The Janssen (Johnson and Johnson) Covid-19 Vaccine



What is Covid-19?

Covid-19 stands for Coronavirus Disease 2019. Coronaviruses are a causation of colds and flu. Scientists say they have identified a new strain of coronavirus and named it after the year it was discovered, 2019, hence the abbreviated Covid-19.

Covid-19 is a respiratory virus that can cause the following symptoms:

A high temperature

A new, continuous cough (three or more coughing episodes in 24 hours or coughing continuously for more than one hour)

Loss or alteration to your sense of smell or taste.

The majority of people who contract Covid-19 will have a mild or moderate illness that requires no treatment.

Those over the age of 70 and with pre-existing conditions such as diabetes, cancer or respiratory disorders are more likely to experience severe effects from coronavirus. One in five over 80 year old's will require hospital treatment and the death rate of coronavirus in that age range is 0.66%.

The Vaccine

The Janssen Johnson and Johnson vaccine is a DNA vaccine. It contains DNA from a genetically engineered human adenovirus that has been <u>cultured on aborted foetal tissue</u>. A gene for the coronavirus spike protein is attached to the human adenovirus. Once injected, the adenovirus pushes its DNA into the nucleus of the vaccinated person's cells and the coronavirus spike instructions are read by the cell and copied into a messenger molecule called RNA. The cell's molecules read these instructions and start making coronavirus spike proteins. Antibodies are then produced against them. Instead of adding the antigen into the vaccine, the person's own body produces the antigen.

An advantage to this vaccine is that DNA vaccines are more stable than mRNA ones so they don't need to be frozen. The Janssen brand of vaccine also only has to be given in one dose for the recipient to be considered 'fully vaccinated'.

However, this type of vaccine technology is brand new and has never been done before so its long-term effects are unknown. It is V.A.N UK's opinion that covid vaccinations are in fact, gene therapy, rather than vaccination. Journalist George Leon wrote in the Press and Journal newspaper that genetically engineered vaccines would 'save millions of lives' and this was the reason why people should <u>all embrace genetic engineering</u>.

Composition of the Vaccine

Adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein**(Ad26.COV2-S) not less than 8.92 log10 infectious units (Inf.U) in each 0.5 mL dose, 2-hydroxypropyl-β-cyclodextrin (HBCD),citric acid monohydrate, ethanol, hydrochloric acid, polysorbate 80, sodium chloride, sodium hydroxide, trisodium citrate dihydrate, water for injections.

Produced in the PER.C6 TetR Cell Line and by recombinant DNA technology.

This product contains genetically modified organisms (GMOs).

The PER.C6 cell line was derived from the <u>eye tissue of an 18 week old fetus that was aborted in 1985.</u> This cell line is being used in the production of adenoviruses and various vaccines and gene therapy as well as human IgG.

Safety and Efficacy Trials

In initial safety and efficacy trials of the Janssen vaccine, the jab was shown to be <u>66.3% effective</u> at preventing laboratory confirmed Covid-19 infection in people with no evidence of being previously infected.

No one who was vaccinated and got Covid had to go to hospital with the infection in the four weeks after they were vaccinated.

However, the <u>European Medicines Agency</u> says that the jab only reduces symptoms in Covid-19 cases and that the jab reduced symptomatic Covid cases by 67% from two weeks after the injection. (There were 116 symptomatic covid cases out of 19,630 vaccinated people).

Long term follow up has not yet been completed as the vaccine is still in trials. The manufacturer state they want to follow up trial participants for a period of two years. They point out that the <u>Janssen vaccine has not been approved or licenced</u> and that it is only being given out through emergency use authorisation and that 'The emergency use of this product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the medical product'.

It is VAN UK's opinion that this is one of the reasons for continuing lockdowns, testing and other measures. Without a continuing state of emergency, it would be illegal for world governments to conduct Covid-19 vaccination programmes since they are experimental.

It is not yet known if any of the Covid-19 vaccines will reduce transmission or if vaccinated people can still carry and spread the virus.

It is not known how long the vaccine protects against Coronavirus.

