WEBINAR

COVID-19 TREATMENT AND VACCINATION FOR PWBDS

March 12, 2021

WFH
WORLD FEDERATION OF HEMOPHILIA
FÉDÉRATION MONDIALE DE L'HÉMOPHILIE
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AGENDA

1. Opening & welcoming remarks
   - Glenn Pierce, WFH VP, Medical
   - Cesar Garrido, WFH President
2. COVID-19: A Refresher
3. COVID-19: Epidemiology in Bleeding Disorders
4. What do we know about new COVID-19 variants: Perspectives from South Africa
5. COVID-19 Vaccines: Guidance for PWBDs
6. COVID-19 Vaccines: An Update on the Allocation of COVID-19 Vaccines
7. Q&A
8. Closing remarks

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WELCOME

CESAR GARRIDO

WFH PRESIDENT

GLENN PIERCE

WFH VICE PRESIDENT, MEDICAL

SPEAKERS

Glenn Pierce, MD PhD
WFH Vice President, Medical
U.S.A.

Miguel Escobar, MD
WFH Medical board member
U.S.A.

Cedric Hermans, MD PhD
WFH Medical board member
Belgium

Johnny Mahlangu, MD MBBCh, MMed, FCPath
Professor of Haematology
South Africa

Radoslaw Kaczmarek, PhD
WFH Coagulation Product Safety, Supply, and Access Committee chair
Poland/U.S.A.

Ioana Ghiga, MPH & PhD
Technical Officer, WHO
Switzerland

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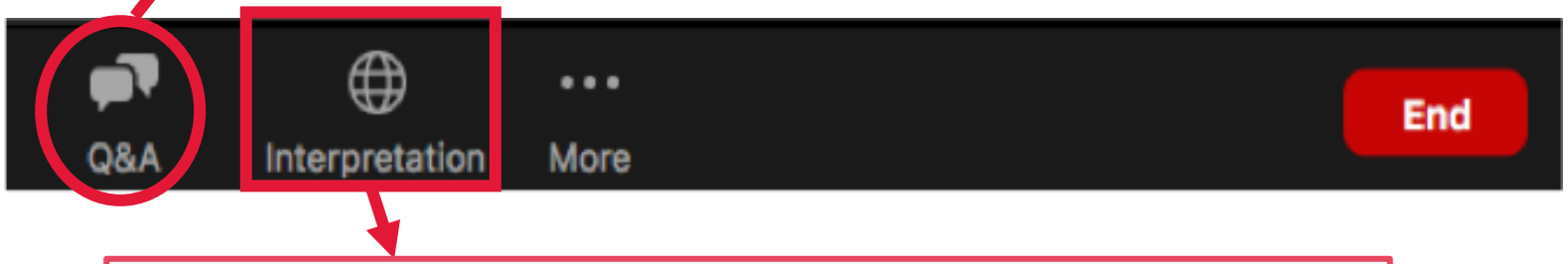
QUESTIONS AND TRANSLATION

FOR COMPUTERS OR TABLETS

Please submit your questions in the Q&A box



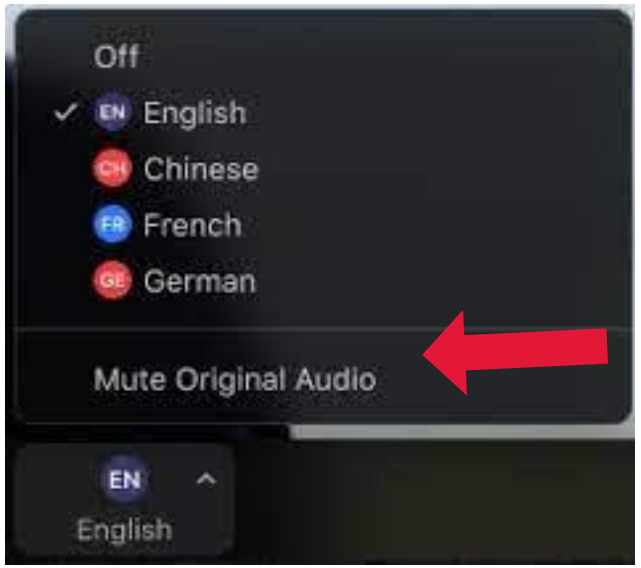
Please select your language of preference now

Por favor seleccione su idioma de preferencia ahora

Veuillez sélectionner votre langue de préférence maintenant

الرجاء اختيار لغتك المفضلة الآن

Пожалуйста выберите язык



Option to mute the original English audio

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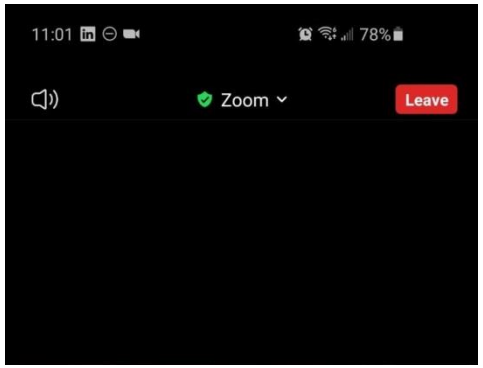
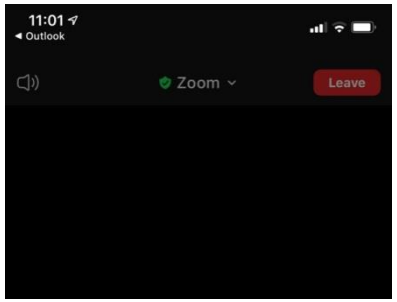
QUESTIONS AND TRANSLATION

FOR MOBILE PHONES





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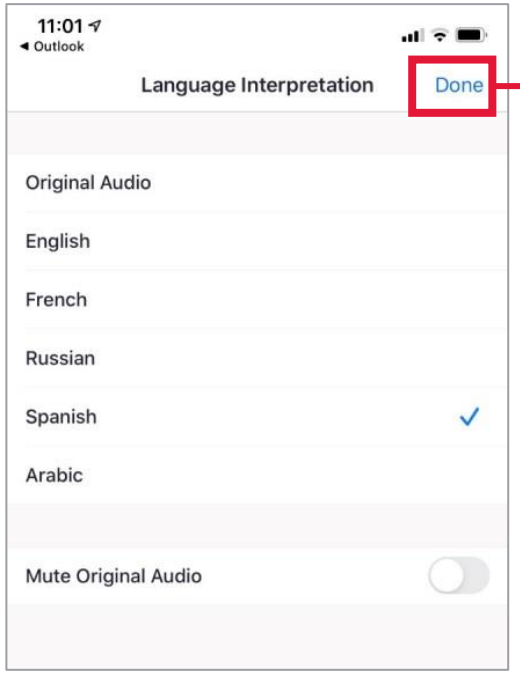

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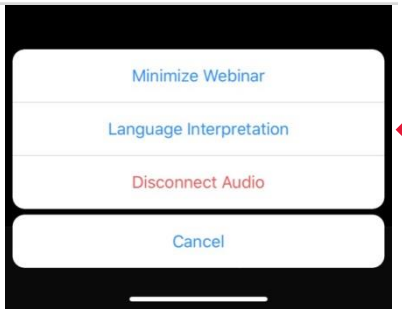

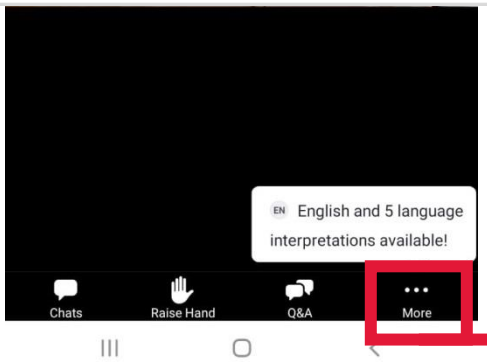

Click on the 3 dots to select the interpretation channel

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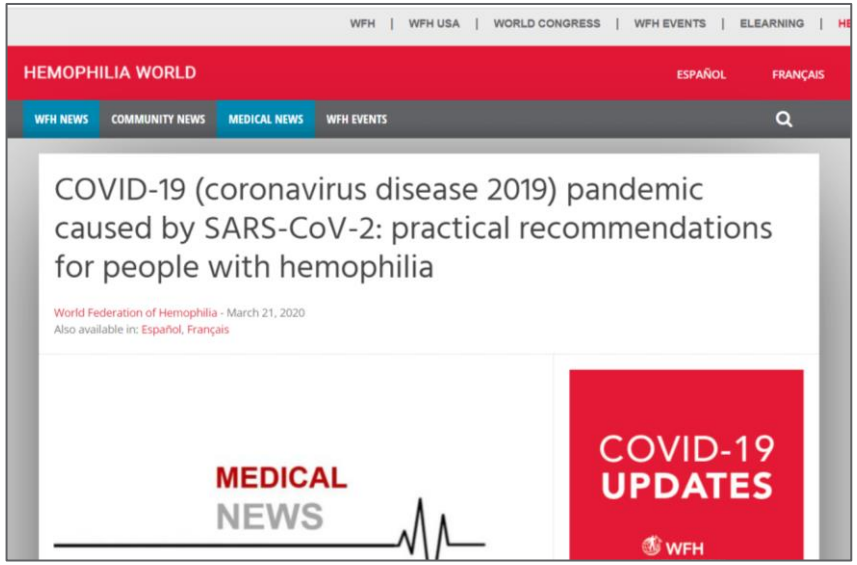
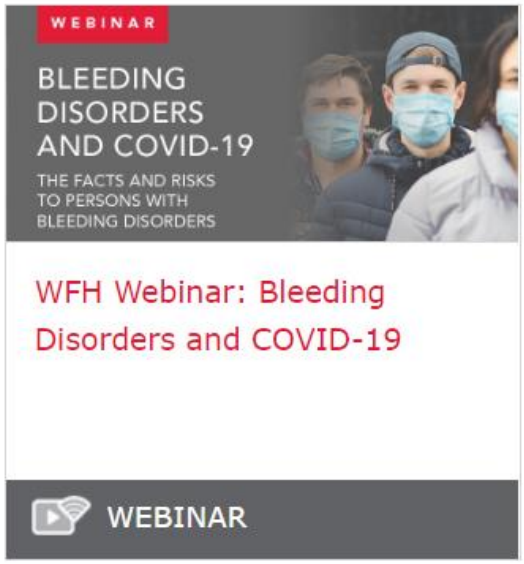
WFH COVID-19 INFORMATION

https://www.wfh.org/en/covid-19-communications

https://elearning.wfh.org/





Received: 22 December 2020 | Revised: 5 January 2021 | Accepted: 22 January 2021
DOI: 10.1111/hae.14271

Haemophilia WILEY

COMMENTARY

Vaccination against COVID-19: Rationale, modalities and precautions for patients with haemophilia and other inherited bleeding disorders

Radoslaw Kaczmarek[1] | Magdy El Ekiaby[1,2] | Daniel P. Hart[1,3,4] | Cedric Hermans[1,5] | Mike Makris[1,6] | Declan Noone[1,6] | Brian O'Mahony[1,7,8] | David Page[1,9] | Flora Peyvandi[1,10,11] | Steven W. Pipe[1,12,13] | Thomas Sannié[1,6,14] | Uwe Schlenkrich[1,15] | Mark W. Skinner[1,16,17] | Alok Srivastava[1,18] | Amanda Bok[6] | Glenn F. Pierce[1,19] | the World Federation of Hemophilia (WFH), European Association for Haemophilia, Allied Disorders (EAHAD), European Haemophilia Consortium (EHC), U.S. National Hemophilia Foundation (NHF)

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WFH RESOURCES AND TOOLS

eLearning Platform: https://elearning.wfh.org/resource/treatment-guidelines/

Supplement Article | Free Access

WFH Guidelines for the Management of Hemophilia, 3rd edition

Alok Srivastava, Elena Santagostino, Alison Dougall, Steve Kitchen, Megan Sutherland, Steven W. Pipe, Manuel Carcao, Johnny Mahlangu, Margaret V. Ragni, Jerzy Windyga, Adolfo Llinás, Nicholas J. Goddard, Richa Mohan, Pradeep M. Poonnoose, Brian M. Feldman, Sandra Zelman Lewis, H. Marijke van den Berg, Glenn F. Pierce ✉, on behalf of the WFH Guidelines for the Management of Hemophilia panelists and co-authors

First published: 03 August 2020 | https://doi.org/10.1111/hae.14046 | Citations: 4

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COVID-19
CORONAVIRUS: WHAT YOU NEED TO KNOW

Miguel A. Escobar, MD
University of Texas Health Science Center
Gulf States Hemophilia Center, Houston

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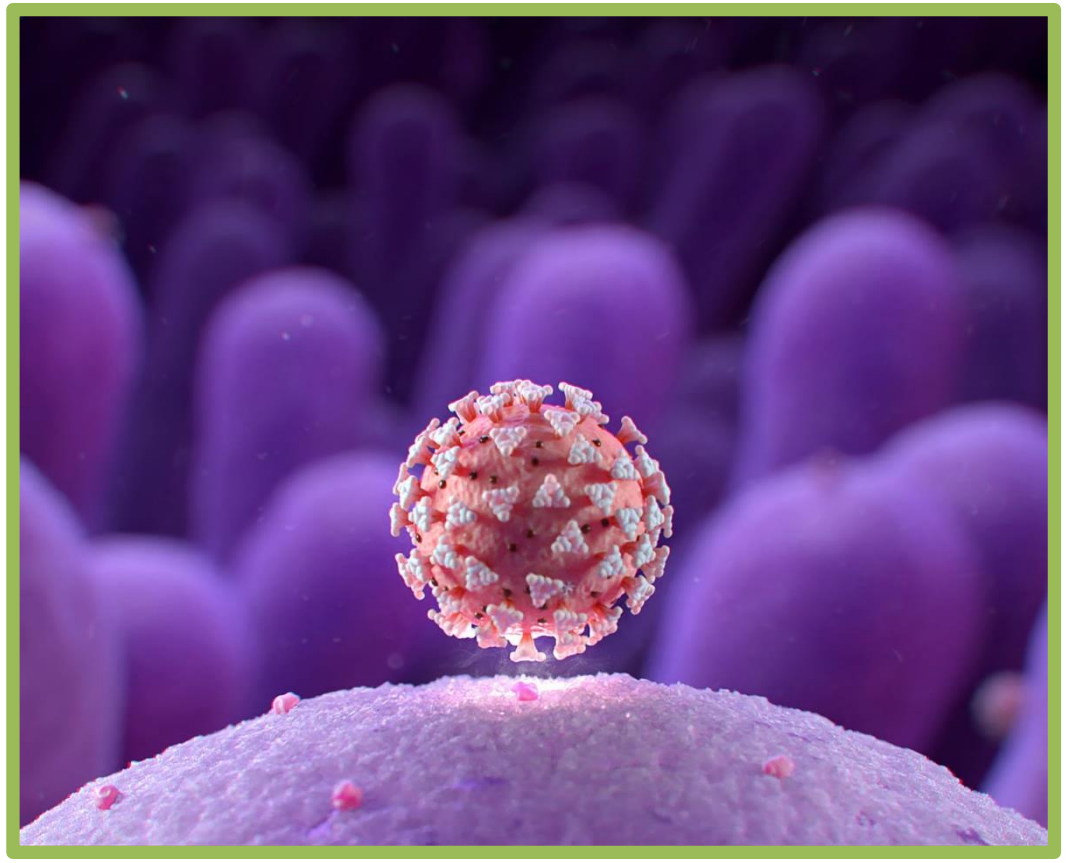
WHAT IS “CORONAVIRUS?”

- COVID-19 is a newly identified strain of a family of viruses called Coronaviruses (CoV).
- Other known Coronaviruses are:
  - Middle East Respiratory Syndrome (MERS-CoV) 2012
  - Severe Acute Respiratory Syndrome (SARS-CoV) 2003



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WHAT IS “CORONAVIRUS?”

