EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 April 2021
EMA/234525/2021
European Medicines Agency

Annex to Vaxzevria Art.5.3 - Visual risk contextualisation

Table of contents

1. Introduction 2

2. COVID-19 hospitalisations prevented with Vaxzevria compared with unusual blood clots with low platelets 3

High infection rate 3
Medium infection rate 4
Low infection rate 5

3. COVID-19 ICU admissions prevented with Vaxzevria compared with unusual blood clots with low platelets 6

High infection rate 6
Medium infection rate 7
Low infection rate 8

4. COVID-19 deaths prevented with Vaxzevria compared with unusual blood clots with low platelets 9

High infection rate 9
Medium infection rate 10
Low infection rate 11

5. Acknowledgements 12

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

© European Medicines Agency, 2021. Reproduction is authorised provided the source is acknowledged.

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.

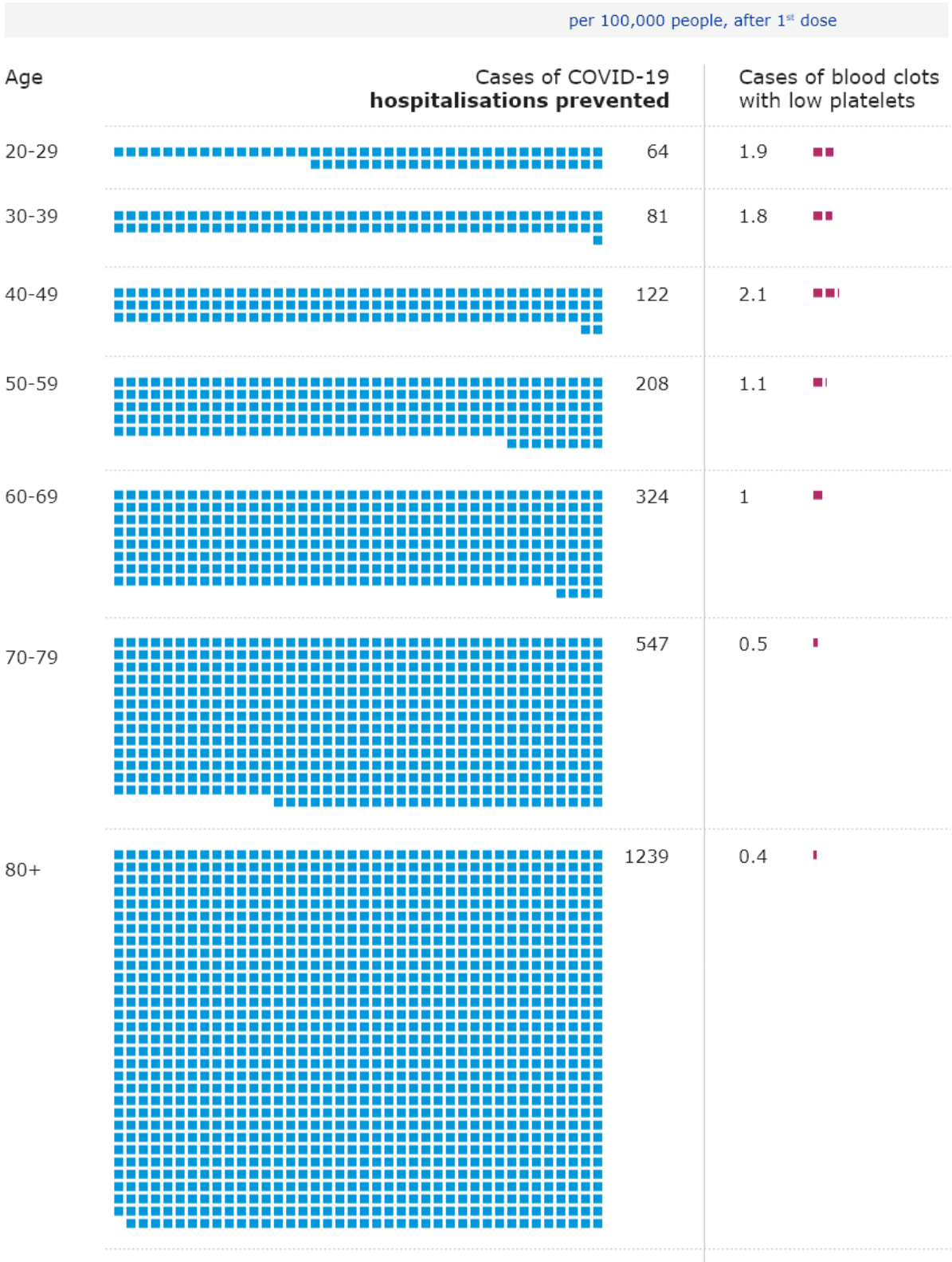
The analysis will inform national decisions on the roll out of the vaccine, taking into account the pandemic situation as it evolves and other factors, such as vaccine availability. The analysis could change as new data become available.

