Webinar COVID-19 – Minerva – huisartsen
15 dec 2020

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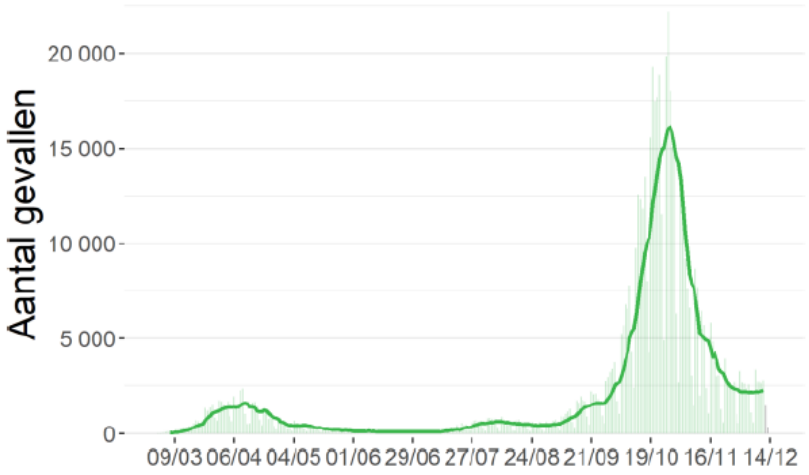
Vaccine & Infectious Disease Institute
Centre for the Evaluation of Vaccination
University of Antwerp, Antwerp, Belgium

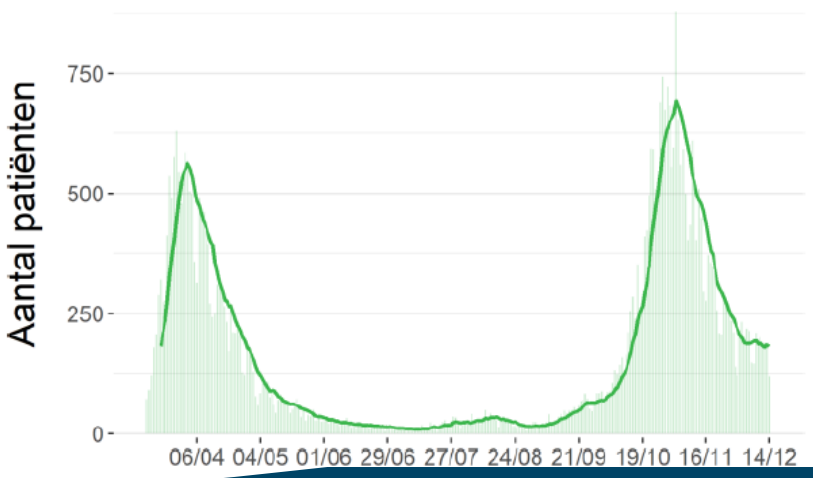
1. Kerncijfers - Trends

Aantal gerapporteerde patiënten	In totaal	Daggemiddelde gedurende de voorlaatste periode van 7 dagen	Daggemiddelde gedurende de laatste periode van 7 dagen	Evolutie
Bevestigde COVID-19 gevallen	609 211	2 151	2 274*	+6%
Opnames in het ziekenhuis	45 051***	192,3	181,6**	-6%
Sterfgevallen****	18 054	108,3	90,0*	-17%
In ziekenhuizen	*10 098*	*64,1*	*52,3*	*-18%*
In woonzorgcentra	*7 801*	*43,3*	*37,6*	*-13%*

Evolutie van het aantal bevestigde gevallen



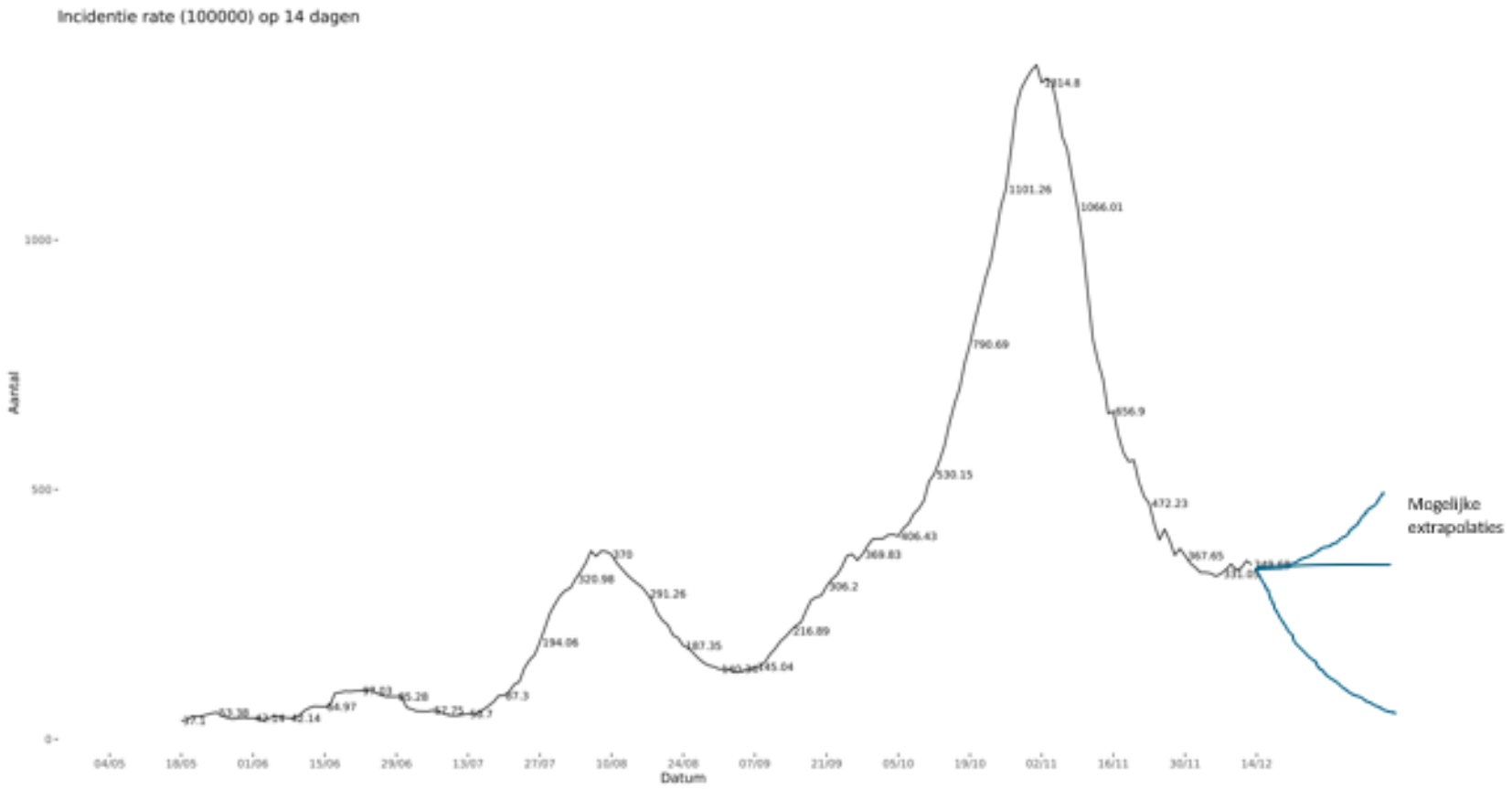
Evolutie van het aantal nieuwe door het labo bevestigde opnames in het ziekenhuis



Verdeling van het aantal bevestigde gevallen en de verdubbelingtijd (of de halveringstijd) voor België, per provincie, voor het Brusselse Hoofdstedelijke Gewest en voor de Duitstalige Gemeenschap, wordt in de onderstaande tabel weergegeven.

	28/11-4/12	5/12-11/12	Verschil (absoluut aantal)	Verschil (percentage)	Verdubbelings-/halveringstijd (dagen)	14-daagse incidentie per 100 000
België	**15 055**	**15 917**	**862**	**+6%**	**87**	**269**
Antwerpen	2 334	2 647	313	+13%	39	266
Brabant wallon	457	447	-10	-2%	219	223
Hainaut	1 957	2 047	90	+5%	108	297
Liège	1 191	1 154	-37	-3%	154	211
Limburg	969	1 086	117	+12%	43	234
Luxembourg	593	530	-63	-11%	43	392
Namur	624	704	80	+13%	40	268
Oost-Vlaanderen	2 239	2 530	291	+13%	40	313
Vlaams-Brabant	1 281	1 206	-75	-6%	80	215
West-Vlaanderen	2 011	2 230	219	+11%	47	353
Brusselse Hoofdstedelijke Gewest	1 172	1 066	-106	-9%	51	184
Deutschsprachige Gemeinschaft	61	95	34	+56%	11	200

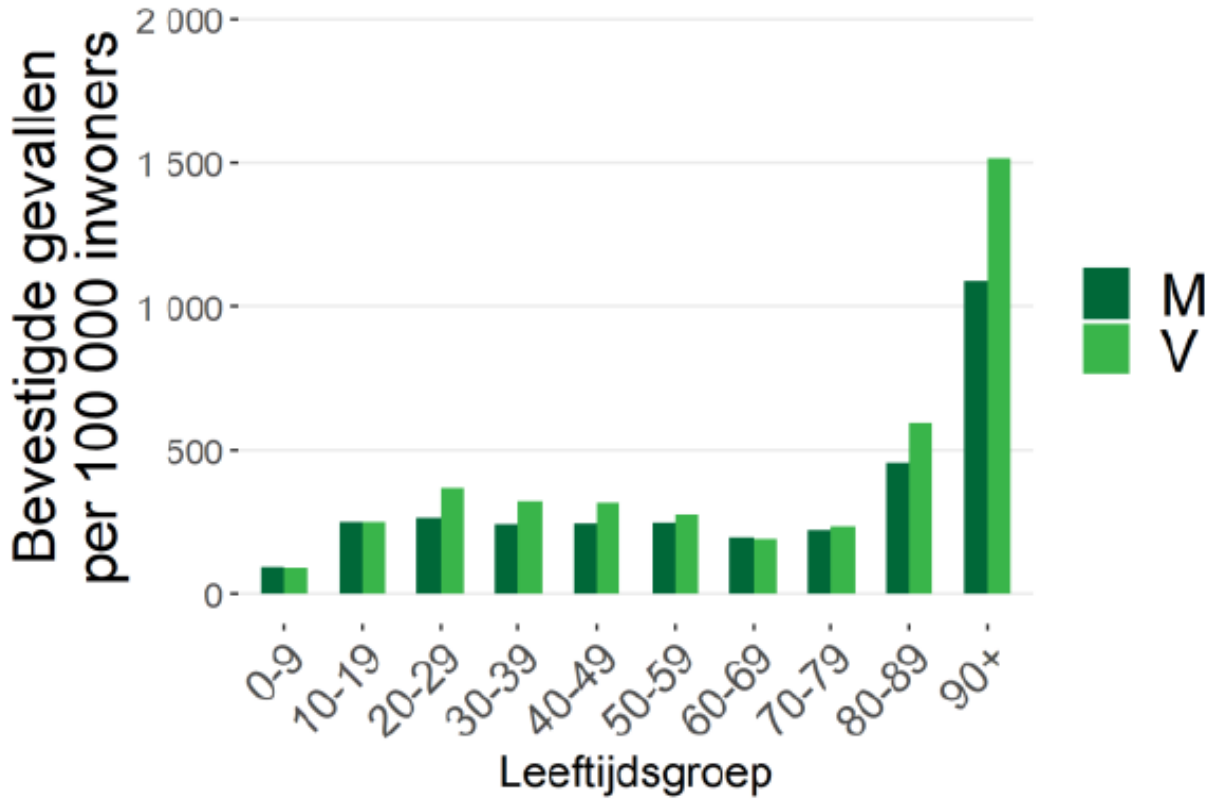
Besmettingen – voortschrijdend over 14 dagen



Reproductiegetal – 14:12:2020

	Mediane schatting	Ondergrens (kwantiel 2.5)	Bovengrens (kwantiel 97.5)
België	**1,040**	**1,024**	**1,057**
Antwerpen	**1,118**	1,076	1,161
Brabant wallon	**1,046**	0,952	1,145
Hainaut	**1,019**	0,975	1,063
Liège	**0,966**	0,911	1,022
Limburg	**1,065**	1,002	1,129
Luxembourg	**0,942**	0,864	1,024
Namur	**1,089**	1,010	1,171
Oost-Vlaanderen	**1,080**	1,039	1,123
Vlaams-Brabant	**0,926**	0,874	0,979
West-Vlaanderen	**1,081**	1,037	1,127
Brusselse Hoofdstedelijke Gewest	**0,949**	0,893	1,007
Deutschsprachige Gemeinschaft	**1,326**	1,074	1,603

Aantal bevestigde gevallen tussen 28/11 en 11/12 per leeftijdscategorie en geslacht per 100 000 inwoners



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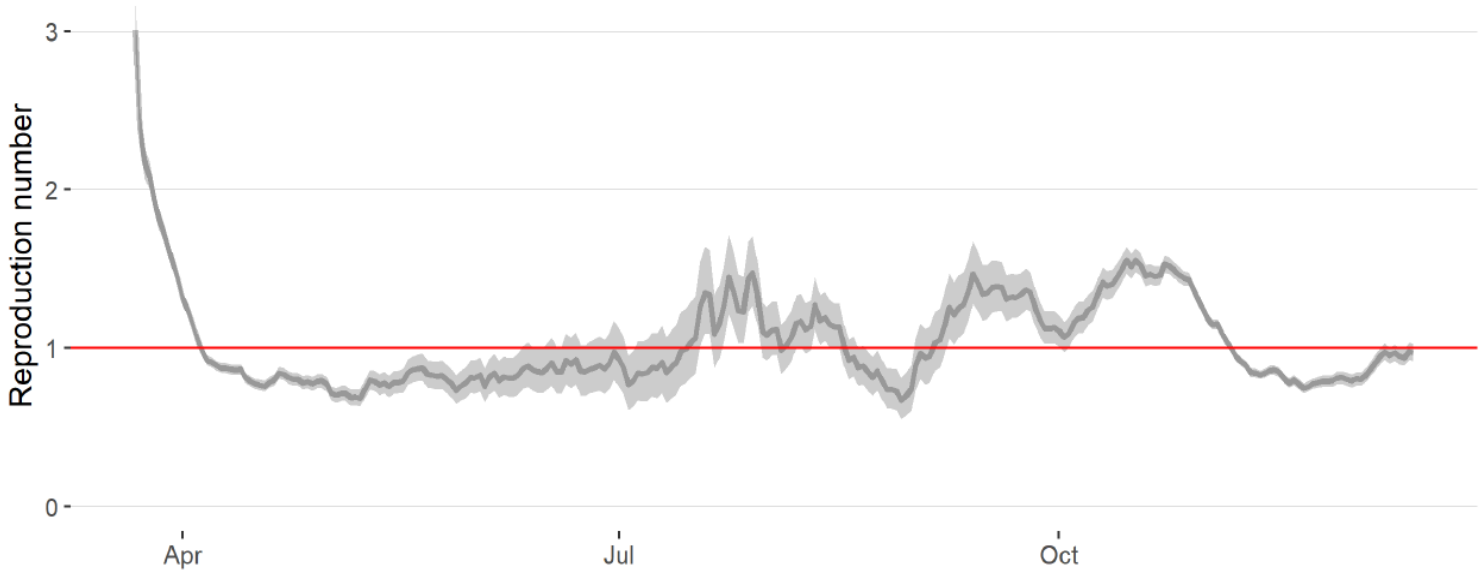
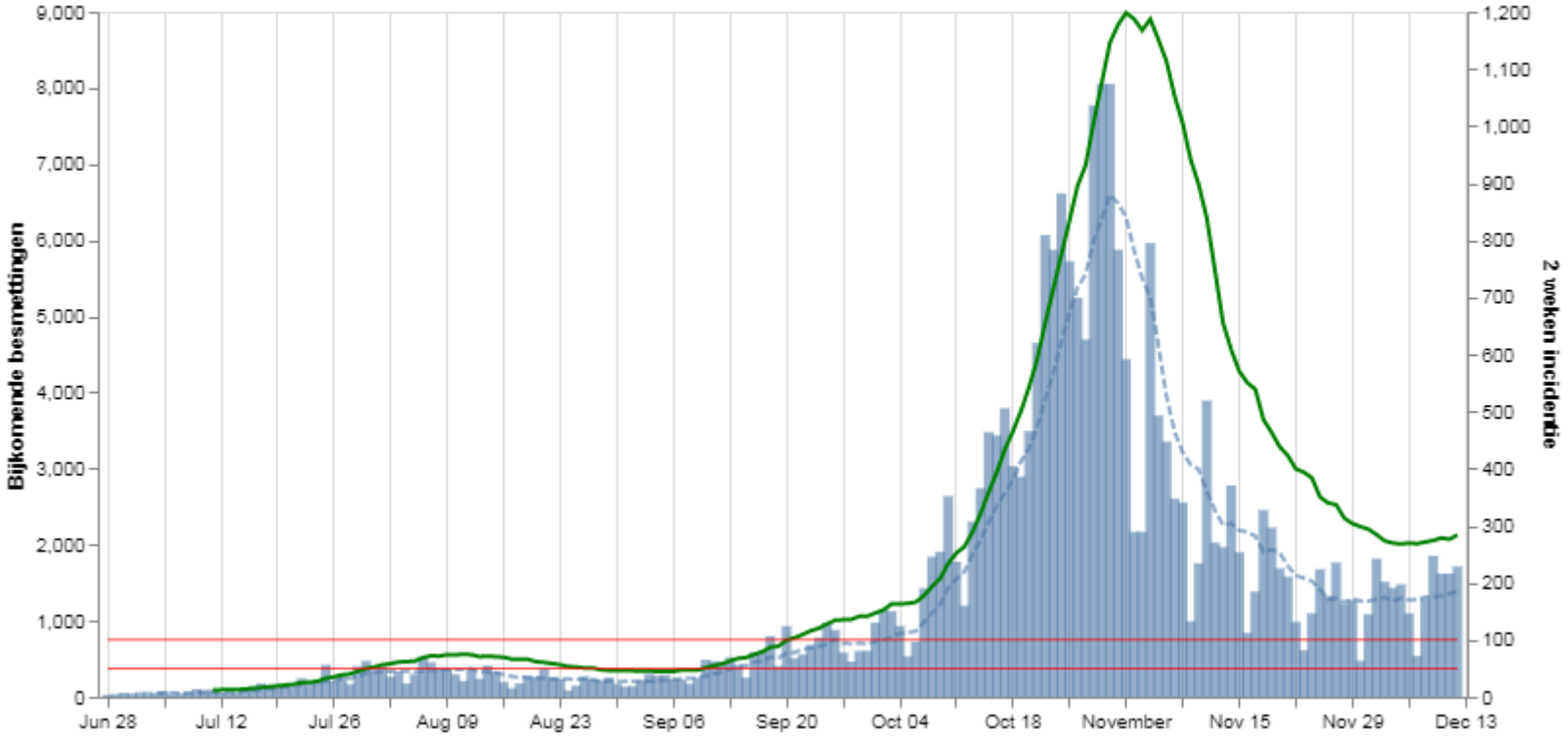