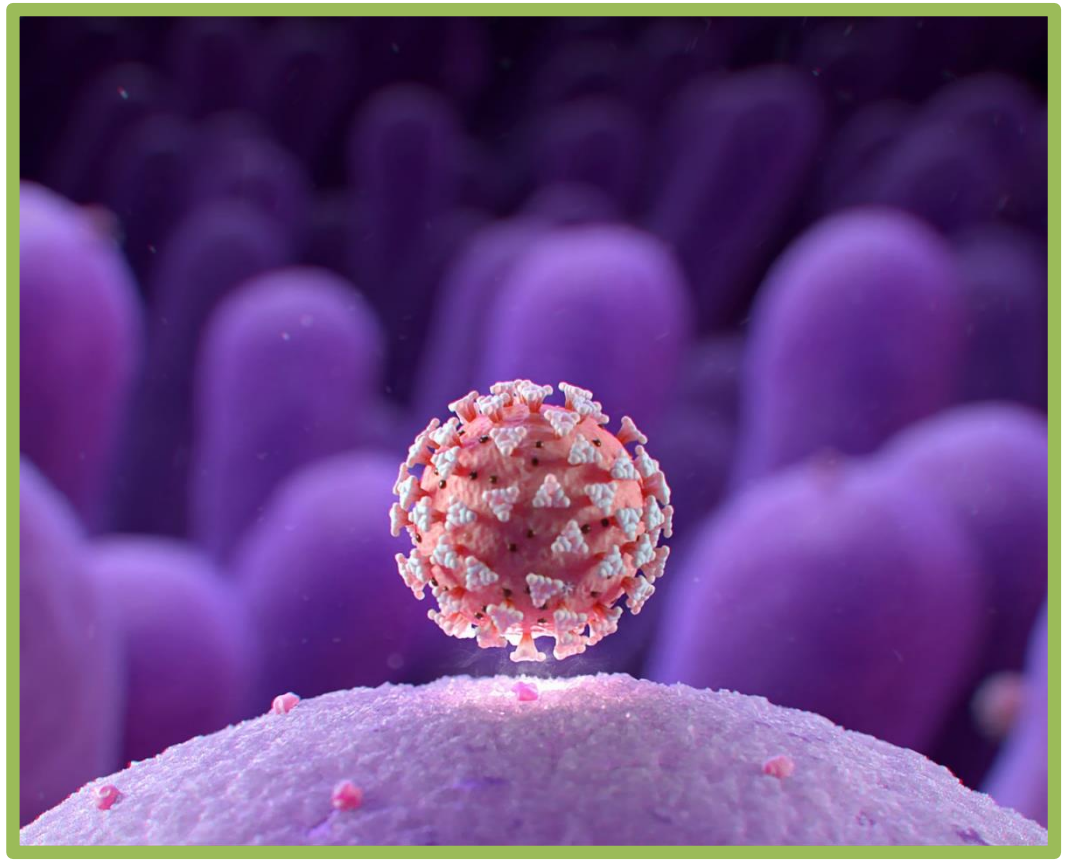
- While this infection is being called ”Coronavirus,” its official names are actually:

COVID-19

or

SARS-CoV-2

(Severe Acute Respiratory Syndrome Coronavirus 2)



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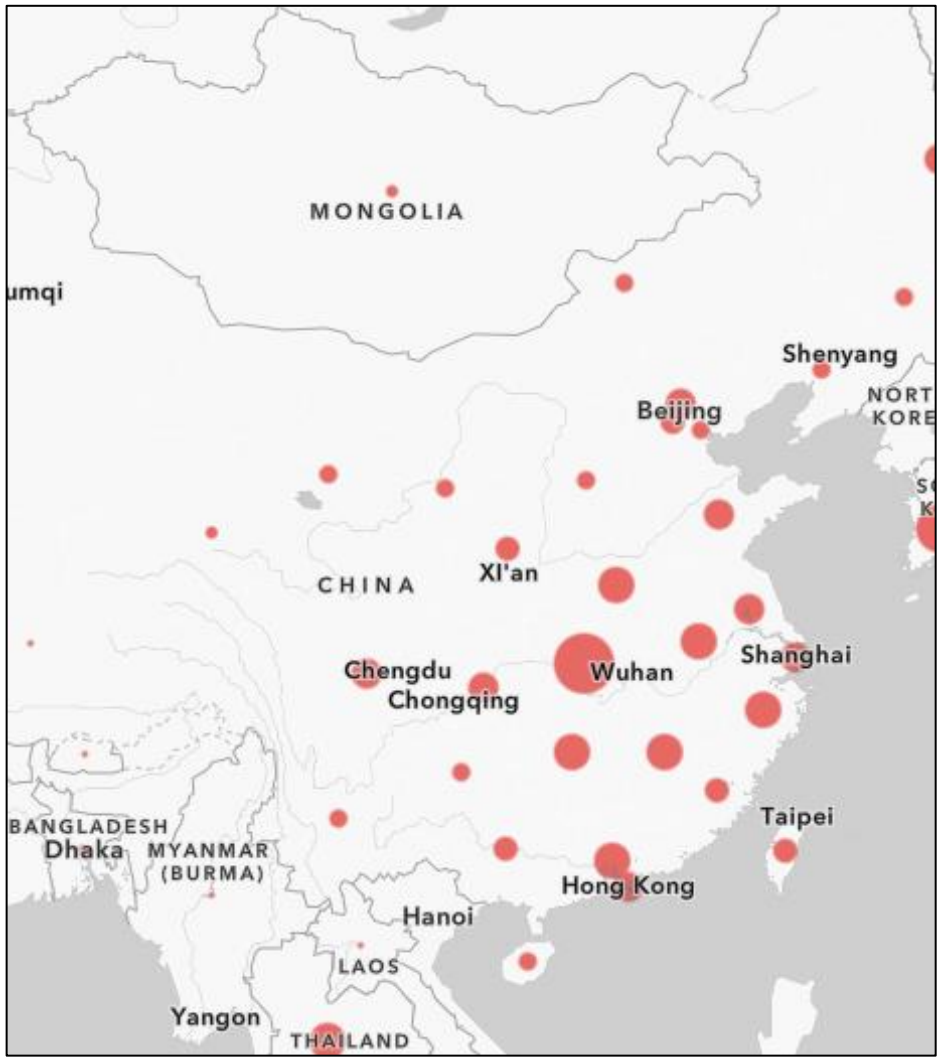
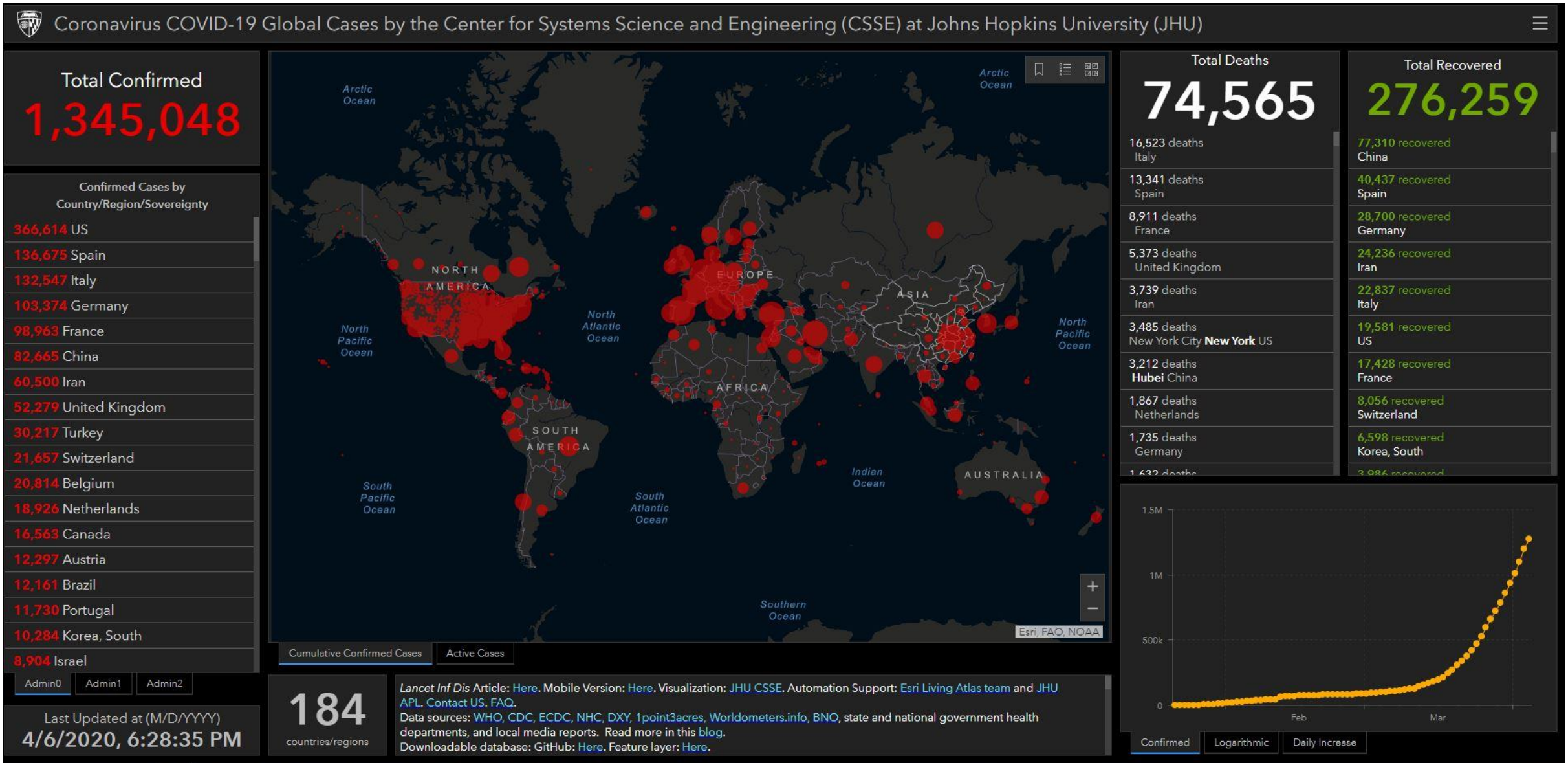


CONFIRMED CASES OF COVID-19 IN CHINA

WHERE DID IT COME FROM?

- In early December 2019, the first pneumonia cases of unknown origin were identified in Wuhan, China
- First US case confirmed on Jan 20

STATISTICS


Coronavirus COVID-19 Global Cases by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)
Total Confirmed
1,345,048
Confirmed Cases by Country/Region/Sovereignty
366,614 US
136,675 Spain
132,547 Italy
103,374 Germany
98,963 France
82,665 China
60,500 Iran
52,279 United Kingdom
30,217 Turkey
21,657 Switzerland
20,814 Belgium
18,926 Netherlands
16,563 Canada
12,297 Austria
12,161 Brazil
11,730 Portugal
10,284 Korea, South
8,904 Israel
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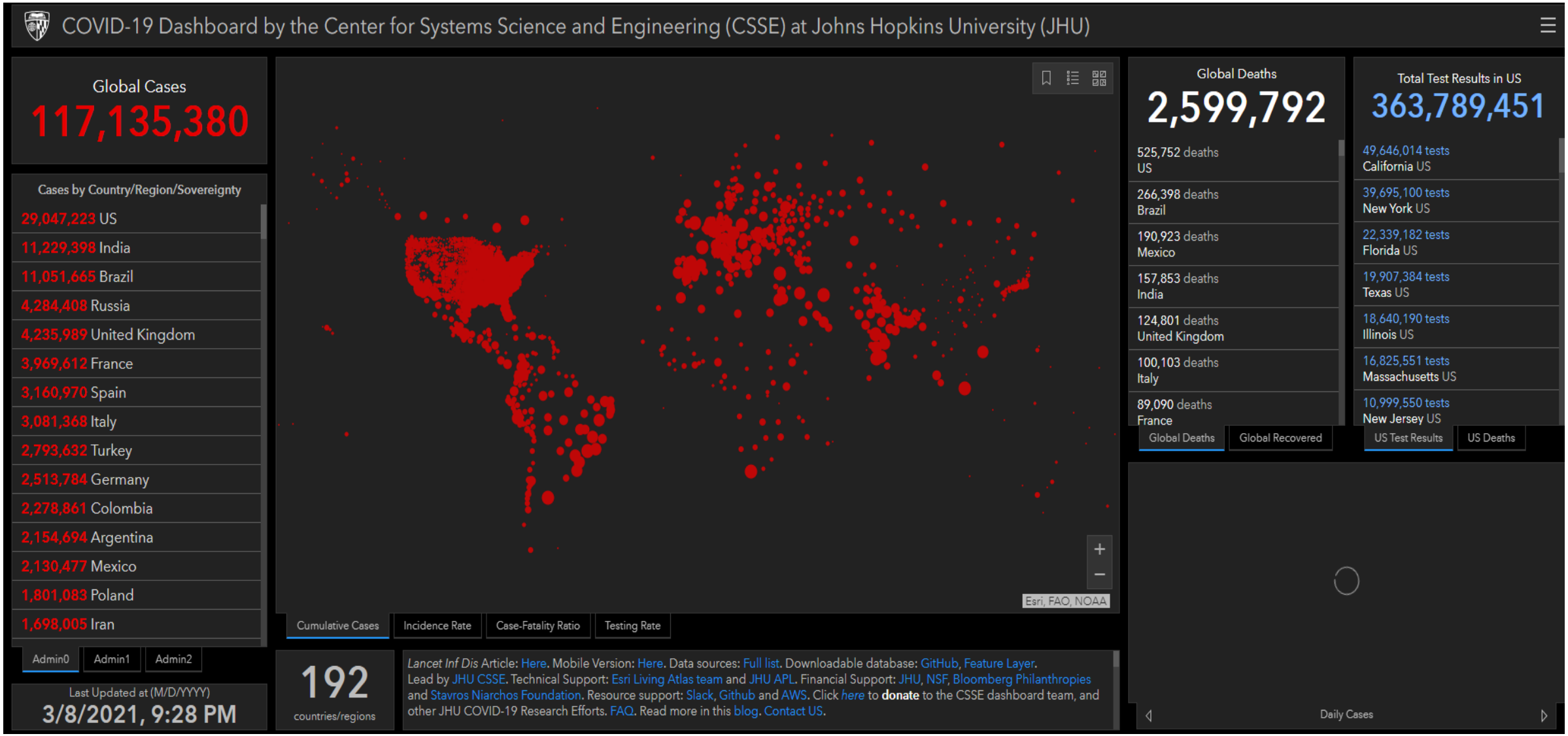
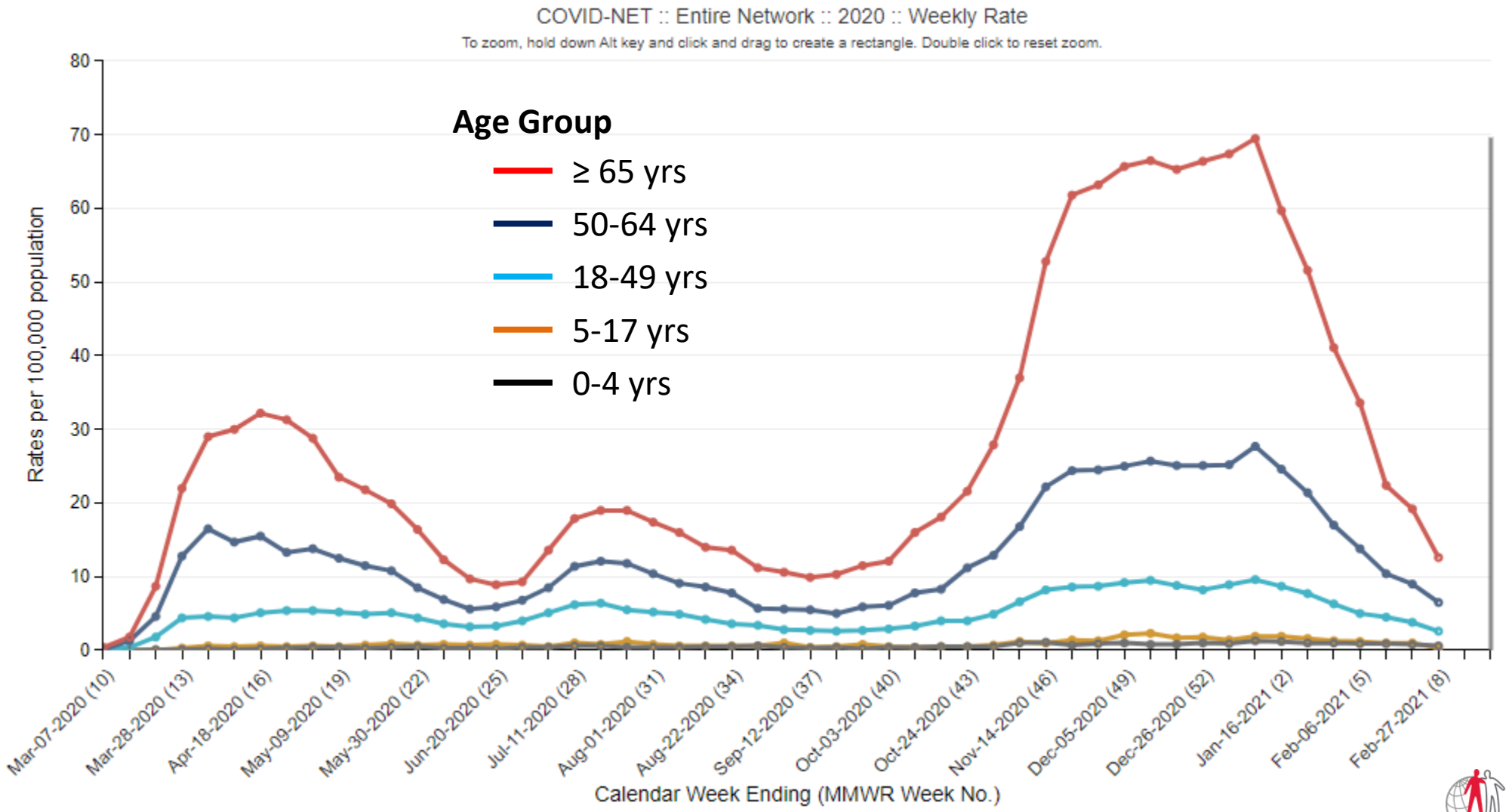
Last Updated at (M/D/YYYY)
4/6/2020, 6:28:35 PM
Arctic Ocean
NORTH AMERICA
EUROPE
ASIA
AFRICA
SOUTH AMERICA
AUSTRALIA
North Atlantic Ocean
North Pacific Ocean
South Pacific Ocean
South Atlantic Ocean
Indian Ocean
Southern Ocean
Esri, FAO, NOAA
Cumulative Confirmed Cases
Active Cases
184
countries/regions
Lancet Inf Dis Article: Here. Mobile Version: Here. Visualization: JHU CSSE. Automation Support: Esri Living Atlas team and JHU APL. Contact US. FAQ.
Data sources: WHO, CDC, ECDC, NHC, DXY, 1point3acres, Worldometers.info, BNO, state and national government health departments, and local media reports. Read more in this blog.
Downloadable database: GitHub: Here. Feature layer: Here.
Total Deaths
74,565
16,523 deaths Italy
13,341 deaths Spain
8,911 deaths France
5,373 deaths United Kingdom
3,739 deaths Iran
3,485 deaths New York City New York US
3,212 deaths Hubei China
1,867 deaths Netherlands
1,735 deaths Germany
Total Recovered
276,259
77,310 recovered China
40,437 recovered Spain
28,700 recovered Germany
24,236 recovered Iran
22,837 recovered Italy
19,581 recovered US
17,428 recovered France
8,056 recovered Switzerland
6,598 recovered Korea, South
1.5M
1M
500k
0
Feb
Mar
Confirmed
Logarithmic
Daily Increase