The Committee analysed the benefits and the risk of unusual blood clots with low platelets in different age groups in the context of the monthly 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.

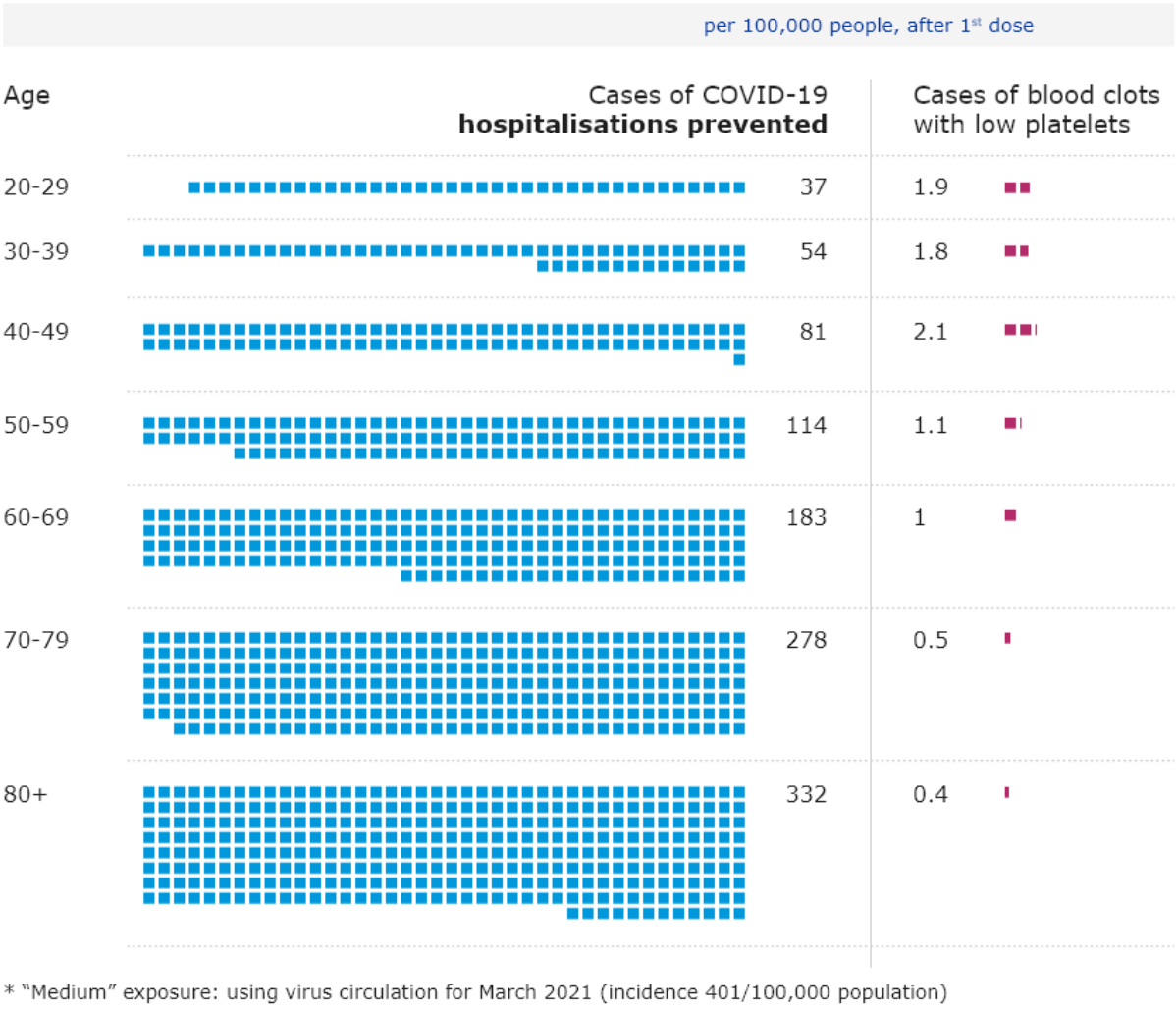
2. COVID-19 hospitalisations prevented with Vaxzevria compared with unusual blood clots with low platelets

