

# GLOBAL VACCINE SAFETY Q&A

(September 2019)

## 1. What is vaccine safety?

Vaccines are administered to healthy people (usually children) to prevent diseases later in life. It is very important that vaccines and vaccination do no harm in the process. Vaccine safety is the science that ensures potential risks related to vaccines and vaccination are kept to the minimum possible level. This is done by monitoring reactions in people who receive vaccines and, if there is a concern, ensuring the necessary resources are available for investigation and corrective action. WHO works to make sure that vaccine safety systems exist everywhere so that anyone who receives a vaccine can have their concerns considered and investigated if needed.

## 2. What makes a vaccine *unsafe*?

To produce protection against a disease, vaccines activate biological reactions in the body. Those reactions vary depending on the type of vaccine and its mode of administration. In addition to developing its protective effect, vaccine reactions may include usually mild irritation that resolves in a few days. Severe reactions occur very rarely (less than one in 100 000 doses of vaccines administered) and these generally occur in people with pre-existing diseases. If this risk factor is known beforehand, it is possible to prevent any potential reaction.

In addition to those very rare adverse reactions, the act of vaccinating itself can cause problems if it is not conducted properly. Poor handling of a vaccine, for example, or unsafe storage can cause infections. Errors in administering the vaccine can also cause damage. If this occurs, it is important to take all corrective measures as rapidly as possible. That is why WHO works with all countries to set up systems for monitoring reactions in people who receive vaccines.

## 3. What does WHO do to promote safe vaccines?

The safety of vaccines is closely monitored by WHO, national regulatory agencies and vaccine manufacturers during the vaccine development phase and after vaccines have been registered and are utilized on a large scale. Possible risks related to vaccines are carefully studied with the help of independent scientists. A vaccine is registered in countries only if it does provide conclusive protection, if it is manufactured according to the highest standards, and if the risks related to its utilization are very low compared to the benefits.

In addition, WHO provides public information about the known risks of vaccines and how to minimize those risks. This information is updated as new data or new issues emerge or when improvements are made that can reduce those risks. For WHO-recommended vaccines, see [information sheets](#).

#### **4. What are WHO's accomplishments of the last 20 years?**

The Global Advisory Committee on Vaccine Safety (GACVS) is the independent expert group that has advised WHO for the past 20 years. It meets twice annually and can be consulted any time a new concern is identified by WHO. GACVS monitors the safety profile of all vaccines recommended by WHO. Its recommendations are publicly available on its [web site](#).

GACVS also publishes warnings every time a particular risk is identified or, importantly, when false rumours can affect the use of a safe vaccine. False rumours or wrong perceptions can endanger the population by depriving it of the protection vaccines provide.

GACVS is the driving force behind [Vaccine Safety Net](#) – a platform run by WHO assembling trusted web sites from all parts of the world providing reliable information about vaccines. Those sites can be recognized because they display a WHO-protected visual identity. As of 19 September 2019, there are 75 sites from 34 countries participating in this network, offering vaccine safety information in 24 languages.

#### **5. What does the summit of 2-3 December 2019 hope to achieve?**

The Summit has two main aims:

- First, to enhance WHO's work on vaccine safety. WHO's current vaccine safety strategy – called the *Global Vaccine Safety Blueprint* – was published in 2012. The Blueprint has made enormous progress improving vaccine safety in low- and middle-income countries in the last eight years. WHO now wants to look to the future and enhance its work to meet the challenges of the new decade and the sustainable development agenda. These include the emergence of many new vaccines, a more interconnected world and the explosion of global communication.
- Second, it will feature the most recent from state-of-the-art vaccine safety science as we transition to the next decade. We have learned a lot in recent years and scientifically resolved many vaccine safety issues from the 20<sup>th</sup> and early 21<sup>st</sup> centuries. New issues, primarily related to novel vaccines, have also appeared and require continuing research. Today we have new tools and methods to resolve those questions quicker, more thoroughly and through broader partnerships. A publication will be produced to inform the global health community about the current situation.

#### **6. What does WHO's strategy on vaccine safety propose for the next 10 years?**

The Blueprint 2.0 will be designed for all countries rather than concentrating on low- and middle-income countries. It will focus on strengthening the capacities of national regulatory authorities, so the quality and safety of vaccines can be assured locally and closer to patients. It will also foster the coordination of efforts between immunization programmes, regulatory agencies and their partners and highlight the responsibility of vaccine manufacturers in monitoring vaccine safety. Coordination will include new mechanisms to ensure that vaccine safety strategies are fully operational and work effectively. Finally, the strategy will highlight the role of communication and reliable information to dispel false allegations

and wrong perceptions to sensitize people on vaccines' tremendous benefits for individual and public health.

## **7. What do we need to achieve the new strategy's goals?**

The mechanisms to implement the strategy are already in place. More funding will be mobilised to ensure success.

Basically, the new strategy is implemented through the Global Vaccine Safety Initiative ([GVSI](#)), a broad network of vaccine safety stakeholders who work jointly to improve vaccine safety in countries and globally. The network develops new tools and methods, provides training, conducts studies related to current issues in vaccine safety, and promotes trusted communication based on science and objectivity. The GVSI has demonstrated its value with the first Blueprint and is well equipped to address the challenges of the next decade. In addition to implementing the strategy, progress will be monitored continuously. The idea is that an independent group, convened by the GVSI Observatory, will do the monitoring. That way, WHO and partners will receive regular information and advice from respected scientists, not directly responsible for Blueprint implementation, on how to better prioritize their efforts.

## **8. What can we say to parents who are hesitant about vaccines?**

There are many reasons why people can be hesitant about vaccines. Concerns about safety are one of those reasons. It is very important to explain that vaccine recommendations are issued based on careful considerations of risks and benefits and that systems are in place to ensure their optimal safety.

## **9. Are new vaccines safer than old ones?**

Vaccine science has progressed, and new vaccines have fewer reactions than older ones. Earlier vaccines frequently included additional components that could cause some adverse effects. Today it is possible to synthesize only the particles that protect and offer purer products.

## **10. What innovations can we expect in the future in terms of vaccine safety?**

Besides products with fewer untoward reactions, novel ways of administering vaccines are also under development. These include pre-filled syringes that avoid any risk related to the transfer from a vial to a syringe. Vaccine administration at the surface of the skin with patches is also at advanced stages of development. The use of nucleic acid that can teach the body to produce self-protection against a disease is another avenue.

There will also be improvements in the way safety is monitored. Larger and faster international information systems will take advantage of new information technology. Agile reporting systems will increase the way vaccine safety concerns are notified. International networks will be able to rapidly join forces and test, through computer-based records, if a possible reaction to a vaccine is found in all places that use the same product.

Finally, information about vaccines and vaccine safety will be increasingly accessible and verified. People will benefit from trusted sources that use rigorous science to explain what is known about vaccine risks and how to minimize them.