COVID-19 in Vlaanderen: 14-daagse incidentie (/100.000) en bijkomende gevallen/dag

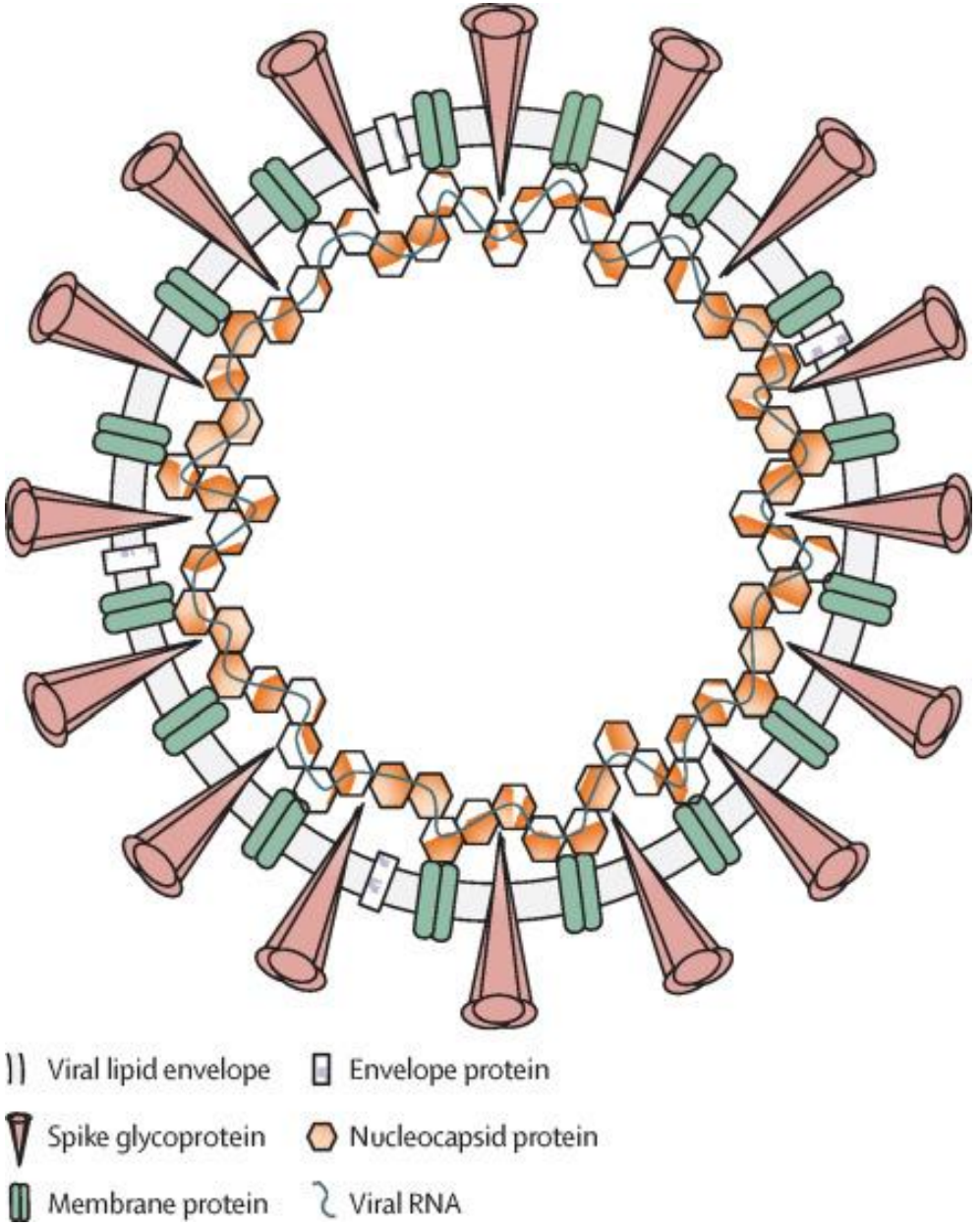


COVID-19 vaccin-ontwikkeling

Updated

30/nov/2020

- SARS-CoV-2 is an enveloped β-coronavirus, with a genetic sequence very similar to SARS-CoV-1 (80%) and bat coronavirus RaTG13 (96.2%).
- The viral envelope is coated by spike (S) glycoprotein, envelope (E), and membrane (M) proteins.
- Host cell binding and entry are mediated by **the S protein**.
- The S1 sub-unit of the S protein contains the receptor binding domain (RBD) that binds to the peptidase domain of angiotensin-converting enzyme 2 (ACE2).



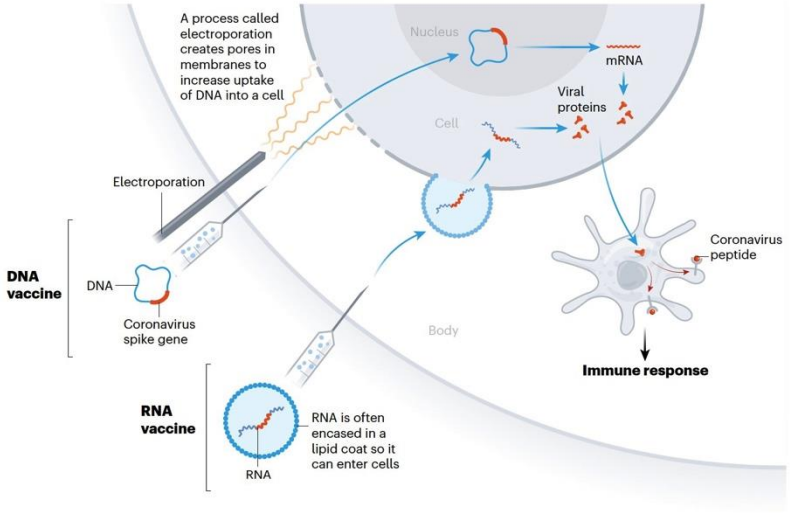
BMJ October 23, 2020, doi: https://doi.org/10.1136/bmj.m3862

Lancet October 13, 2020 DOI:https://doi.org/10.1016/S0140-6736(20)32137-1

NUCLEIC-ACID VACCINES

At least 20 teams are aiming to use genetic instructions (in the form of DNA or RNA) for a coronavirus protein that prompts an immune response. The nucleic acid is inserted into human cells, which then churn out copies of the virus protein; most of these vaccines encode the virus's spike protein.

RNA- and DNA-based vaccines are safe and easy to develop: to produce them involves making genetic material only, not the virus. But they are unproven: no licensed vaccines use this technology.



VIRUS VACCINES

At least seven teams are developing vaccines using the virus itself, in a weakened or inactivated form. Many existing vaccines are made in this way, such as those against measles and polio, but they require extensive safety testing. Sinovac Biotech in Beijing has started to test an inactivated version of SARS-CoV-2 in humans.

Weakened virus

A virus is conventionally weakened for a vaccine by being passed through animal or human cells until it picks up mutations that make it less able to cause disease. Codagenix in Farmingdale, New York, is working with the Serum Institute of India, a vaccine manufacturer in Pune, to weaken SARS-CoV-2 by altering its genetic code so that viral proteins are produced less efficiently.

Inactivated virus

In these vaccines, the virus is rendered uninfectious using chemicals, such as formaldehyde, or heat. Making them, however, requires starting with large quantities of infectious virus.

VIRAL-VECTOR VACCINES

Around 25 groups say they are working on viral-vector vaccines. A virus such as measles or adenovirus is genetically engineered so that it can produce coronavirus proteins in the body. These viruses are weakened so they cannot cause disease. There are two types: those that can still replicate within cells and those that cannot because key genes have been disabled.

Replicating viral vector (such as weakened measles)

The newly approved Ebola vaccine is an example of a viral-vector vaccine that replicates within cells. Such vaccines tend to be safe and provoke a strong immune response. Existing immunity to the vector could blunt the vaccine's effectiveness, however.

Non-replicating viral vector (such as adenovirus)

No licensed vaccines use this method, but they have a long history in gene therapy. Booster shots can be needed to induce long-lasting immunity. US-based drug giant Johnson & Johnson is working on this approach.

PROTEIN-BASED VACCINES

Many researchers want to inject coronavirus proteins directly into the body. Fragments of proteins or protein shells that mimic the coronavirus's outer coat can also be used.

Protein subunits

Twenty-eight teams are working on vaccines with viral protein subunits — most of them are focusing on the virus's spike protein or a key part of it called the receptor binding domain. Similar vaccines against the SARS virus protected monkeys against infection but haven't been tested in people. To work, these vaccines might require adjuvants — immune-stimulating molecules delivered alongside the vaccine — as well as multiple doses.

Virus-like particles

Empty virus shells mimic the coronavirus structure, but aren't infectious because they lack genetic material. Five teams are working on 'virus-like particle' (VLP) vaccines, which can trigger a strong immune response, but can be difficult to manufacture.

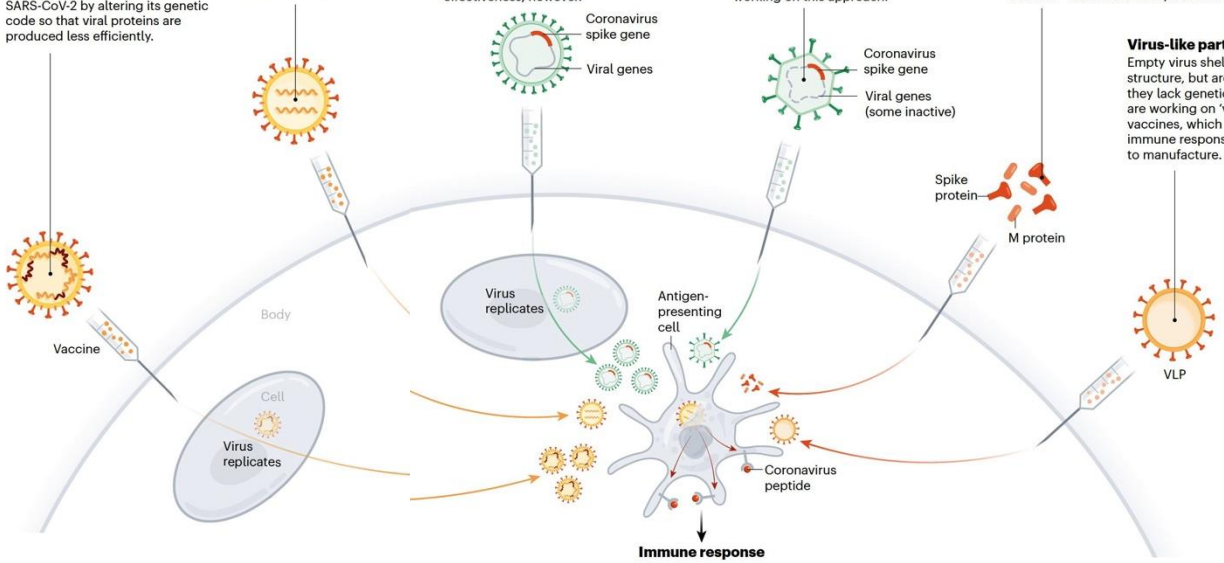


CHART SOURCES: *NATURE* ANALYSIS BASED ON WHO COVID-19 VACCINE LANDSCAPE/MILKEN INSTITUTE COVID-19 TREATMENT AND VACCINE TRACKER/T. THANH LE *ET AL. NATURE REV. DRUG. DISC.* HTTP://DOI.ORG/GGRNBR (2020)/F. AMANAT & F. KRAMMER *IMMUNITY* 52, 583–589 (2020)/N. SHANG *ET AL. HUM VACCINES* 5, 16 (2020)

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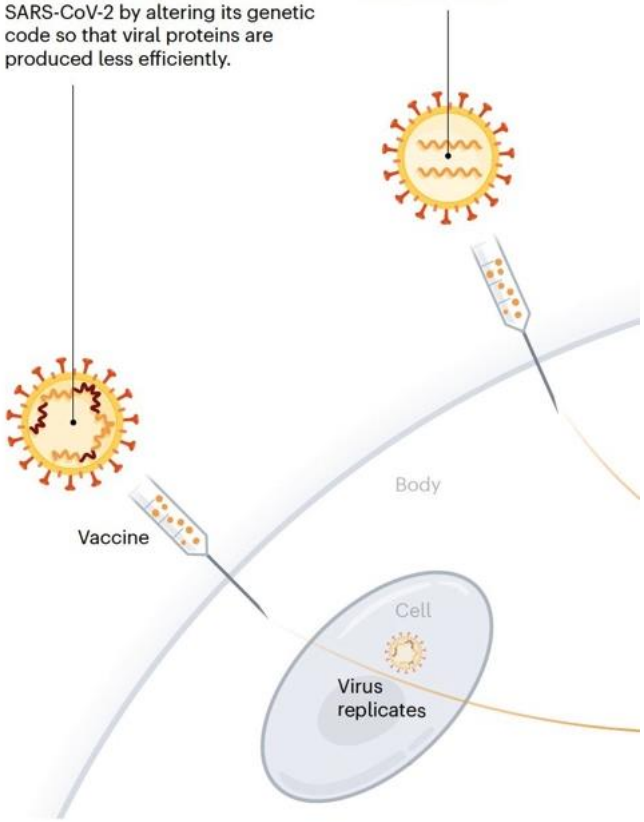

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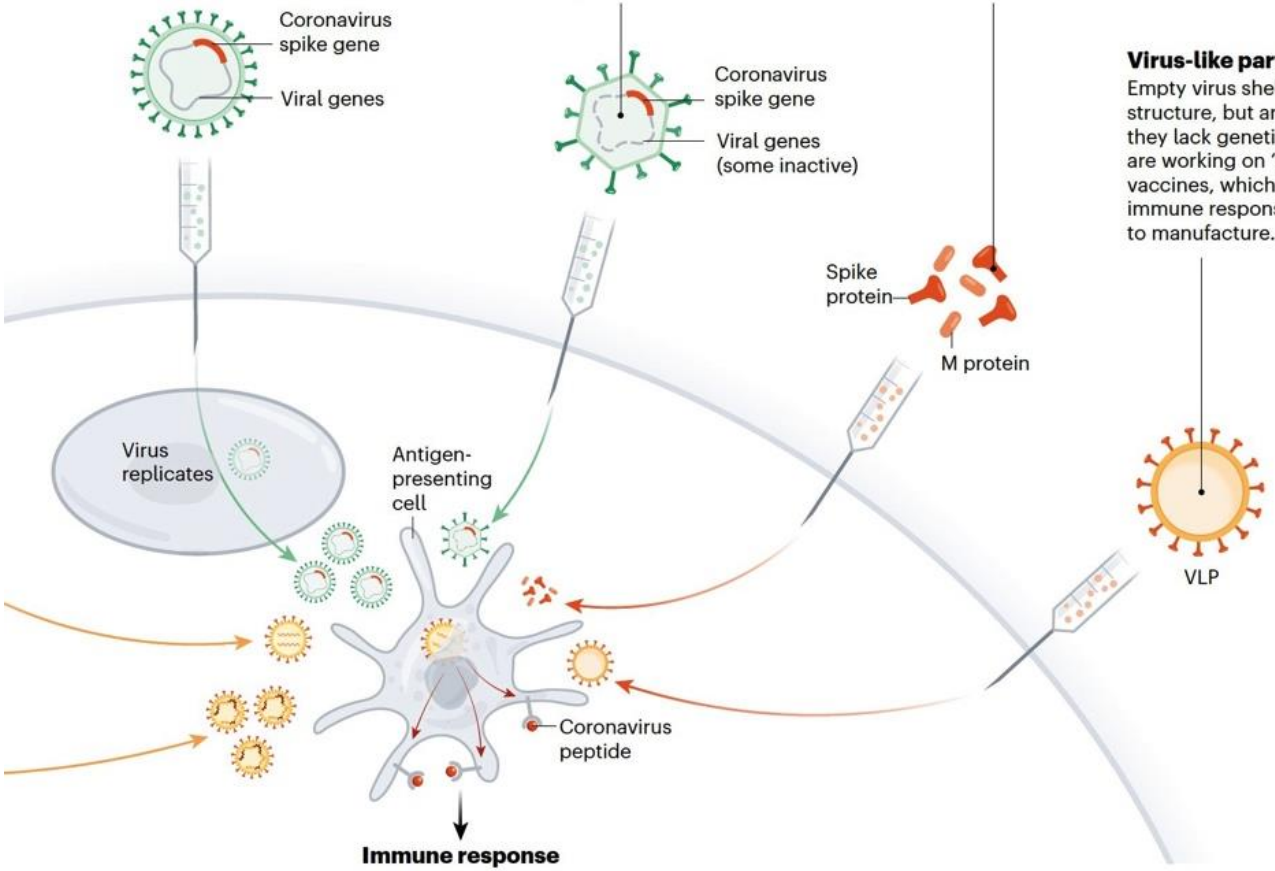