High infection rate*



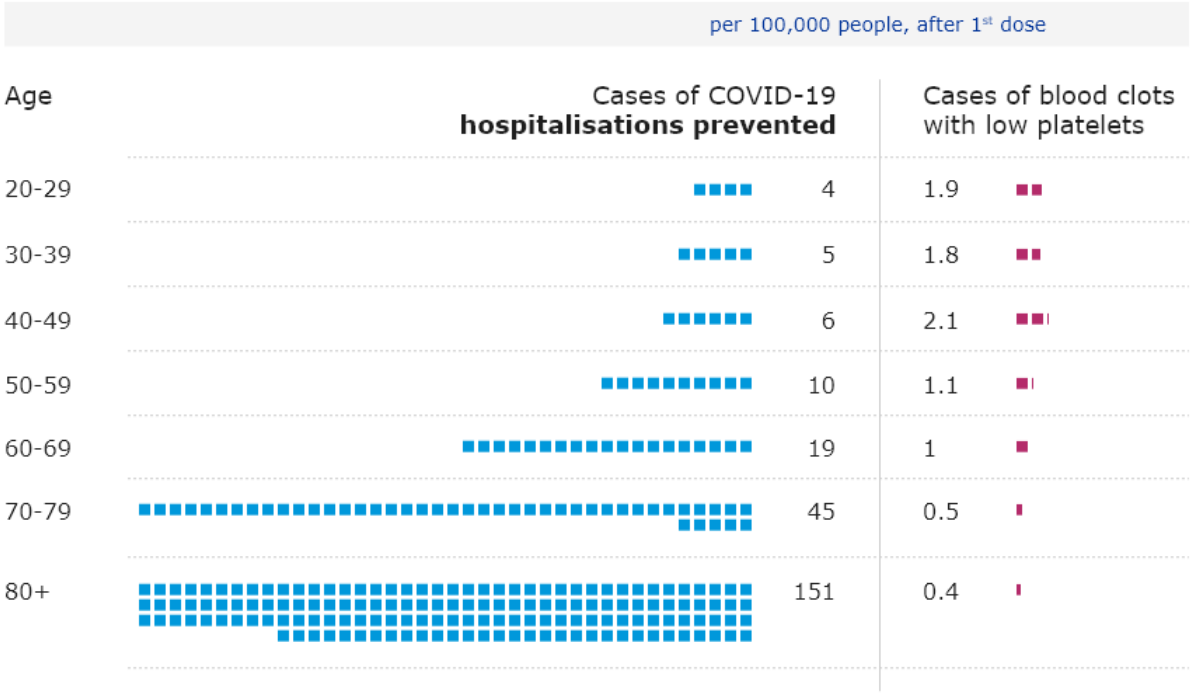
* "High" exposure: using virus circulation for January 2021 (incidence 886/100,000 population)

