



# GUIDE TO MAKING AN EXPLICIT INFORMED CHOICE TO GET THE JANSSEN VACCINE

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### 1.1. Vaccination not compulsory, but no free choice of vaccine

Everyone is free to get vaccinated against COVID-19, according to the principle of informed choice. This means that you will be given all the necessary information about the advantages and disadvantages of your choice, as provided for in the Patients' Rights Act. However, you cannot choose your vaccine freely, as the number of vaccines is still limited for the time being. Vaccines are therefore allocated to certain age or risk groups in a certain order, according to the benefits and risks of the vaccine.

### 1.2. 40-year-olds and those who are younger can make an informed choice for the Janssen vaccine

The Janssen vaccine is one of four COVID-19 vaccines currently licensed in the European Union. It is approved for people aged 18 and over and is the only vaccine that requires just one injection.

Our country was expecting a delivery of 1.4 million Janssen vaccines in the period April to June. These numbers have since been reduced, but the vaccine still plays a very important role in the Belgian vaccination campaign.

On 26 May, it was decided to temporarily impose an age limit on the Janssen vaccine. It was decided that it would no longer be given to Belgian residents under 41 years of age. The reason was the death of a young foreign woman in a Belgian hospital. After her vaccination, she developed severe but very rare blood clots, combined with a reduced platelet count (thrombosis with thrombocytopenia syndrome, abbreviated as TTS).

This age limit, along with later and reduced deliveries, threatens to delay the vaccination campaign for younger populations. On 9 June 2021, it was therefore decided that people aged 18 to 40 could voluntarily opt for the Janssen vaccine on the basis of an explicit informed choice. If you do not choose a Janssen vaccine, you are still eligible for a Pfizer or Moderna vaccine.

### 1.3. How do you make this explicit informed choice for the Janssen vaccine?

Are you under 41 years of age and interested in being vaccinated with the Janssen vaccine?

- read this information about the advantages and disadvantages of the vaccine
- if you need any additional explanation, the doctor at the vaccination centre can help you
- then sign the statement of informed consent for the Janssen vaccine

## 1.4. Do the health benefits of the Janssen vaccine outweigh the risks?

### 1.4.1. *Health benefits*

After about 4 weeks, the Janssen vaccine gives you 85% to 100% protection against hospitalisation, admission to intensive care and death due to COVID-19. One shot is enough to be fully protected.

### 1.4.2. *Risk of serious side effects*

As with other vaccinations, some mild side effects are possible after vaccination with the Janssen vaccine. These disappear by themselves within 48 hours. They include pain, redness, muscle stiffness at the injection site, and in some cases some fever, fatigue, headache and nausea.

Serious side effects can also occur, such as, in very rare cases, blood clots in combination with a low platelet count (TTS). It is estimated that this serious side effect occurs in an average of 1 in 100,000 vaccinated people. This leads to death in approximately 1 in 1 million vaccinated people. Other very rare side effects are also being studied by the Belgian and European Medicines Agency (EMA).

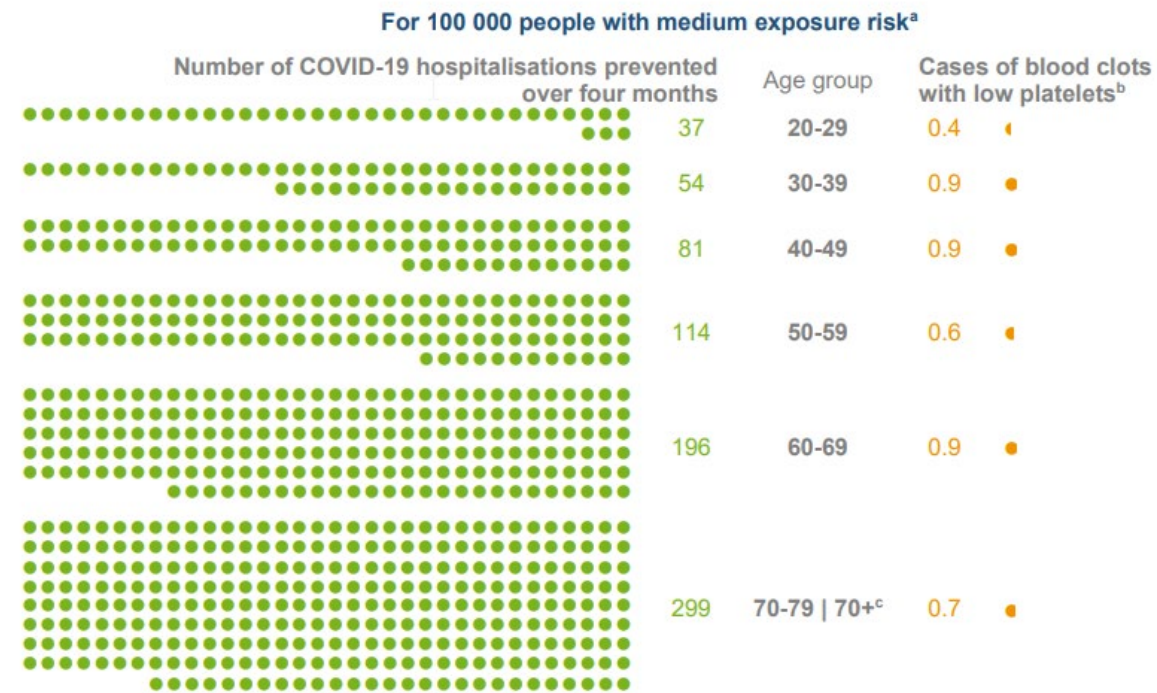
### 1.4.3. *Balancing the health benefits against the risk of serious side effects*

