



H1N1 Vaccine Guidelines for People Living with HIV/AIDS



Question

What is the safety and effectiveness of the H1N1 vaccine among people with HIV/AIDS?

Key Take-Home Messages

- Although there is no specific data on the safety and effectiveness of the H1N1 vaccine – or seasonal flu vaccines – among people with HIV/AIDS, there is also no evidence of increased risk.
- Previous studies on seasonal flu vaccines have indicated that people with HIV/AIDS may be at increased risk of having a poor immune response to the standard 15 microgram dose of seasonal flu vaccine. Similar studies have shown that people with HIV/AIDS who received the larger dose of seasonal flu vaccine, had enhanced protective immune response. Clinical trials are underway to determine whether or not a larger dose of the H1N1 vaccine will be more effective than the standard dose among HIV/AIDS positive pregnant women and youths in the US (5).
- The US, Canadian, Australian and UK governments all recommend that people with chronic illness – including people with HIV/AIDS – get the H1N1 vaccine (1-4).
- These recommendations caution that the risk of potential side effects of H1N1 influenza among people with chronic illness, greatly outweigh any possible side effects of the H1N1 vaccine that are known at this time.

The Issue and Why It's Important

People with HIV/AIDS are generally considered to be at increased risk of complications from H1N1 influenza. Ontario will be distributing H1N1 vaccine, and has identified people with HIV/AIDS as a priority to receive the vaccine. In

EVIDENCE INTO ACTION

The OHTN Rapid Response Service offers HIV/AIDS programs and services in Ontario quick access to research evidence to help inform decision making, service delivery and advocacy. In response to a question from the field, the Rapid Response Team reviews the scientific and grey literature, consults with experts, and prepares a brief fact sheet summarizing the current evidence and its implications for policy and practice.

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trials, the vaccine has proven to be safe and effective in the general population; however, people with HIV/AIDS may be concerned about its safety and efficacy in the presence of HIV/AIDS.

What We Found

- The Public Health Agency of Canada lists people with chronic health conditions as one of the groups of people who will benefit **the most** from receiving the H1N1 vaccine. According to the Public Health Agency of Canada, chronic conditions include people with weakened immune systems, which include people with HIV/AIDS (2). Among flu-related ICU cases in Canada, 2/168 were people living with HIV/AIDS, despite the fact that national HIV prevalence is approximately 0.2%. This supports the assertion that people living with HIV/AIDS are at higher risk of flu-related illness and complications (6).
- There is currently no published data on the safety or effectiveness of the H1N1 vaccine among people with HIV/AIDS. Trials are currently underway in the US to test the safety and effectiveness of a larger dose of the H1N1 vaccine among people with HIV/AIDS (5).
- The Public Health Agency of Canada has released information that shows the potential adverse effects of getting H1N1 versus the potential adverse effects of getting a vaccine, although there is no detailed information for people with HIV/AIDS. The chart is available online at: <http://www.phac-aspc.gc.ca/alert-alerte/h1n1/fs-fi-chronic-chronique-eng.php> (2). While there is reason to believe that the influenza vaccine may be less efficacious in people living with HIV/AIDS, the benefits of vaccination are significant. Protection against severe disease and death is likely much higher than protection against infection (6).
- The Ontario Government also recommends the H1N1 vaccine for people with chronic conditions (including people with HIV/AIDS). People with immunosuppressive illnesses, including HIV/AIDS, are priority #1 for vaccination. The H1N1 vaccine will be available through health care providers and designated flu clinics in Ontario in late October and priority will be given to people who will benefit the most from the vaccine, which includes people with chronic conditions (e.g. HIV/AIDS) (6, 7).
- The Governments of Australia, US, and UK all recommend the H1N1 vaccine for people who are immunosuppressed or who have a chronic condition (including HIV/AIDS) (1,3,4).
- The H1N1 vaccine that is being tested among people with HIV/AIDS in the US contains inactivated H1N1 virus and does not contain adjuvant (naturally occurring oil, water and vitamin E) (5). The Canadian H1N1 vaccine that will become available in Ontario next week is also inactivated, but contains adjuvant, which boosts the effectiveness of the vaccine. A non-adjuvant version will be made available in November. Ontario recommends the non-adjuvant vaccine for pregnant women due to potential side effects on a developing fetus; however, there is currently no clinical data on the effects of adjuvant vaccines in pregnant women and children. No statement has been made about any side effects of the adjuvant vaccine on people with HIV/AIDS (8-9).

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- There is very little data available on the safety and effectiveness of the seasonal flu vaccine among people with HIV/AIDS. Recent systematic reviews of the available data have concluded that evidence to support the effectiveness of flu vaccination among people with HIV/AIDS is limited and/or poor and that no conclusions can be made at this point (10-12). There is no published data that shows that seasonal flu vaccine is harmful to people with HIV/AIDS.
- Previous studies on seasonal flu vaccines have indicated that people with HIV/AIDS may be at increased risk of having a poor immune response to the standard 15 microgram dose of seasonal flu vaccine. Similar studies have shown that people with HIV/AIDS who received the larger dose of seasonal flu vaccine, had enhanced protective immune response. This may lead researchers to look at the effects of increased dosages of the flu vaccine among people with HIV/AIDS. Increased dosages of H1N1 vaccine for pregnant women and young people with HIV/AIDS are currently being examined in the US (5, 13).

Clinical Trials in the US

The National Institutes of Health in the US is currently funding clinical trials of the H1N1 vaccine in HIV-positive pregnant women and youth. The study, led by The International Maternal Pediatric Adolescent Clinical Trials Group, began in early October and will look at whether people with HIV/AIDS have a stronger and longer-lasting protective immune response when given a larger dose of the H1N1 vaccine (two 30 microgram doses, as compared to the standard 15 microgram dose) (5).

Factors that May Impact Local Applicability

- The non-adjuvant H1N1 vaccine being tested among people with HIV/AIDS in the US is not the same as the H1N1 adjuvant vaccine being made available in Canada.
- There are no clinical trials currently being conducted on the safety or effectiveness of the H1N1 vaccine on people with HIV/AIDS in Canada.

What We Did

We searched for global news articles on the H1N1 vaccine and people with HIV/AIDS for current information on studies and/or guidelines. In addition, we searched American, UK, Australian and Canadian government websites for information pertaining to H1N1 risk in people with HIV/AIDS, as well as vaccine guidelines and national clinical trials currently underway. Finally, we searched the PubMed database for any studies on flu vaccinations and HIV/AIDS, going back five years (PubMed keywords used: flu vaccine AND HIV; H1N1 vaccine AND HIV). We also consulted with experts at the Public Health Agency of Canada and the Ontario Agency for Health Protection and Promotion.

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