STATISTICS


COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)
Global Cases
117,135,380
Cases by Country/Region/Sovereignty
29,047,223 US
11,229,398 India
11,051,665 Brazil
4,284,408 Russia
4,235,989 United Kingdom
3,969,612 France
3,160,970 Spain
3,081,368 Italy
2,793,632 Turkey
2,513,784 Germany
2,278,861 Colombia
2,154,694 Argentina
2,130,477 Mexico
1,801,083 Poland
1,698,005 Iran
Admin0
Admin1
Admin2
Last Updated at (M/D/YYYY)
3/8/2021, 9:28 PM
Esri, FAO, NOAA
Cumulative Cases
Incidence Rate
Case-Fatality Ratio
Testing Rate
192
countries/regions
Lancet Inf Dis Article: Here. Mobile Version: Here. Data sources: Full list. Downloadable database: GitHub, Feature Layer.
Lead by JHU CSSE. Technical Support: Esri Living Atlas team and JHU APL. Financial Support: JHU, NSF, Bloomberg Philanthropies
and Stavros Niarchos Foundation. Resource support: Slack, Github and AWS. Click here to donate to the CSSE dashboard team, and
other JHU COVID-19 Research Efforts. FAQ. Read more in this blog. Contact US.
Global Deaths
2,599,792
525,752 deaths
US
266,398 deaths
Brazil
190,923 deaths
Mexico
157,853 deaths
India
124,801 deaths
United Kingdom
100,103 deaths
Italy
89,090 deaths
France
Global Deaths
Global Recovered
Total Test Results in US
363,789,451
49,646,014 tests
California US
39,695,100 tests
New York US
22,339,182 tests
Florida US
19,907,384 tests
Texas US
18,640,190 tests
Illinois US
16,825,551 tests
Massachusetts US
10,999,550 tests
New Jersey US
US Test Results
US Deaths
Daily Cases

COVID-NET: Lab-Confirmed COVID-19–Associated Hospitalization Rates Stratified by Age



https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html

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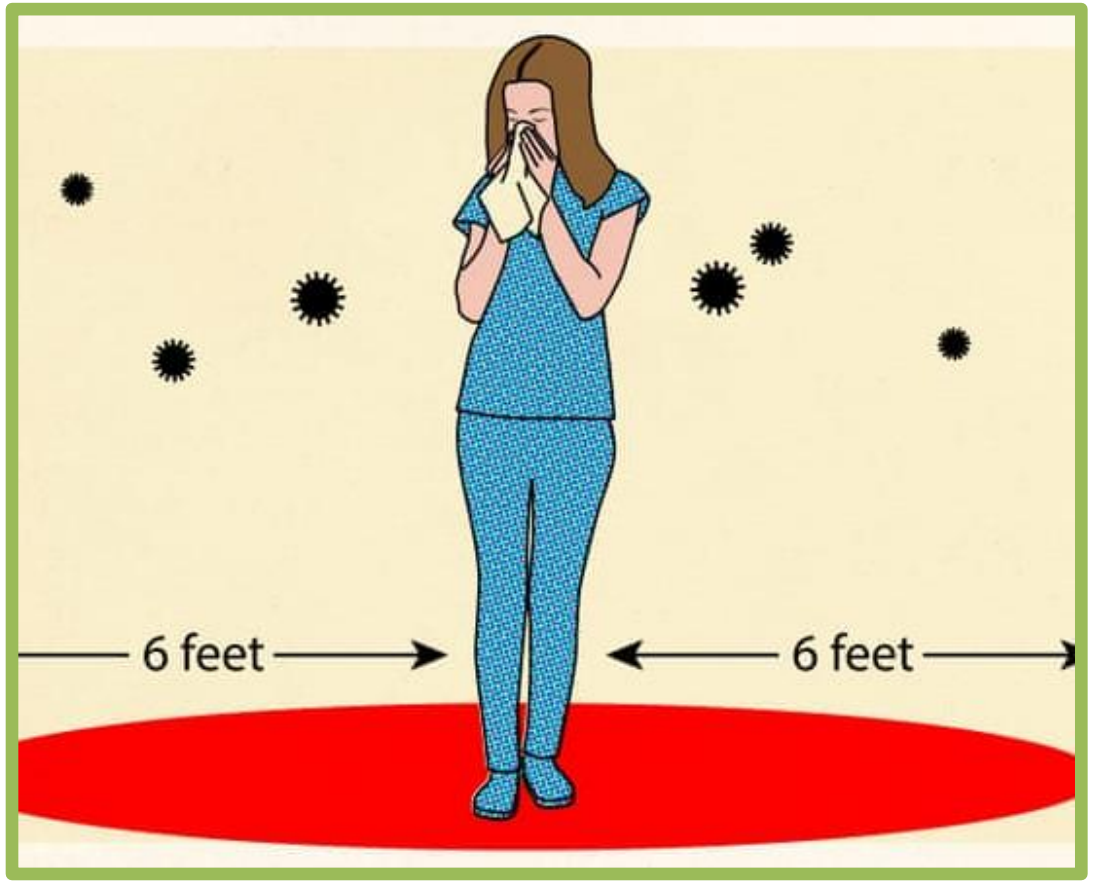
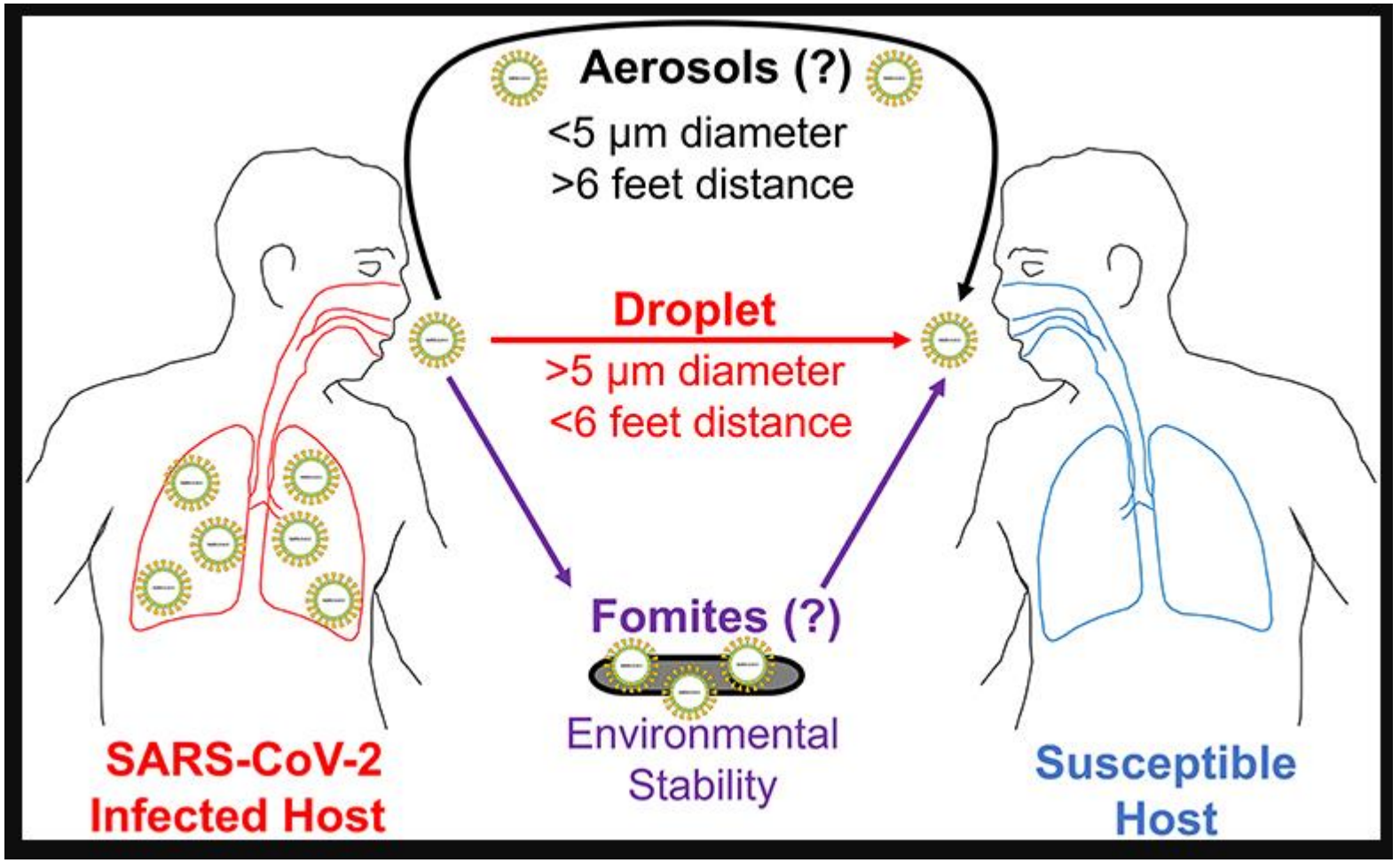
HOW DO YOU GET INFECTED?

- The virus spreads **MAINLY** from **person-to-person.**
  - between people who are in close contact with one another (~6 ft.)
  - through bodily fluids produced when an infected person coughs or sneezes
- Touching a surface or object that has the virus on it and then touching your face
- Presymptomatic transmission?



PROPOSED ROUTES OF COVID-19 TRANSMISSION



Front Public Health 2020:8;163

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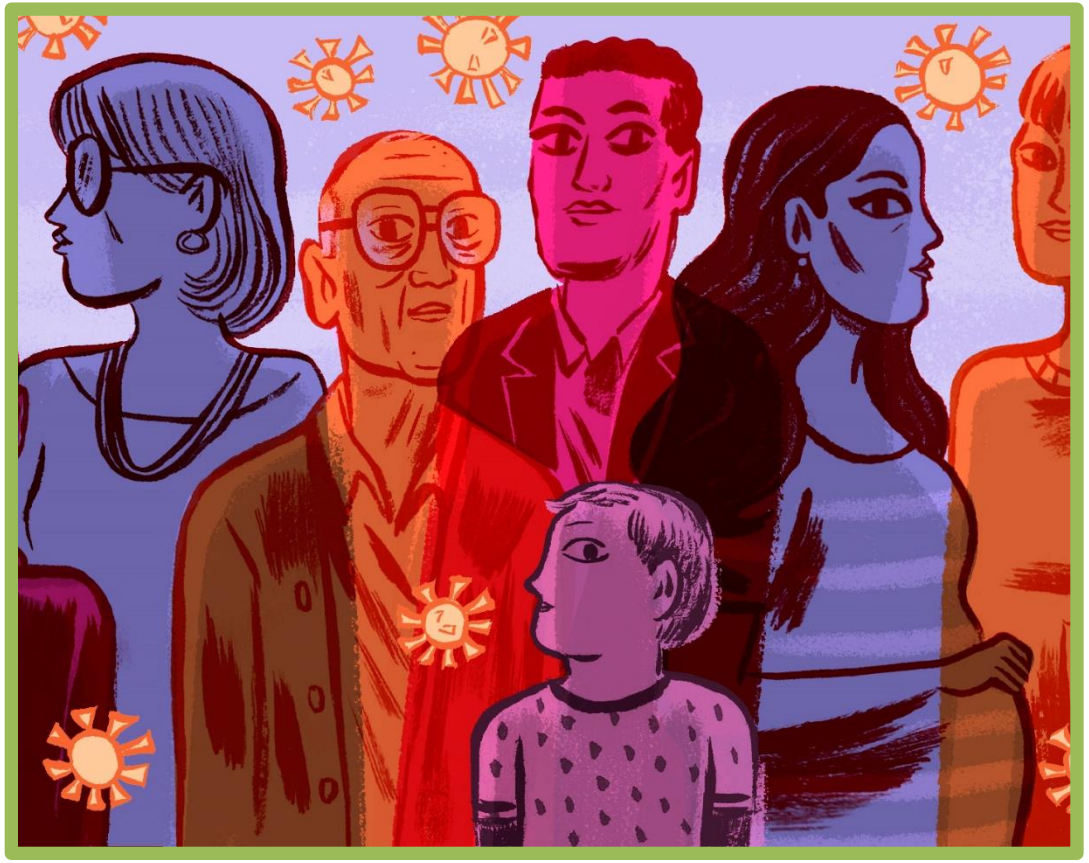
POPULATION AT RISK