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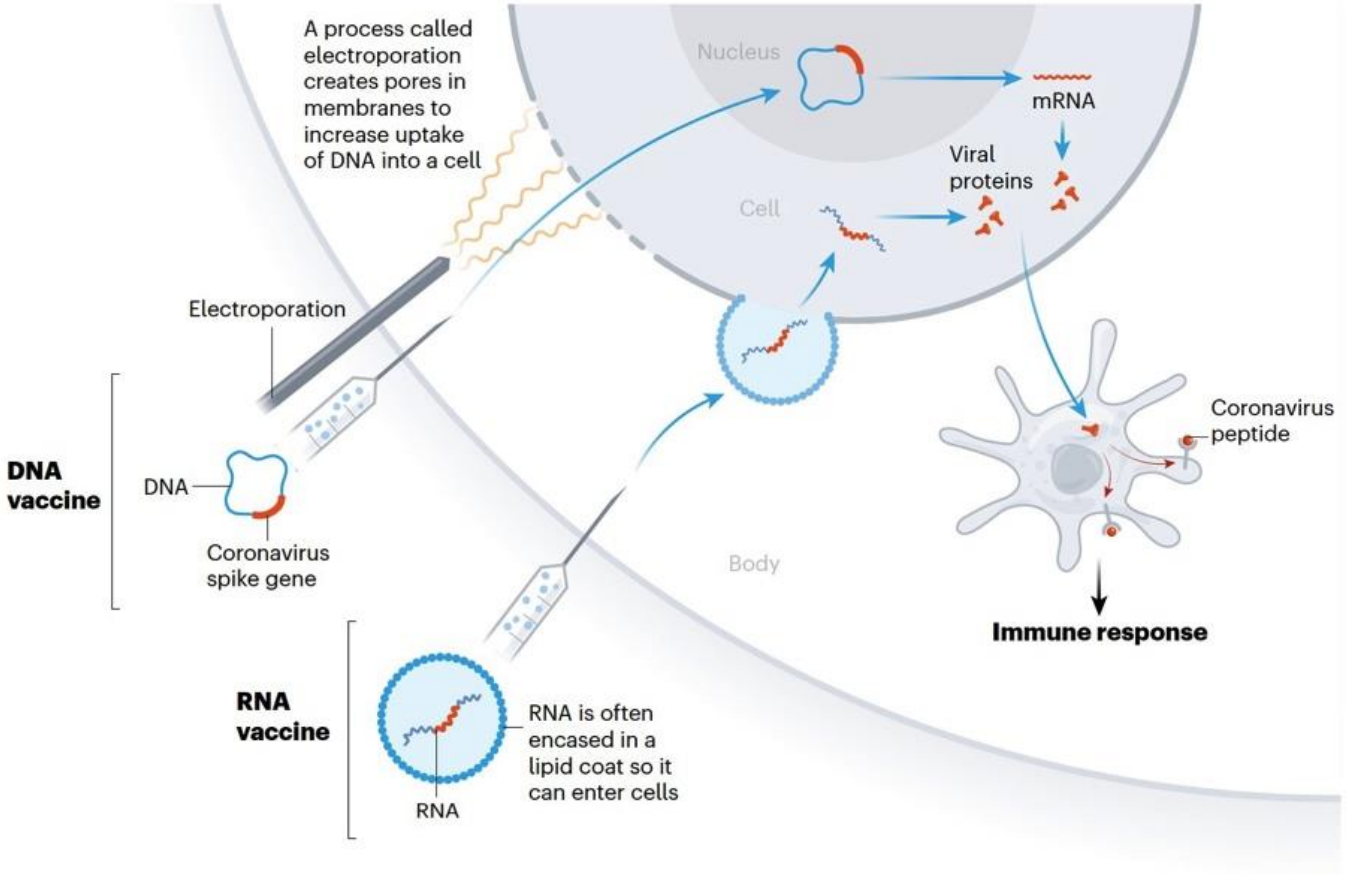
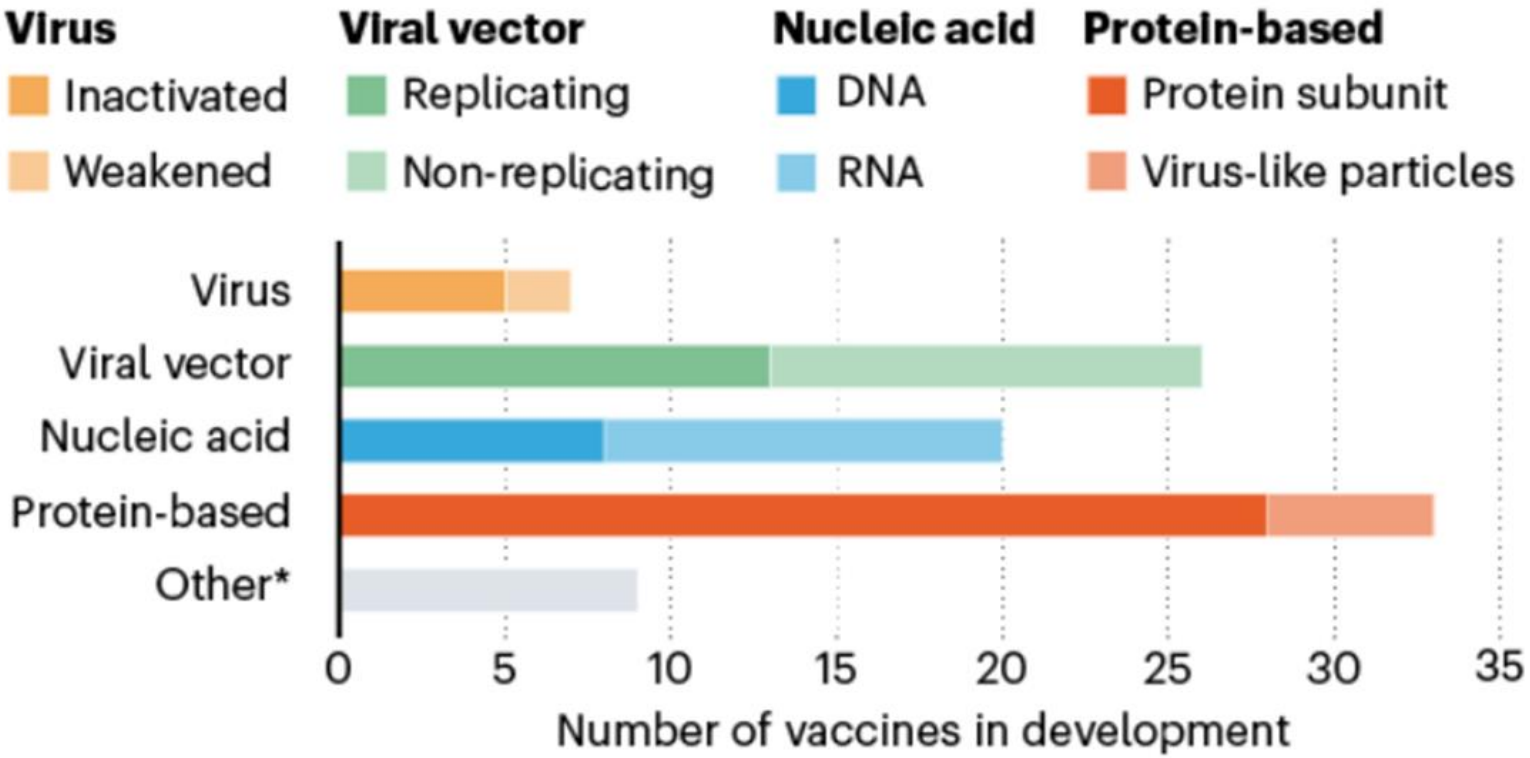


AN ARRAY OF VACCINES



* Other efforts include testing whether existing vaccines against poliovirus or tuberculosis could help to fight SARS-CoV-2 by eliciting a general immune response (rather than specific adaptive immunity), or whether certain immune cells could be genetically modified to target the virus.

Sources: *Nature* analysis based on: WHO COVID-19 Vaccine Landscape/Milken Institute COVID-19 Treatment and Vaccine Tracker/T. Thanh Le *et al. Nature Rev. Drug. Disc.* http://doi.org/ggrnbr (2020)/F. Amanat & F. Krammer *Immunity* **52**, 583–589 (2020)/W. Shang *et al. npj Vaccines* **5**, 18 (2020).

World Health Organization

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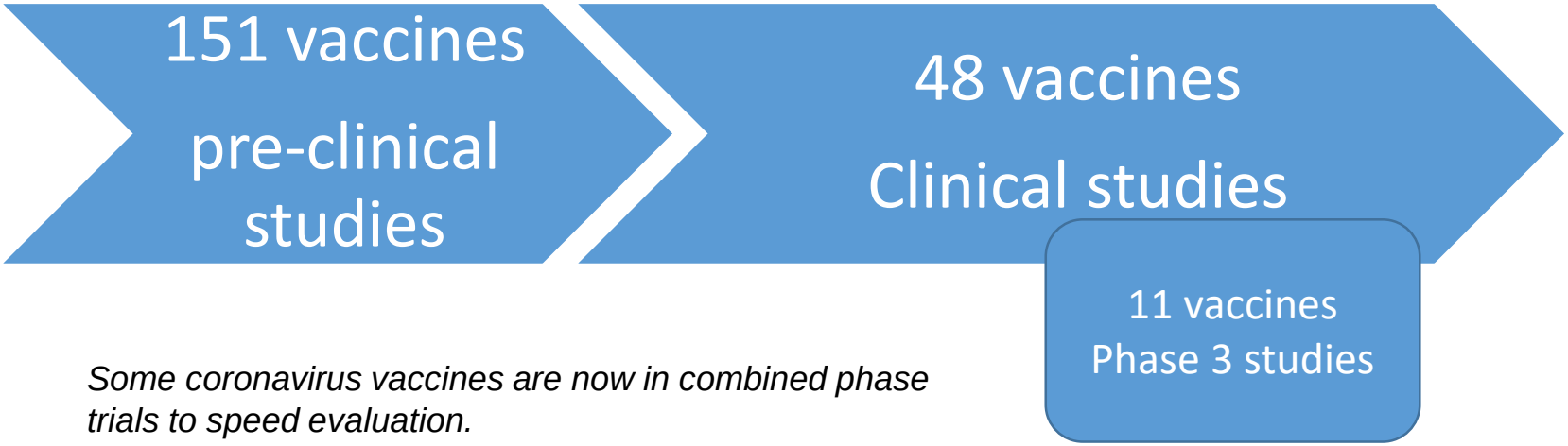
- There are **currently 48 vaccines (phase 1 / 2 and 3)** in clinical evaluation, and **> 164 in pre-clinic evaluation.**

- WHO is fostering regular open dialogue between researchers and vaccine developers to expedit the **exchange of scientific results**, debate concerns and propose rapid and robust methods for vaccine evaluation.

Covid-19 Vaccine development globally



Some coronavirus vaccines are now in combined phase trials to speed evaluation.

Update 23/nov/2020

DRAFT landscape of COVID-19 candidate vaccines – 10 December 2020

52 candidate vaccines in clinical evaluation

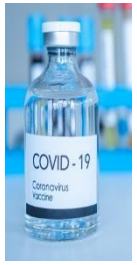
COVID-19 Vaccine developer/manufacturer	Vaccine platform	Type of candidate vaccine	Number of doses	Timing of doses	Route of Administration	Clinical Stage			
						Phase 1	Phase 1/2	Phase 2	Phase 3
Sinovac	Inactivated	Inactivated	2	0,14 days	IM		NCT04383574 NCT04352608 Study Report NCT04551547		NCT04456595 669/UN6.KEP/EC/2020 NCT04582344 NCT04617483
Wuhan Institute of Biological Products/Sinopharm	Inactivated	Inactivated	2	0,21 days	IM		ChiCTR2000031809 Interim Report		ChiCTR2000034780 ChiCTR2000039000 NCT04612972
Beijing Institute of Biological Products/Sinopharm	Inactivated	Inactivated	2	0,21 days	IM		ChiCTR2000032459 Study Report		ChiCTR2000034780 NCT04560881
Bharat Biotech	Inactivated	Whole-Virion Inactivated	2	0, 28 days	IM		CTRI/2020/07/026300 CTRI/2020/09/027674		CTRI/2020/11/028976 NCT04641481
University of Oxford/AstraZeneca	Non-Replicating Viral Vector	ChAdOx1-S	2	0,28 days	IM		PACTR202006922165132 2020-001072-15 NCT04568031 Interim Report	2020-001228-32 Study Report	ISRCTN89951424 NCT04516746 NCT04540393 CTRI/2020/08/027170
CanSino Biological Inc./Beijing Institute of Biotechnology	Non-Replicating Viral Vector	Adenovirus Type 5 Vector	1		IM	ChiCTR2000030906 NCT04568811 Study Report		ChiCTR2000031781 NCT04566770 Study Report	NCT04526990 NCT04540419
Gamaleya Research Institute	Non-Replicating Viral Vector	Adeno-based (rAd26-S+rAd5-S)	2	0,21 days	IM		NCT04436471 NCT04437875 Study Report	NCT04587219 NCT04640233	NCT04530396 NCT04564716 NCT04642339
Janssen Pharmaceutical Companies	Non-Replicating Viral Vector	Adenovirus Type 26 vector	1 2	0 0, 56 days	IM		NCT04436276 NCT04509947	NCT04535453	NCT04505722 ISRCTN14722499
Novavax	Protein Subunit	Full length recombinant SARS CoV-2 glycoprotein nanoparticle vaccine adjuvanted with Matrix M	2	0,21 days	IM		NCT04368988 Study Report	NCT04533399 (phase 2b)	2020-004123-16 NCT04611802
Anhui Zhifei Longcom Biopharmaceutical/Institute of Microbiology, Chinese Academy of Sciences	Protein Subunit	Adjuvanted recombinant protein (RBD-Dimer) expressed in CHO cells	3	0, 28, 56 days	IM	NCT04445194 NCT04636333	NCT04550351	NCT04466085	ChiCTR2000040153
Moderna/NIAID	RNA	LNP-encapsulated mRNA	2	0,28 days	IM	NCT04283461 Interim Report final Report		NCT04405076	NCT04470427
BioNTech/Fosun Pharma/Pfizer	RNA	3 LNP-mRNAs	2	0,21 days	IM	NCT04368728 Study Report	2020-001038-36 ChiCTR2000034825 NCT04537949 NCT04588480 Study Report1 Study Report2		NCT04368728
Medicago Inc.	VLP	Plant-derived VLP adjuvanted with AS03.	2	0, 21 days	IM	NCT04450004			NCT04636697

Vaccins in fase 3 – Nov 2020

- Sinovac
- Sinopharm
- Bharat Biotech
- AstraZeneca
- CanSino Biological
- Gamalea Research Institute
- Janssen Pharmaceutical
- Novavax
- Moderna (12 jan 2021)
- Pfizer-BioNtech (21 dec 2020)

- Aangekocht door EU (+ GSK-Sanofi, Curevac) door België: (+ Curevac)

Commission européenne



- 27 Août 2020: **AstraZeneca** (300 million + 100 million doses).
- 18 Septembre 2020: Sanofi-GSK (300 million doses).
- 8 Octobre 2020: **Janssen Pharmaceutica** (200 million + 200 million)
- 12 Novembre 2020: **Pfizer/BioNTech** (200 millions + 100 millions doses)
- 17 Novembre 2020: CureVac (225 millions + 180 doses)
- 25 Novembre 2020: **Moderna** (80 millions + 80 millions doses)

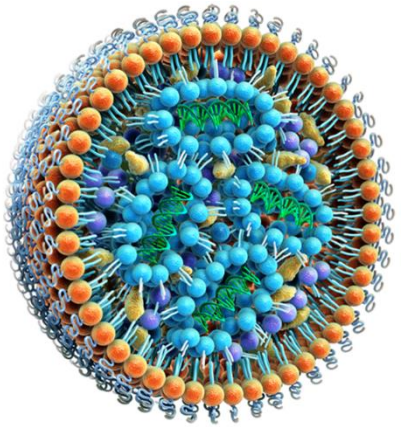
Voor België: .be

21 août 2020: **AstraZeneca (7,5 m. doses)**
19 octobre 2020: **Janssen Pharmaceutical (5 m. doses)**
18 novembre 2020: **Pfizer/BioNTech (5 m. doses)**
24 novembre 2020: **CureVac (2,9 m. de doses)**
2 décembre 2020: **Moderna (2 m. de doses)**

Recentere vaccins:

- **mRNA vaccins**
  - Informatie die codeert voor het antigeen wordt in een menselijke cel (vaak een immuuncel type APC) geïntroduceerd en die maakt het antigeen aan waartegen we antilichamen vormen
  - Vb. COVID19

Lipid Nanoparticles
Lipid nanoparticles (LNPs) are the most clinically advanced non-viral gene delivery system.



- **Viraal vector vaccins**
  - Mazelenvirus, adenovirus, ..
  - Virus wordt aangepast zodat het virus het pathogeen-specifieke antigeen tot expressie brengt –
  - Vb. Ebola, Lassa, COVID19, ..

COVID-19 vaccins en koude keten

Current thermal stability claims for mRNA formulations in clinical development

	Moderna[1]	Pfizer/BioNTech[2]	Curvevac	Imperial[3]	Arcturus[4]	Walvax
Shipment	-20^{0}C (up to 6 mo)	-70^{0}C	Not disclosed	-70^{0}C or 2-8^{0}C	Lyophilized DP being tested at 2-8^{0}C & RT	Not disclosed
Post-thawing	2-8^{0}C (up to 7 days) RT (up to 12 hrs)	2-8^{0}C (up to 5 days)	Not disclosed	2-8^{0}C (data up to 3months available)		Not disclosed

Several claims have yet to provide supportive data

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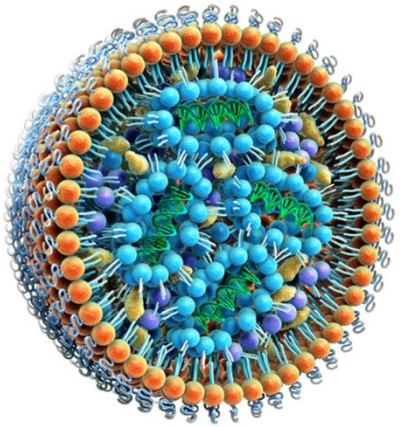

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Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial

Pedro M Folegatti, Katie J Ewer*, Parvinder K Aley, Brian Angus, Stephan Becker, Sandra Belij-Rammerstorfer, Duncan Bellamy, Sagida Bibi, Mustapha Bittaye, Elizabeth A Clutterbuck, Christina Dold, Saul N Faust, Adam Finn, Amy L Flaxman, Bassam Hallis, Paul Heath, Daniel Jenkin, Rajeka Lazarus, Rebecca Makinson, Angela M Minassian, Katrina M Pollock, Maheshi Ramasamy, Hannah Robinson, Matthew Snape, Richard Tarrant, Merryn Voysey, Catherine Green*, Alexander D Douglas*, Adrian V S Hill*, Teresa Lambe*, Sarah C Gilbert*, Andrew J Pollard*, on behalf of the Oxford COVID Vaccine Trial Group†*

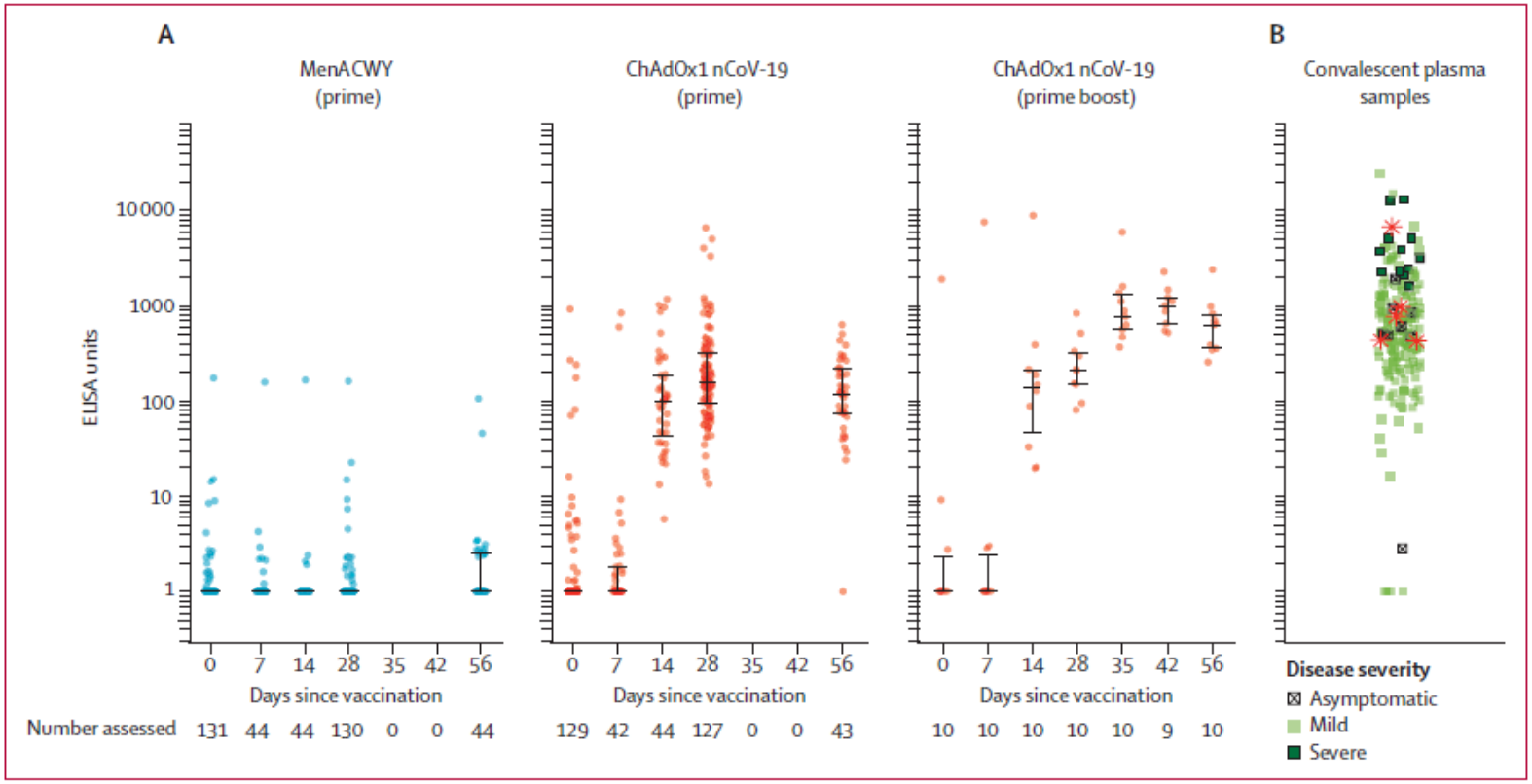


Figure 3: **SARS-CoV-2 IgG response by standardised ELISA to spike protein in trial participants (A) and in 180 convalescent plasma samples from 172 patients with PCR-confirmed COVID-19 and eight asymptomatic health-care workers (B)**