Medium infection rate*



* "Medium" exposure: using virus circulation for March 2021 (incidence 401/100,000 population)

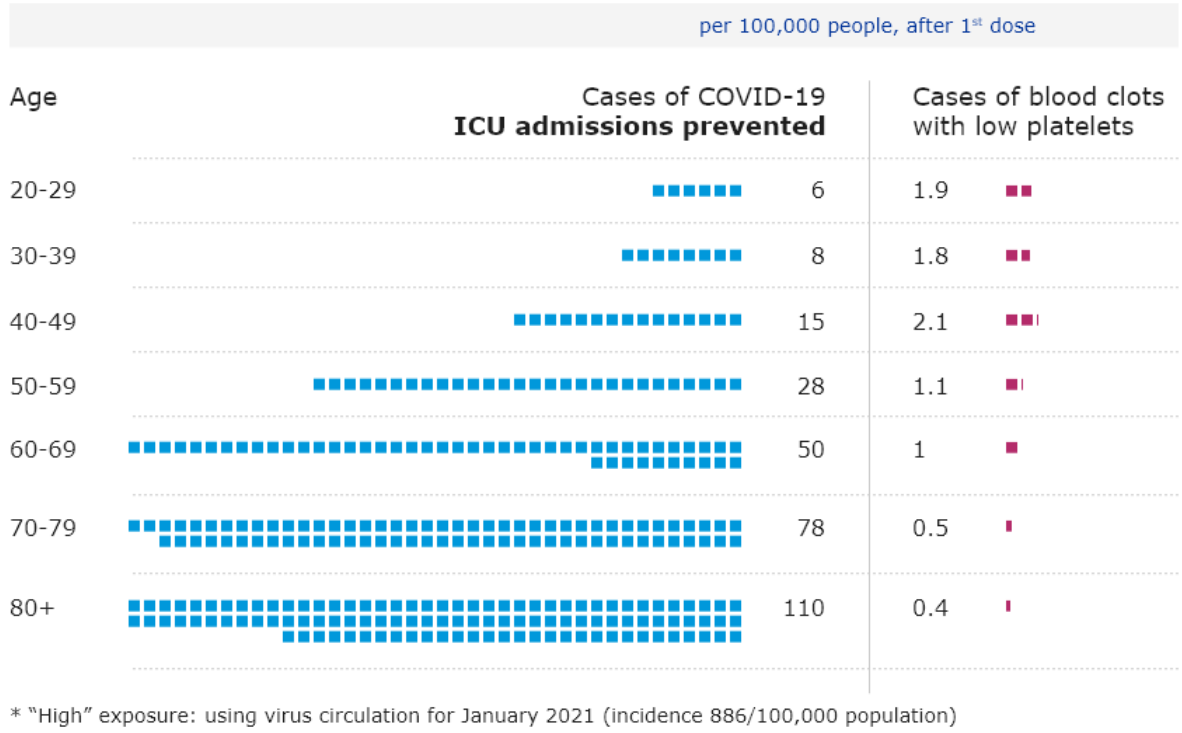
Low infection rate*



* "Low" exposure: using virus circulation for September 2020 (incidence: 55/100,000 population)