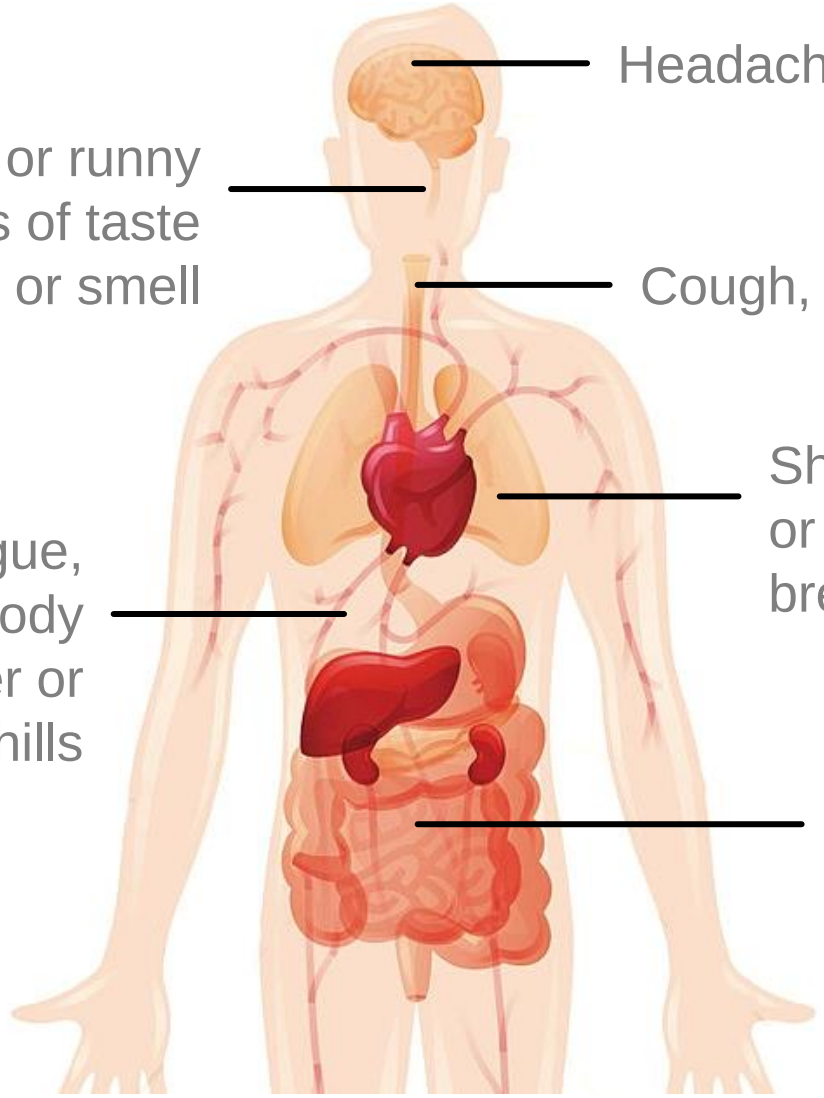
- Older populations (60+)
- Immunocompromised individuals
- Those with:
  - underlying resp conditions
  - Diabetes, HTN, Cancer, CKD
  - cardiovascular disease
  - Obesity



https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

SYMPTOMS OF COVID-19

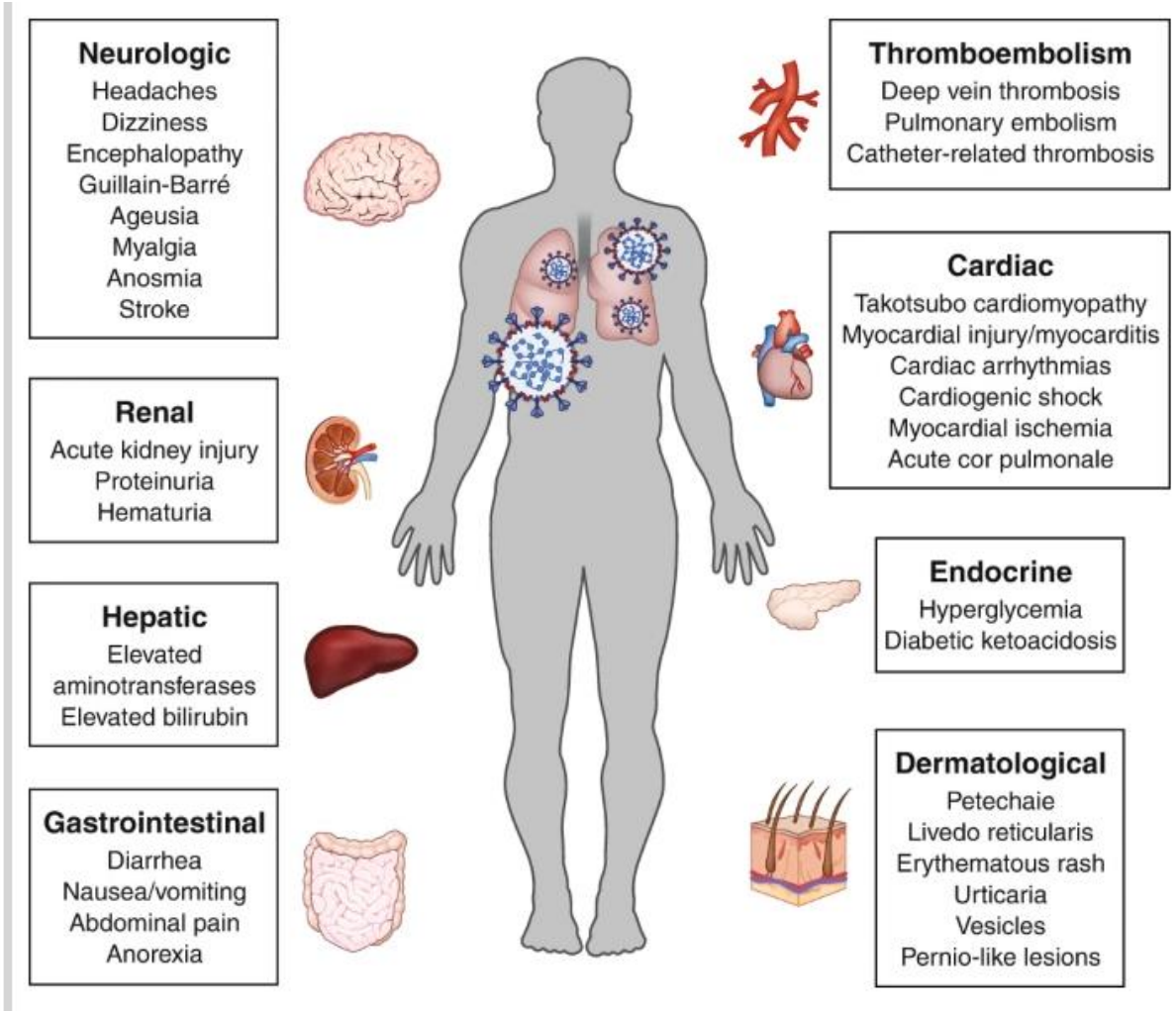
"Symptoms may appear **2-14 days after exposure** to the virus"



Slide credit: clinicaloptions.com

Li. J Med Virol. 2020;92:577.
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

OTHER MANIFESTATION OF COVID-19 INFECTION



Nature Med 2020;26:1017-1032

WHEN TO SEEK MEDICAL ATTENTION

- If you begin to develop symptoms, **CALL YOUR DOCTOR FIRST**
  - most cases are **mild**; you'll recover with rest and fluids from just as you would with a normal flu

- If you develop **EMERGENCY WARNING SIGNS** for COVID-19, you should seek medical attention **IMMEDIATLEY**!
  - Emergency warning signs include (but are not limited to):
    - trouble breathing
    - persistent pain or pressure in the chest
    - new confusion or inability to arouse
    - bluish lips or face

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HOW CAN YOU AVOID GETTING INFECTED?

https://www.harnett.org/publicinfo/covid19-prevention.asp

SHOULD I GET TESTED?

- **NOT EVERYONE NEEDS TO BE TESTED**
- Most people have MILD ILLNESSES and are able to RECOVER AT HOME
- If you have symptoms of COVID-19 contact your Doctor **FIRST**!

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THANK YOU

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COVID-19: Epidemiology in Bleeding Disorders

Cedric Hermans, MD PhD
WFH Medical board member
Belgium

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EPIDEMIOLOGY OF COVID-19 : The questions

How many patients with inherited bleeding diseases developed COVID-19 in the different parts of the world ?

Is the incidence different from the general population ?

How many of these patients required hospital admission, transfer in intensive care, assisted ventilation ? What was their outcome ?

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EPIDEMIOLOGY OF COVID-19 : Available evidence

Literature review

European data : Preliminary results of the Advance COVID-19 Registry

Personal experience in Brussels - Belgium

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HAEMOSTASIS AND THROMBOSIS

Letter to the Editor

Prevalence and clinical features of COVID-19 in Iranian patients with congenital coagulation disorders

Mehran Karimi[1], Sezaneh Haghpanah[1], Amin Shahsavani[1]

The prevalence of COVID-19 was 7.3 per 10,000 in patients with inherited coagulation disorders, in comparison with a prevalence of 16.6 per 10,000 in the general Iranian population.
The mortality rate in the infected general population was 5.4% but was zero in our patients' cohort.

Blood Transfus 2020; ***18****: 413-4* DOI 10.2450/2020.0223-20

Received: 19 May 2020 | Revised: 27 June 2020 | Accepted: 29 June 2020
DOI: 10.1111/hae.14108

ORIGINAL ARTICLE
Clinical haemophilia

Haemophilia WILEY

Management of haemophilia patients in the COVID-19 pandemic: Experience in Wuhan and Tianjin, two differently affected cities in China

Ai Zhang[1] | Wei Liu[2] | Man-Chiu Poon[3,4] | Aiguo Liu[1] | Xiaoping Luo[1] | Lingling Chen[2] | Qun Hu[1] | Renchi Yang[2]

No epidemiological data provided

REGISTRY OF PATIENTS WITH CONGENITAL BLEEDING AND COVID-19 IN MADRID

Alvarez-Roman et al.
Haemophilia, In press

345 patients with inherited bleeding diseases
42 patients with symptoms suggestive of COVID-19
RT-PCR positive in 6 patients
Cumulative incidence : 1.73 %
The clinical evolution of all infected patients was mild

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Epidemiology, diagnosis and management of COVID-19 (SARS-CoV-2) in patients aged ≥ 40 years with hemophilia A/B registered in ADVANCE HTCs

Primary objectives:

Compare rates of infection and outcomes between the national hemophilia and non-hemophilia populations within ADVANCE-represented countries

Identify specific issues with treatment and management of older PWH with COVID-19 infection

Provide guidance on the management of older PWH during the COVID-19 pandemic

Study population:

All people ≥ 40 years old with hemophilia A and B registered in ADVANCE HTCs

Study type:
Retrospective and prospective observational cohort surveys

Study design:
Survey-based, undertaken at two time points

- Mar 2020 – Nov 2020
- Dec 2020 – pandemic end

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ADVANCE:
25 Members – 16 Countries – 3,700+ HEM patients

STEERING COMMITTEE

- Cedric Hermans | Belgium
- Roseline d'Oiron | France
- Robert Klamroth | Germany
- Maria Elisa Mancuso | Italy
- Pal Andre Holme | Norway ***Chairman***
- Jan Astermark | Sweden
- Gerry Dolan | UK ***Chairman***

Identifying and researching key issues in the aging (>40 years) hemophilia population

