

23 April 2021 Corr¹ EMA/234525/2021 European Medicines Agency

Annex to Vaxzevria Art.5.3 - Visual risk contextualisation

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1. Introduction

To support national authorities making decisions on how to best use the vaccine in their territories, EMA's human medicines committee (CHMP) has further analysed available data to put the risks of very rare blood clots (thrombosis with thrombocytopenia syndrome, TTS) in the context of the benefits for different age groups and different rates of infection.

The analysis will inform national decisions on the roll out of the vaccine, taking into account the pandemic situation as it evolves and other factors, such as vaccine availability. The analysis could change as new data become available.

The Committee analysed the benefits and the risk of unusual blood clots with low platelets in different age groups in the context of the monthly¹ infection rate: low (55 per 100,000 people), medium (401 per 100,000 people) and high (886 per 100,000 people).

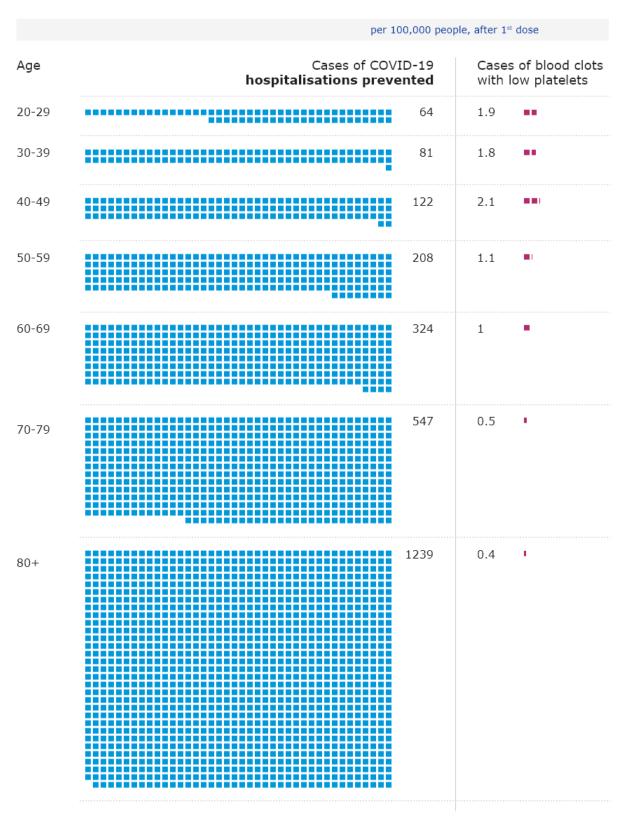
The analysis looked at prevention of hospitalisations, ICU admissions and deaths due to COVID-19, considering an 80% vaccine effectiveness over a period of four months. The details of the full analysis and methodology are available in the assessment report which will be published shortly.

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¹ Correction on page 2 to state that the infection rates were monthly and not daily rates

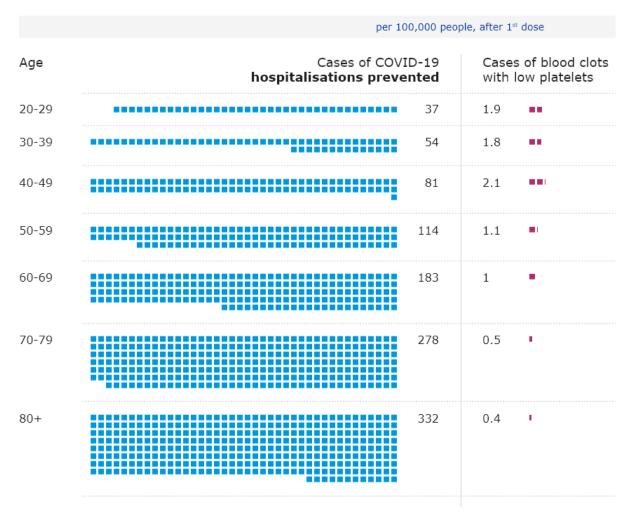
2. COVID-19 hospitalisations prevented with Vaxzevria compared with unusual blood clots with low platelets

High infection rate*



^{* &}quot;High" exposure: using virus circulation for January 2021 (incidence 886/100,000 population)

Medium infection rate*



^{* &}quot;Medium" exposure: using virus circulation for March 2021 (incidence 401/100,000 population)

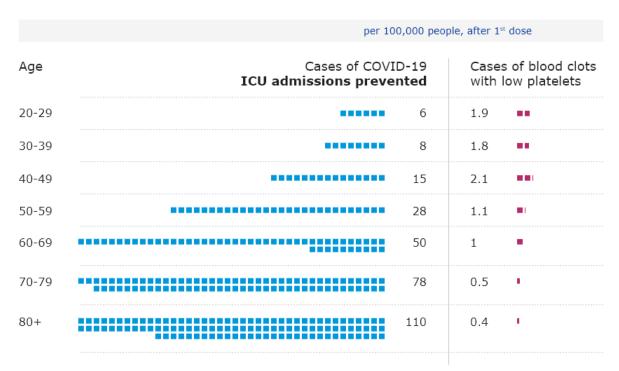
Low infection rate*

| | per 100,000 people, after 1st dose | | | |
|-------|---|-----|---|--|
| Age | Cases of COVID-19 hospitalisations prevented | | Cases of blood clots with low platelets | |
| 20-29 | 4 | 1.9 | •• | |
| 30-39 | ••••• 5 | 1.8 | •• | |
| 40-49 | 6 | 2.1 | | |
| 50-59 | 10 | 1.1 | •1 | |
| 60-69 | 19 | 1 | • | |
| 70-79 | 45 | 0.5 | 1 | |
| 80+ | 151 | 0.4 | 1 | |

