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A simple clinical analysis of the Covid vaccine efficacy data

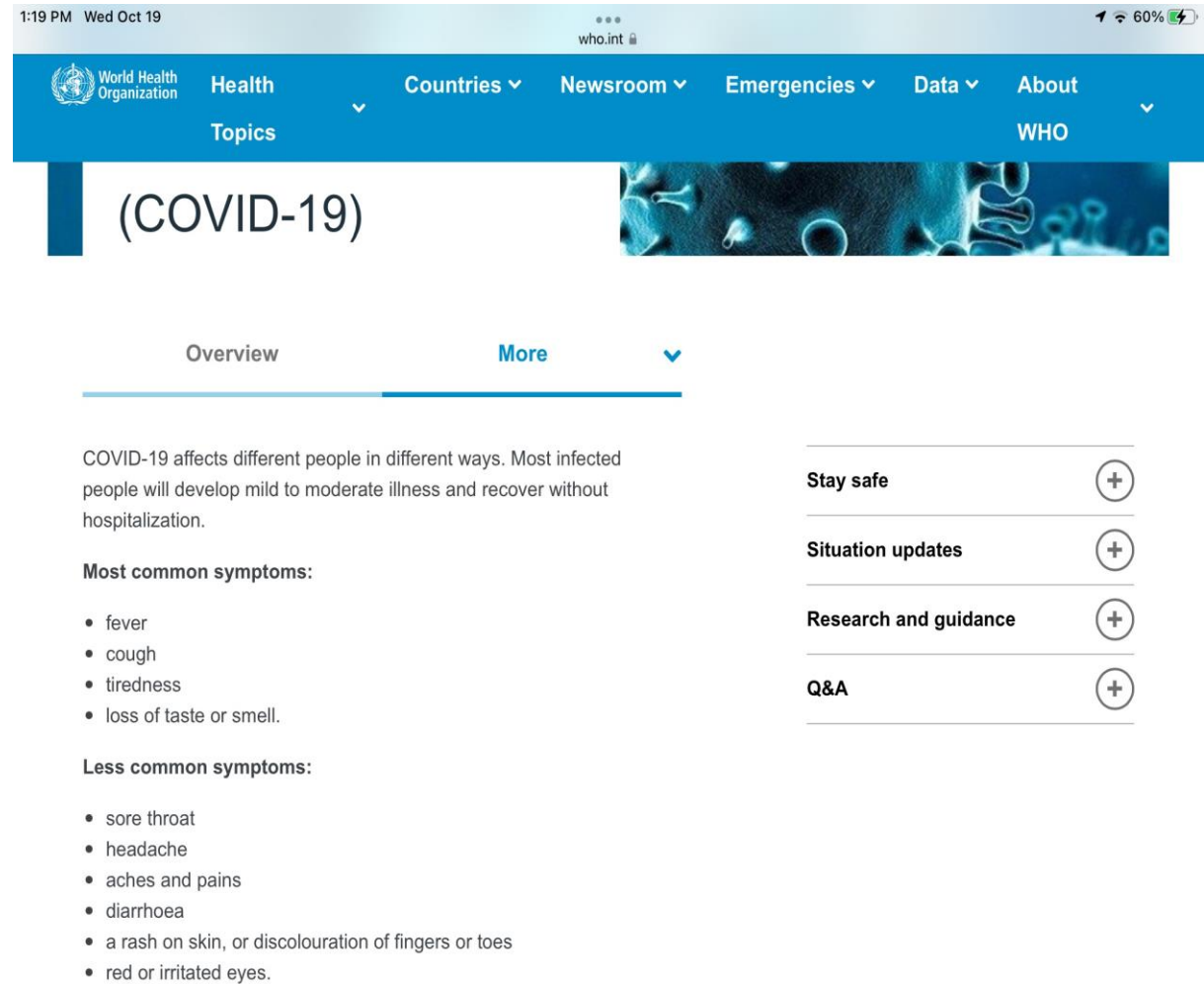


A screenshot of a mobile browser displaying the website of the Centre for Evidence-Based Medicine (CEBM). The browser's address bar shows 'cebm.ox.ac.uk'. The website header includes the Nuffield Department of Primary Care Health Sciences logo and navigation links for 'ABOUT', 'RESEARCH', 'STUDY WITH US', 'TEAM', 'PUBLIC INVOLVEMENT', 'NEWS', and 'EVENTS'. Below the header, the CEBM logo and 'Centre for Evidence-Based Medicine' text are visible, along with links for 'Site Map', 'Contact', 'Cookies', and 'Log in'. A search bar is located on the right. The main content area features a breadcrumb trail: 'Forms library / The Lack of Scientific Freedom: Causes, Consequences and Cures conference Copenhagen, Denmark 24 - 25 October 2022'. The title of the page is 'The Lack of Scientific Freedom: Causes, Consequences and Cures conference Copenhagen, Denmark 24 - 25 October 2022'. Underneath, there are two sections: 'FORMS LIBRARY' with a link to 'EBHC skill workshops - express your interest!' and 'ABSTRACT Submission Form' with the text 'The deadline for submissions is July 31st 2022.' and 'Abstracts will be reviewed and notifications of decisions sent by June 30th 2022.'

www.brownstone.org
www.conservativewoman.co.uk
www.achgut.com

Covid-19

- Clinical symptoms: Common cold or flu
- Risk: Atypical pneumonia ("severe form"), death
- Risk Factors: Advanced age, comorbidities, obesity
- Clinically, ***not a specific disease***



The screenshot shows the WHO website for COVID-19. The top navigation bar includes the WHO logo, 'World Health Organization', and menu items for 'Health Topics', 'Countries', 'Newsroom', 'Emergencies', 'Data', and 'About WHO'. Below the navigation bar, the page title '(COVID-19)' is displayed next to a microscopic image of the virus. A tabbed interface shows 'Overview' and 'More'. The main content area provides an overview of the disease, listing common and less common symptoms. A sidebar on the right contains expandable sections for 'Stay safe', 'Situation updates', 'Research and guidance', and 'Q&A'.

1:19 PM Wed Oct 19 who.int

World Health Organization Health Topics Countries Newsroom Emergencies Data About WHO

(COVID-19)

Overview More