In an analysis, the Belgian Health Care Knowledge Centre (KCE) and the Federal Agency for Medicines and Health Products (FAMHP) weighed up the potential benefits of the Janssen vaccine against the risk of this TTS per age group (risk/benefit analysis) and for three infection levels in our country: high, medium and low. Currently (June 2021) we are at an average level of infection. There is insufficient data available to differentiate between men and women.

In general, the benefits of Janssen vaccination increase with age, but there are differences between age groups. We are looking here at people in their twenties and thirties, who now have the choice of being vaccinated with the Janssen vaccine. Data is only available from the age of 20, but we can assume that it also applies to 18- and 19-year-olds.

a) Avoiding hospitalisation due to COVID-19

Figure 1 – Risk/benefit analysis of Janssen vaccine – prevented hospital admissions at average infection level



<sup>a</sup> COVID-19 incidence of 401 per 100 000 people per month (EU March 2021).

<sup>b</sup> Increased with 20% to attenuate possible underreporting (see method section for details).

<sup>c</sup> Cases of blood clots with low platelets data are available aggregated for 70+, while the EMA data are available for 70-79 and 80+. We conservatively chose to compare with the 70-79 age group as the benefits for 80+ are higher (see method section for details).

**Twenty-somethings (including 18- and 19-year-olds)**

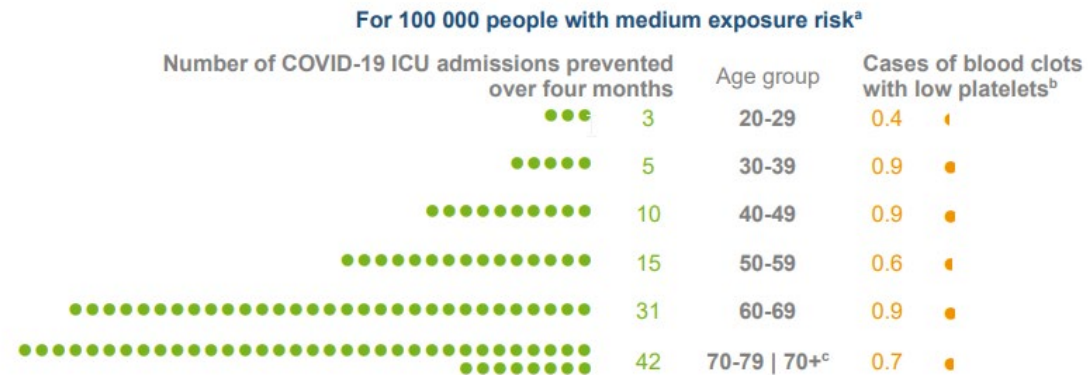
In 100,000 vaccinated people in their twenties, less than 1 person (0.4) may develop TTS. In the same group, vaccination may prevent 37 hospital admissions due to COVID-19.

**Thirty-somethings**

In 100,000 vaccinated people in their thirties, less than 1 person (0.9) may develop TTS. In the same group, vaccination may prevent 54 hospital admissions due to COVID-19.

**b) Avoiding admission to intensive care units due to COVID-19**

**Figure 2 – Risk/benefit analysis of Janssen vaccine – prevented intensive care admissions at average infection level**



<sup>a</sup> COVID-19 incidence of 401 per 100 000 people per month (EU March 2021).

<sup>b</sup> Increased with 20% to attenuate possible underreporting (see method section for details).

<sup>c</sup> Cases of blood clots with low platelets data are available aggregated for 70+, while the EMA data are available for 70-79 and 80+. We conservatively chose to compare with the 70-79 age group as the benefits for 80+ are higher (see method section for details).