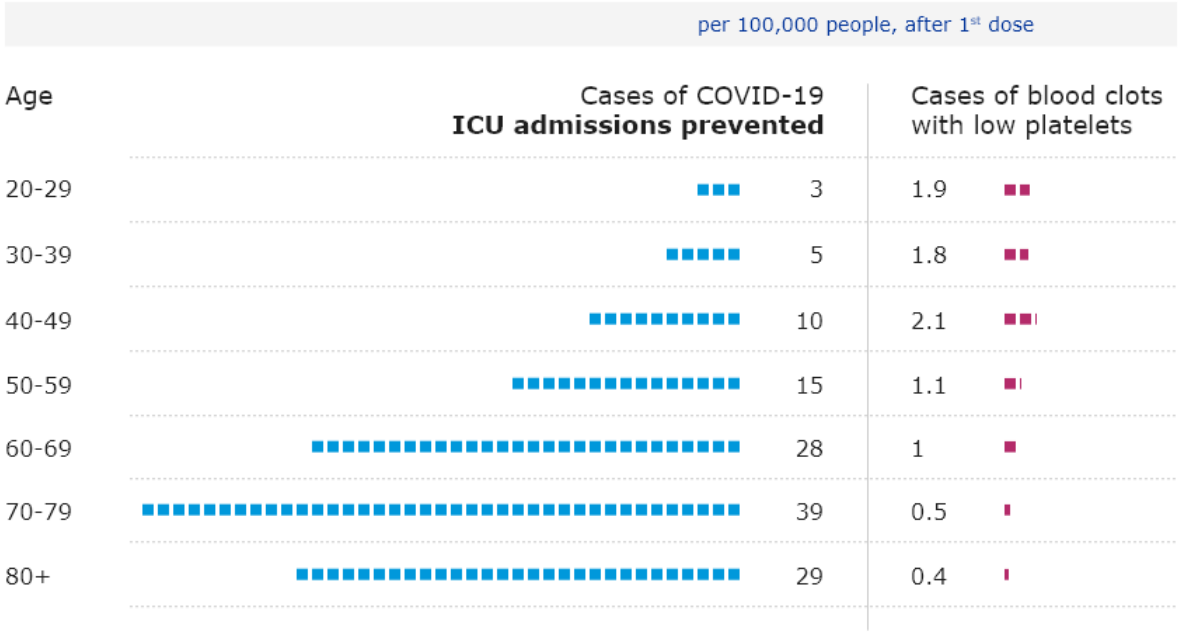
3. COVID-19 ICU admissions prevented with Vaxzevria compared with unusual blood clots with low platelets

High infection rate*



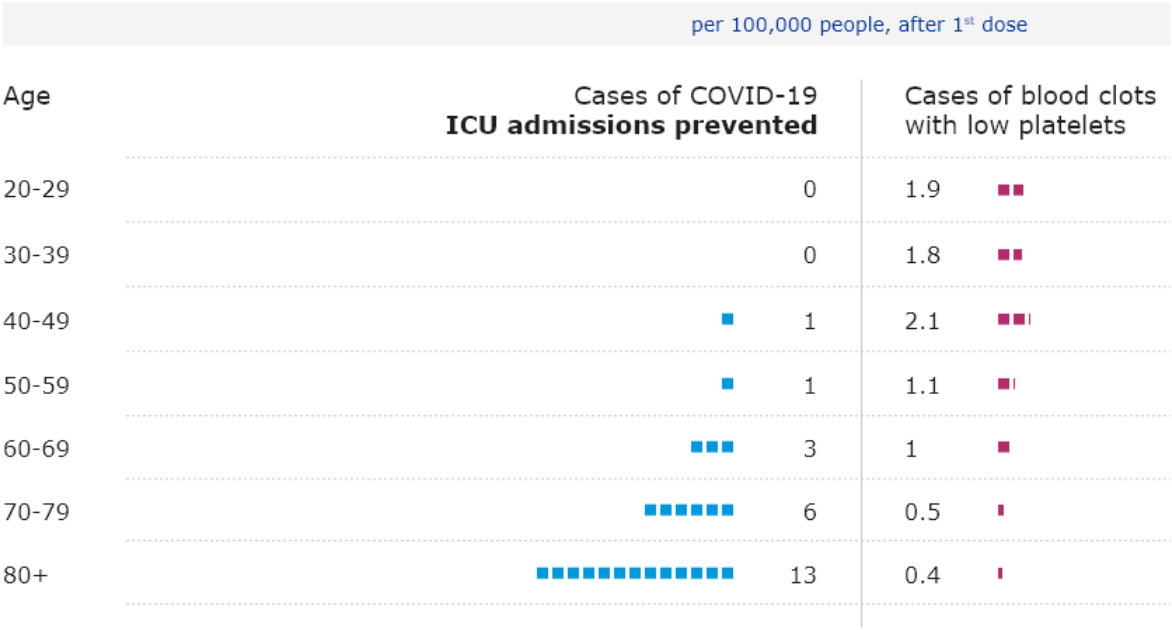
* "High" exposure: using virus circulation for January 2021 (incidence 886/100,000 population)