Error bars show median (IQR). Participants in the prime boost group received their second dose at day 28. Lower limit of quantification is 1 ELISA unit. Red stars in panel B show five samples also tested on the Marburg VN assay (see figure 4). MenACWY=meningococcal group A, C, W-135, and Y conjugate vaccine. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

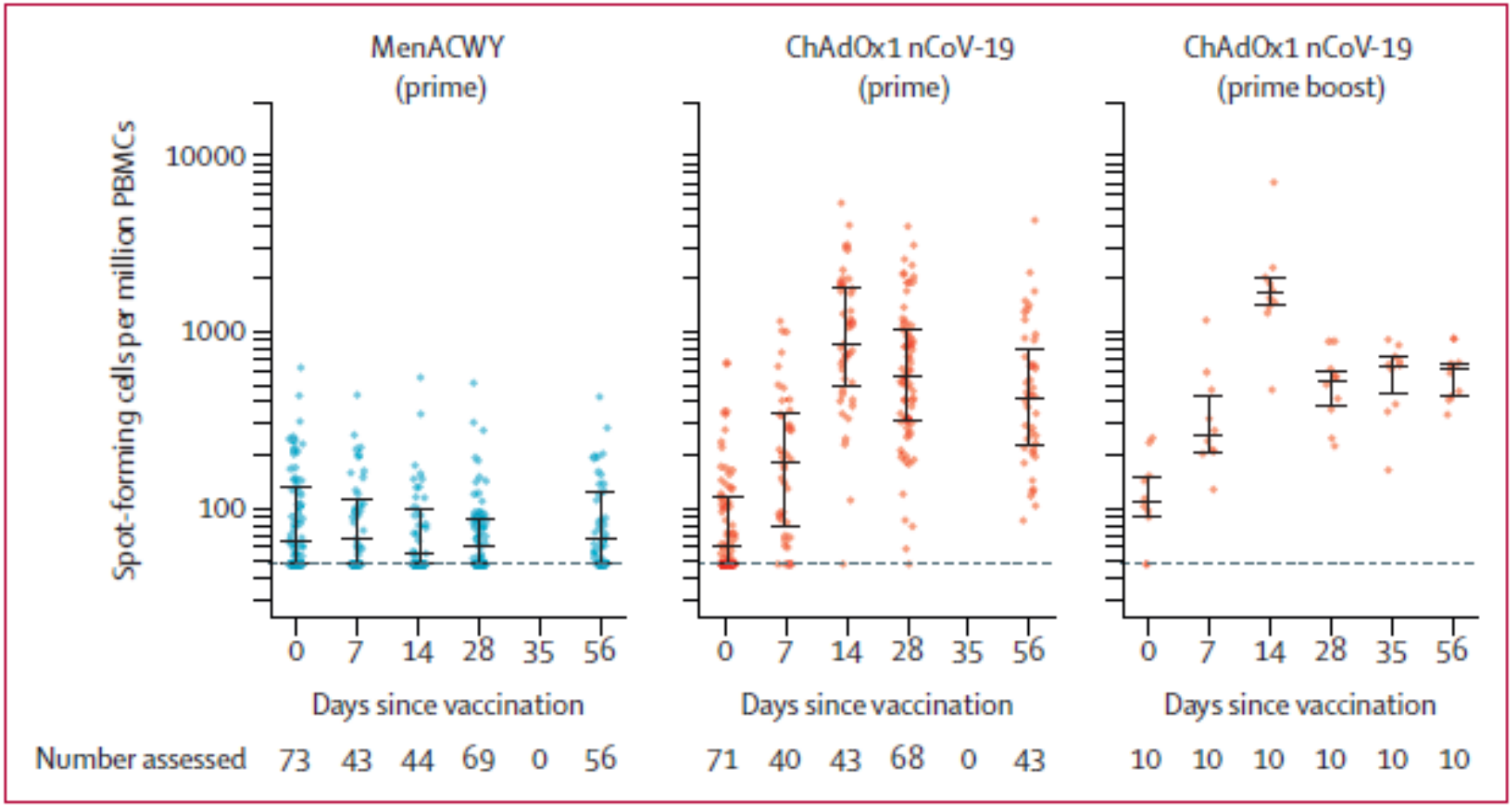


Figure 6: **Interferon-γ ELISpot response to peptides spanning the SARS-CoV-2 spike vaccine insert**

Error bars show median (IQR). The lower limit of detection, indicated with the dotted line, is 48 spot-forming cells per million PBMCs. PBMC=peripheral blood mononuclear cell. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. ELISpot=enzyme linked immunospot. MenACWY=meningococcal group A, C, W-135, and Y conjugate vaccine.

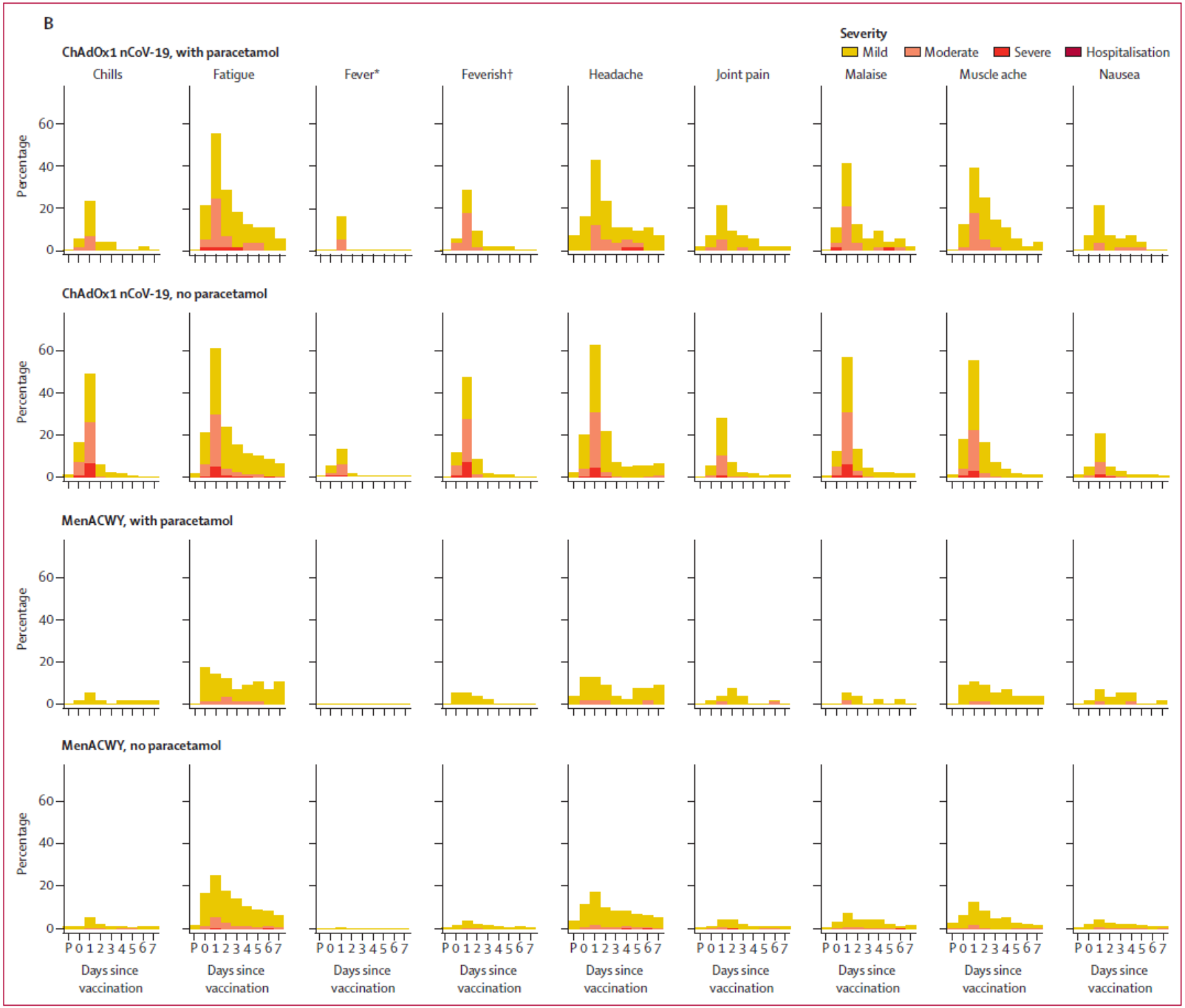
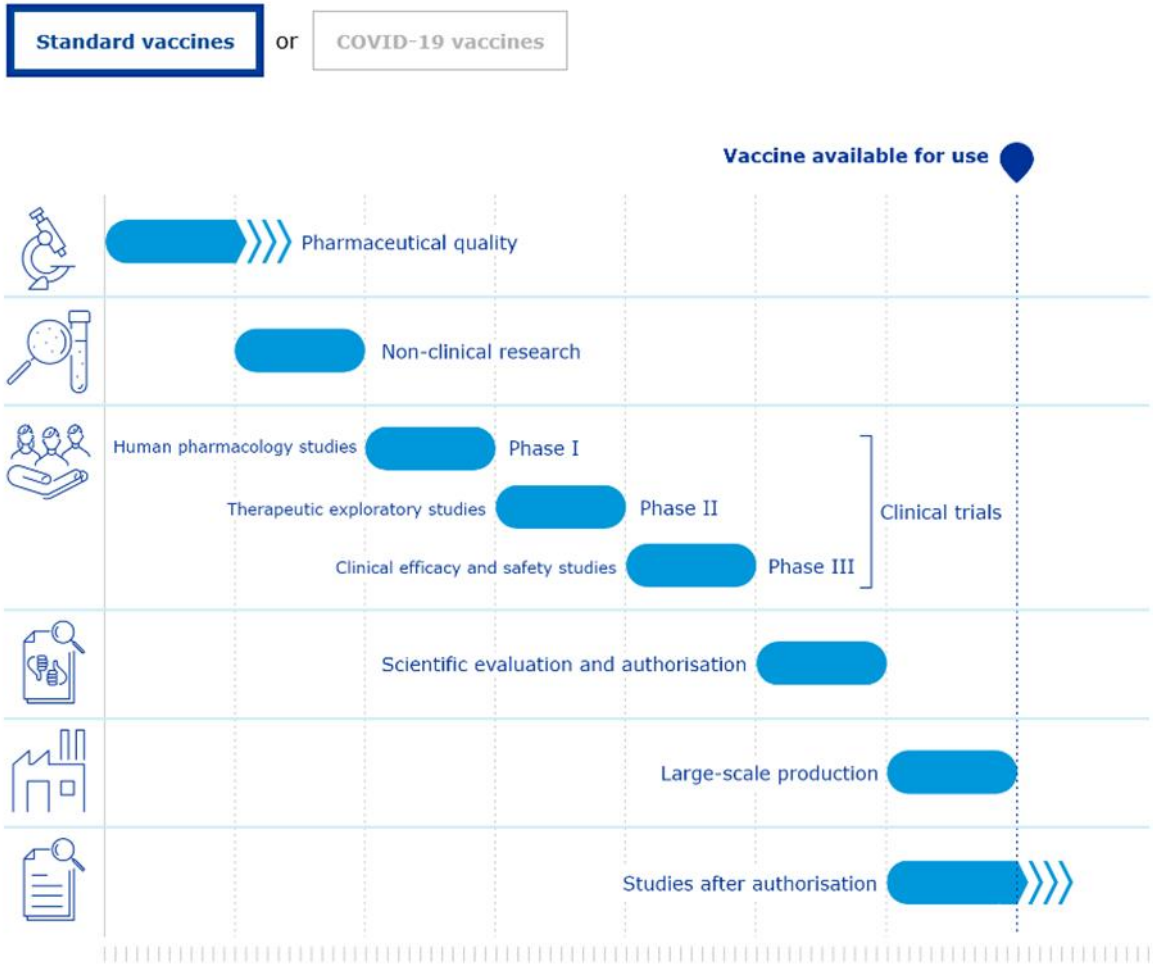


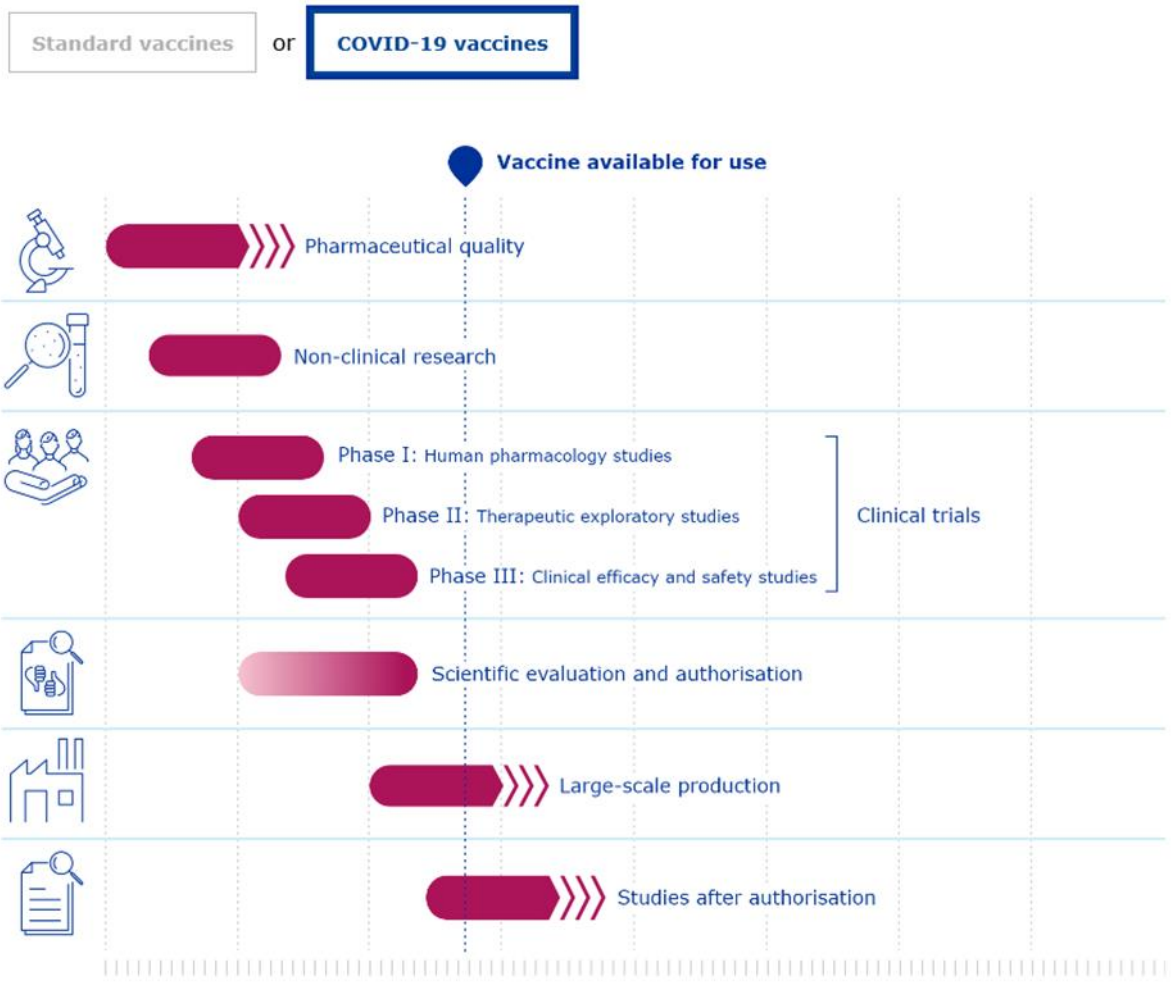
Figure 1: **Solicited local (A) and systemic (B) adverse reactions in first 7 days after vaccination as recorded in participant symptom electronic diaries**

Day 0 is the day of vaccination. P=60-min post-vaccination observation period in the clinic. MenACWY=meningococcal group A, C, W-135, and Y conjugate vaccine. *Mild: 38·0°C to <38·5°C; moderate:

Waarom kan een COVID-19 vaccin zo snel ontwikkeld worden?