Safety Concerns

The Janssen vaccine rollout was temporarily paused in the United States due to the potential for blood clots after the vaccine. The side-effect, thrombosis with thrombocyopenia (TTS - blood clots and low platelets) is serious and affects mainly women under the age of 50. The CDC says that there is a <u>plausible causal link</u> between the Janssen vaccine and TTS. They suggest that women under this age range who want to be vaccinated should pick a different brand of the vaccine.

The risk of TTS is increased in the first one to two weeks after vaccination. They estimate that the risk for vaccinated women aged 18-49 is 7 per one million. However, less than 1% of all vaccine adverse reactions are reported to VAERS as well as only 1-13% of all serious adverse drug reactions in general so the actual number of people getting blood clots after covid-19 vaccinations is probably much higher.

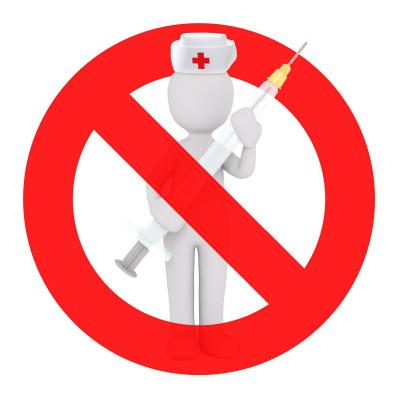
Prior Animal Studies and Their Implications for Human Trials

Scientists have been trying to develop coronavirus vaccines for decades but prior tests on animals meant they would be unsafe to extend to humans. When vaccines including those based on DNA were given to mice and ferrets, they developed antibodies but had auto-immune lung disease when challenged. Since the 1960's, it has been known that vaccinated animals can have antibody dependent enhancement of disease. That is, after being vaccinated they initially respond with high antibodies thought to correlate with immunity, but on being exposed to the wild virus, instead of being immune they develop a severe form of the illness. When cats were injected with a vaccine with the feline infectious peritonitis spike protein, using the same technology as the covid-19 mRNA vaccines, they died earlier than the unvaccinated animals when challenged with infectious peritonitis.

RSV is a similar respiratory virus to coronavirus. When a RSV vaccine was attempted in people without proper testing in 1965, the recipients produced antibodies and appeared well at first, but when they later came into contact with RSV, instead of being protected they contracted an enhanced version of the disease. Of the 20 babies who received the vaccine, 16 required hospitalisation, including two who died. Only one of the 21 babies who received the placebo was hospitalised (placebos are usually other vaccines) and no one died. Research into the vaccine was halted by the FDA in America.

Now specialists have warned that participants in covid-19 vaccine trials could not have given informed consent because they were not told that vaccines could worsen disease upon natural exposure. They wrote:

'The specific and <u>significant COVID-19 risk of ADE</u> should have been and should be prominently disclosed to research subjects currently in vaccine trials....in order to meet the medical ethics standard of patient comprehension for informed consent.'



Side-Effects

<u>Very common side-effects</u> (experienced by more than one in 10 people) are: headache, nausea, muscle aches, injection site pain and feeling very tired.

Common side-effects (experienced by up to one in 10 people) are: redness and swelling at the injection site, chills, joint pain, cough and fever.

Uncommon side-effects (experienced by up to one in 100 people) are: rash, muscle weakness, arm or leg pain, feeling weak or generally unwell, sneezing, sore throat, back pain, tremor and excessive sweating.

Rare side-effects (experienced by up to one in 1,000 people) are: allergic reactions and hives.

Very Rare side-effects (experienced by up to one in 10,000 people) are: Blood clots with low platelets. Blood clots can be in unusual places such as the brain, liver, bowel and spleen. These cases have occurred within three weeks of vaccination and occurred mostly in women under the age of 60. Fatal outcomes have occurred. This group is not at risk from covid-19 unless they have pre-existing conditions.

Data on how many serious side-effects and deaths have occurred after the Janssen vaccine is unknown and the Yellow Card Reporting System have not published data on this brand.