advance
Age-related DeVelopments ANd ComorbiditiEs in hemophilia

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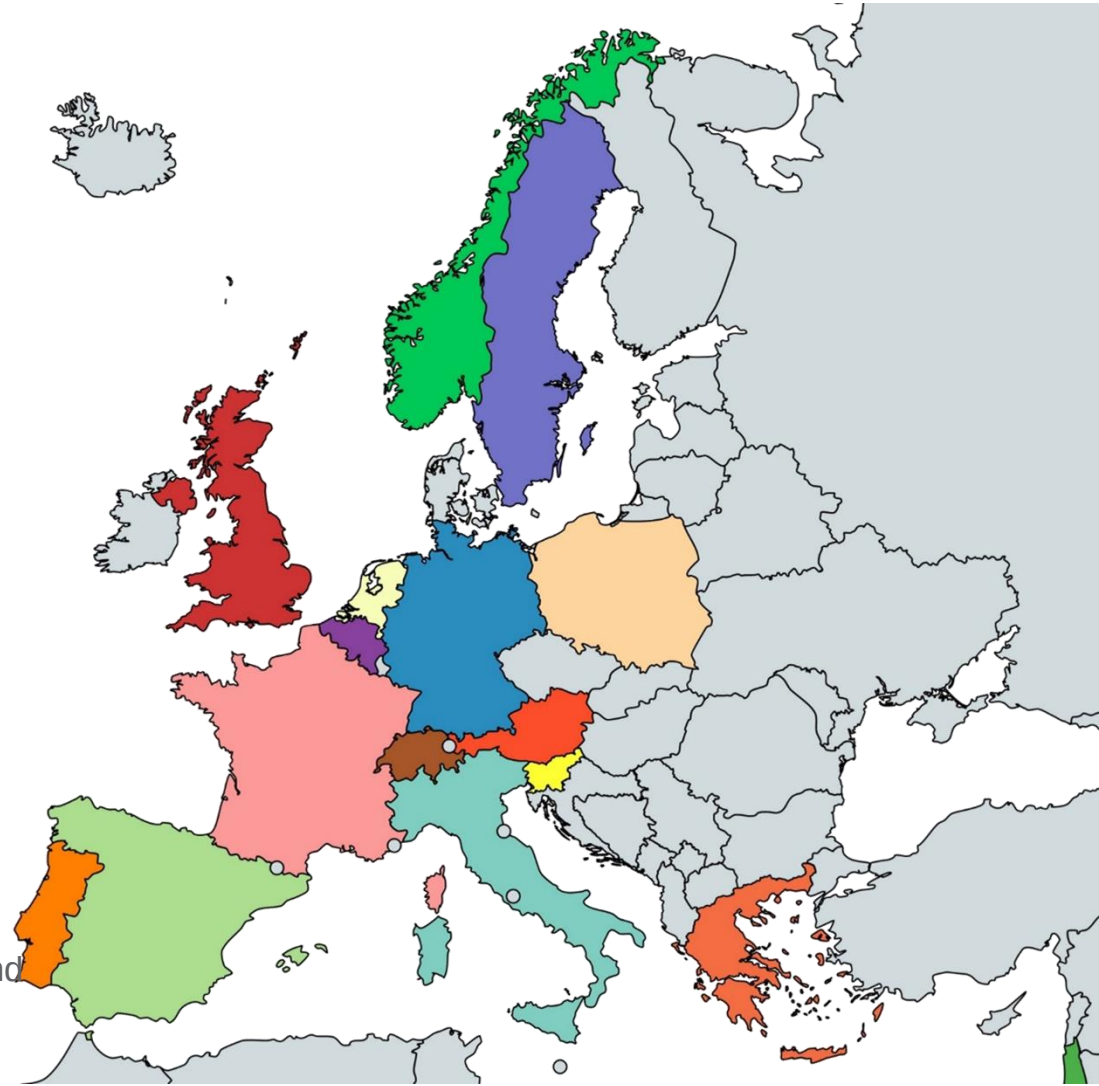
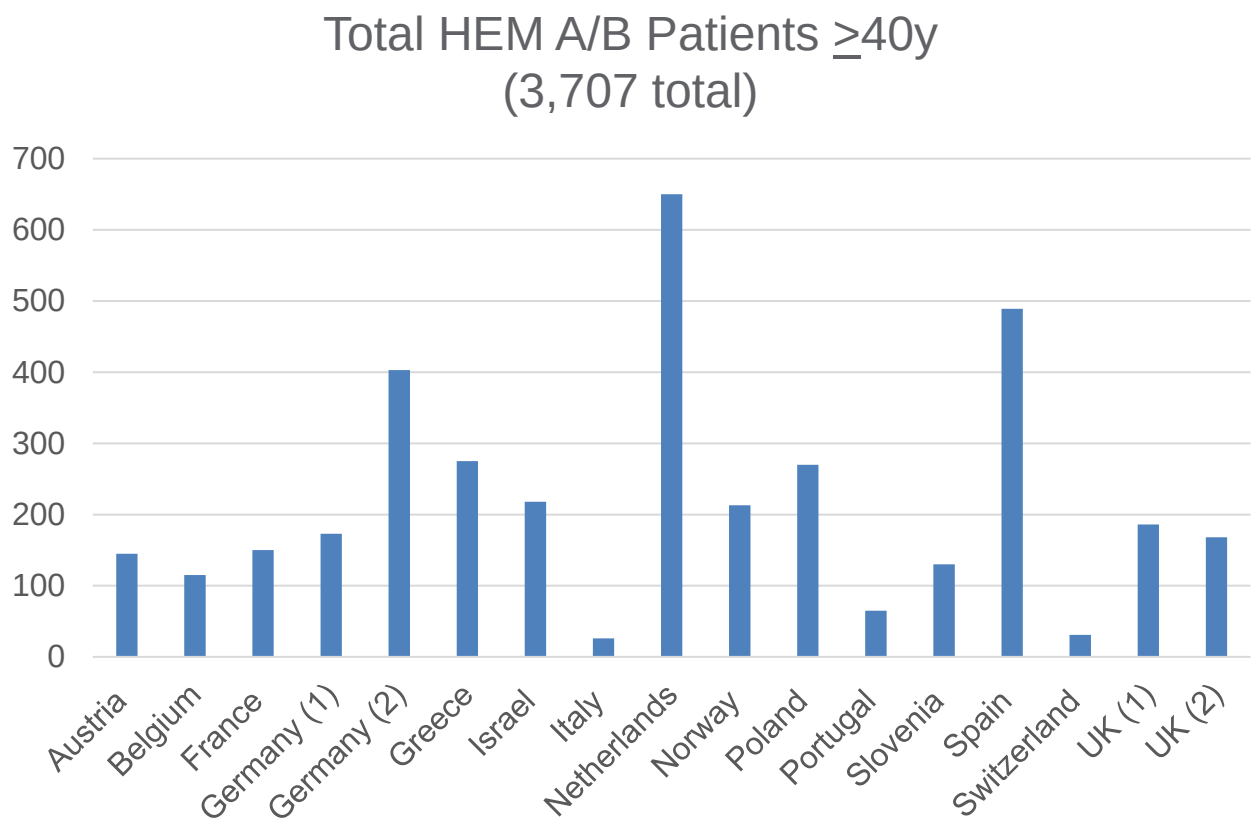
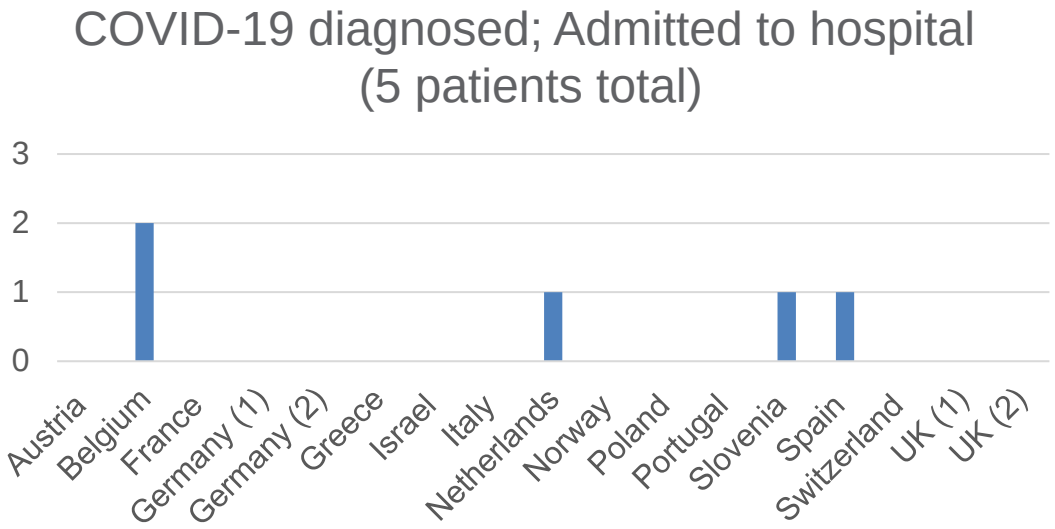
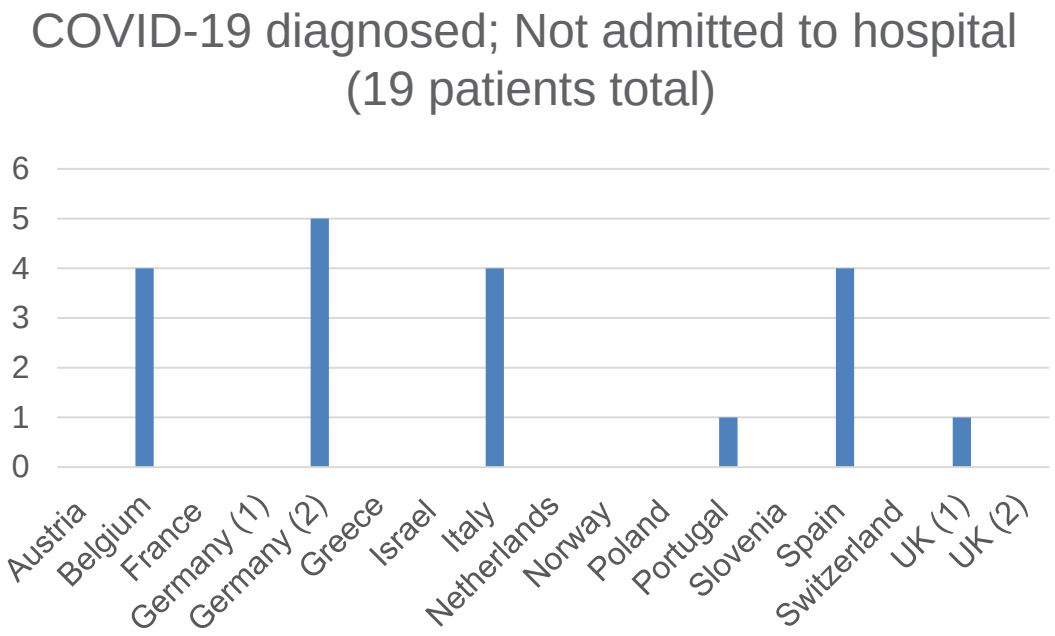
- Pierre Fontana | Switzerland
- Philippe de Moerloose | Switzerland
- Ryan Rodgers | UK



ADVANCE COVID-19 Study:
Preliminary demographic data by center to Nov 2020







Patients with Haemophilia followed at the HTC of the Cliniques universitaires Saint-Luc – Brussels BELGIUM

Age groups	HEMOPHILIA A			HEMOPHILIA B		
	Severe	Moderate	Mild	Severe	Moderate	Mild
0 - 9	12	0	8	4	2	1
10 - 19	10	3	15	1	2	1
20 - 29	15	7	17	1	2	3
30 - 39	9	2	12	2	6	2
40 - 49	19	2	6	2	4	3
50 - 59	13	3	11	1	2	0
60 - 69	3	1	8	5	3	1
70 - 79	6	1	6	0	1	3
80 - 89	0	1	3	0	1	0
> 90	0	0	2	0	0	0
TOTAL	87	20	88	16	23	14
248	195 HA			53 HB		

111/248 patients older than 50

COVID-19 in our registered PWHs

10 patients developed COVID-19

3 admitted in Hospital (> 50 year)

1 ICU admission / ventilation / died

2 did not require ICU admission / survived

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PWHs with severe COVID-19 who required hospital admission at the Brussels HTC

- ❑ 54-year-old male
- ❑ Severe HA
- ❑ Multiple comorbidities
- ❑ On EHL-FVIII
- ❑ ICU / ventilation
- ❑ Died

- ❑ 65-year-old male
- ❑ Severe HB
- ❑ No comorbidity
- ❑ Gene therapy in 11.2019
- ❑ No ICU admission
- ❑ Survived

- ❑ 80-year-old male
- ❑ Severe HA
- ❑ Factor V Leiden
- ❑ Atrial Fibrillation
- ❑ On Emicizumab
- ❑ No ICU admission
- ❑ Survived

Acta Haematol. 2020 Sep 25 : 1–3

CT: Computed tomography; ICU: Intensive care unit; LMWH: Low molecular weight heparin; PCR: Polymerase chain reaction; SARS: Severe acute respiratory syndrome.
Illustrative case provided by speaker.

CONCLUSIONS

Limited data currently available on the demography of COVID-19 in patients with inherited bleeding diseases

Several on-going registries are collecting data

Available data and personal experience do not support that the demography of COVID-19 is different from the general population

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What do we know about new COVID-19 variants: Perspectives from South Africa

Johnny Mahlangu
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Charlotte Maxeke Johannesburg Hospital and
Department of Molecular Medicine and Haematology
NHLS and University of the Witwatersrand, Johannesburg

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

NATIONAL HEALTH LABORATORY SERVICE

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DISCLOSURES

Grant/Research Support	BioMarin, CSL, Novo Nordisk, Pfizer, Sobi, Roche, Unique
Consultant/ Scientific board	CSL Berhing, Catalyst Biosciences, Novo Nordisk, Roche and Spark
Speaker bureau	Novo Nordisk, Pfizer, Sobi, Shire, Roche, ISTH and WFH
Employee	None
Shareholder	None
Director	None

AGENDA

- What do we know about COVID-19 variants?
- Implications for COVID-19 variants on vaccine development
- The B.1.351 variant laboratory and clinical data
- Concluding remarks

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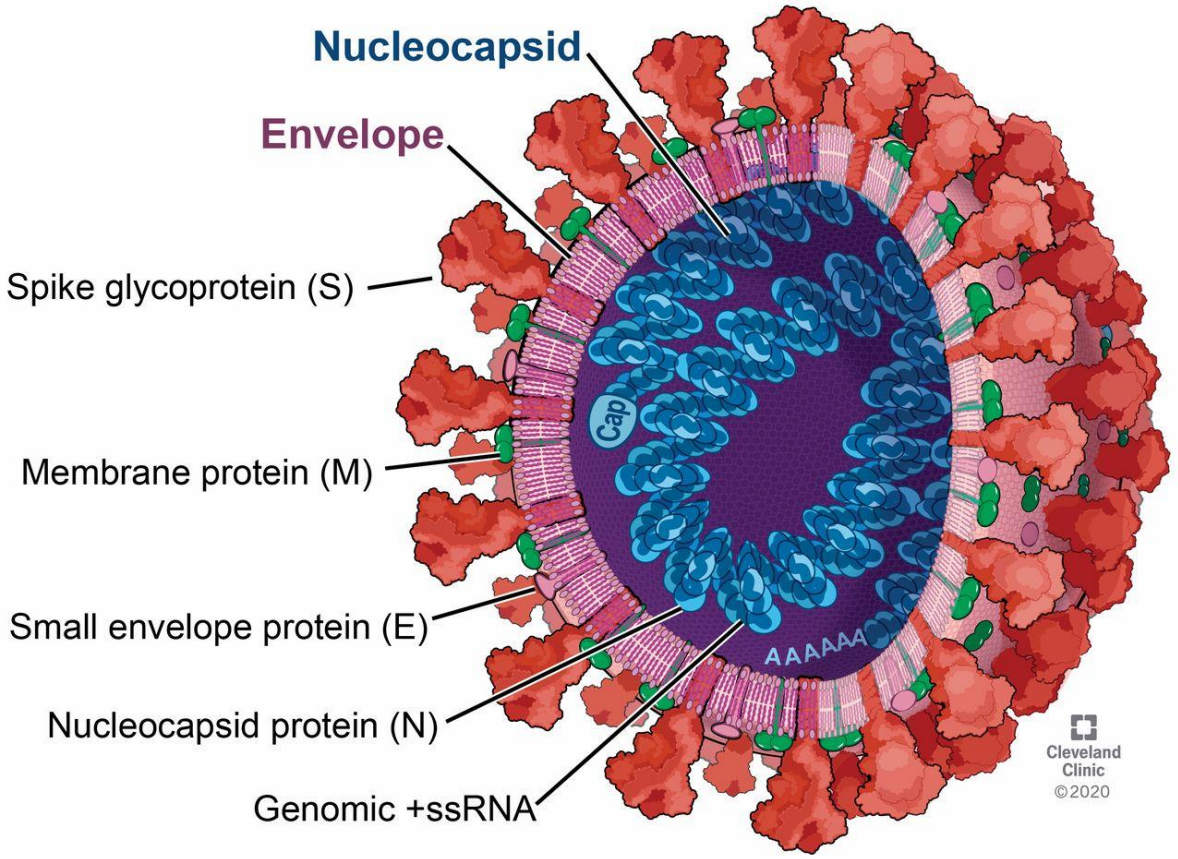
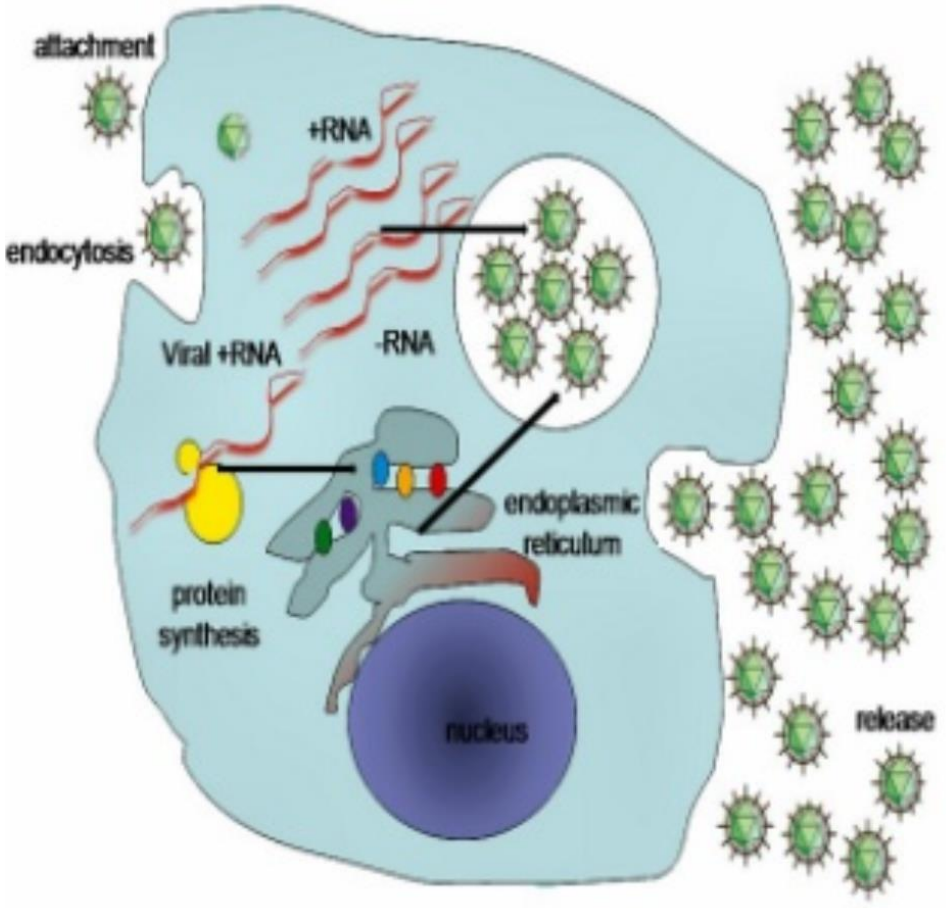
ARE VIRUSES LIVING ORGANISMS?

- Genetic material coding for proteins
- Incapable of independent existence- require host for survival
- 8% of human genome comprise of viral sequences
- Viruses exist to replicate



WHY DO VIRAL VARIANTS DEVELOP?

- Viruses only replicate in living cells
  - Host energy
  - Host machinery
- Viral genome produce mRNA
- Host produce viral proteins
- Replication errors are common Evolution of viral variants
- Variant survival dependents on environmental selection/pressure



PATHOGENIC COVID-19 VARIANTS ARE MANY..

