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SUMMARY OF NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) RAPID RESPONSE OF JUNE 10, 2022

Interim guidance on the use of Imvamune® in the context of monkeypox outbreaks in Canada

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Également disponible en français sous le titre :

Résumé de la réponse rapide du Comité consultatif national de l'immunisation (CCNI) du 10 juin 2022 : Orientation provisoires sur l'utilisation d'Imvamune[MD] dans le contexte des éclosions de variole simienne au Canada

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OVERVIEW

- On June 10, 2022, the Public Health Agency of Canada (PHAC) released interim guidance from the National Advisory Committee on Immunization (NACI) on the use of Imvamune® in the context of monkeypox outbreaks in Canada. This guidance is based on current evidence and NACI's expert opinion.

- Canada first declared cases of monkeypox on May 19, 2022, and continues to experience an outbreak with 81 confirmed cases as of June 7, 2022.

- Imvamune® is an *orthopoxvirus* vaccine made by Bavarian Nordic that is authorized by Health Canada for immunization against smallpox, monkeypox and other pox viruses in adults 18 years of age and older who are at high risk of exposure.

- In the context of the rapidly evolving monkeypox outbreak, NACI has provided options for the use of the Imvamune® vaccine for post-exposure prophylaxis against monkeypox. Post-exposure prophylaxis is when a medical intervention is taken to prevent disease after a possible exposure. In developing these options, NACI reviewed data on the current status of the monkeypox outbreak and evidence on the safety and protection offered by the Imvamune® vaccine.

- **For post-exposure prophylaxis (PEP), NACI recommends:**

    - **A single dose of the Imvamune® vaccine may be offered to people with high risk exposures (to be defined by PHAC) of a probable or confirmed case of monkeypox, or within a setting where transmission is happening. This dose should be offered as soon as possible, ideally within 4 days of exposure, but may be considered up to 14 days since last exposure. PEP should not be offered to people who have current monkeypox infection.**

    - **A second dose may be offered after 28 days if an assessment indicates an ongoing risk of exposure.**

    - **People with a history of myocarditis and/or pericarditis linked to a previous dose of an *orthopoxvirus* vaccine should discuss the benefits and risks of receiving Imvamune® with their doctor.**

- NACI recommends that Imvamune® be given at least 4 weeks before or after an mRNA COVID-19 vaccine, if possible. However, Imvamune® vaccination should not be delayed due to the receipt of an mRNA COVID-19 vaccine.

- Unrelated to the current monkeypox outbreak, NACI has also provided guidance on the use of Imvamune® for pre-exposure prophylaxis in routine laboratory research settings where replicating *orthopoxviruses* are studied.

For the full statement, including supporting evidence and rationale, please see NACI Rapid Response: Interim guidance on the use of Imvamune® in the context of monkeypox outbreaks in Canada.

WHAT YOU NEED TO KNOW

- The monkeypox virus is an *orthopoxvirus* that is genetically related to the variola virus, the virus that causes smallpox.

- Recent cases of monkeypox have been reported in a number of countries where it is not usually seen, including in Canada. Canada first declared cases of monkeypox on May 19, 2022, and continues to experience an outbreak with 81 confirmed cases as of June 7, 2022.

- Evidence and details continue to emerge with regard to the 2022 monkeypox virus outbreaks, including symptoms, modes of transmission and groups at high risk for severe outcomes. Available information suggests that infection may be transmitted via close physical contact with someone who has monkeypox symptoms.

- While the evidence is limited, Imvamune®, a non-replicating *orthopoxvirus* vaccine, may provide some protection against monkeypox. Imvamune® is authorized by Health Canada for immunization against smallpox, monkeypox and other pox viruses in adults 18 years of age and older who are at high risk for exposure.

- Imvamune® post-exposure prophylaxis (PEP) may be offered to people who have been exposed to the virus or who are in a setting where monkeypox transmission is happening.

- Some populations may be at increased risk of severe monkeypox disease, including people who are immunocompromised, people who are pregnant and young children. Data on the use of Imvamune® in immunosuppressed populations are limited, but the vaccine has been studied in people living with human immunodeficiency virus (HIV) and safety was comparable to immunocompetent controls. While there is a lack of evidence on the safety and efficacy of Imvamune® in people who are pregnant and young children, there are no known safety signals and people in these populations may particularly benefit from receiving the vaccine. An individual benefit-risk analysis should be conducted when offering the vaccine.

- Recommendations to consider Imvamune® for children under 18 years of age are off-label and should follow an individual benefit-risk analysis.

- Other *orthopoxvirus* vaccines and mRNA COVID-19 vaccines may have a risk of myocarditis and/or pericarditis. The risk of myocarditis and/or pericarditis with Imvamune® is unknown. NACI recommends receiving Imvamune® at least 4 weeks before or after receiving an mRNA COVID-19 vaccine to help identify which vaccine myocarditis and/or pericarditis is linked to, should it occur. However, protection from monkeypox should be prioritized and prior mRNA vaccination should not delay the receipt of Imvamune®.

- It is important to obtain informed consent when offering the Imvamune® vaccine for monkeypox. The limited data available on monkeypox infection and disease, as well as the limited data available on the safety and efficacy of Imvamune®, should be discussed along with potential benefits and risks.

- Provinces and territories continue to closely monitor and investigate outbreak dynamics in their jurisdictions, and will determine how to best use the Imvamune® vaccine, informed by this NACI advice, in their jurisdictions.

- NACI and PHAC continue to monitor the evolving data on the monkeypox outbreak. The situation is rapidly evolving and there may be additional considerations in the coming weeks.

For the full statement, including supporting evidence and rationale, please see NACI Rapid Response: Interim guidance on the use of Imvamune® in the context of monkeypox outbreaks in Canada.

QUOTES

"In response to outbreaks of monkeypox in Canada, NACI reviewed available evidence for the Imvamune® smallpox vaccine which was authorised in Canada in 2020 for prevention of monkeypox. The Imvamune® vaccine is expected to be an important part of the outbreak response in some settings, but is not needed for the entire population. At this time, NACI has focussed on assessment of post-exposure prophylaxis to protect adults who were recently exposed to monkeypox in contexts where transmission could be likely. This live vaccine is not expected to replicate, and it may be considered for those who are immunocompromised or pregnant and who have been exposed in a context where transmission could be likely. There will also be circumstances where the vaccine may be considered for off-label use in children, knowing that historically monkeypox can cause severe disease in children. We expect to learn more about the disease in coming weeks and months, including more information about the most effective ways to use vaccine as part of an outbreak response strategy."

- Dr. Shelley Deeks, NACI Chair

"Canada is currently experiencing outbreaks of monkeypox. Canada is fortunate to have access to Imvamune®, a Health Canada authorized vaccine that may provide some protection against monkeypox. NACI's guidance on the use of Imvamune® provides a foundation for provinces and territories to determine how best to use the vaccine to have the greatest public health impact in their communities. Local jurisdictions are well placed to understand where and how transmission of monkeypox is taking place in their communities and PHAC supports provinces and territories in their efforts to use the vaccine as part of focussed strategies to prevent the spread of Monkeypox in their jurisdictions. There are still many unknowns about the monkeypox outbreaks and we will continue to learn more and refine our approaches as the situation evolves. I thank NACI for continuing to provide timely, expert advice to help protect the health of Canadians."

- Dr. Theresa Tam, Chief Public Health Officer