- Een verhaal van voorrang… niet van snelheid!
- Men vertrekt voor de meeste vaccins van bestaande vaccin-constructies
- Voorrangsprocedure voor COVID19 dossiers bij EC, FDA, EMA, FAGG, ..
- Voorrangsprocedure in de vaccinatiecentra
- Parallel uitvoeren van fase 2 en 3 vaccin trials
- Start van de productie alvorens de resultaten te kennen van de fase 2 en 3 studies


Standard vaccines
or
COVID-19 vaccines
Vaccine available for use
Pharmaceutical quality
Non-clinical research
Human pharmacology studies
Phase I
Therapeutic exploratory studies
Phase II
Clinical efficacy and safety studies
Phase III
Clinical trials
Scientific evaluation and authorisation
Large-scale production
Studies after authorisation


Standard vaccines
or
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Vaccine available for use
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Phase I: Human pharmacology studies
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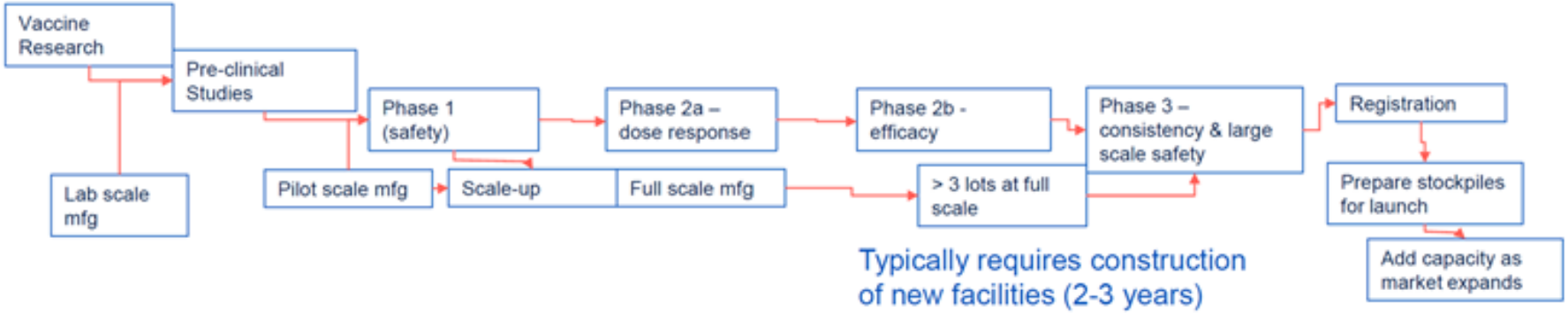
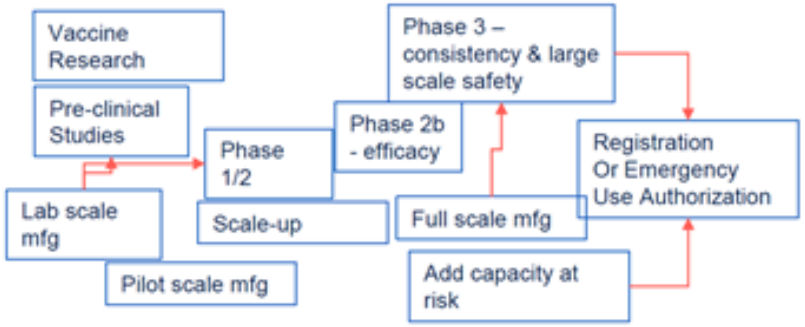
Phase III: Clinical efficacy and safety studies
Clinical trials
Scientific evaluation and authorisation
Large-scale production
Studies after authorisation

COVID-19 Manufacturing in Fast Forward

Typical Vaccine Development Process & Timing (4-7 years on average)



COVID-19 Vaccine Development (12-18 months)



The European Journal of Health Economics
https://doi.org/10.1007/s10198-020-01208-6

EDITORIAL

Once we have it, will we use it? A European survey on willingness to be vaccinated against COVID-19

Sebastian Neumann-Böhme[1] · Nirosha Elsem Varghese[2] · Iryna Sabat[3] · Pedro Pita Barros[3] · Werner Brouwer[1,4] · Job van Exel[1,4] · Jonas Schreyögg[5] · Tom Stargardt[5]

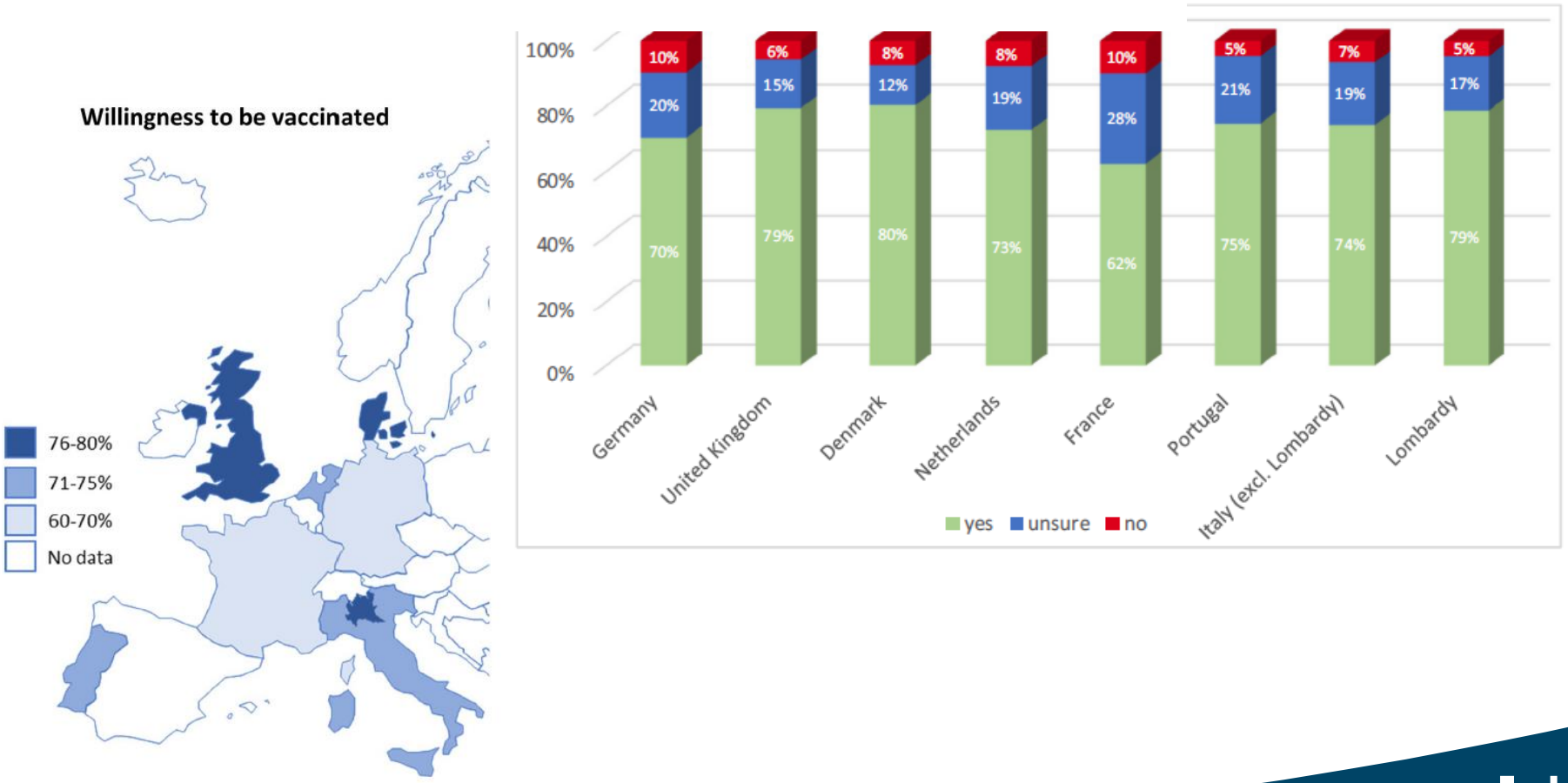
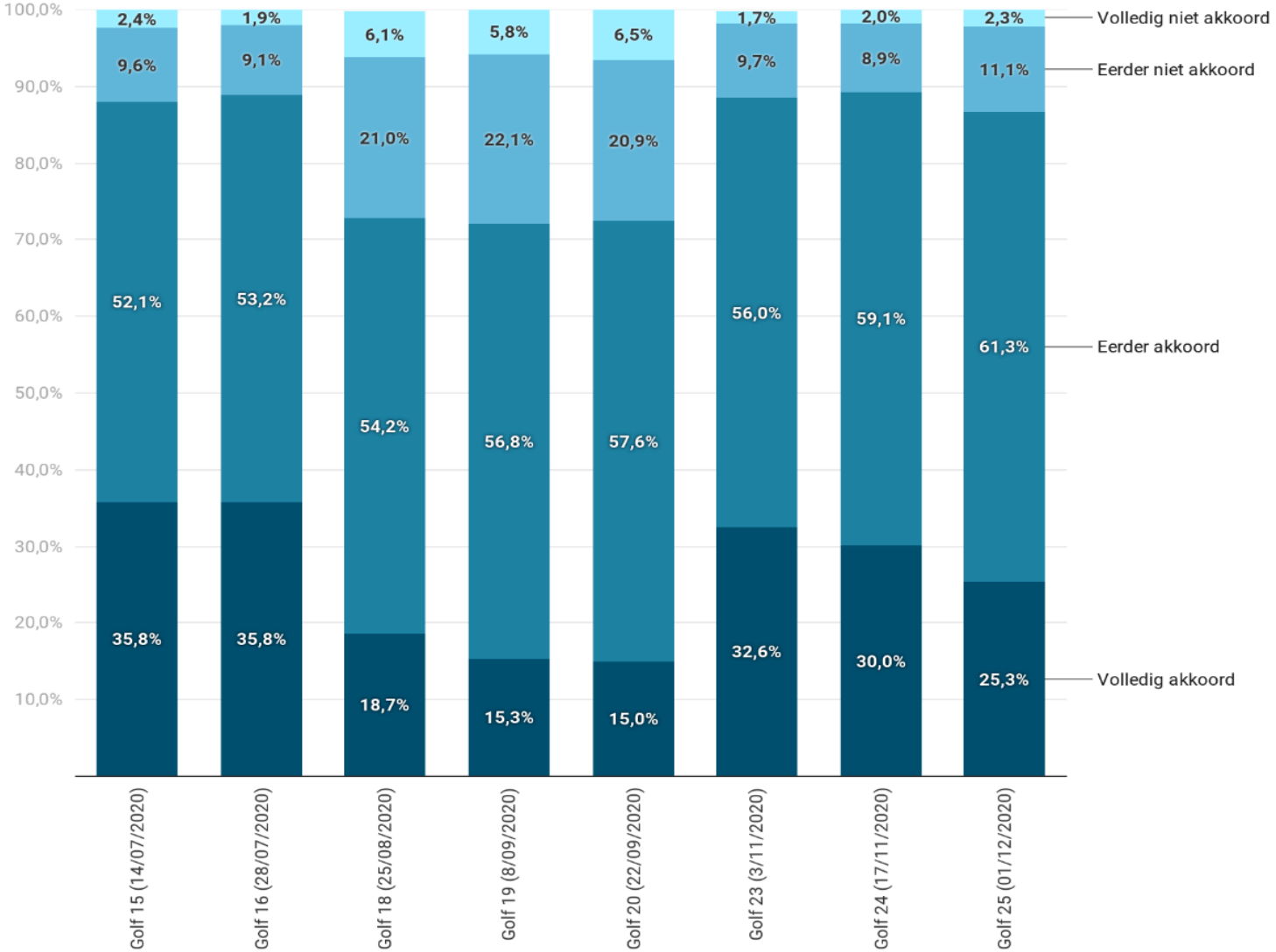


Fig. 1 Proportion of respondents who stated they would be willing to be vaccinated against the novel coronavirus per country

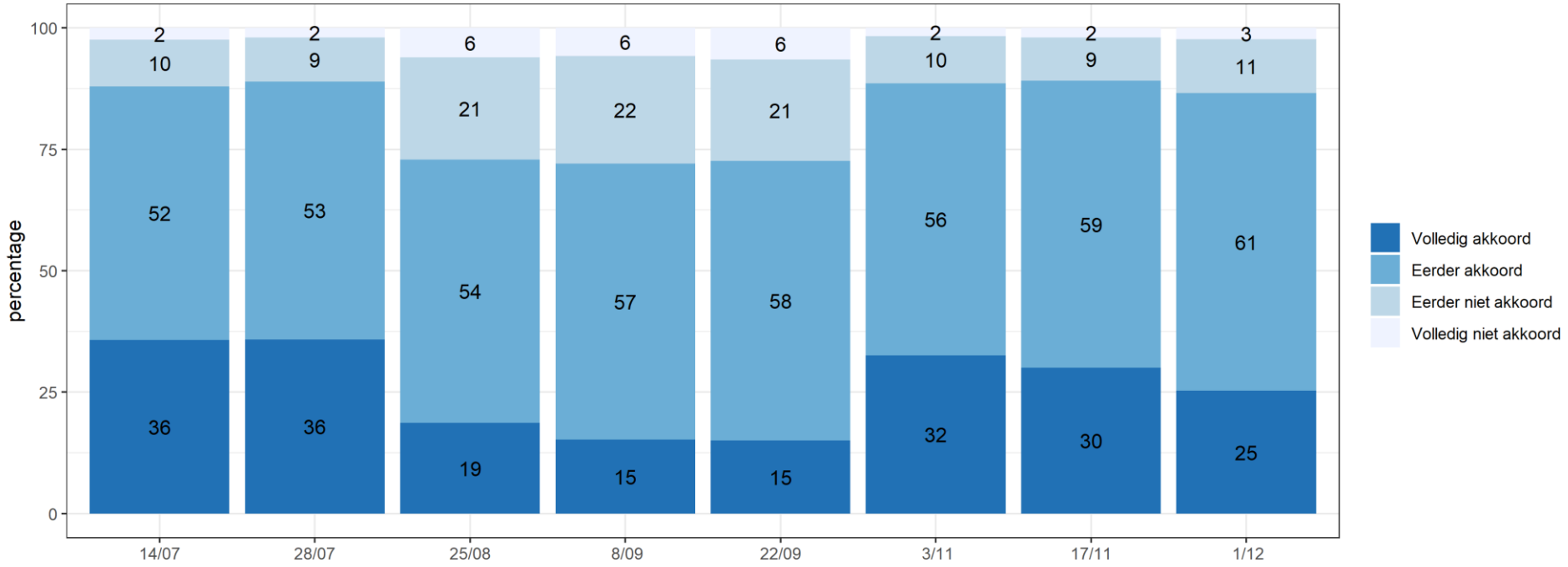
De Grote Corona studie 2020: De informatie die ik ontvang in verband met de aanbevolen vaccins, is betrouwbaar en geloofwaardig.

Evolutie vragen vaccin golf 15, 16, 18-20, 23-25



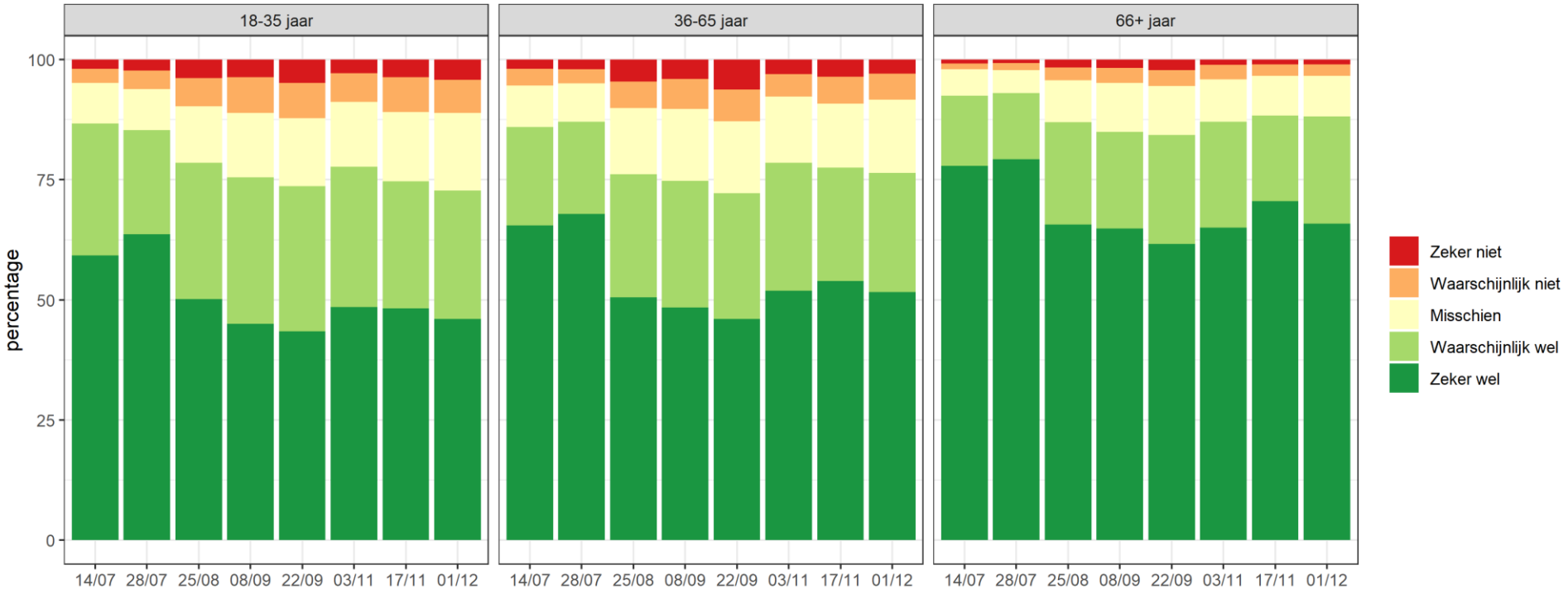
Grafiek: UAntwerpen - UHasselt - KU Leuven Corona studie 2020 - golf 15, 16, 18 - 20, 23-25 (gewogen data) • Bron: UAntwerpen • Gecreëerd met Datawrapper

De informatie die ik ontvang in verband met de aanbevolen vaccins, is betrouwbaar en geloofwaardig.



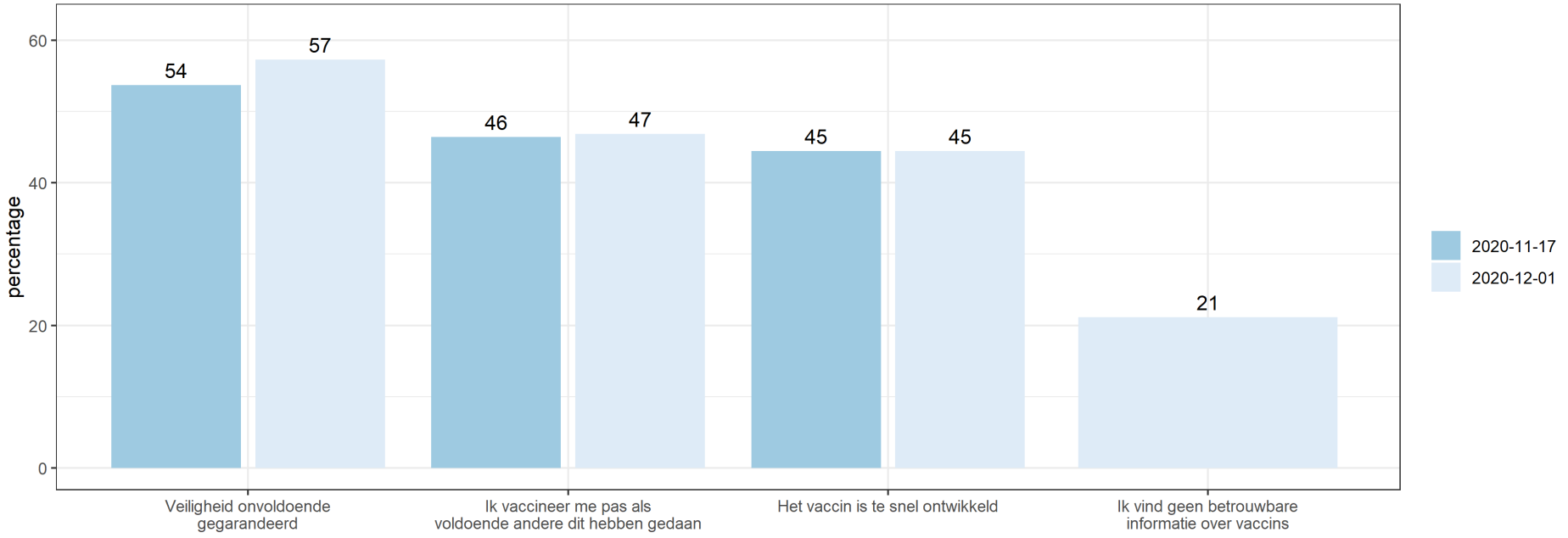
De Grote Coronastudie 2020 (UAntwerpen, UHasselt, KU Leuven) - Golven 15-25 - www.corona-studie.be

Zou je je laten vaccineren tegen COVID-19 als er een veilig, werkzaam en gratis vaccin is?