COVID-19 variant	Country first identifies	Mutation in the RBD
B.1.1.7. (501Y.V1)	UK	E484K, N501Y, D614G; 681H
B.1.351 (501Y.V2)	South Africa (18 Dec 2020)	E484K, N501Y, D614G
P1 (501Y.V3)	Japan (6 Jan 2021) Brazil (12 Jan 2021)	E484K, N501Y
B.1.429 (501Y.V1)	USA(July 2020)	L452R, D614G
B.1.1.207	Nigeria (August 2020	D614G, P681H
B.1.1.317	Australia	D614G
B.1.1.318	UK (21 Feb 2021)	N501Y, D614G
B.1.1.525	UK	D614G

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WHAT DO THE VARIANT MUTATION CONFER?

Mutation in the RBD	Impact
E484K	Escape mutation
N501Y	Escape mutation
D614G	Increased binding of RBD to ACE2
P681H	Increased binding of RBD to ACE2
L452R	Escape mutation

COVID-19 VARIANTS OF GLOBAL CONCERN

COVID-19 variant	Country first identifies	
B.1.1.7. (501Y.V1)	UK (December 2020)	46-72% more transmissible
B.1.351 (501Y.V2)	South Africa (18 Dec 2020)	Higher viral load increased transmissibility
P1 (501Y.V3)	Japan (6 Jan 2021) Brazil (12 Jan 2021)	Causes reinfection

WHICH VACCINE CLASSES ARE EFFECTIVE AGAINST THE B.1.351?

mRNA vaccines	Inactivated Vaccines	Protein subunit vaccine	Viral vector vaccine
Pfizer and Moderna are effective	Sinopharm- reduction in neutralization	Novavax - 49% (vs 89 in UK)	A-Z- 22% (vs 67% in UK) J-J – 57% (vs 72 US)

WHICH VACCINES ARE EFFECTIVE AGAINST THE B.1.351 IN VITRO?

Astra-Zeneca	3-86 fold decrease
Johnson-Johnson	No data
Moderna	6.4 fold decrease
Novavax	No data
Pfizer	1-3 fold decrease
Sinopharm	1.6 fold decrease

WHICH VACCINES HAVE CLINICAL EFFICACY AGAINST B.1.351?

	Mild/moderate disease	Severe disease/ Hospitalization/ death
Astra-Zeneca	22%	-
Johnson-Johnson	57%	85%
NovaVax	49%	-
Novavax	-	-
Pfizer	-	-
Sinopharm	-	-

CONCLUDING REMARKS

- Laboratory studies indicate that current vaccines have difficulty in neutralizing the B.1.351 variant
- Clinical studies on mild/moderate COVID-19 disease show
  - A-Z- declines from 66% to 22%
  - Novavax – decline from 89% to 49%
  - Johnson and Johnson – decline from 72% to 57%
  - No data on Pfizer, Sinopharm and Gamaleya
- Clinical studies on COVID-19 severe disease/ hospitalization
  - Johnson and Johnson shows 85% efficacy
  - No data on others

- Key considerations for a sustainable vaccine program in South Africa
  - Safety
  - Efficacy
  - Cost
  - Ease of storage and administration
  - Single or two doses

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COVID-19 Vaccines: Guidance for PWBDs

Radek Kaczmarek, PhD

Chair WFH CPSSA Committee

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INTRODUCTION

The latest paper on vaccination published on behalf of the WFH, EAHAD, EHC and NHF, introduces a set of recommendations on vaccination against COVID-19 for people with bleeding disorders.

Received: 22 December 2020 | Revised: 5 January 2021 | Accepted: 22 January 2021
DOI: 10.1111/hae.14271

Haemophilia WILEY

COMMENTARY

Vaccination against COVID-19: Rationale, modalities and precautions for patients with haemophilia and other inherited bleeding disorders

Radoslaw Kaczmarek[1] | Magdy El Ekiaby[1,2] | Daniel P. Hart[1,3,4] | Cedric Hermans[1,5] | Mike Makris[1,6] | Declan Noone[1,6] | Brian O'Mahony[1,7,8] | David Page[1,9] | Flora Peyvandi[1,10,11] | Steven W. Pipe[1,12,13] | Thomas Sannié[1,6,14] | Uwe Schlenkrich[1,15] | Mark W. Skinner[1,16,17] | Alok Srivastava[1,18] | Amanda Bok[6] | Glenn F. Pierce[1,19] | the World Federation of Hemophilia (WFH), European Association for Haemophilia, Allied Disorders (EAHAD), European Haemophilia Consortium (EHC), U.S. National Hemophilia Foundation (NHF)

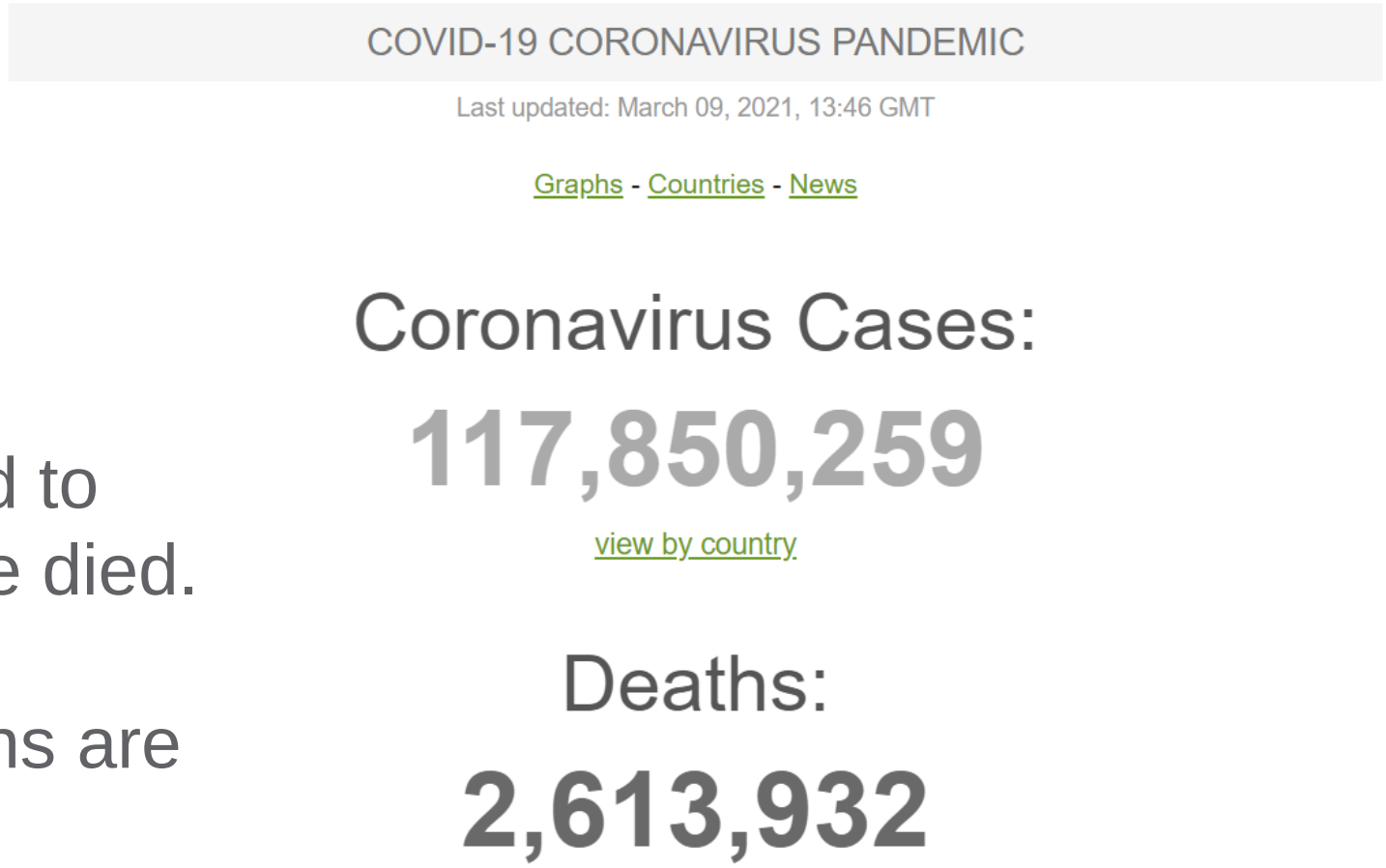
Kaczmarek et al, Haemophilia, 2021, DOI: 10.1111/hae.14271

INTRODUCTION

COVID-19 is far from being eradicated.

As of March 9th, 117,850,259 individuals have been infected to date, 2,613,932 of whom have died.

Efficient vaccination campaigns are vital to limit the spread of the SARS-CoV-2 virus.



https://www.worldometers.info/coronavirus/

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INTRODUCTION

Safety concerns and misinformation may slow down vaccination rates.

The following is a factual perspective to help healthcare providers and people with bleeding disorders make informed decisions on vaccination.

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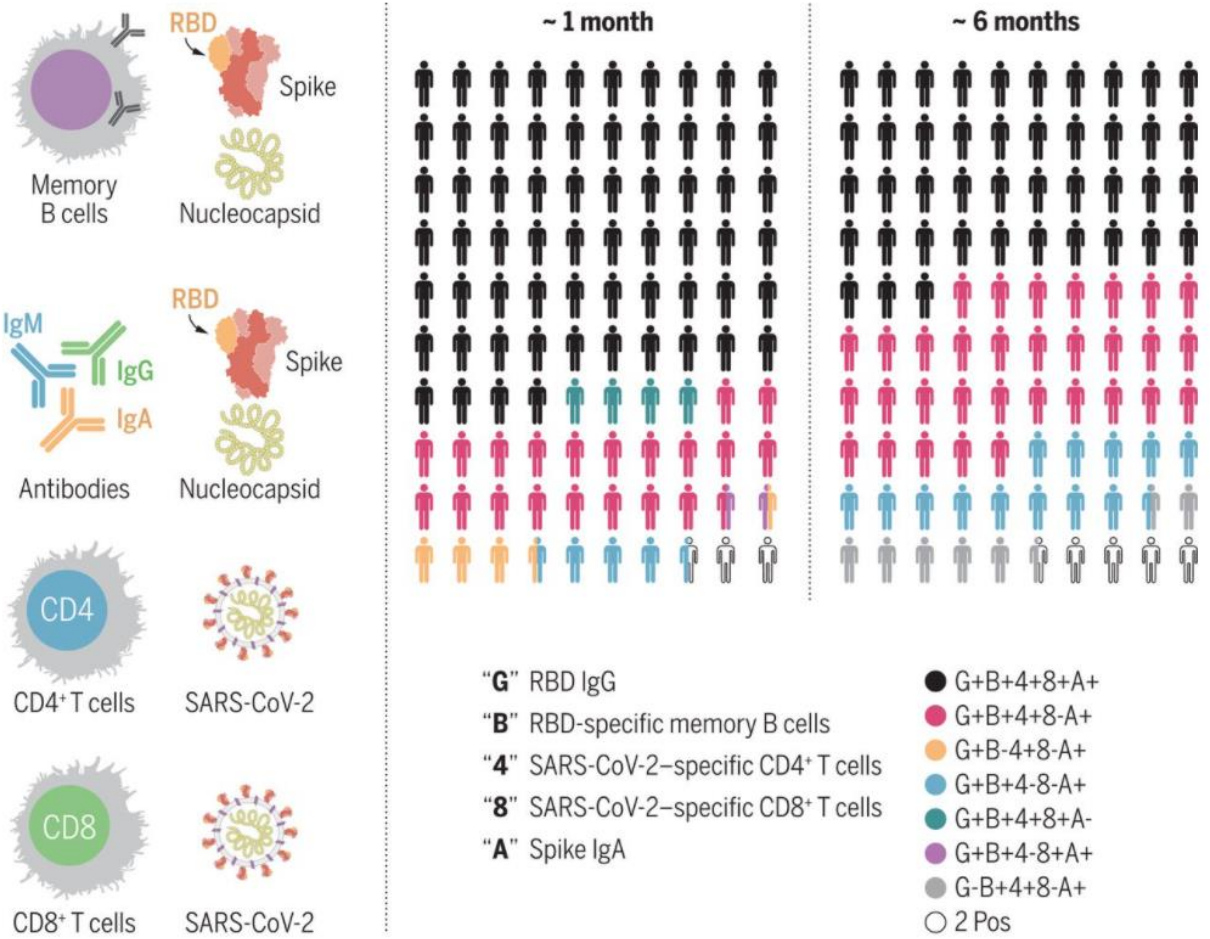
INTRODUCTION

The rationale behind vaccination is to provide protection against the SARS-CoV-2 virus.

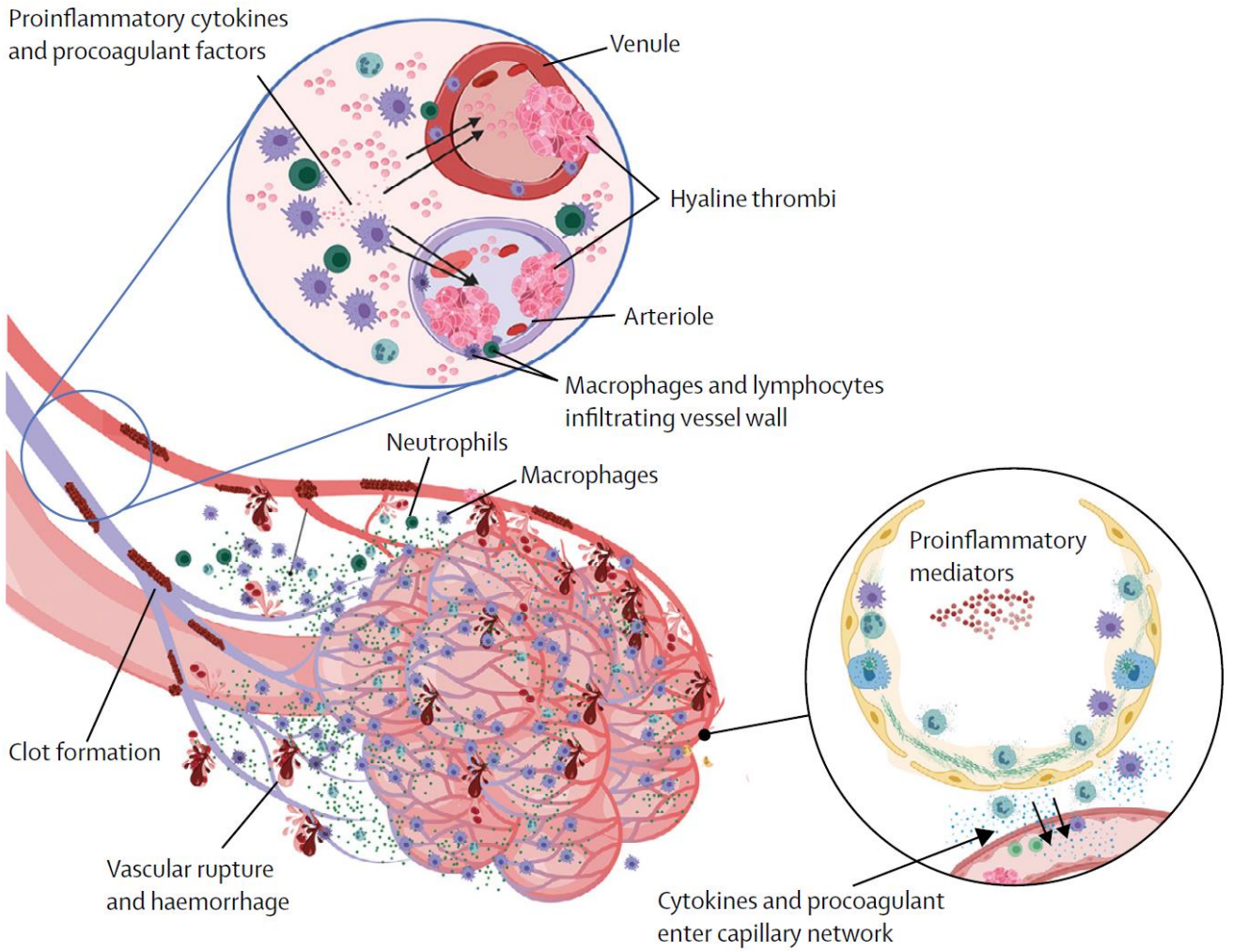
This is achieved by stimulating the immune system to produce antibodies against the virus, to develop immunological memory and thus the ability to fight off the virus for a long time.



