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Universiteit Antwerpen
Faculteit Geneeskunde en
Gezondheidswetenschappen

19de VALENTIJN VACCINATIESYMPOSIUM COVID-19 vaccins: waar staan we?

5 februari 2021

Centrum voor de Evaluatie van Vaccinaties
Vaccin & Infectieziekten Instituut
Universiteit Antwerpen

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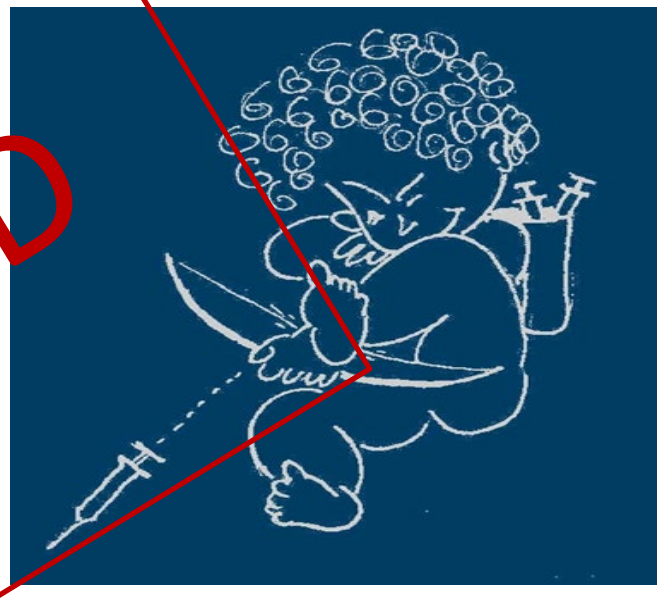
Welkom



PRE-CORONA TIJD

18de Valentijn Vaccinatiesymposium - Hoe wordt een vaccin 'gratis'?

Centrum voor de Evaluatie van Vaccinaties
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-update 2020

AFRICA KICKS OUT WILD POLIO

1.8 million
wild polio cases averted*

9 billion
oral polio vaccine doses provided*

220 million
children vaccinated multiple times every year

2 million
volunteer vaccinators support polio campaigns every year

* *Estimates between 1996-2020*

In 1996, the great African leader Nelson Mandela launched the Kick Polio Out of Africa campaign with Rotary International's support, setting out a vision for a polio-free Africa. At the time, wild polio paralysed 75,000 children each year. To protect communities from this crippling disease, African leaders, health workers, volunteers, parents, global donors and organizations united to reach every child with polio vaccines.

On 25 August 2020, after four years without a single case of wild polio, the African region has been certified free of wild poliovirus. Decades of extraordinary investment has paid off.

Yet, the job is not finished. These efforts must continue to prevent wild polio from returning and to end all forms of polio for

Beantwoorden | Allen beantwoorden | Doorsturen | IM

wo 3/02/2021 21:00

Ananda Bandyopadhyay <Ananda.Bandyopadhyay@gatesfoundation.org>

Liberia: 'ready' to use n OPV2

Aan Pierre Van Damme; 'rruttimann@fidec-online.org'; Ralf Clemens (clemens.ralf@outlook.com); Sueannclemens@outlook.com; jose.jimeno@vaxtrials.com; Xavier Saez Llorens; Fred' 'Zepp (zepp@uni-mainz.de)

U hebt dit bericht doorgestuurd op 3/02/2021 22:17.

Friends – happy to share that following a rigorous readiness verification assessment process coordinated by the nOPV2 Working Group with regional and country partners, Liberia has just been designated to be "ready" for n OPV2 use, and two nationwide polio campaigns (~3.2 million doses total) have been recommended to be implemented in ~Feb – March period in the country. Next steps involve WHO DG release of the doses from stockpile and vaccine shipment, among other activities.

At least 3 other countries – Nigeria, Benin
requirements per EUL as you are aware), a
succession with the Liberia campaign, dep

I wanted to ensure you all are aware of thi
we don't share this information too broad

Quite unbelievable to see how far we have
milestone.

Thanks as always,
Ananda

Ananda S. Bandyopadhyay MBBS, MPH
pronouns | he / him / his
Senior Program Officer – Polio
Global Development
V +1 206 770 2310

Safety and immunogenicity of two novel type 2 oral poliovirus vaccine candidates compared with a monovalent type 2 oral poliovirus vaccine in healthy adults: two clinical trials

Ilse De Coster, Isabel Leroux-Roels*, Ananda S Bandyopadhyay, Christopher Gast, Kanchanamala Withanage, Katie Steenackers, Philippe De Smedt, Annelies Aerssens, Geert Leroux-Roels, M Steven Oberste, Jennifer L Konopka-Anstadt, William C Weldon, Alan Fix, John Konz, Rahnuma Wahid, John Modlin, Ralf Clemens, Sue Ann Costa Clemens, Novilia S Bachtiar, Pierre Van Damme*

