Why pause the JnJ vaccine?

7.4 million doses of JnJ had been administered at the time of the pause. There were 12 reported cases of a "rare and severe" blood clot. In addition, one case had been reported in a trial participant who received the vaccine during a clinical trial.

- The majority of the cases were in women aged 18-39. Only 1 case was in a man.
- Symptoms occurred 1-3 weeks after vaccination.
- These 12 individuals showed no traditional risk factors for clotting & presented with a range of symptoms, including headaches and back pain. Some were obese, and one was on a contraceptive. This means there was - and is - no "profile" of who might develop a severe blood clot.
- No similar cases were seen in people who received the JnJ vaccine in South Africa.

Talking about blood clots

- A blood clot is a clump of blood that has changed from a liquid to a gel-like state. Clotting is a necessary process that can prevent you from losing too much blood in certain instances, such as when you're injured or cut.
- When a clot forms inside one of your veins, it won't always dissolve on its own. This can become dangerous.
- If a blood clot breaks free and travels through your veins to your heart and lungs, it can get stuck and prevent blood flow. This is a medical emergency.
- Globally, hundreds of thousands of people die from clots every year.
- The cases of rare but serious blood-clotting disorders seen in some people who received the Johnson & Johnson vaccine are much more unusual and dangerous than regular clots. One of the reasons they are very dangerous is that the treatment that normally works for blood clots does not work for these rare but serious cases.
- We do not know for sure if the vaccine is causing the rare but serious blood-clotting disorder.

We don't know for sure that the JnJ vaccine causes these clots.

Who is the FDA?

- The United States Food and Drug Administration is responsible for protecting public health by ensuring that medications are safe and work.
- The FDA first recommended pausing the use of the JnJ vaccine until they could investigate further.
- Because the FDA is a globally respected body, health leadership in South Africa (as well as in several other countries) have also decided to pause the distribution of the JnJ vaccine.
- This allowed local regulators to compare South African data with international data and consult with international bodies, including the World Health Organization (WHO).
- This shows that scientists are being transparent and collaborating globally on a pandemic affecting every country on the planet.
- SAHPRA (the South African equivalent of the FDA), in consultation with the Department of Health and the Research Ethics Committee, also reviewed the information along with the South African Medical Research Council, and a decision was made to continue providing the Johnson and Johnson vaccine to health workers.

Did the vaccine research process miss something?

These are very rare events (almost 2 in a million) and may not be caught during clinical trials that normally enrol up to 50,000 people.

- This is why there are such intensive safety monitoring mechanisms in place for vaccines after public distribution.
- It is normal for researchers to continue monitoring serious adverse events of a new medicine or vaccine after clinical trials have ended in order to track what happens when a product is distributed to millions of people.

What about other COVID-19 vaccines?

- This condition (rare but serious blood clots) is very similar to a condition linked to the AstraZeneca/Oxford vaccine.
- Researchers believe that this has to do with the fact that the two vaccines (AZ and JnJ) are similar. However, since millions of people have received the AZ and JnJ vaccines, researchers believe that if the vaccines alone were responsible, there would be many more cases.
- There is currently no evidence of what the people who have developed these rare clots have in common, but close monitoring will continue - as with any other COVID-19 vaccine.

Wasn't the AZ vaccine paused elsewhere and later restarted? What can we learn about this regarding JnJ?

- This is correct. After an intense investigation on the rare severe blood clots, some scientists concluded that the benefits of the AZ vaccine far outweigh the risks.
- Certain countries (like South Africa and the United States) decided not to proceed with any AZ distribution. Other countries have continued distribution while making choices on who should get the vaccine, based on an analysis of benefit vs risk.
- For example, since the rare severe blood clots are mainly affecting younger people, some countries are opting to limit AZ vaccinations to individuals over 50 years of age.
- Scientists in the United States have said that they will consider this option since – for most people – the benefits of COVID-19 vaccines far outweigh any potential risks.

What now for South Africa?

Communities must continue to raise their voices to demand access to COVID-19 vaccines for everyone, everywhere free of charge.

- South Africa has resumed the use of the Johnson & Johnson vaccination after an extensive review of the information available.
- This is critical and will offer some much-needed relief to a country that is yet to start its mass vaccination rollout.

I received the JnJ vaccine. Should I be worried?

Remember: these events are extremely rare!

- If you have had the vaccine in the past three weeks, keep an eye on your symptoms (if they arise).
- If you develop a severe headache, abdominal pain, leg pain or shortness of breath:
  - contact your health care provider urgently
  - tell them you have been vaccinated
  - ask them to call the Sisonke help desk on 0800 014 956

Are these issues happening because the vaccine research was rushed?

All the correct safety processes were in place and adhered to.

- SAHPRA does not authorise vaccines that do not meet South Africa's high safety standards.

www.africanalliance.org

African Alliance

#VaxFacts