Waarom ben je niet zeker om je te laten vaccineren tegen COVID-19? (Meerdere antwoorden mogelijk)

Vraag gesteld aan deelnemers die niet aangeven zich zeker te laten vaccineren.



De Grote Coronastudie 2020 (UAntwerpen, UHasselt, KU Leuven) - Golven 24-25 - www.corona-studie.be

groepsimmuniteit

- COVID19 Ro = 2-3 – kritische drempel: >60%
- Mazelen Ro = 12-16 – kritische drempel: >95%

- Voorwaarden:
  - Indien rekenen op groepsimmuniteit via ziekte: liefst zeer lange levenslange bescherming nodig
  - Indien rekenen op groepsimmuniteit via vaccinatie: liefst zeer lange levenslange bescherming nodig
  - Random verdeling van beschermden in de bevolking
  - Transmissie van mens op mens

groepsimmuniteit

- COVID19 Ro = 2-3 – kritische drempel: >60%
- Mazelen Ro = 12-16 – kritische drempel: >95%

  - Ifv doeltreffendheid bepaalde vaccinatiegraad nodig:
    - >90% doeltreffendheid – vaccinatiegraad: minstens 70%
    - 70% doeltreffendheid – vaccinatiegraad van minstens 90%
  - Dus ofwel > 70% zieken, maar tijdelijk beschermd en enorme ziektelast
  - Enkel vaccinatie van kwestbaren?
    - 10% blijft onbeschermd
    - Circulatie bij jongeren, met deels ziektelast en deels tijdelijke bescherming
    - Zij die niet mogen ingeënt worden genieten niet van groepsimmuniteit

Table 1 | Characteristics of ongoing phase III covid-19 vaccine trials

	Moderna	Pfizer	AstraZeneca (US)	AstraZeneca (UK)
Vaccine name	mRNA-1273	BNT162	AZD1222	AZD1222
Registration No	NCT04470427	NCT04368728	NCT04516746	NCT04400838 (UK), NCT04536051 (Brazil), NCT04444674 (South Africa)
Target enrolment	30 000	43 998	30 000	19 330
Ages eligible	18+	12+	18+	5-12, 18+
Protocol publicly available	Y	Y	Y	N†
Notable excluded populations:				
Children and adolescents	Excluded	Many excluded	Excluded	13-17 excluded
Immunocompromised patients	Excluded	Excluded	Excluded	Excluded
Pregnant or breastfeeding women	Excluded	Excluded	Excluded	Excluded
Endpoints undergoing formal study‡:				
Prevention of symptomatic disease in vaccine recipient	Y	Y	Y	Y
Reduction in severe covid-19 (hospital admission, ICU, or death)	N	N	N	N¶
Interruption of transmission (person to person spread)	N	N	N	N

BMJ 21 Octobre 2020;371:m4037 http://dx.doi.org/10.1136/bmj.m4037

doeltreffendheidsgegevens

	BioNTech BNT162 (b1/b2)	Moderna mRNA-1273	Oxford ChAdOx1-S
Developer(s)	BioNTech, Fosun Pharma, Pfizer	Moderna, NIAID	University of Oxford, AstraZeneca
Platform	RNA	RNA	Non-replicating viral vector
Dosing	2 doses, intramuscular	2 doses, intramuscular	2 doses, intramuscular
Description	Lipid nanoparticle-formulated mRNA encoding full-length spike (S) protein	Lipid nanoparticle-encapsulated mRNA encoding pre-fusion spike (S) protein	Simian adenovirus vector containing codon-optimised spike (S) protein
Efficacy data	Vaccine efficacy against COVID-19 reported to be 95% based on primary efficacy analysis of 170 confirmed cases (18 Nov 2020). These included 10 cases of severe COVID-19, 9 of which occurred in the placebo group.	Vaccine efficacy against COVID-19 reported to be 94.5% based on interim data from 95 cases (16 Nov 2020). These included 11 cases of severe COVID-19, all of which occurred in the placebo group.	Vaccine efficacy against COVID-19 reported to be 62–90% based on interim data from 131 cases (23 Nov 2020). No cases of severe COVID-19 had occurred in vaccine recipients at the time of the analysis.
Storage requirements	Ultra-cold (-60°C to -80°C)	Refrigeration (2°C to 8°C) for up to 30 days or frozen (-15°C to -25°C) for long-term storage	Refrigeration (2°C to 8°C)
ONE Vaccine Access Test score	BioNTech and Pfizer given scores of 1 out of 15 and 2.8 out of 15, respectively	Moderna given score of 1.7 out of 15	AstraZeneca given score of 8.6 out of 15
Manufacture projections	50 million doses in 2020 and up to 1.3 billion doses in 2021 (09 Nov 2020)	500 million to 1 billion doses per year (26 Oct 2020)	3 billion doses in 2021 (23 Nov 2020)
Approval/licensure	Not yet approved for widespread use	Not yet approved for widespread use	Not yet approved for widespread use

Table 1. Demographic Characteristics of the Participants in the Main Safety Population.*

Characteristic	BNT162b2 (N=18,860)	Placebo (N=18,846)	Total (N=37,706)
Sex — no. (%)			
Male	9,639 (51.1)	9,436 (50.1)	19,075 (50.6)
Female	9,221 (48.9)	9,410 (49.9)	18,631 (49.4)
Race or ethnic group — no. (%)†			
White	15,636 (82.9)	15,630 (82.9)	31,266 (82.9)
Black or African American	1,729 (9.2)	1,763 (9.4)	3,492 (9.3)
Asian	801 (4.2)	807 (4.3)	1,608 (4.3)
Native American or Alaska Native	102 (0.5)	99 (0.5)	201 (0.5)
Native Hawaiian or other Pacific Islander	50 (0.3)	26 (0.1)	76 (0.2)
Multiracial	449 (2.4)	406 (2.2)	855 (2.3)
Not reported	93 (0.5)	115 (0.6)	208 (0.6)
Hispanic or Latinx	5,266 (27.9)	5,277 (28.0)	10,543 (28.0)
Country — no. (%)			
Argentina	2,883 (15.3)	2,881 (15.3)	5,764 (15.3)
Brazil	1,145 (6.1)	1,139 (6.0)	2,284 (6.1)
South Africa	372 (2.0)	372 (2.0)	744 (2.0)
United States	14,460 (76.7)	14,454 (76.7)	28,914 (76.7)
Age group — no. (%)			
16–55 yr	10,889 (57.7)	10,896 (57.8)	21,785 (57.8)
>55 yr	7,971 (42.3)	7,950 (42.2)	15,921 (42.2)
Age at vaccination — yr			
Median	52.0	52.0	52.0
Range	16–89	16–91	16–91
Body-mass index‡			
≥30.0: obese	6,556 (34.8)	6,662 (35.3)	13,218 (35.1)

* Percentages may not total 100 because of rounding.

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

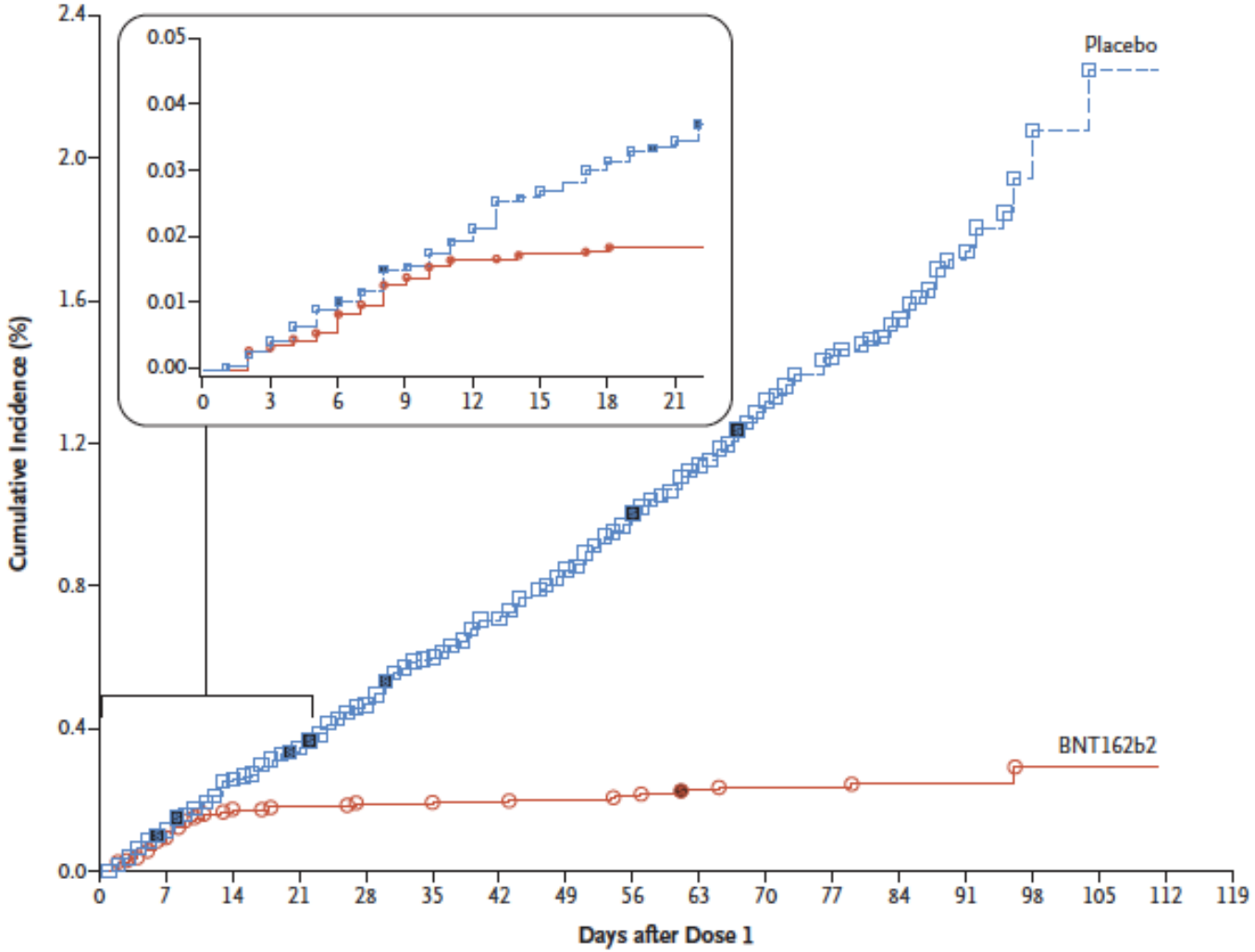
F.P. Polack, et al. DOI: 10.1056/NEJMoa2034577

Efficacy:

The vaccine showed some early protection 12 days after the first dose; 7 days after the second dose, 95% efficacy was observed.

	BNT162b2 Vaccine	Placebo
Symptomatic Covid-19	8	162
	N=18198	N=18325
Severe Covid-19	1	9
	N=21669	N=21686

Vaccine efficacy of 95% (95% credible interval, 90.3–97.6%)



Efficacy End-Point Subgroup	BNT162b2, 30 μg (N=21,669)		Placebo (N=21,686)		VE (95% CI)
	No. of participants	Surveillance time *person-yr (no. at risk)*	No. of participants	Surveillance time *person-yr (no. at risk)*	*percent*
Covid-19 occurrence					
After dose 1	50	4.015 (21,314)	275	3.982 (21,258)	82.0 (75.6–86.9)
After dose 1 to before dose 2	39		82		52.4 (29.5–68.4)
Dose 2 to 7 days after dose 2	2		21		90.5 (61.0–98.9)
≥7 Days after dose 2	9		172		94.8 (89.8–97.6)

Moet de 2° dosis exact na 21 of 28 dagen gegeven worden?

- Er is zeker speling, in de fase 3 studieprotocols:
  - plus minus 2 dagen
- Principe in de vaccinologie:
  - Langere intervals dan aanbevolen kunnen – liever een langer interval dan te kort (< 21 of 28 dagen)
- ““The FDA reviewers also argue that analyses suggested the vaccine prevents Covid-19 following the first dose, meaning that even if people miss their second dose they may get some protection from transmission. However, the FDA scientists cautioned the results “cannot support a conclusion on the efficacy of a single dose of the vaccine” because there is not enough data””.

Mensen vaccineren die COVID-19 positief zijn?

- Aantonen van antistoffen, of weet hebben van vroegere COVID-19 infectie, etc…
- Geen contra-indicatie voor COVID-19 vaccinatie
- COVID-19 infectie geeft geen lange termijn bescherming, we zien ook her-infecties
- Van vaccinatie wordt verwacht dat het langer beschermd – wordt opgevolgd en herhalingsvaccinatie is mogelijk!
- Wat met iemand die recent een COVID-19 infectie doormaakte:
  - Vaccinatie overwegen 15 dagen na genezing.

Seronegative and seropositive

Table 2. Vaccine Efficacy against Covid-19 at Least 7 days after the Second Dose.*

Efficacy End Point	BNT162b2		Placebo		Vaccine Efficacy, % (95% Credible Interval)‡	Posterior Probability (Vaccine Efficacy >30%)§
	No. of Cases	Surveillance Time (n)†	No. of Cases	Surveillance Time (n)†		
		(N=18,198)		**(N=18,325)**		
Covid-19 occurrence at least 7 days after the second dose in participants without evidence of infection	8	2.214 (1,7411)	162	2.222 (17,511)	95.0 (90.3–97.6)	>0.9999
		(N=19,965)		**(N=20,172)**		
Covid-19 occurrence at least 7 days after the second dose in participants with and those without evidence of infection	9	2.332 (18,559)	169	2.345 (18,708)	94.6 (89.9–97.3)	>0.9999

* The total population without baseline infection was 36,523; total population including those with and those without prior evidence of infection was 40,137.

† The surveillance time is the total time in 1000 person-years for the given end point across all participants within each group at risk for the end point. The time period for Covid-19 case accrual is from 7 days after the second dose to the end of the surveillance period.

‡ The credible interval for vaccine efficacy was calculated with the use of a beta-binomial model with prior beta (0.700102, 1) adjusted for the surveillance time.

§ Posterior probability was calculated with the use of a beta-binomial model with prior beta (0.700102, 1) adjusted for the surveillance time.

Subgroups: including age and comorbidities

Table 4. Demographic Characteristics, Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy (7 Days) Population

Characteristic	BNT162b2 (N[a]=20033) N[b] (%)	Placebo (N[a]=20244) N[b] (%)	Total (N[a]=40277) N[b] (%)
Sex: Female	9794 (48.9)	10107 (49.9)	19901 (49.4)
Sex: Male	10239 (51.1)	10137 (50.1)	20376 (50.6)
Age at Vaccination: Mean years (SD)	50.3 (15.73)	50.1 (15.78)	50.2 (15.76)
Age at Vaccination: Median (years)	51.0	51.0	51.0
Age at Vaccination: Min, max (years)	(12, 89)	(12, 91)	(12, 91)
Age Group: 16 to <18 years	77 (0.4)	76 (0.4)	153 (0.4)
Age Group: 16 to 55 years	11589 (57.8)	11743 (58.0)	23332 (57.9)
Age Group: >55 years	8396 (41.9)	8454 (41.8)	16850 (41.8)
Age Group: ≥65 years	4294 (21.4)	4319 (21.3)	8613 (21.38)
Age Group: ≥75 years	860 (4.3)	852 (4.2)	1712 (4.3)
Race: American Indian or Alaska Native	131 (0.7)	122 (0.6)	253 (0.6)
Race: Asian	880 (4.4)	883 (4.4)	1763 (4.4)
Race: Black or African American	1957 (9.8)	1972 (9.7)	3929 (9.8)
Race: Native Hawaiian or Other Pacific Islander	54 (0.3)	29 (0.1)	83 (0.2)
Race: White	16387 (81.8)	16619 (82.1)	33006 (81.9)
Race: Multiracial	523 (2.6)	493 (2.4)	1016 (2.5)
Race: Not reported	101 (0.5)	126 (0.6)	227 (0.6)
Ethnicity: Hispanic or Latino	5272 (26.3)	5281 (26.1)	10553 (26.2)
Ethnicity: Not Hispanic or Latino	14652 (73.1)	14847 (73.3)	29499 (73.2)
Ethnicity: Not reported	109 (0.5)	116 (0.6)	225 (0.6)
Comorbidities[c]: Yes	9278 (46.3)	9314 (46.0)	18592 (46.2)
Comorbidities: No	10755 (53.7)	10930 (54.0)	21685 (53.8)
Comorbidity: Obesity	6934 (34.6)	7093 (35.0)	14027 (34.8)

[a].N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
[b].n = number of participants with the specified characteristic.
[c]. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index (Appendix B, page 52) category or obesity only (BMI ≥30 kg/m^2).

Subgroups: including age…

Table 3. Vaccine Efficacy Overall and by Subgroup in Participants without Evidence of Infection before 7 Days after Dose 2.

Efficacy End-Point Subgroup	BNT162b2 (N=18,198)		Placebo (N=18,325)		Vaccine Efficacy, % (95% CI)†
	No. of Cases	Surveillance Time (No. at Risk)*	No. of Cases	Surveillance Time (No. at Risk)*	
Overall	8	2.214 (17,411)	162	2.222 (17,511)	95.0 (90.0–97.9)
Age group					
16 to 55 yr	5	1.234 (9,897)	114	1.239 (9,955)	95.6 (89.4–98.6)
>55 yr	3	0.980 (7,500)	48	0.983 (7,543)	93.7 (80.6–98.8)
≥65 yr	1	0.508 (3,848)	19	0.511 (3,880)	94.7 (66.7–99.9)
≥75 yr	0	0.102 (774)	5	0.106 (785)	100.0 (–13.1–100.0)
Sex					
Male	3	1.124 (8,875)	81	1.108 (8762)	96.4 (88.9–99.3)
Female	5	1.090 (8,536)	81	1.114 (8,749)	93.7 (84.7–98.0)
Race or ethnic group‡					
White	7	1.889 (14,504)	146	1.903 (14,670)	95.2 (89.8–98.1)
Black or African American	0	0.165 (1,502)	7	0.164 (1,486)	100.0 (31.2–100.0)
All others	1	0.160 (1,405)	9	0.155 (1,355)	89.3 (22.6–99.8)
Hispanic or Latinx	3	0.605 (4,764)	53	0.600 (4,746)	94.4 (82.7–98.9)
Non-Hispanic, non-Latinx	5	1.596 (12,548)	109	1.608 (12,661)	95.4 (88.9–98.5)
Country					
Argentina	1	0.351 (2,545)	35	0.346 (2,521)	97.2 (83.3–99.9)
Brazil	1	0.119 (1,129)	8	0.117 (1,121)	87.7 (8.1–99.7)
United States	6	1.732 (13,359)	119	1.747 (13,506)	94.9 (88.6–98.2)

Wat met patiënten die anti-virale middelen nemen (HIV, hepC, hepB, ..)