Dan et al, Science, 2021, DOI: 10.1126/science.abf4063

INTRODUCTION

Individuals infected with SARS-CoV-2 mount the same kind of response to the virus but can develop severe and potentially fatal complications.



McGonagle et al, Lancet Rheumatol, 2020

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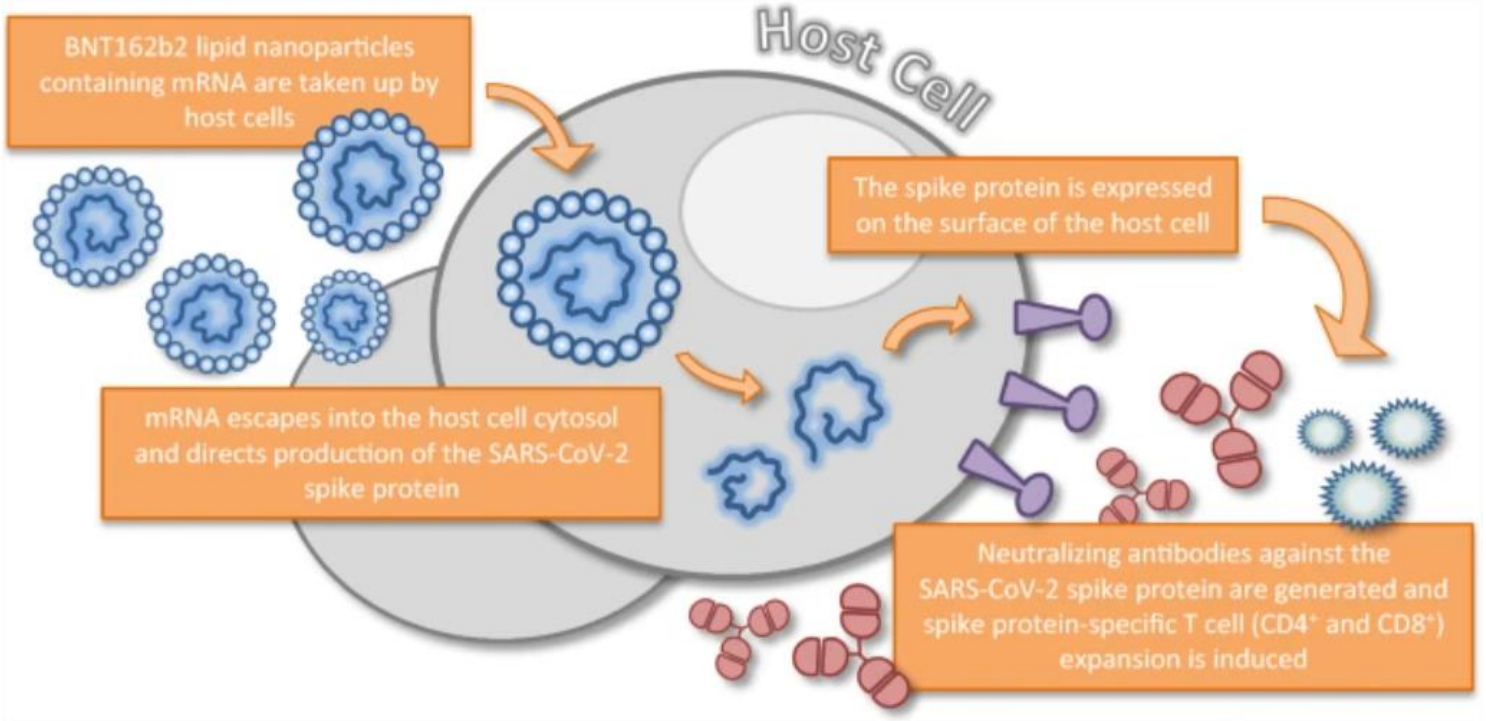
INTRODUCTION

Vaccination exposes the immune system to viral proteins that will elicit a response.
This can be achieved by administering:

- recombinant viral proteins
- genetic information encoding those proteins (mRNA)
- another gutted virus engineered to encode proteins of the target virus

The first two approved vaccines are mRNA vaccines.



Prompting the cells to produce viral proteins mimics what the virus does in the course of natural infection to replicate itself but without causing morbidity.

All approved vaccines have shown safety and effectiveness.

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Lamb, Drugs, 2021, https://doi.org/10.6084/m9.figshare.13557800

RECOMMENDATION 1

People with bleeding disorders (PWBD) are not at greater risk of contracting COVID-19 or developing a severe form of the disease, and so they are not considered a priority group for vaccination. The general selection rules will apply to people with hemophilia. Hemophilia patients belonging to risk groups according to their age, state of health or occupation will be vaccinated as a priority like others in the general population with the same risk profile.

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RECOMMENDATION 2

There is currently no reason to select a particular type of vaccine for patients with bleeding disorders. Some vaccines under development and some that have been already approved use an adenovirus. **Adenovirus is unrelated to adeno-associated Viruses (AAV) and is not being used in hemophilia gene therapy, thus there is no contraindication for using it in the bleeding disorders population. No vaccines against SARS-CoV-2 using AAV viruses are currently in clinical trials**, but caution may be required for the future. PWBD who are contemplating AAV gene therapy in the future or have received it in the past should avoid any future vaccines using modified AAV. This type of virus is widely used as a vector for gene therapy treatments.

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RECOMMENDATION 3

The vaccine should be administered intramuscularly. The smallest gauge needle available (25-27 gauge) should be used, if possible. Some vaccines must be administered using the accompanying needle-syringe combination, and so the use of an alternative needle may not be possible or desirable. Pressure should be applied to the site for at least 10 minutes post-injection to reduce bleeding and swelling. Additionally, self-inspection/palpation of the injection area several minutes and 2-4 hours later is recommended to ensure that there is no delayed hematoma. **Discomfort in the arm felt for 1-2 days after injection should not be alarming unless it worsens and is accompanied by swelling. Any adverse events (e.g., hematoma, allergic reaction) should be reported to a hemophilia treatment centre.**

… continued

RECOMMENDATION 3

Anticipatory guidance should be given to patients to contact their physician immediately or go to the nearest hospital emergency room right away if they experience an allergic reaction (fever, warmth, redness, itchy skin rash, shortness of breath, or swelling of the face or tongue) as it can be life-threatening. **Patients with a history of allergic reactions to extended half-life clotting factor concentrates containing polyethylene glycol (PEG) should discuss vaccine choice with their physician because some vaccines contain PEG as an excipient. PWH and other PWBD who have had a history of allergic or anaphylactic reactions to blood products, including factor concentrates, plasma and cryoprecipitate, but have not had reactions to previous vaccines, are at no greater risk than the overall population for a reaction to a COVID-19 vaccine.**

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RECOMMENDATION 4

We recognize many individuals with bleeding disorders may not have ready access to hemostatic therapies prior to vaccination. In these cases, make efforts to access **WFH Humanitarian Aid** program or other clotting factors if possible. Alternatively, follow the instructions above making sure the smallest possible needle is used and maintain pressure for more than 10 minutes.

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RECOMMENDATION 5

For patients with severe/moderate hemophilia or Type 3 von Willebrand disease (VWD) (regardless of whether they routinely receive prophylaxis or on-demand treatment) the injection should be given after a FVIII or FIX injection, or following a von Willebrand factor-containing injection, respectively. **Vaccinations have not been shown to prime FVIII or FIX inhibitor formation in patients with hemophilia.** In particular, vaccines against viruses with RNA genomes (influenza, mumps, measles, rubella), like SARS-CoV-2, did not enhance inhibitor formation in an animal model. Mild hemophilia patients with baseline FVIII or FIX levels below 10% may also need haemostatic treatment prior to vaccination and should consult their hemophilia treatment center.

… continued

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RECOMMENDATION 5

For patients with a basal FVIII or FIX level above 10%, no haemostatic precautions are required. Similarly, patients on emicizumab (with or without an inhibitor) can be vaccinated by intramuscular injection at any time without extra haemostatic protection. Depending on their baseline VWF activity levels patients with Type 1 or 2 VWD should use therapies (ie, DDAVP if available, tranexamic acid), in consultation with their hemophilia treatment center. **All rare bleeding disorder patients (including those with thrombocytopenia and/or platelet function disorders) should be vaccinated.** Haemostatic support would depend on the severity of the disorder and should be decided in consultation with their treatment center.

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RECOMMENDATION 6

There are no specific contraindications to vaccination related to complications of hemophilia and other bleeding disorders or their therapies. **Immune tolerance, treatment of hepatitis C and HIV and other conditions do not contraindicate vaccination.** However, the U.K. Medicines and Healthcare Products Regulatory Agency and the Centers for Disease Control and Prevention have advised caution in using the Pfizer/BioNtech vaccine in people with a history of significant allergic reactions. Specific recommendations for people with a history of allergic/anaphylactoid reactions can be found in advisories published by both agencies. Other potential contraindications should be discussed individually with the physician because recommendations vary in different jurisdictions due to lack of data in special populations (e.g. pregnant or breastfeeding women).

RECOMMENDATION 7

Vaccination is not contraindicated for patients on immunosuppressive agents (cortisone, other immunosuppressive drugs), but their immune responses and protection from infection may be reduced.

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RECOMMENDATION 8

For patients in a clinical study, vaccination should be discussed with and reported to the study investigators.

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RECOMMENDATION 9

It is important that **hemophilia treatment centres, in close collaboration with patient associations**, take action to inform patients about the vaccines and contribute to an effective vaccination program.

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CONCLUSIONS

Vaccines against COVID-19 are safe and effective.

People with bleeding disorders should be vaccinated.

The success of the fight against the COVID-19 pandemic will depend on expeditious vaccination of the largest possible number of well-informed individuals worldwide.

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An Update on

The Allocation of COVID-19 Vaccines

THE LATEST ON THE COVID-19 GLOBAL SITUATION
& GLOBAL VACCINE ALLOCATION

Ioana Ghiga, MPH & PhD
Technical Officer, WHO
Switzerland

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OVERVIEW

- Global access to COVID-19 vaccines
- COVAX Facility
- Global COVID-19 vaccine allocation
- Allocation of vaccines within individual countries
- What is the humanitarian buffer?
- COVAX secured vaccines allocation rounds to date
- Additional resources

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CURRENT GLOBAL SITUATION

As of 10:16am CET, 10 March 2021

- **> 117 million cases**
- 5 countries with highest cumulative number of cases

 United States of America

 India

 Brazil

 Russian Federation

 The United Kingdom

- **> 2.6 million deaths**
- 5 countries with highest cumulative number of deaths

 United States of America

 Brazil

 Mexico

 India

 The United Kingdom

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COVID-19 VACCINES

- Currently, COVID-19 vaccine supply is limited due to insufficient manufacturing capacity and extraordinarily high demand
- While efforts to accelerate the development and production of vaccines are underway, a coordinated response is essential to ensure the fair distribution of vaccines to all countries
- The WHO Emergency Use Listing Procedure (EUL) is a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics with the ultimate aim of expediting the availability of these products to people affected by a public health emergency
- As of 12 March 2021, Pfizer/BioNTech and AZ/Serum Institute of India and AZ/SK Bio, Korea vaccines have already undergone the EUL procedure

https://www.who.int/teams/regulation-prequalification/eul

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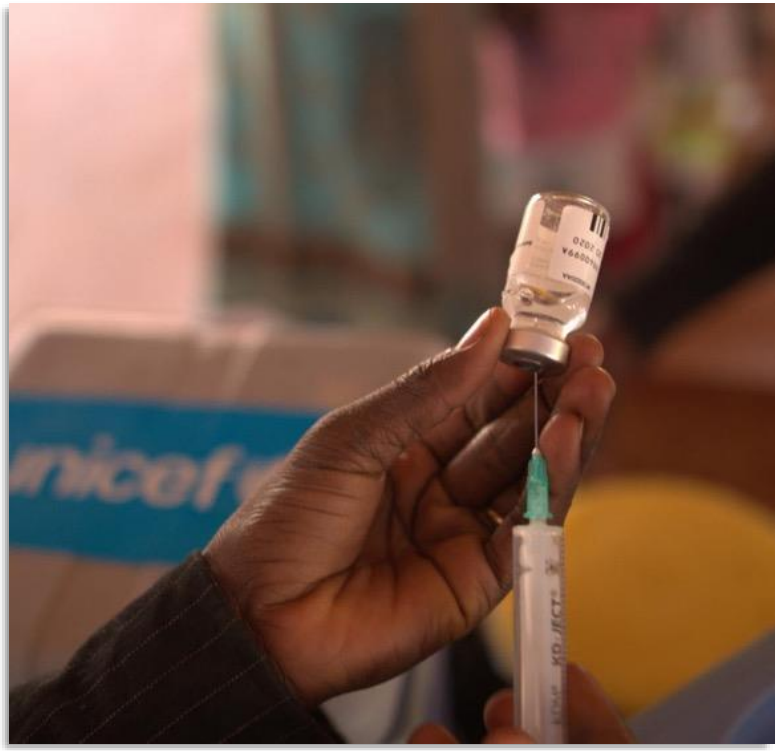
WHY GLOBAL ACCESS TO COVID-19 VACCINES IS IMPORTANT

- Our interconnected world means that SARS-CoV-2 transmission will continue between countries and regions until we are all protected
- It is our moral imperative to provide vaccines to all
- Equitable global access will not only mitigate the **public health impact** but also the **economic impact** of the pandemic as shown by a study of the International Chamber of Commerce Research Foundation
  - ➢ The study shows that if some countries vaccinate all their citizens, while in other countries infection continues to spread, the global economy could lose as much as $9.2 trillion2



© UNICEF/UN023959/Clark

https://iccwbo.org/publication/the-economic-case-for-global-vaccinations/

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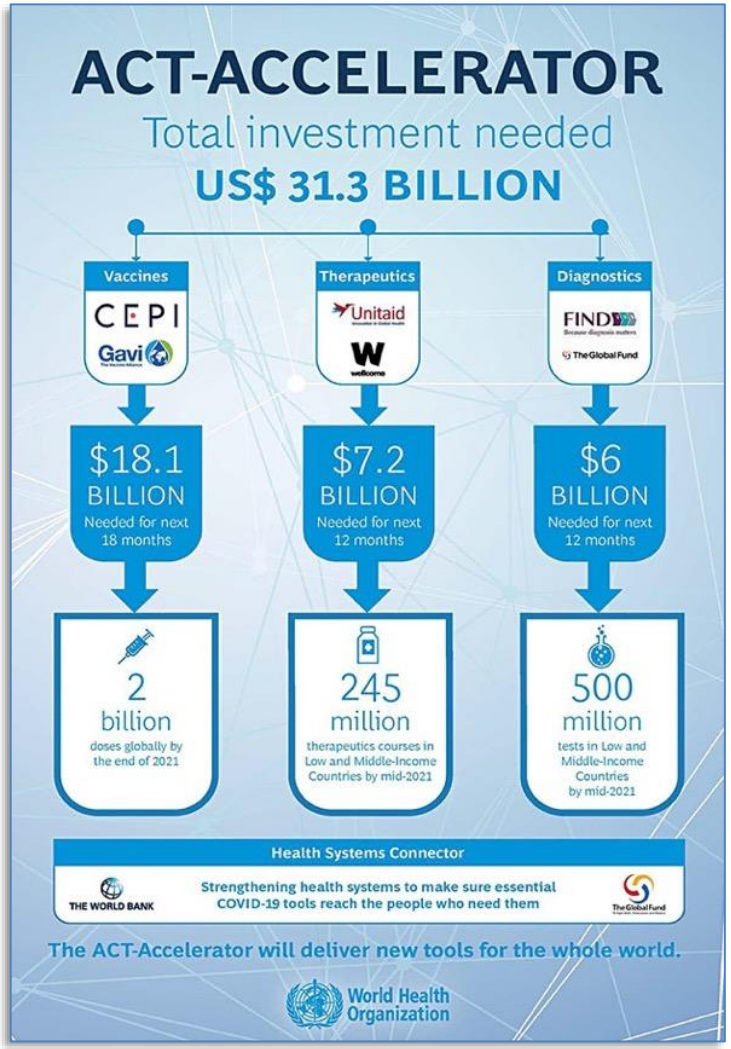
WORKING TOGETHER TO END THE ACUTE PHASE OF THE PANDEMIC