Medium infection rate*



* "Medium" exposure: using virus circulation for March 2021 (incidence 401/100,000 population)

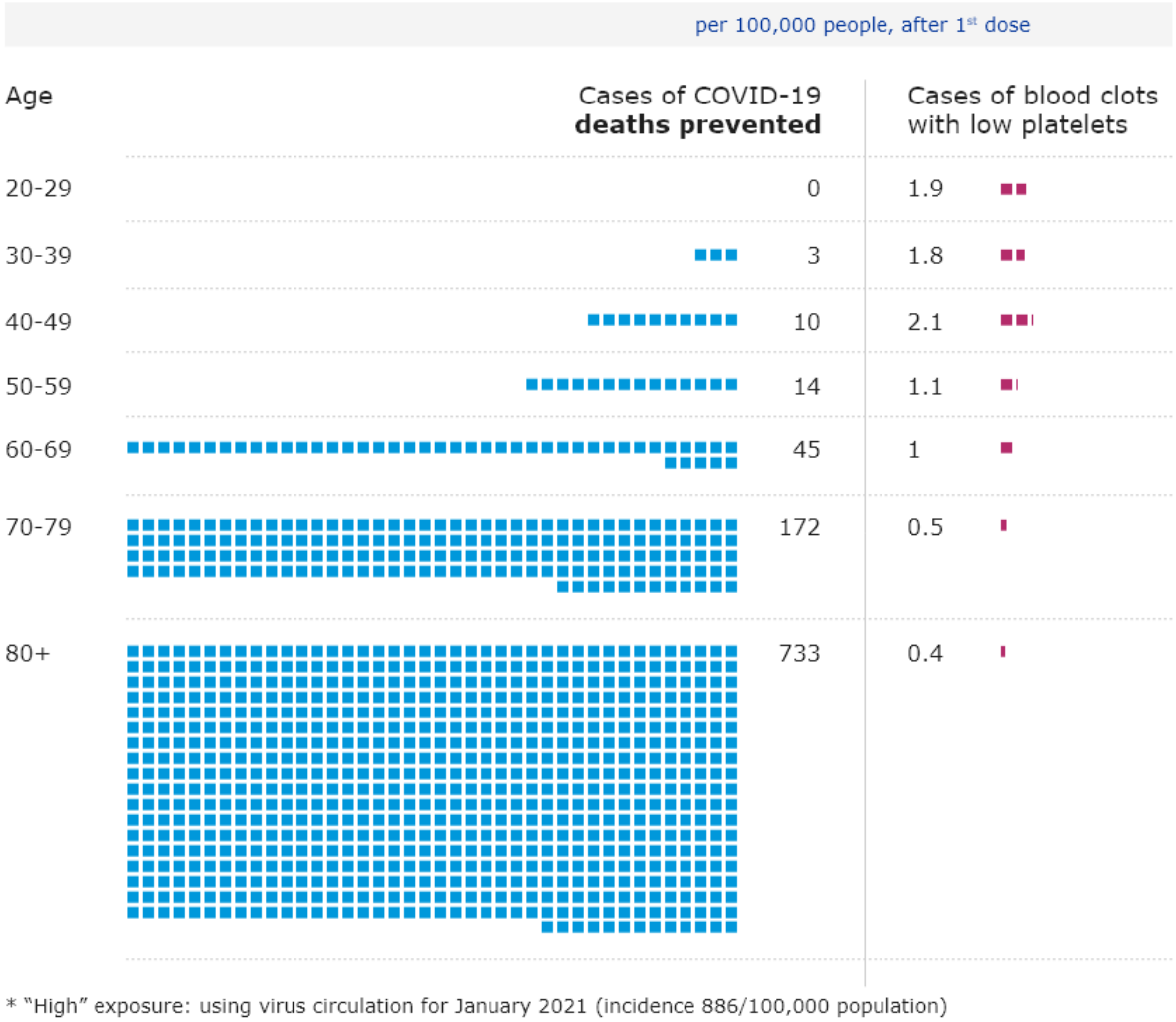
Low infection rate*