- Mogen zij het vaccin krijgen?
  - Toegelaten als inclusie in de fase 3 studies
  - Niet-levend vaccin
  - Resultaten co-morbiditeit geven geen argument om deze mensen niet in te enten

Subgroepen: co-morbiditeit

Pfizer-BioNTech COVID-19 Vaccine
VRBPAC Briefing Document

Characteristic	BNT162b2 N=18801 n (%)	BNT162b2 n (%)	BNT162b2 n (%)	BNT162b2 n (%)	Placebo N=18785 n (%)	Placebo n (%)	Placebo n (%)	Placebo n (%)	Total N=37586 n (%)
Age (years)	16 to <18	18 to <65	65 to <75	≥75	16 to <18	18 to <65	65 to <75	≥75	
Baseline Evidence of Prior SARS-CoV-2 Infection									
Negative	48 (0.3)	13879 (73.8%)	3109 (16.5)	805 (4.3)	47 (0.3%)	13858 (73.8%)	3115 (16.6%)	788 (4.2%)	35649 (94.8%)
Positive	3 (0.0)	473 (2.5%)	53 (0.3)	16 (0.1)	3 (0.0%)	520 (2.8%)	52 (0.3%)	5 (0.0%)	1125 (3.0%)
Missing	2 (0.0)	338 (1.8%)	65 (0.3)	10 (0.1)	0 (0.0%)	314 (1.7%)	68 (0.4%)	15 (0.1%)	812 (2.2%)
Comorbidities									
No	48 (0.3)	12353 (65.7%)	2081 (11.1)	444 (2.4)	37 (0.2%)	12412 (66.1%)	2118 (11.3%)	470 (2.5%)	29963 (79.7%)
Yes	5 (0.0)	2337 (12.4%)	1146 (6.1)	387 (2.1)	13 (0.1%)	2280 (12.1%)	1117 (5.9%)	338 (1.8%)	7623 (20.3%)
Diabetes Without Chronic Complication	0 (0.0)	814 (4.3%)	497 (2.6)	156 (0.8)	1 (0.0%)	849 (4.5%)	491 (2.6%)	132 (0.7%)	2940 (7.8%)
Chronic Pulmonary Disease	5 (0.0)	1093 (5.8%)	286 (1.5)	89 (0.5)	12 (0.1%)	1060 (5.6%)	309 (1.6%)	66 (0.4%)	2920 (7.8%)
Myocardial Infarction	0 (0.0)	82 (0.4%)	71 (0.4)	41 (0.2)	0 (0.0%)	73 (0.4%)	83 (0.4%)	31 (0.2%)	381 (1.0%)
Peripheral Vascular Disease	0 (0.0)	26 (0.1%)	67 (0.4)	31 (0.2)	0 (0.0%)	29 (0.2%)	52 (0.3%)	33 (0.2%)	238 (0.6%)
Liver Disease (mild, moderate or severe)	0 (0.0)	83 (0.4%)	34 (0.2)	7 (0.0)	0 (0.0%)	67 (0.4%)	17 (0.1%)	6 (0.0%)	214 (0.6%)
Diabetes With Chronic Complication	0 (0.0)	47 (0.2%)	36 (0.2)	15 (0.1)	0 (0.0%)	47 (0.3%)	47 (0.3%)	18 (0.1%)	210 (0.6%)
Congestive Heart Failure	0 (0.0)	44 (0.2%)	26 (0.1)	17 (0.1)	0 (0.0%)	36 (0.2%)	30 (0.2%)	16 (0.1%)	169 (0.4%)
AIDS/HIV	0 (0.0)	0 (0.0%)	0 (0.0)	0 (0.0)	0 (0.0%)	1 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.0%)

Characteristic	BNT162b2 N=18801 n (%)	BNT162b2 n (%)	BNT162b2 n (%)	BNT162b2 n (%)	Placebo N=18785 n (%)	Placebo n (%)	Placebo n (%)	Placebo n (%)	Total N=37586 n (%)
Age (years)	16 to <18	18 to <65	65 to <75	≥75	16 to <18	18 to <65	65 to <75	≥75	
Hypertension only	0 (0.0)	2569 (13.7%)	1528 (8.1)	488 (2.6)	1 (0.0%)	2621 (14.0%)	1569 (8.4%)	432 (2.3%)	9208 (24.5%)

Source: FDA-generated table.
Abbreviations: n = number of participants with the specified characteristic; N = number of participants ≥16 years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo, N is denominator for the percentage calculations; SD = standard deviation; min, max = minimum, maximum; Nat. HI = Native Hawaiian; Pac. Isl. = Pacific Islander
Data analysis cutoff date: November 14, 2020.

Subgroepen: co-morbiditeit

Table 10. Vaccine Efficacy: First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status, Among Participants Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy (7 Days) Population

Efficacy Endpoint Subgroup	BNT162b2 (30 µg) N[a]=18198 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=18325 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI[e])
Overall	8 2.214 (17411)	162 2.222 (17511)	95.0 (90.0, 97.9)
Comorbidity			
No comorbidity	4 1.189 (9381)	76 1.197 (9482)	94.7 (85.9, 98.6)
Any comorbidity[f]	4 1.025 (8030)	86 1.025 (8029)	95.3 (87.7, 98.8)
Any malignancy	1 0.092 (704)	4 0.090 (681)	75.7 (-145.8, 99.5)
Cardiovascular	0 0.067 (534)	5 0.062 (492)	100.0 (-0.8, 100.0)
Chronic pulmonary disease	1 0.175 (1374)	14 0.171 (1358)	93.0 (54.1, 99.8)
Diabetes	1 0.176 (1372)	19 0.176 (1374)	94.7 (66.8, 99.9)
Obese (BMI≥30.0 kg/m^2)	3 0.763 (6000)	67 0.782 (6103)	95.4 (86.0, 99.1)
Hypertension	2 0.567 (4413)	44 0.567 (4437)	95.4 (82.6, 99.5)
Diabetes (including gestational diabetes)	1 0.177 (1381)	20 0.178 (1384)	95.0 (68.7, 99.9)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

Note: Participants who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

[a] N = number of participants in the specified group.

[b] n1 = Number of participants meeting the endpoint definition.

[c] Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

[d] n2 = Number of participants at risk for the endpoint.

[e] Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.

[f] Subject who had 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as participants who had at least one of the Charlson comorbidity index (Appendix B, page 52) category or BMI ≥30 kg/m2.

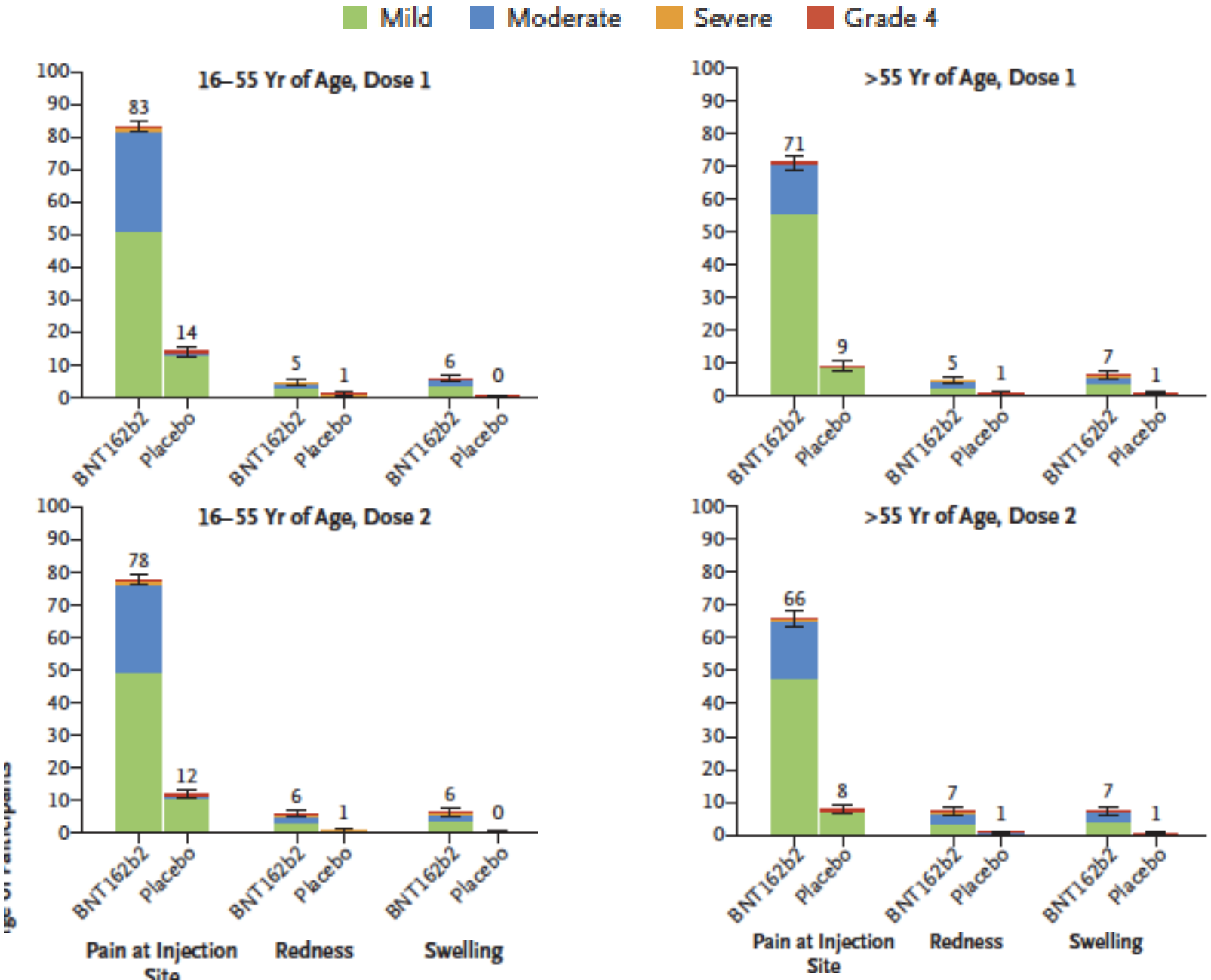
Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

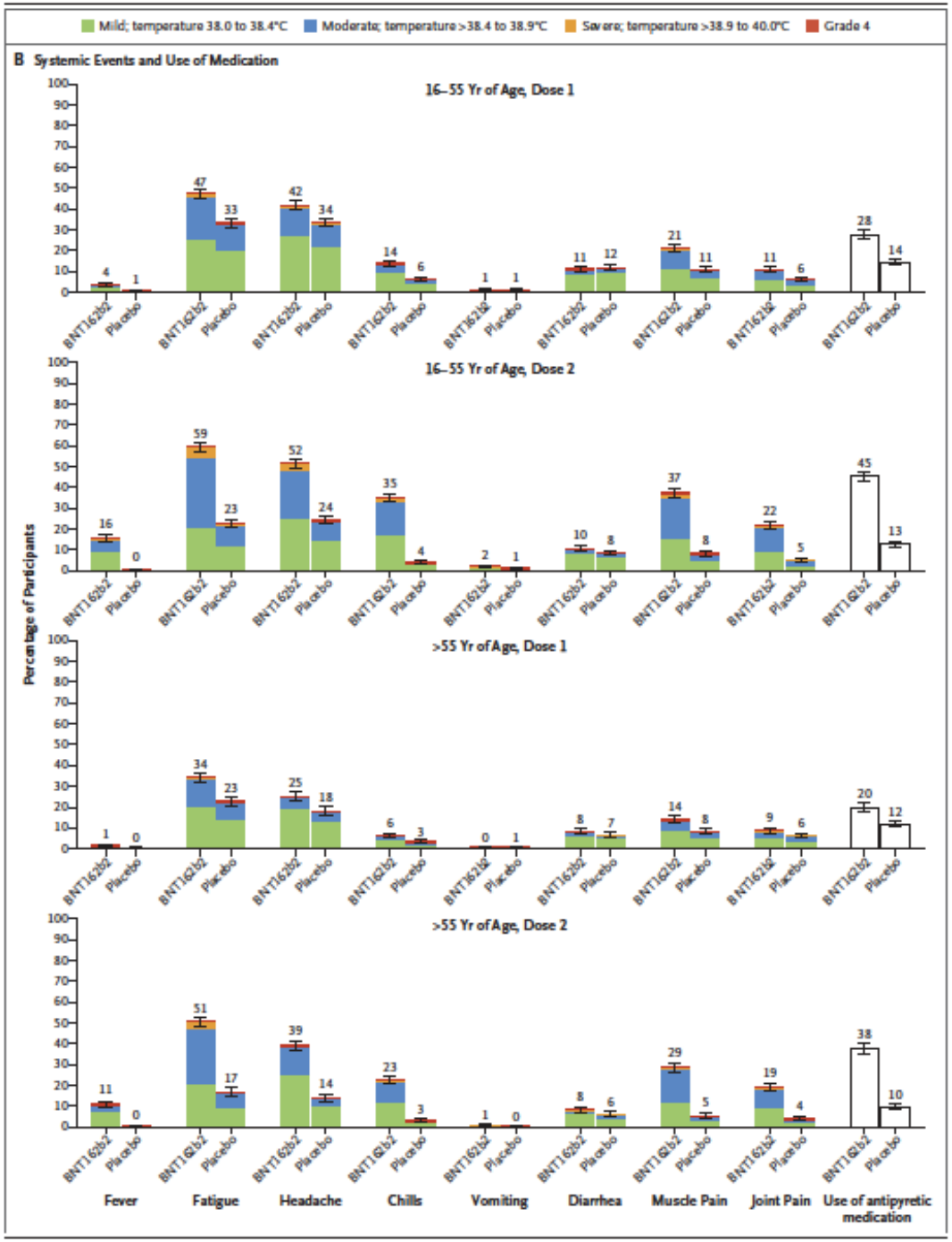
F.P. Polack, et al. DOI: 10.1056/NEJMoa2034577

Safety:

Vaccine recipients had local reactions (pain, erythema, swelling) and systemic reactions (e.g., fever, headache, myalgias) at higher rates than placebo recipients, with more reactions following the second dose. Most were mild to moderate and resolved rapidly.

Local events




Mild; temperature 38.0 to 38.4°C
Moderate; temperature >38.4 to 38.9°C
Severe; temperature >38.9 to 40.0°C
Grade 4
B Systemic Events and Use of Medication
16–55 Yr of Age, Dose 1
16–55 Yr of Age, Dose 2
>55 Yr of Age, Dose 1
>55 Yr of Age, Dose 2
Percentage of Participants
BNT162b2
Placebo
Fever
Fatigue
Headache
Chills
Vomiting
Diarrhea
Muscle Pain
Joint Pain
Use of antipyretic medication

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

F.P. Polack, et al. DOI: 10.1056/NEJMoa2034577

The frequency of any severe systemic event:

After the first dose was < 0.9%
After either dose < 2%

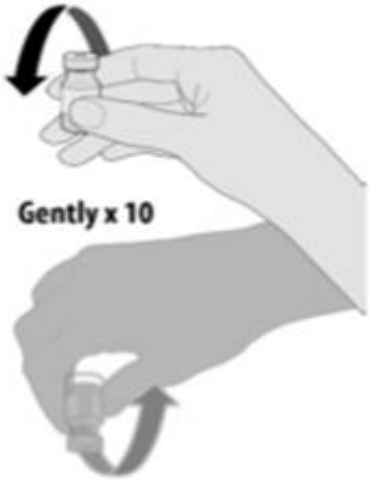
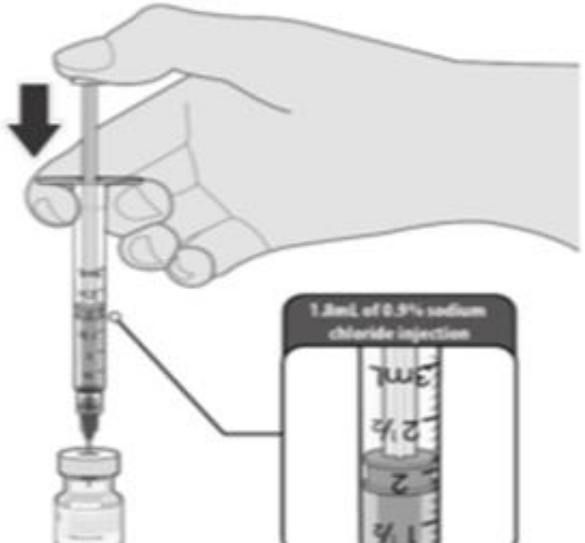
Except for fatigue (in 3.8%) and headache (in 2.0%) after the second dose.

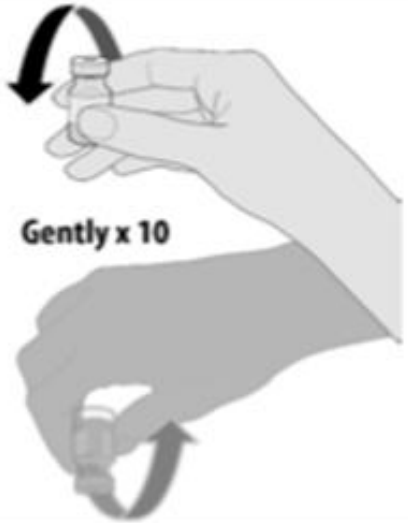
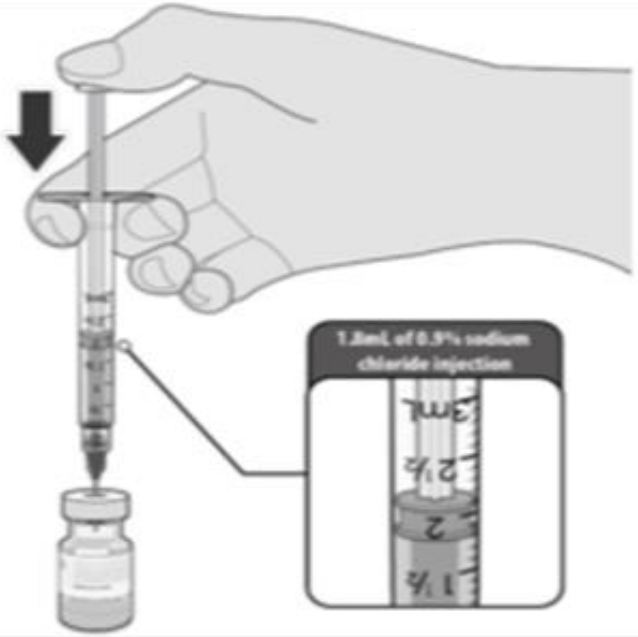
Pfizer vaccin: samenstelling

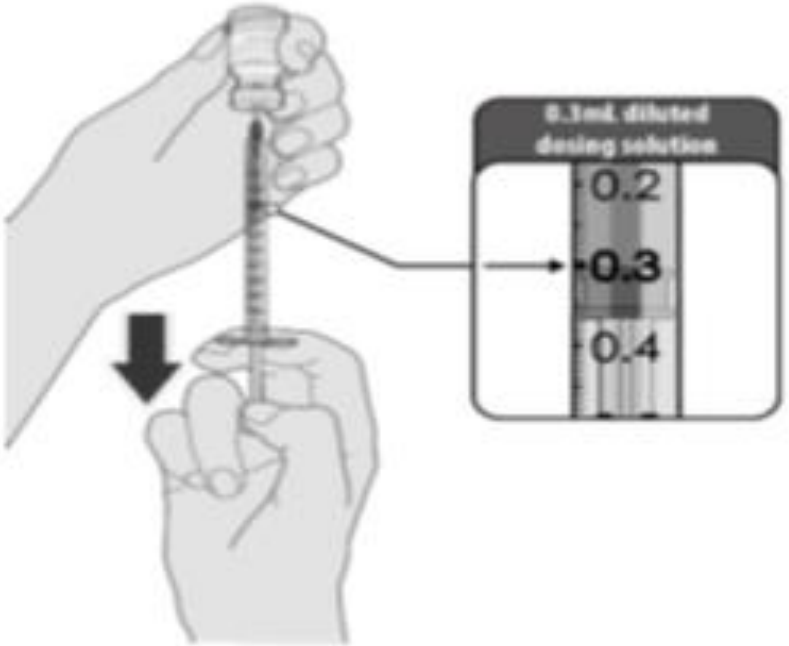
The Pfizer-BioNTech COVID-19 Vaccine is a white to off-white, sterile, preservative-free, frozen suspension for intramuscular injection. The vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2. The vaccine also includes the following ingredients: lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen [between -80°C to -60°C (-112°F to -76°F)] multi-dose (5-dose) vial. The vaccine must be thawed and diluted in its original vial with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to administration. After dilution, the vial contains 5 doses of 0.3 mL per dose. After dilution, the multiple-dose vials must be stored between 2°C to 25°C (35°F to 77°F) and used within 6 hours from the time of dilution.