Menstrual Changes after Covid-19 Vaccinations

There have been reports in the general population of menstrual changes after the receipt of covid-19 vaccinations. After Dr Kate Clancy, a medical anthropologist, had a moderna vaccine she had a very heavy menstrual cycle and on mentioning it on social media, had a slew of responses from other women, stating they too had had either heavy, late or missed periods after the jab. Some women have reported the return of their periods after menopause. Due to the response, Dr Clancy started a survey on menstrual changes, which can be <u>found here</u>.

Dr Victoria Male, a Reproductive Immunologist from Imperial College London, suspects that these changes are caused by the vaccine, due to people bleeding after menopause or after taking drugs which normally stop menstruation. This could be occurring because the uterine lining contains immune cells that are normally instrumental in the formation, maintenance and the breaking down of the lining. The immune response triggered by the vaccine could cause early or abnormal bleeding, according to Dr Male.

Mainstream news sources like <u>the BBC</u> say there is no evidence that the vaccine causes miscarriage. However, pregnant women were excluded from the trials. Pfizer began <u>testing theirs on pregnant women</u> in February 2021 and tests will not be

concluded until 2023 so it is far too early to say whether Covid-19 vaccines cause a risk to fertility.

Interestingly, unvaccinated women who have been in close proximity to vaccinated people have also reported changes in their menstrual cycles. It is unclear why this might be. Pfizer are considering whether their brand of vaccine can 'shed' or transmit. In the 'exposure during pregnancy' section of their trial information, they wrote that exposure during pregnancy (EDP) occurs if:

'A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception'

And:

'A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure.'

If shedding cannot happen with mRNA/DNA vaccines, what is 'environmental exposure?' Pfizer clarify further:

'A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact.'

And:

'A male family member or healthcare provider who has been exposed to the study intervention by inhalation or skin contact then exposes his female partner prior to or around the time of conception.'

They are at least considering that their mRNA vaccine may be transmittable by breath or skin contact if they think that a vaccinated man could expose his unvaccinated partner to the vaccine. In fact, genetic engineering of vaccines such as Covid-19 vaccines have created shots that are more transmittable than traditional kinds. This is an effect that researchers find desirable to increase herd immunity and possibly to get around vaccine refusal.

Researchers published in Trends in Microbiology, wrote:

'Regardless of the transmission capacity of contemporary vaccines, genome engineering has expanded the capacity to create new vaccines far more prone to transmission 1, 3, 7, 8, 9. In some wildlife applications, transmission is even a goal...The technology of genome engineering has advanced by leaps, enabling many new transmissible vaccine designs.'

This may be why Pfizer are concerned about inadvertent exposure by inhalation or skin contact and it may provide an explanation for the anecdotal reports of menstrual change in unvaccinated women.

The medical and legal requirement for informed consent was barely given a mention in the Trends in Microbiology paper, which contains only one sentence regarding 'possible social objections to human vaccine transmission.' If the new generation of mRNA/DNA vaccines are to be transmittable then no thought has been given to the issue of contraindications either. What would happen if a contraindicated person (for example, through previous allergic reaction) were to receive the vaccine through transmission? Deaths and injuries will undoubtedly occur in an unconsenting population. The issue is far more than just a social one.

Contraindications and Warnings

The only absolute contraindication listed is an allergy to any of the ingredients or excipients.

The vaccination should be postponed in people suffering severe febrile illness or acute illness.

Individuals with a history of thrombocytopenia or thrombosis induced by heparin (HITT or HIT type 2) should only receive the Janssen vaccine if the potential benefits outweigh the risks.

Those vaccinated should seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg pain, leg swelling or persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches, seizures, mental status changes, blurred vision or who

experiences skin bruising (petechia) beyond the site of vaccination after a few days should seek prompt medical attention.

Individuals diagnosed with thrombocytopenia within 3 weeks of vaccination should be actively investigated for thrombosis. Similarly, individuals who present with thrombosis within 3 weeks of vaccination should be investigated for thrombocytopenia.

Those taking anti-coagulants or with a coagulation disorder are at increased risk of bleeding after intramuscular injections.

