalmologic	Ocular Manifestations	X	LC16m8	NO	NO	NO
Respiratory	Pneumonitis/ARDS	X	LC16m8	YES†	YES†	NO†

Safety Platform for Emergency vACcines

Body System	Possible AESI	Specific to mpox disease	Specific to vaccine platform	Published BC Case Definition	Completed Companion Guide	Simplified Data form ('RedCap ready')
Relevant to pediatric populations						
Dermatologic	Severe Vaccinal Eruption or Local Reactogenicity (Hives, Erythema, Poor healing, Scarring)		MVA-BN, LC16m8	NO§	NO	NO
Dermatologic and Systemic	Secondary infections (bacterial)*	X	MVA-BN, LC16m8	NO	NO	NO
Neurologic	Febrile seizure	X	MVA-BN, LC16m8	NO¶	NO¶	NO¶
Relevant to pregnant populations**						
Maternal	Stillbirth	X	MVA-BN, LC16m8	YES++	YES	YES
	Spontaneous Abortion/Miscarriage	X	MVA-BN, LC16m8	YES	YES	YES
	Antenatal hemorrhage	X	MVA-BN, LC16m8	YES	NO	YES
	Preeclampsia/Eclampsia		MVA-BN, LC16m8	YES§§	NO	YES
Neonatal	Fetal Vaccinia (congenital infection)		MVA-BN, LC16m8	NO	NO	YES
	Congenital anomalies	X	MVA-BN, LC16m8	YES	NO	YES
	Preterm delivery/birth	X	MVA-BN, LC16m8	YES	YES	YES
	Neonatal vaccinia/mpox infection in infant of mother vaccinated in pregnancy	X	MVA-BN, LC16m8	YES¶¶	NO	YES
Relevant for people with HIV and other immunocompromised populations***						
Immunologic	Progression of HIV	X	MVA-BN, LC16m8	NO	NO	NO
	Opportunistic infections+++	X	MVA-BN, LC16m8	NO	NO	NO
	Progressive vaccinia		MVA-BN, LC16m8	YES	NO	NO

## Safety Platform for Emergency vACcines

\*Secondary bacterial infection of lesions, or resulting in sepsis after vaccination should be captured.

†BC tools exist for ARDS, but not a digitalized data collection form. No BC tools exist for pneumonitis.

§BC tools do not exist for all the AESIs listed for special populations. However, there are other tools (e.g. toxicity grading scales) that may be applied.

¶BC tools exist for Generalized convulsive seizure and Fever.

\*\*Guidelines for data collection exists as part of the GAIA project: <https://brightoncollaboration.org/global-alignment-of-immunization-safety-assessment-in-pregnancy-gaia/>

††The Stillbirth CD publication update is pending.

§§BC CD for hypertensive disorder of pregnancy

¶¶BC CD exists for Neonatal infection.

\*\*\*Including malnutrition

†††Viral infection or live-attenuated viral vaccination can worsen immunosuppressive states.

### References:

[https://www.hosp.ncgm.go.jp/isc/vaccines/MNK/Vaccination\\_Procedure\\_Guideline\\_for\\_Lc16.pdf](https://www.hosp.ncgm.go.jp/isc/vaccines/MNK/Vaccination_Procedure_Guideline_for_Lc16.pdf)

Ladhani SN, Dowell AC, Jones S, et al. Early evaluation of the safety, reactogenicity, and immune response after a single dose of modified vaccinia Ankara-Bavaria Nordic vaccine against mpox in children: a national outbreak response. *Lancet Infect Dis.* 2023 Sep;23(9):1042-1050. doi: 10.1016/S1473-3099(23)00270-0. Epub 2023 Jun 16. PMID: 37336224.