* "Low" exposure: using virus circulation for September 2020 (incidence: 55/100,000 population)

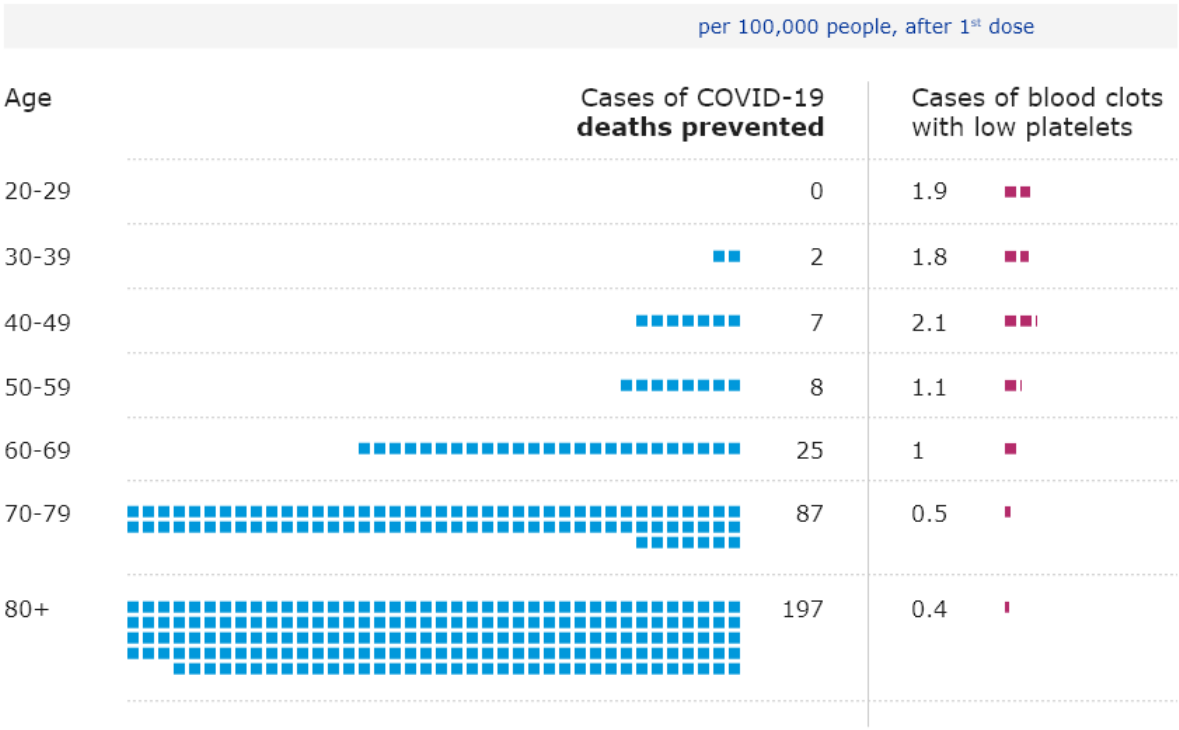
4. COVID-19 deaths prevented with Vaxzevria compared with unusual blood clots with low platelets

