



QUESTION AND ANSWERS

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POLIO VACCINE AND SV40

What is Polio? What causes it?

Poliomyelitis, more commonly called polio, is an infectious disease caused by a virus. The virus infects and destroys certain nerve cells and the muscles become weak or paralysed. About one out of every 100 people infected with the polio virus will develop paralysis with permanent nerve damage. During the last polio epidemic in Canada in 1959, many patients could not breathe by themselves and had serious complications or died because the virus paralysed their chest muscles.

There are three different types of poliovirus: types 1, 2, and 3. The poliovirus is spread by direct contact with an infected person or by contamination of water, food or hands. The virus can survive in the environment for long periods of time.

Are Canadians still at risk for polio?

As long as polio still exists in parts of the world, Canadians, especially those not protected by vaccination, are still at risk. Polio still exists in certain parts of the world, including Africa and the Indian subcontinent. People who are not protected against the disease can get it while visiting countries where the disease is still present. As well, someone visiting Canada could bring the disease into the country. The last time a person brought the disease to Canada was in 1996, but the infection did not lead to paralytic disease. Vaccination with a safe and effective vaccine is the only sure way to protect against polio.

What is the relationship between Simian Virus 40 (SV40) and polio?

SV40 is a monkey (simian) virus that infects several monkey species without making the animals sick. The virus can be found in the kidneys of these infected monkeys. Kidney cells from infected monkeys were used in the production of polio vaccines before the discovery of SV40 in 1960. As a result, some individuals who received those vaccines between 1955 and 1963 may have been exposed to SV40.

Why are there concerns about the polio vaccine and this SV40 virus?

Polio vaccines were originally grown in rhesus monkey cells. Early in 1960, scientists discovered that some of the monkeys whose cells were used to grow the vaccine had been infected with the SV40 virus. As a result, there were concerns that people who had received those first batches of polio vaccine may have been exposed to SV40.

What is the risk to people who received the vaccine?

When it was first discovered that some monkey cells had been infected with SV40, the potential health effect of the virus on people exposed to contaminated polio vaccine was unknown. Studies done in 1961 showed that the SV40 virus could cause cancer in rodents, such as hamsters. Studies since have described a way in which SV40 contributes to the development of cancers. The SV40 virus has also been detected in

some patients with three rare cancers in humans; mesothelioma (cancer of the lining of the chest or abdomen, known to be caused by exposure to a certain type of asbestos fibre), osteosarcoma (cancer of the bones) and ependymoma (a childhood brain tumour). However, most cancers have many potential causes.

In 2003, the Institute of Medicine in the United States concluded that there was not enough scientific information to determine if the SV40 in polio vaccines produced before 1963 has caused human cancers.

Should I be concerned?

To date, there is no epidemiological evidence that shows people exposed to the SV40 contaminated polio vaccine are at increased risk of developing the type of cancers that rodents developed after direct exposure to SV40. A number of epidemiologic studies have been done to see if there was a connection between an increase in cancer rates and possible exposure to SV40 before 1963. To date, the studies have not found an increase in cancer rates. The cancers studied included the rare cancers found in rodents: mesothelioma, ependymoma, choroid plexus tumour, as well as non-Hodgkin's lymphoma, intracranial tumours and leukemia.

What was done to eliminate SV40 from vaccines?

Following the discovery of SV40 in the early 1960s, several steps were taken to eliminate SV40 from vaccines: the materials used to produce the polio vaccines were tested to make sure they were free of SV40, and, in the early 1990s, a new system was introduced for producing the vaccine that is completely free of materials that could have been infected by SV40. All polio vaccines used in Canada are manufactured using materials that have been subjected to strict quality control tests to ensure their safety and sterility.

Could polio vaccines used in Canada today be contaminated with SV40?

No, polio vaccines used in Canada are not contaminated with SV40 because they are produced using materials completely free of SV40. Currently, the only polio vaccines used are those made with inactivated polio virus (IPV). An inactivated virus is one that will not make you sick but instead makes you produce antibodies that protect you from being infected with the polio virus.

Polio vaccines given to Canadians have been free of SV40 since the early 1960s. These vaccines are manufactured according to the highest standards in the world.

How does Health Canada make sure that vaccines are free of SV40?

Health Canada regulates all vaccines for human use. Like all medicines, vaccines go through rigorous tests before they are approved. Health Canada also monitors all aspects of vaccine production by the manufacturers. As well, the factory where the vaccine is manufactured must be inspected to ensure that all stages of production meet the requirements for safety, sterility and quality control. Before the manufacturers can release the polio vaccine, each batch has to be tested for safety and quality under guidelines specified by Health Canada. Testing is also carried out by Health Canada to confirm the manufacturer's results.

The vaccines used in Canada are safe and effective and there is a well developed system for monitoring and evaluating vaccine associated adverse events in Canada

that includes: a national vaccine adverse events surveillance system, a paediatric hospital-based surveillance system and a national panel of experts that looks at serious vaccine-associated adverse events.

When was the last major polio epidemic in Canada?

The last major epidemic in Canada occurred in 1959. During this epidemic, 1,887 cases resulted in paralysis, out of approximately 190,000 poliovirus infections.

What was the impact of immunization on polio?

In Canada, the disease has been eliminated following the introduction of inactivated polio virus vaccines (IPV; containing only dead virus and given by injection) in 1955 and oral polio virus vaccine (OPV; containing live, weakened virus) in 1962.

The Pan American Health Organization certified that Canada was polio free in 1994. The Working Group on Polio Elimination in Canada, a Health Canada advisory committee of experts, reviews data collected by Health Canada and by organizations around the world to ensure that we continue to take the steps that are necessary to make sure Canada remains polio free.

Thanks to continued polio vaccination campaigns world wide, polio was eliminated from the Western hemisphere in 1995. The WHO is working towards eliminating the disease world-wide by 2005.