**Twenty-somethings (including 18- and 19-year-olds)**

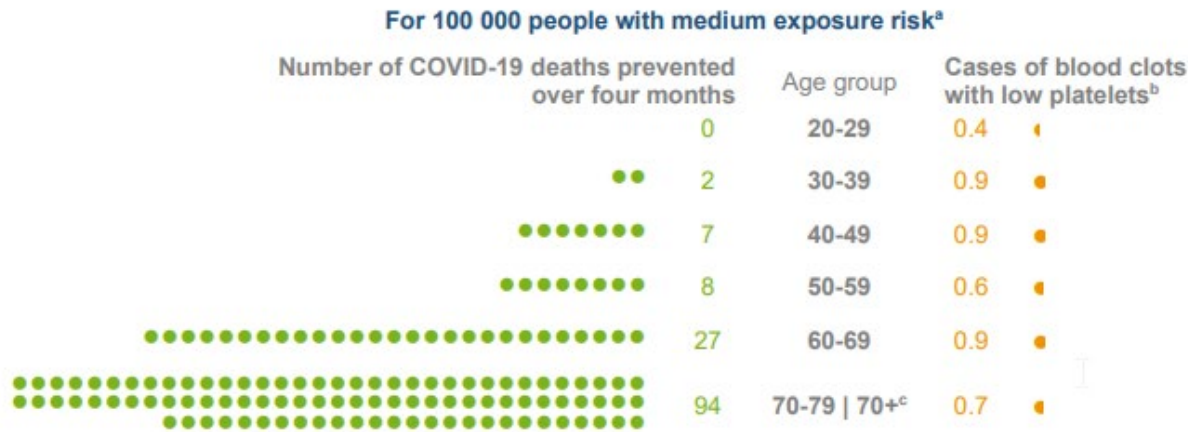
In 100,000 vaccinated people in their twenties, less than 1 person (0.4) may develop TTS. In the same group, vaccination may prevent 3 intensive care admissions due to COVID-19.

**Thirty-somethings**

In 100,000 vaccinated people in their thirties, less than 1 person (0.9) may develop TTS. In the same group, vaccination may prevent 5 intensive care admissions due to severe COVID-19.

**c) Avoidance of death due to COVID-19**

**Figure 3 – Risk/benefit analysis of Janssen vaccine – prevented deaths at average infection level**



<sup>a</sup> COVID-19 incidence of 401 per 100 000 people per month (EU March 2021).

<sup>b</sup> Increased with 20% to attenuate possible underreporting (see method section for details).

<sup>c</sup> Cases of blood clots with low platelets data are available aggregated for 70+, while the EMA data are available for 70-79 and 80+. We conservatively chose to compare with the 70-79 age group as the benefits for 80+ are higher (see method section for details).

**Twenty-somethings (including 18- and 19-year-olds)**

In 100,000 vaccinated people in their twenties, less than 1 person (0.4) may develop TTS. In the same group, vaccination does not prevent deaths due to COVID-19.

**Thirty-somethings**

In 100,000 vaccinated people in their thirties, less than 1 person (0.9) may develop TTS. In the same group, vaccination may prevent two deaths due to COVID-19.



### 1.5. In short

This paper provides information on the potential health benefits (avoidance of hospitalisation and admission to intensive care and death due to COVID-19) and the risks of TTS after vaccination. This should help in making an individual choice for vaccination with the Janssen vaccine.

Only the individual health benefits of the vaccine were taken into account. The collective benefits of vaccination in general, i.e. achieving higher vaccination coverage and ultimately group immunity, were not included. After all, the more people are vaccinated, the more the further spread of the virus and its variants is stopped. Nor was any account taken of possible conditions for travelling to certain countries, for example.

### 1.6. Need more information?

More information on the Janssen vaccine: [https://www.fagg.be/nl/menselijk\\_gebruik/geneesmiddelen/geneesmiddelen/covid\\_19/vaccins/vragen\\_en\\_antwoorden\\_over\\_0](https://www.fagg.be/nl/menselijk_gebruik/geneesmiddelen/geneesmiddelen/covid_19/vaccins/vragen_en_antwoorden_over_0)

More information on corona vaccines and the vaccination campaign in our country: [www.info-coronavirus.be](http://www.info-coronavirus.be) or [www.laatjevaccineren.be](http://www.laatjevaccineren.be)

More information about the risk/benefit analysis of the KCE and the FAMHP [https://kce.fgov.be/sites/default/files/atoms/files/TTS\\_risk\\_contextualisation\\_JJ\\_report.pdf](https://kce.fgov.be/sites/default/files/atoms/files/TTS_risk_contextualisation_JJ_report.pdf)

Do you still have questions? Ask your doctor, pharmacist or doctor in the vaccination centre.