^{* &}quot;Low" exposure: using virus circulation for September 2020 (incidence: 55/100,000 population)

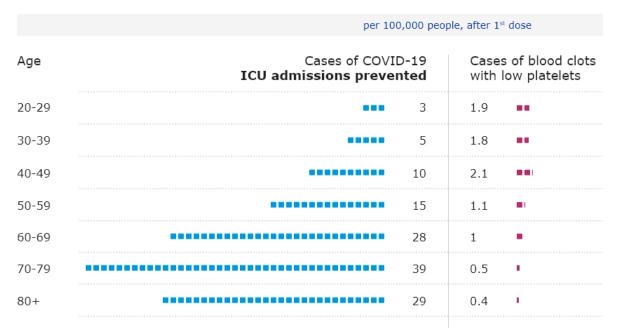
3. COVID-19 ICU admissions prevented with Vaxzevria compared with unusual blood clots with low platelets

High infection rate*



^{* &}quot;High" exposure: using virus circulation for January 2021 (incidence 886/100,000 population)

Medium infection rate*



^{* &}quot;Medium" exposure: using virus circulation for March 2021 (incidence 401/100,000 population)

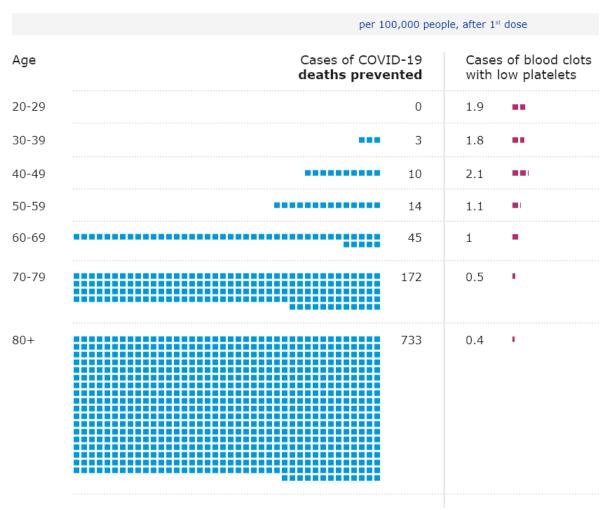
Low infection rate*

| | per 100,000 people, after 1st dose | | | | |
|-------|------------------------------------|----|--|------------|--|
| Age | Cases of COVI ICU admissions preve | | Cases of blood clots with low platelets | | |
| 20-29 | | 0 | 1.9 | •• | |
| 30-39 | | 0 | 1.8 | •• | |
| 40-49 | • | 1 | 2.1 | •• | |
| 50-59 | • | 1 | 1.1 | ■ 1 | |
| 60-69 | ••• | 3 | 1 | • | |
| 70-79 | | 6 | 0.5 | 1 | |
| 80+ | | 13 | 0.4 | 1 | |

^{* &}quot;Low" exposure: using virus circulation for September 2020 (incidence: 55/100,000 population)

4. COVID-19 deaths prevented with Vaxzevria compared with unusual blood clots with low platelets

High infection rate*



^{* &}quot;High" exposure: using virus circulation for January 2021 (incidence 886/100,000 population)

Medium infection rate*

| | per 100,000 people, after 1st dose | | | |
|-------|---|-----|--|------------|
| Age | Cases of COVID-19 deaths prevented | | Cases of blood clots with low platelets | |
| 20-29 | | 0 | 1.9 | •• |
| 30-39 | •• | 2 | 1.8 | •• |
| 40-49 | ****** | 7 | 2.1 | |
| 50-59 | ******* | 8 | 1.1 | ■ 1 |
| 60-69 | *************************************** | 25 | 1 | • |
| 70-79 | | 87 | 0.5 | 1 |
| 80+ | | 197 | 0.4 | 1 |

^{* &}quot;Medium" exposure: using virus circulation for March 2021 (incidence 401/100,000 population)

Low infection rate*

| | per 100,000 people, after 1st dose | | | |
|-------|------------------------------------|----|--|------------|
| Age | Cases of COVII deaths preve | | Cases of blood clots with low platelets | |
| 20-29 | | 0 | 1.9 | •• |
| 30-39 | | 0 | 1.8 | •• |
| 40-49 | | 1 | 2.1 | = |
| 50-59 | | 1 | 1.1 | = 1 |
| 60-69 | ••• | 3 | 1 | • |
| 70-79 | | 14 | 0.5 | • |
| 80+ | | 90 | 0.4 | 1 |

^{* &}quot;Low" exposure: using virus circulation for September 2020 (incidence: 55/100,000 population)

5. Acknowledgements

These visuals are based on <u>similar ones</u> produced by the Winton Centre for Risk and Evidence Communication. Additional risk-communication experts and healthcare professional representatives were consulted during the preparation of these visuals:

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