Immunocompromised People

The safety, efficacy and immunogenicity of the vaccine have not been evaluated in immuno-compromised people, including those on immuno-suppressive therapy.

Interaction with other Medicinal Products

No interaction studies have been performed on the Janssen vaccine. This includes on its administration with other vaccines. There is no science at all on the UK government's 'mix and match' approach, in which they have encouraged UK citizen's to get a different brand of vaccine for their second dose than the one they received as a first.

Fertility, Pregnancy and Lactation

Janssen vaccine has not been tested on pregnant women. Initial studies on rabbits don't show any fertility or pregnancy related issues.

Administration of the vaccine in pregnancy should only be considered where the benefits outweigh the risks to the mother and unborn baby.

It is **not known** if the vaccine is excreted in human milk.

Carcinogenicity and Genotoxicity

The vaccine has <u>not been studied for its ability to mutate cells or cause cancer</u> because 'the components of the vaccine are not expected to cause cancer.'

Pediatric Population

The full manufacturer's data sheet has a rather curious statement on the use of the vaccine in children. They write:

'The licencing authority has deferred the obligation to submit the results of studies with Covid-19 vaccine Janssen in one or more subsets of the pediatric population in the prevention of Covid-19.'

This sounds as if they have information but are not willing to release it to the public even though an under 18's vaccination campaign is set to begin in the UK in September 2021.

Duration of Protection

The duration of protection afforded by the vaccine is unknown and is still being determined by ongoing clinical trials.

Effects on Ability to Drive and Use Machines

Some of the side-effects associated with Janssen vaccine may temporarily affect the ability to drive or use machines.

Is the Covid-19 Vaccine Mandatory?

The British Prime Minister, Boris Johnson, has said that like other vaccinations, the covid-19 vaccine will be entirely voluntary. On 2nd December 2020, he said, <u>"There is no part of our culture or our ambition in this country to make vaccines mandatory."</u> He did, however, say that he strongly urged people to take it.

It is also voluntary for healthcare workers and places of employment have no legal basis with which to force vaccination on their workers. They might do so as part of their private health and safety policy, although doing so would leave them open to discrimination and unfair dismissal claims if it is related to a protected characteristic under UK law. For example, if a worker refuses the vaccine on the basis of a health condition or pregnancy. Mandatory vaccination in the workplace could also infringe a

worker's right to privacy under the Human Rights Act 1998, particularly when less invasive health and safety measures are available.

No medical procedure can be carried out without consent on a person who has the capacity to give consent and in respect of trial medications the voluntary consent of the subject is essential. If vaccines are coerced then the vaccine provider is acting illegally.

The government is, however, planning the introduction of 'vaccine passports' or 'green certificates' which would require people to prove they have had a Covid-19 vaccination, This is set to begin in September 2021. They deny that this is mandating vaccination, stating that a person who doesn't wish to be vaccinated can have a test instead, however, after banning unvaccinated people from nightclubs they have since back-tracked and said that natural immunity or a negative test will not be good enough and that only double jabbed people will be allowed entry.

This has been described as a medical aparteid and will undoubtedly <u>cause</u> <u>discrimination and hate crime</u> if it is introduced. It is difficult to see how such a scheme would work when it isn't yet known if vaccinated people can still transmit the virus and vaccinated people can still test positive. Lawsuits would likely emerge to overturn such legislation, which is illegal as it breaks informed consent laws.

Exemptions to the NHS Covid Pass

The government has also failed to publicise the fact that there is a medical exemption for health conditions, learning difficulties and people with disabilities. The medical exemption only needs to be self-declared. No doctor's letter is required just as with mask exemptions and establishments cannot legally ask the nature of the exemption without risking an equality lawsuit.

The government says this about exemptions to the NHS Covid Pass:

'If you have a medical reason which means you cannot be vaccinated or tested, you may be asked to self-declare this medical exemption.'

The NHS goes further to explain exemptions. They write:

'There will also be a small number of exemptions for individuals who have a medical reason which means they cannot vaccinate or test. These individuals will need to self-declare their medical exemption directly with you.