High infection rate*



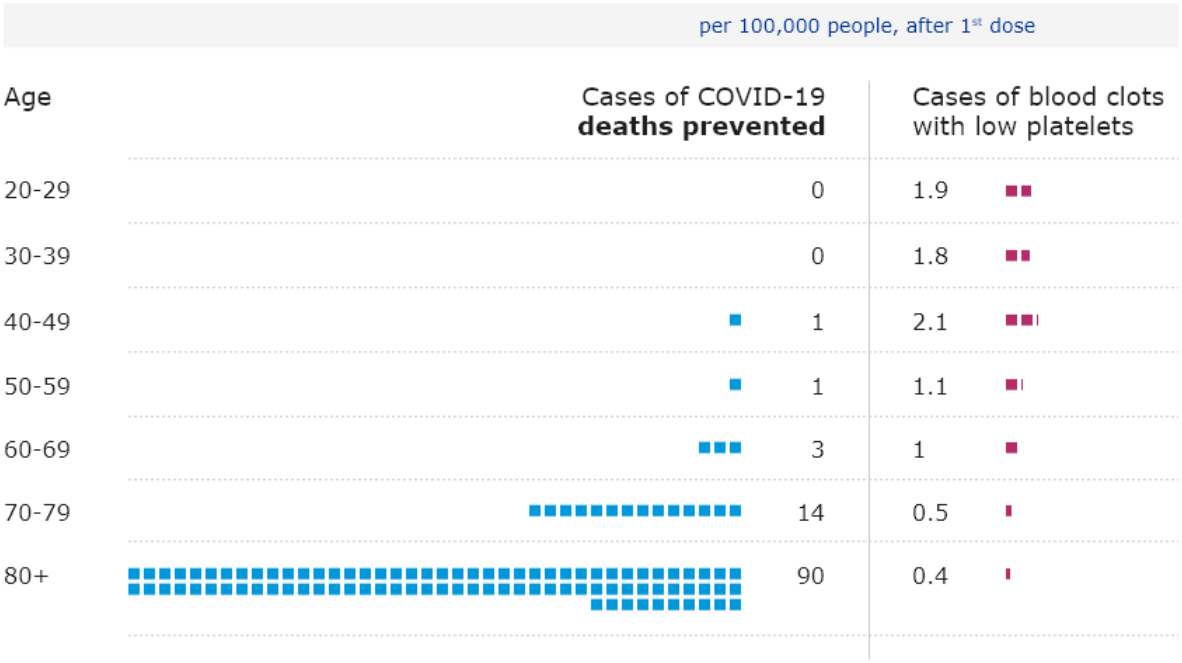
* "High" exposure: using virus circulation for January 2021 (incidence 886/100,000 population)

Medium infection rate*



* "Medium" exposure: using virus circulation for March 2021 (incidence 401/100,000 population)

Low infection rate*



* "Low" exposure: using virus circulation for September 2020 (incidence: 55/100,000 population)

5. Acknowledgements

These visuals are based on similar ones 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:

John Aston - Winton Centre for Risk and Evidence Communication, United Kingdom

Frederic Bouder - University of Stavanger, Norway

Carine Dochez – University of Antwerp, Belgium

Alexandra Freeman - Winton Centre for Risk & Evidence Communication, United Kingdom

Wolfgang Gaissmaier - University of Konstanz, Germany

Barbara Gallani - European Food Safety Authority, Italy

Heidi Larson - London School of Hygiene and Tropical Medicine, United Kingdom

Anita Simonds - European Respiratory Society (ERS)

David Spiegelhalter - Winton Centre for Risk and Evidence Communication, United Kingdom

Tiago Villanueva - European Union of General Practitioners (UEMO)