COVID-19 affects different people in different ways. Most infected people will develop mild to moderate illness and recover without hospitalization.

Most common symptoms:

- fever
- cough
- tiredness
- loss of taste or smell.

Less common symptoms:

- sore throat
- headache
- aches and pains
- diarrhoea
- a rash on skin, or discolouration of fingers or toes
- red or irritated eyes.

Stay safe (+)

Situation updates (+)

Research and guidance (+)

Q&A (+)

Demonstration of vaccine efficacy in pivotal studies

- What should have been / should be carried out:

Mortality trials in the at-risk population

(e.g.: >65 years of age, at least one serious comorbidity and/or BMI > 35)

- What was carried out:

Common cold trials in people 16 years of age and older

Clinical endpoints in pivotal trials

Pfizer	Moderna
(at least one symptom)	(at least two symptoms)
Fever	Fever
New or increased cough	Chills
New or increased shortness of breath	Myalgia
Chills	Headache
New or increased muscle pain	Sore throat
New loss of taste or smell	New olfactory or taste disorder
Sore throat	Respiratory symptoms: Cough, shortness of breath, Clinical or radiologic evidence of pneumonia
Diarrhea or Vomiting	

Patients who reported these symptoms were submitted to SARS-CoV-2 PCR-testing. If the test was positive (no CT threshold in the protocol), the endpoint of "symptomatic Covid-19" was considered as having been reached.

Results

- Presented as: Significant decrease of "Covid-19 illness" ("95% protection")
- What was shown: A significant decrease in the number of positive PCR tests in people presenting with common cold / flu symptoms
- What was **not** shown: A decrease in common cold / flu symptoms

The image shows two screenshots from a web browser. The top screenshot is from the New England Journal of Medicine (NEJM) website, displaying the article "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine" by Fernando P. Polack et al., published on December 31, 2020. The article's abstract is visible, starting with "BACKGROUND Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and the resulting coronavirus disease 2019 (Covid-19) have afflicted tens of millions of people in a worldwide pandemic. Safe and effective vaccines are needed urgently." The bottom screenshot is from the FDA website, showing a PDF document titled "FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine" with a sponsor listed as "Pfizer and BioNTech".