The Pfizer-BioNTech COVID-19 Vaccine, BNT162b2 (30 µg), is administered intramuscularly (IM) as a series of two 30 µg doses (0.3 mL each) 21 days apart.

Frozen vials should be transferred to 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw (see section 6.4). Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 25 °C for immediate use. Once thawed, the undiluted vaccine can be stored for up to 5 days at 2 °C to 8 °C, and up to 2 hours at temperatures up to 25 °C.	
Allow the thawed vial to come to room temperature and gently invert 10 times prior to dilution. Do not shake. Prior to dilution the vaccine should present as an off-white solution with no particulates visible. Discard the vaccine if particulates or discolouration are present.	
The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and **aseptic** techniques. **Warning:** Unpreserved sodium chloride 9 mg/mL (0.9%) solution for injection is the **only** diluent that should be used. This diluent is not provided in the vaccine carton.	

stored for up to 5 days at 2 °C to 8 °C, and up to 2 hours.at temperatures up to 25 °C.	
Allow the thawed vial to come to room temperature and gently invert 10 times prior to dilution. Do not shake. Prior to dilution the vaccine should present as an off-white solution with no particulates visible. Discard the vaccine if particulates or discolouration are present.	
The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and **aseptic** techniques. **Warning:** Unpreserved sodium chloride 9 mg/mL (0.9%) solution for injection is the **only** diluent that should be used. This diluent is not provided in the vaccine carton.	

The diluted vials should be marked with the dilution date and time and stored between 2 °C to 25 °C. Use immediately, and within 6 hours after dilution.	
After dilution, the vial contains 5 doses of 0.3 mL. Withdraw the required 0.3 mL dose of diluted vaccine using a sterile needle and syringe and discard any unused vaccine within 6 hours after dilution.	

UK - Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 vaccine

- ***Contraindications***

- ***Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.***

- **ALC-0315 = (4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate),**
- **ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide,**
- **1,2-Distearoyl-sn-glycero-3-phosphocholine,**
- **cholesterol,**
- **potassium chloride,**
- **potassium dihydrogen phosphate,**
- **sodium chloride,**
- **disodium hydrogen phosphate dihydrate,**
- **sucrose,**
- **water for injections**

https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine

Pfizer vaccin en allergie: 2 gevallen van anafylactoide reacties op 9 dec 2020

9th of December 2020 UK, MHRA!

- The MHRA advice states: “Any person with a history of a significant allergic reaction to a vaccine, medicine or food (such as previous history of anaphylactoid reaction or those who have been advised to carry an adrenaline autoinjector) should not receive the Pfizer/BioNtech vaccine. Resuscitation facilities should be available at all times for all vaccinations. Vaccination should only be carried out in facilities where resuscitation measures are available.”

https://www.theguardian.com/world/2020/dec/09/pfizer-covid-vaccine-nhs-extreme-allergy-sufferers-regulators-reaction

“As is common with new vaccines, the MHRA have advised on a precautionary basis that people with a significant history of allergic reactions do not receive this vaccination,” said Stephen Powis, national medical director for the NHS.

Zwangerschap & Pfizer vaccin

- There are no or limited amount of data from the use of COVID-19 mRNA Vaccine BNT162b2.
- Animal reproductive toxicity studies have not been completed.
- COVID-19 mRNA Vaccine BNT162b2 is not recommended during pregnancy.
- For women of childbearing age, pregnancy should be excluded before vaccination. In addition, women of childbearing age should be advised to avoid pregnancy for at least 2 months after their second dose.

Vaccinatie en zwangerschap: JCVI - UK

- the temporary exclusion of pregnant women for now: *"Given the lack of evidence, JCVI favours a precautionary approach, and does not currently advise COVID-19 vaccination in pregnancy. Women should be advised not to come forward for vaccination if they may be pregnant or are planning a pregnancy within three months of the first dose.*

Borstvoeding

- It is unknown whether COVID-19 mRNA Vaccine BNT162b2 is excreted in human milk. A risk to the newborns/infants cannot be excluded. COVID-19 mRNA Vaccine BNT162b2 should not be used during breast-feeding

links

- Q&A voor burgers en professionals
- https://www.laatjevaccineren.be/ziektes/covid-19
- https://www.fagg.be/nl/MENSELIJK_gebruik/geneesmiddelen/geneesmiddelen/covid_19/vaccins/vragen_en_antwoorden_over_vaccins#C2
- https://www.gezondheidenwetenschap.be/dossiers/coronavirus

- Vergelijking van lopende studies
- https://www.fagg.be/nl/MENSELIJK_gebruik/geneesmiddelen/geneesmiddelen/covid_19
- nCOV vaccinlandschap: COVID-19 vaccin tracker (London School of Hygiene & Tropical Medicine)
- https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

Eerste toediening van het Pfizer vaccin in het VK: 8 december 2020

9 december 2020 – 21.40h

CORONACRISIS

Cyberaanval op Europees Geneesmiddelenbureau: documenten over coronavaccin van Pfizer/BioNTech ingekeken

Het Europees Geneesmiddelenagentschap (EMA) in Amsterdam is het doelwit geworden van een cyberaanval. Daarbij zouden de hackers documenten over het coronavaccin van Pfizer/BioNTech hebben kunnen inkijken. Dat meldt BioNTech in een persberic...

LEES MEER

1. **Bewoners en personeel° in woonzorgcentra voor ouderen**, gevolgd door **de collectieve zorginstellingen,** met inbegrip van de vrijwilligers.
2. **Zorgprofessionals° in ziekenhuizen en zorgprofessionals° die in de eerste lijn werken.** Deze categorie omvat alle personen die een hoog risico op besmetting lopen door nauw contact met Covid-19 patiënten in het kader van hun beroepsactiviteit.
3. **Andere medewerkers in ziekenhuizen en gezondheidsdiensten** met inbegrip van structuren die investeren in preventie (bijvoorbeeld vaccinatie- en kankerscreening centra, Kind & Gezin en Office de la Naissance et de l'Enfance (ONE). Deze categorie omvat alle personen die in het kader van hun beroepsactiviteit een lager risico op besmetting lopen.
4. **Personen van 65 jaar en ouder,** ofwel zonder onderscheid, ofwel in aflopende leeftijdscategorieën, afhankelijk van de beschikbaarheid van het vaccin.

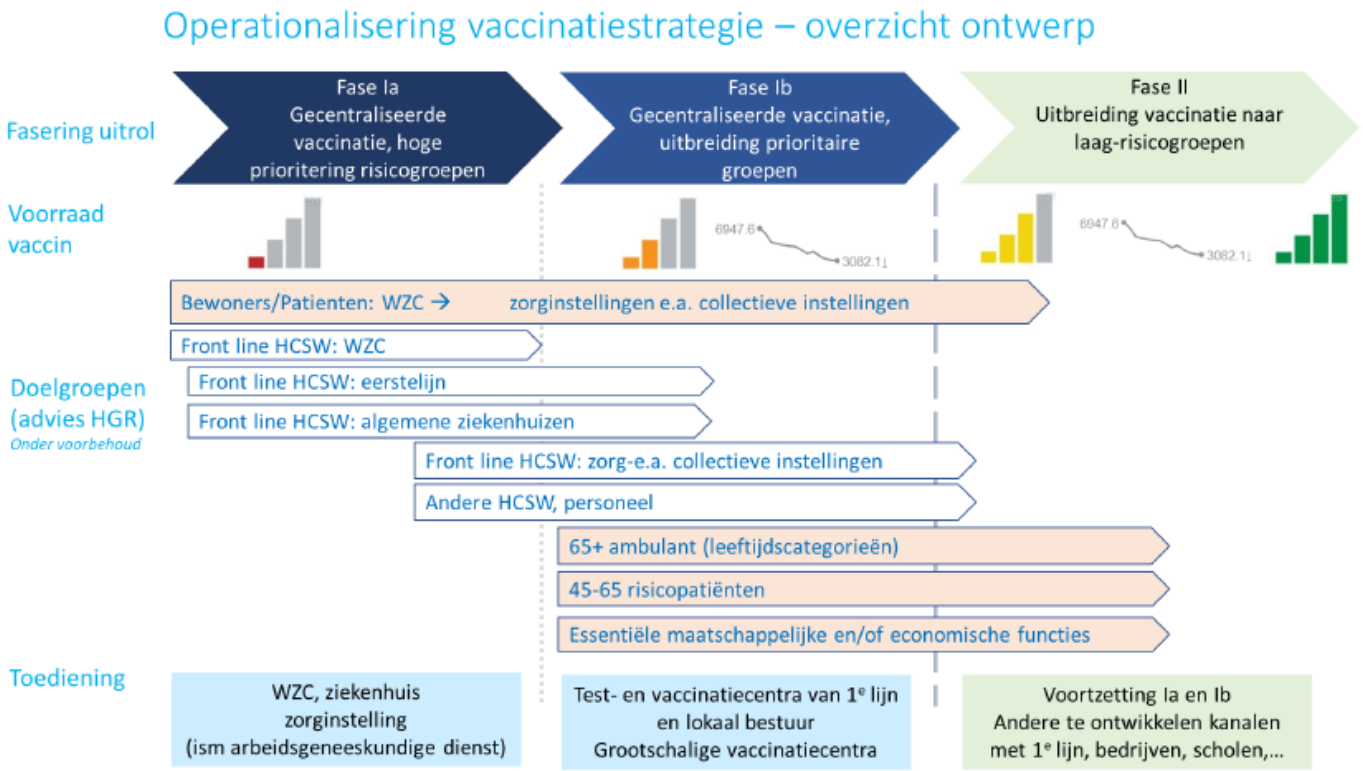
° De stagiairs in opleiding voor de uitoefening van een gezondheids(zorg)beroep worden voor de vaccinatie op gelijke voet behandeld als de gediplomeerden.

5. **Personen van 45-65 jaar met specifieke comorbiditeiten**: obesitas (BMI ≥ 30), diabetes, hypertensie, cardiovasculaire ziektes, chronische long-, nier- en leverziekten en hematologische maligniteiten tot 5 jaar na de diagnose en alle recente solide kankers (of recente kankerbehandelingen). De lijst van comorbiditeiten is nog niet definitief afgesloten. Uitbreiding moet worden overwogen als uit wetenschappelijke gegevens blijkt dat er nieuwe groepen zijn voor prioritaire vaccinatie (effect op de overdracht).
6. Personen die een **essentiële maatschappelijke en/of economische functies** uitoefenen, volgens criteria die verder zullen bepaald worden.

Operationalisering vaccinatiestrategie – overzicht ontwerp

	Fase Ia Gecentraliseerde vaccinatie, hoge prioritering risicogroepen	Fase Ib Gecentraliseerde vaccinatie, uitbreiding prioritaire groepen	Fase II Uitbreiding vaccinatie naar laag-risicogroepen
Fasering uitrol			
Eigenschappen vaccin	• Erg beperkte hoeveelheid • 1 of 2 vaccins • Multi-dose vials • Specifieke opslag (-75°C)	• Grotere aantallen • Meer vaccins • Multi-dose vials • Minder complexe opslag (°C)	• Ruime voorraad • Diverse vaccins • Multi-dose & single-dose • Eenvoudige opslag (°C)
Doelgroepen (advies HGR)	• Bewoners & personeel WZC → zorginstellingen • Zorgprofessionals (1e lijn, ziekenhuis…)	• 65+ ambulant (leeftijdscateg.) • 45-65 risicopatiënten • Essentiële maatschappelijke en/of economische functies	• Andere risicopatiënten • Volwassen populatie (Te definiëren ifv nieuwe wetenschappelijke inzichten)
Toediening	WZC, ziekenhuis zorginstelling (ism arbeidsgeneeskundige dienst)	Triage- en vaccinatiecentra van 1e lijn en lokaal bestuur Grootschalige vaccinatiecentra	Voortzetting Ia en Ib Andere te ontwikkelen kanalen met 1e lijn, bedrijven, scholen,…
Distributie	Centrale opslag FAGG of producent specifieke logistiek (-70°C) Prioriteit hoog volume hub (ZH)	Centrale opslag Specifiek en aangepaste logistiek (uit bvb. lokaal depot of ZH)	Meer decentrale opslag en distributie
Communicatie	Informatie aangepast aan fase via diverse kanalen		

Figuur 4 – Fasering uitrol



Het maximaal aantal toe te dienen vaccins kan globaal ingeschat worden per fase op basis van beschikbare gegevens van FOD Volksgezondheid, het RIZIV, de deelstaten en andere bronnen. Dat leidt tot het volgende voorlopige overzicht voor fase Ia (Tabel 3).

Tabel 3 – Overzicht Fase Ia

Kandidaten om te vaccineren	Voorlopige ramingen
Bewoners WZC	150 000
Personeel WZC	60 000
Zorgprofessionals 1e lijn	120 000
Zorgprofessionals algemene ziekenhuizen	140 000
Andere gezondheidswerkers	(meer dan) 200 000

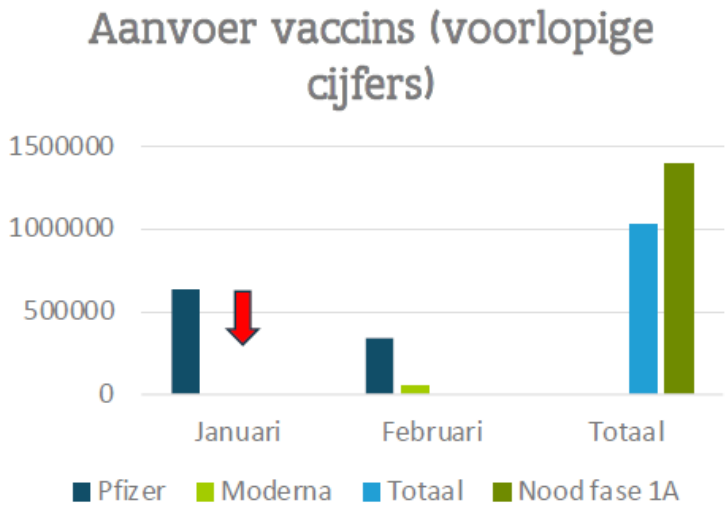
Voor fase Ib bedraagt het aantal 65-plussers 2 050 000 personen en levert een eerste inschatting 1 300 000 risicopatiënten tussen 45-65 jaar.

Vaccinatiestrategie

	Fase 1A	Fase 1B	Fase 2
Uitrolstrategie	**Gecentraliseerde vaccinatie, hoge prioriteit voor risicogroepen**	Gecentraliseerde vaccinatie, uitbreiding prioritaire groepen	Uitbreiding vaccinatie naar laag-risicogroepen
Voorraad?	**Erg beperkte hoeveelheid, 1 of 2 verschillende vaccins beschikbaar**	Grotere aantallen, meer vaccins beschikbaar	Ruime voorraad, diverse vaccins beschikbaar
Hoe wordt het toegediend?	**2 dosissen per persoon**	2 dosissen per persoon	1 of 2 dosissen per persoon, afhankelijk van het vaccin
Wat is de doelgroep?	**Bewoners en personeel van woonzorgcentra, zorgprofessionals**	Eerst 65-plussers, daarna risicopatiënten tussen 45 en 65 jaar en (later) essentiële maatschappelijke en of economische functies	Andere risicopatiënten, volwassen populatie
Waar wordt het toegediend?	**In WZC, ziekenhuizen en zorginstellingen**	In triage- en vaccinatiecentra van 1ste lijn en lokaal bestuur. Grootschalige vaccinatiecentra	Voortzetting 1A en 1B. + andere te ontwikkelen kanalen met 1ste lijn, bedrijven, scholen
Opslag?	**Specifieke opslag (-75°C)**	Minder complexe opslag (°C)	Eenvoudige opslag (°C)

Doelgroep fase 1A

- Bewoners en personeel van woonzorgcentra en zorgprofessionals
- Plaats van vaccinatie WZC, ziekenhuizen en zorginstellingen
- Nood aan 1 400 000 vaccins (700 000 mensen) voor de volledige doelgroep Fase 1A



Vlaanderen
is zorg

Primaire doelgroep van fase 1a

1. *Bewoners en personeel (stagiairs/studenten) en geregistreerde vrijwilligers in woonzorgcentra*
2. *Personeel (stagiairs/ studenten) dagverzorgingscentra verbonden aan WZC*
3. *Personeel en inwoners (GAW) aan WZC*

- We leren van deze fase om te weten wat andere instellingen nodig hebben (VAPH,...)
- Ook gefaseerd owv supply problemen

Vlaanderen
is zorg

Wanneer komen die vaccins er aan?

- We moeten 5 januari 2021 klaar zijn
  - 1. WZC-bewoners en personeel en collectieve zorginstellingen
  - 2. ziekenhuis personeel en huisartsen/apothekers
  - 3. andere medewerkers in ziekenhuizen en gezondheidsdiensten
  - 4. 65-plussers
  - 5. ….
- Eerste vaccin = Pfizer (2 dosissen – 21 dagen tussen)
- Tweede vaccin = Moderna (2 dosissen – 28 dagen tussen)
- Derde vaccin = ? Astra Zeneca (2 dosissen – 28 dagen tussen)
- …

- Vaccinnet+: databank met alle gegevens – toegang via excel lijsten per dag die worden gedownload (via CRA, bedrijfsarts, huisarts, …)
- Wie vaccineert?
  - Huisartsen, bedrijfsartsen, verpleegkundigen, …