- **The ACT-Accelerator* is a global collaboration to:**
  - **accelerate** development, production, and access to COVID-19 vaccines, diagnostics and therapeutics
  - **distribute** COVID-19 vaccines, diagnostics and therapeutics fairly around the world
- **ACT-A brings together** governments, scientists, businesses, civil society, philanthropists and global health organizations
- **ACT-A** aims to deliver **2 billion doses of vaccine globally by the end of 2021**



https://www.who.int/initiatives/act-accelerator

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THE COVAX FACILITY IS PART OF THE ACT-A VACCINES PILLAR

- **The aim of the COVAX Facility is that all participating countries, regardless of income levels, will have access to COVID-19 vaccines**
- **COVAX Facility** has 191 donors, confirmed participants and participants eligible to join under the AMC92 offer
- These 92 countries are eligible for financial support through the COVAX Advance Market Commitment (AMC)*

* https://www.gavi.org/vaccineswork/gavi-covax-amc-explained

OVERARCHING PRINCIPLES TO ENSURE EQUITABLE ACCESS TO HEALTH PRODUCTS IN THE CONTEXT OF COVID-19

Solidarity: Joining forces to confront this unique challenge together and overcome this pandemic

Accountability: Clearly defined roles and responsibilities to ensure procedural justice

Transparency: To build and maintain trust

Responsiveness to public health needs: Health products are carefully selected and allocated to address the public health need

Equity and fairness: to inform the allocation process together with public health needs

Affordability: Consideration is given to pricing and procurement strategies to improve affordability of health products

Collaboration: Collaborative efforts amongst relevant global and national stakeholders is enhanced to accelerate and scale-up the response

Regulatory and procurement efficiency: Agile and comprehensive regulatory and procurement approaches are incorporated to improve timely access to safe, efficacious and quality health products for all countries in need

https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility

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GLOBAL COVID-19 VACCINE ALLOCATION

- The allocation of COVID-19 vaccines is guided by public health objectives. For the initial phase these objectives are:
  - Reduce mortality
  - Protect health systems
- To maximise the public health impact of a **limited supply of COVID-19 vaccines**, the global vaccines allocation mechanism targets:
  - **high risk groups** (people over the age of 65, people with cardiovascular diseases, cancer, diabetes, chronic respiratory disease or obese) **to reduce severe disease and mortality**
  - **health workers to protect the health system**
- These groups correspond to 20% of the global population
- Therefore, the first phase of COVID-19 vaccines allocation will be up to 20% of a country's population

https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility
https://www.who.int/publications/m/item/allocation-mechanism-for-covax-facility-vaccines-explainer

ALLOCATION OF VACCINES WITHIN INDIVIDUAL COUNTRIES

- The COVAX distribution mechanism **does not decide for countries which populations should be prioritized for immunization**
- Individual countries can use their allocated doses based upon their own situation and guidance from national policy makers
- Countries may consider the *recommendations regarding prioritizing groups* issued by WHO Strategic Advisory Group of Experts on Immunization (SAGE) to maximise public health impact when vaccine supplies are limited

https://www.who.int/publications/m/item/who-sage-roadmap-for-prioritizing-uses-of-covid-19-vaccines-in-the-context-of-limited-supply
https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf?ua=1

HOW WILL COVID-19 VACCINES SECURED THROUGH THE COVAX FACILITY BE ALLOCATED?

The allocation of vaccines to COVAX countries is based on the Global Allocation Framework and occurs through phases

PHASE 1
Proportional distribution up to 20% of the population of a country

- **COVAX countries receive doses for 20% of their population**
- Once all countries have reached 20% coverage, the allocation moves on to phase 2

PHASE 2
Weighted distribution beyond 20% of the population of a country

- Countries receive vaccines to expand coverage requested for their population
- If supply constraints persist, a weighted allocation approach would be adopted, taking into account a country's COVID-19 threat and vulnerability

https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility
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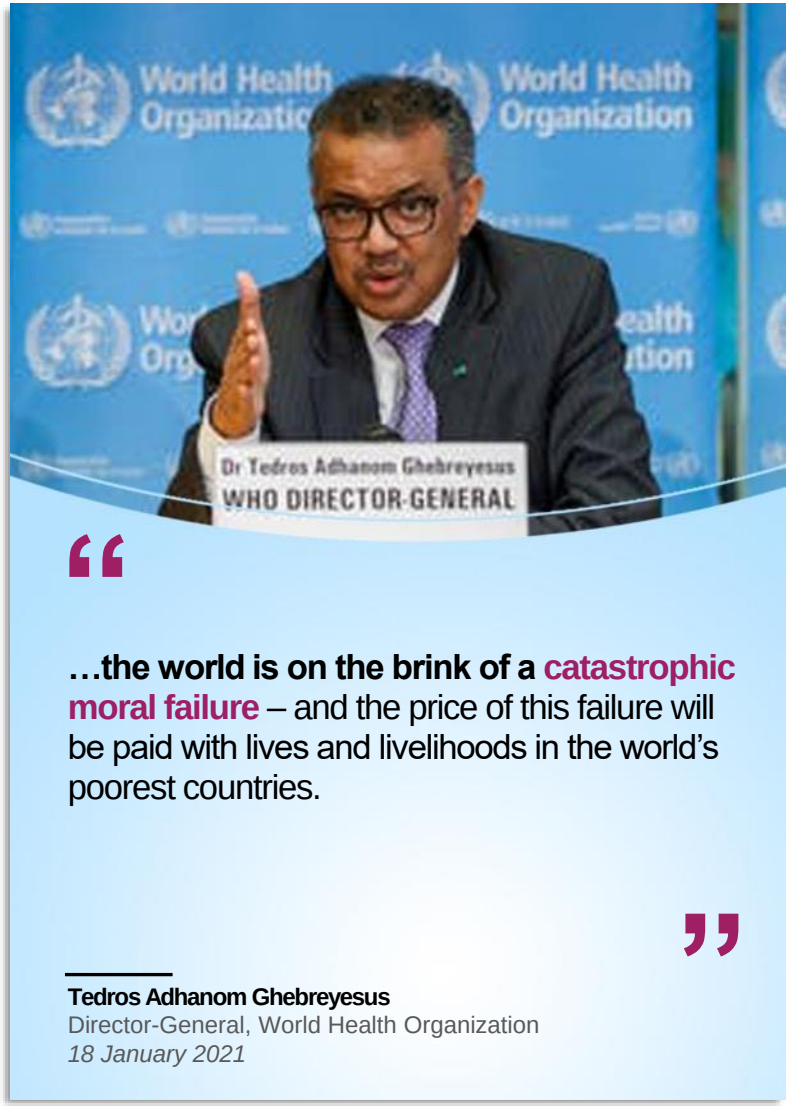
WHAT IS THE HUMANITARIAN BUFFER?

- The humanitarian buffer is meant to overcome any further equity gaps in access and allocation
- It represents **up to 5 % of the total number of available vaccine doses supplied by the COVAX Facility, and reserved for vulnerable populations** such as:
  - refugees and displaced populations
  - migrants
  - asylum seekers
- The humanitarian buffer aims to serve as a provider of last resort to reach certain populations

GLOBAL ACCESS TO COVID-19 VACCINES

- **9 March 2021, a total of 268,205,245 vaccine doses** have been administered[1]
  - **Vaccination has started in 129 economies** incl. 65 HICs, 36 UMICs, 25 LMIC and 3 LIC



[1] https://covid19.who.int/

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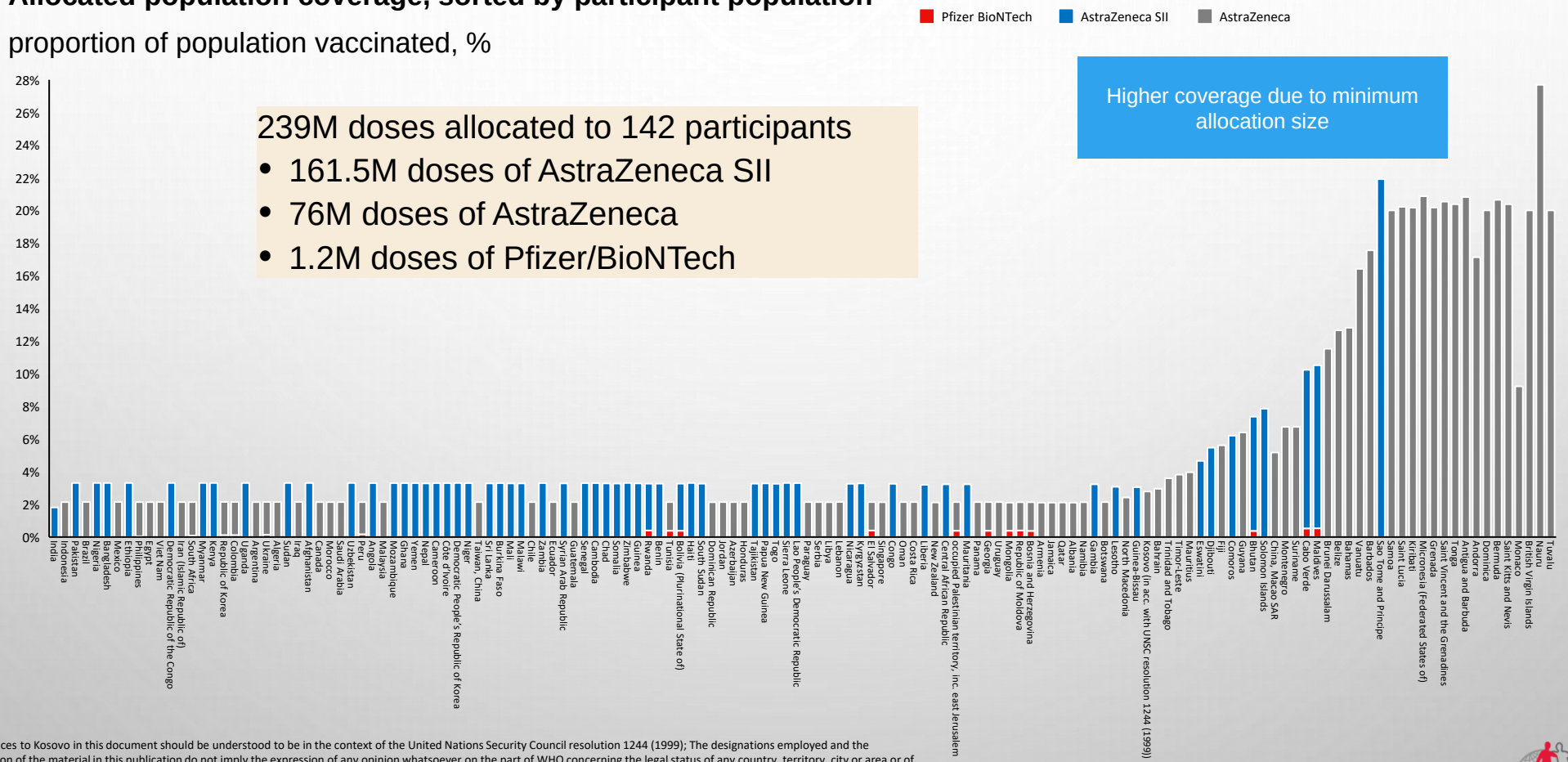
ALLOCATIONS FOR COVAX FACILITY SECURED VACCINES TO DATE

Product Name	WHO EUL date	Allocation round	IAVG approval or allocation communication date	Supply allocated
"Pfizer" BNT162b2/COMIRNATY Tozinameran	30 Dec 2020	1	29 Jan 2021	**1,200,420 doses** for Feb and Mar supply forecast
"SII AZ" Serum Institute of India Pvt Ltd - COVID-19 Vaccine (ChAdOx1-S [recombinant]) - COVISHIELD™	15 Feb 2021	2	23 Feb 2021	**161,472,000** for Jan to May supply forecast
"AZ" AstraZeneca/SKBio - COVID-19 Vaccine (ChAdOx1-S [recombinant]) AZD1222	15 Feb 2021	2	23 Feb 2021	**75,996,000** for Jan to May supply forecast

ALLOCATIONS FOR COVAX FACILITY SECURED VACCINES TO DATE

Allocated population coverage, sorted by participant population

proportion of population vaccinated, %



239M doses allocated to 142 participants

- 161.5M doses of AstraZeneca SII
- 76M doses of AstraZeneca
- 1.2M doses of Pfizer/BioNTech

Higher coverage due to minimum allocation size

ALLOCATIONS FOR COVAX FACILITY SECURED VACCINES TO DATE

	Weighted average coverage	Minimum coverage	Maximum Coverage
AMC	2.55%	1.81%	21.92%
SFP	2.18%	2.11%	27.69%
Overall	2.47%	1.81%	27.69%

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WHO GLOBAL VACCINATION TRACKER – AS OF 9 MARCH 2021

WHO Vaccination Tracker: https://covid19.who.int/

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RESOURCES

- **Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility**
  https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility
  https://www.who.int/publications/m/item/allocation-mechanism-for-covax-facility-vaccines-explainer

- **WHO SAGE values framework for the allocation and prioritization of COVID-19**
  https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf?ua=1

- **COVAX Advance Market Commitment explained**
  https://www.gavi.org/vaccineswork/gavi-covax-amc-explained
  https://www.who.int/publications/m/item/allocation-mechanism-for-covax-facility-vaccines-explainer

- **WHO vaccination dashboard**
  https://covid19.who.int/

- **COVID-19 vaccine introduction toolkit**

  https://www.who.int/tools/covid-19-vaccine-introduction-toolkit#Data%20and%20monitoring

- **WHO SAGE Roadmap For Prioritizing Uses Of COVID-19 Vaccines In The Context Of Limited Supply**
  https://www.who.int/publications/m/item/who-sage-roadmap-for-prioritizing-uses-of-covid-19-vaccines-in-the-context-of-limited-supply

THANK YOU

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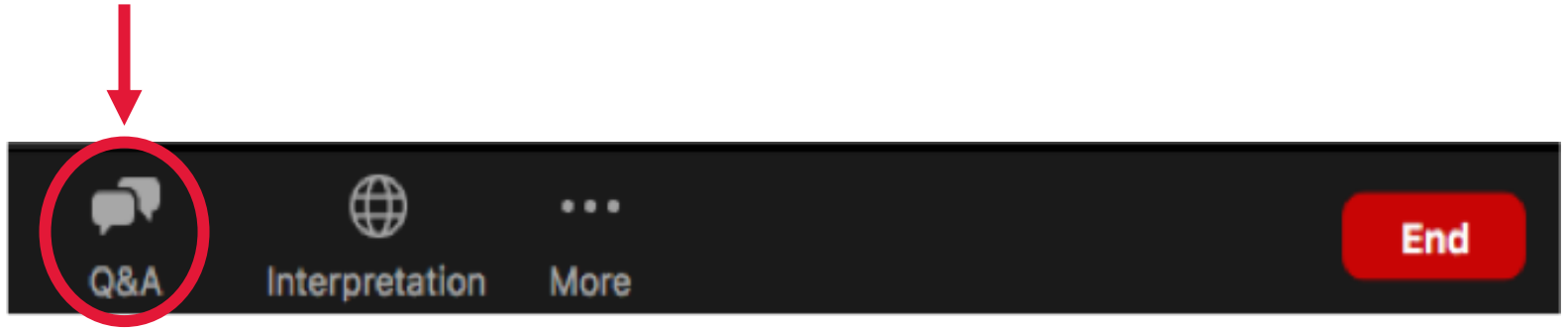
QUESTION & ANSWER

Please submit your questions in the Q&A box



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THANK YOU!

¡GRACIAS!

MERCI!

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СПАСИБО

STAY SAFE!

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