11:26 AM Thu Oct 20
nejm.org
ORIGINAL ARTICLE
Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine
Fernando P. Polack, M.D., Stephen J. Thomas, M.D., Nicholas Kitchin, M.D., Judith Absalon, M.D., Alejandra Gurtman, M.D., Stephen Lockhart, D.M., John L. Perez, M.D., Gonzalo Pérez Marc, M.D., Edson D. Moreira, M.D., Cristiano Zerbini, M.D., Ruth Bailey, B.Sc., Kena A. Swanson, Ph.D., et al., for the C4591001 Clinical Trial Group*

December 31, 2020
N Engl J Med 2020; 383:2603-2615
DOI: 10.1056/NEJMoa2034577
Chinese Translation 中文翻译

13 References 6446 Citing Articles Letters

Abstract

BACKGROUND
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and the resulting coronavirus disease 2019 (Covid-19) have afflicted tens of millions of people in a worldwide pandemic. Safe and effective vaccines are needed urgently.

METHODS
In an ongoing multinational, placebo-controlled, observer-blinded, pivotal

11:27 AM Thu Oct 20
fda.gov
1 of 53
FDA Briefing Document
Pfizer-BioNTech COVID-19 Vaccine
Sponsor:
Pfizer and BioNTech
5

"Efficacy" Data from the Pfizer trial

	BNT162b2 (Vaccine)	Placebo	Total
"Symptomatic Covid-19" (symptoms + positive test)	8	162	170
"Suspected Covid-19" (symptoms + negative test)	1,594	1,816	3,410
"Suspected Covid-19" within 7 days of vaccination	409	287	696

"Suspected Covid-19" cases:

More than 20 times as many people with exactly the same clinical symptoms (but with a negative PCR test) – simply and completely dropped from the analysis

Adverse Events in the Pfizer trial: The same non-specific clinical symptoms, again

"Solicited Systemic Adverse Events"

	BNT162b2	Placebo
Fever	331	10
Fatigue	1,247	479
Headache	1,085	506
Chills	737	79
Myalgia	783	173
Diarrhoea	4	1
Vomiting	40	25

Frequency up to 7 days after Dose 2 in the reactogenicity subset (around 10%) of the safety population, 18 to 55 years of age

" Unsolicited AEs"

	BNT162b2	Placebo
Fatigue	1,029	260
Pyrexia	1,146	61
Chills	999	87
Myalgia	909	126
Headache	973	304
Diarrhoea	194	149
Nausea	216	63

Frequency from Dose 1 to one month after Dose 2, total Phase 2/3 safety population

Conclusions from vaccine trials

- Reduction in test-positivity for SARS-CoV-2 virus: Interesting **biological** result (if real)
- **Clinically**, people were much sicker (*more fever, more chills, more myalgia, more diarrhoea and vomiting, more headaches*) in the vaccine than in the placebo group
- No conclusions whatsoever can be drawn for severe forms of pneumonia and mortality
 - Claimed reductions in "severe Covid-19" not statistically significant
 - All-cause pneumonias and hospitalisations not analysed
 - 6-month mortality in Pfizer trial: 21 in the vaccine and 15 in the placebo group
- Non-specific disease – pivotal trial endpoint would have to be *all-cause pneumonias* and *all-cause mortality*, in order to gauge an intervention's clinical benefit (or harm)
- Covid mortality (at average age of >80 years) part of normal and unavoidable population mortality – to be prevented by a vaccine?

Questions

- How did the vaccine trials - full of sound and fury, signifying nothing – pass peer reviews of the world’s most prestigious medical journals?
- How on earth did / do these data pass regulatory scrutiny?
- What does all this mean for scientific freedom and truth?



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