Please be mindful and respectful where there are potentially circumstances where a customer or individual cannot safely demonstrate their COVID-19 status by taking a vaccination or a test. This could include people:

- with learning disabilities or autistic individuals, or with a combination of impairments which result in the same distress.
- those suffering from or under medical supervision for acute or evolving serious diseases or those receiving palliative care or undergoing treatment with unpleasant side effects.

Event or venue organisers in England that choose to use the NHS COVID Pass as a condition of entry can decide whether to accept self-declared medical exemptions where an individual cannot vaccinate or test, ensuring they comply with the <u>Equalities</u> Act 2010.

Your customers may declare a medical exemption directly with you. You and your staff should not ask for evidence of the exemption.

If businesses decide to require evidence of Covid-19 status as a condition of entry, they should ensure that they comply with all the relevant legal obligations (for example, the Equalities Act 2010) and guidance that applies.

(Below: A photo showing 'vaccine passport' signage outside a foreign library, where the unvaccinated are being made to wait outside for their books).



Report an Adverse Event: If you or a loved one have had this vaccine and experienced side-effects, you can report them via the UK's Yellow Card Reporting System at https://coronavirus-yellowcard.mhra.gov.uk/

References

Symptoms of Coronavirus, NHS, page accessed 31/07/21.

Coronavirus, World Health Organization, page accessed 31/07/21.

Covid-19: One in five over 80's need hospitalisation and death rate is 0.66%, Imperial College London (31st March 2020), page accessed 31/07/21.

How the Johnson and Johnson Covid-19 Vaccine Works, Nebraska Medicine (12th April 2021), page accessed 31/07/21.

Patient Information Leaflet for Covid-19 Vaccine Janssen, Gov.uk, page accessed 31/07/21.

George Leon: Covid Vaccine Highlights Need to Accept Genetic Engineering, The Press and Journal (2nd January 2021), page accessed 31/07/21.

PER.C6 Cell Lines, GMP Creative Biolabs, page accessed 31/7/21.

Johnson and Johnson's Janssen Covid-19 Vaccine Overview and Safety, CDC, page accessed 31/07/21.

Clinical Data for Johnson and Johnson's Janssen Covid-19 Vaccine, Janssen, page accessed 31/07/21.

Covid-19 Vaccine Janssen, European Medicines Agency, page accessed 01/08/21.

Electronic Support for Public Health - Vaccine Adverse Event Reporting System (ESP: VAERS), Harvard Pilgrim Healthcare, Inc, page accessed 01/08/21.

PLoS One. 2012; 7(4): e35421.

Nature Reviews Microbiology, 19, pages 211–219 (2021).

Int J Clin Pract, 2021 Mar;75(3):e13795. doi: 10.1111/ijcp.13795. Epub 2020 Dec 4.

Patient Information Leaflet for Covid-19 Vaccine Janssen (updated 23 June 2021), Gov.uk, page accessed 10/08/21.

Menstrual Experiences with Covid-19 Vaccines, Research Consent Form, University of Illinois, USA, page accessed 10/08/21.

Covid Vaccine: Period Changes Could be a Short-Term Side Effect, BBC News (13 May 2021), page accessed 10/08/21.

Pfizer Starts Covid Vaccine Trials in Pregnant Women, WebMD (22 February 2021), page accessed 10/08/21.

A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS, Pfizer, page accessed 10/08/21.

Trends in Microbiology, Volume 26, Issue 1, January 2018, Pages 6-15, https://doi.org/10.1016/j.tim.2017.09.007

Covid-19 Vaccine Janssen Suspension for Injection, Data Sheet for Health Professionals, Electronic Medicines Compendium (EMC), page accessed 15/08/21.

England Health Officials Defend Contingency Plan to Mix Covid Vaccines, The Guardian, (2nd January 2021), accessed 15/08/2021.

Covid-19: Proof of Full Vaccination Condition of Entry to Nightclubs From September, Sky News (11th August 2021), page accessed 15/08/21.

NHS Covid Pass, Gov.uk, page accessed 15/08/21.

Using the NHS Covid Pass, NHS.UK, page accessed 15/08/21.