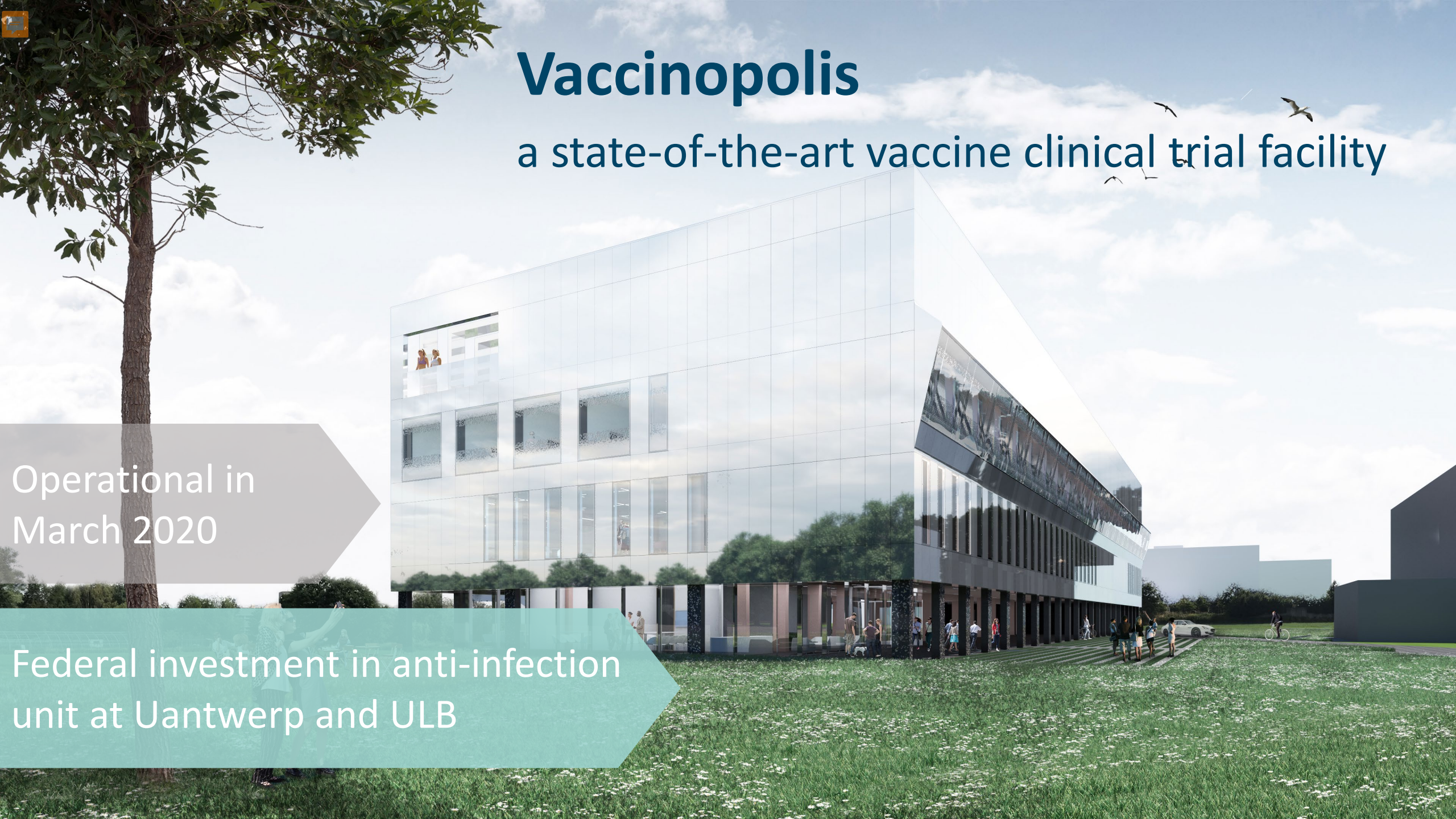
Summary

Background Two novel type 2 oral poliovirus vaccine (OPV2) candidates, novel OPV2-c1 and novel OPV2-c2, designed to be more genetically stable than the licensed Sabin monovalent OPV2, have been developed to respond to ongoing polio outbreaks due to circulating vaccine-derived type 2 polioviruses.

Published Online
December 9, 2020
https://doi.org/10.1016/
S0140-6736(20)32541-1

Vaccinopolis

a state-of-the-art vaccine clinical trial facility



Operational in
March 2020

Federal investment in anti-infection unit at Uantwerp and ULB

3ième Symposium Saint-Valentin

5 février 2021

SARS-CoV2 et vaccination: État des lieux

GIEV
GROUPE INTERUNIVERSITAIRE D'EXPERTS EN VACCINOLOGIE

La vaccination: opinion publique et communication
Yvon Englert (Délégué COVID-19 pour la Wallonie)

Développement vaccinal en Fast Track
Pieter Neels (UNamur)

Vaccination en pratique: qui vacciner?
Yves Van Laethem (porte parole interfédéral COVID-19)

Vaccination SARS-CoV 2

Immunité et SARS-CoV2
Arnaud Marchant (ULB)

Pharmacovigilance: avant et après commercialisation
Françoise Wuillaume/
Elena Prokoyeva AFMPS

Vaccins disponibles en Belgique: efficacité - immunogénicité - sécurité
Jean-Michel Dogné (UNamur)

ULB UNIVERSITÉ LIBRE DE BRUXELLES

LIÈGE université

UCLouvain

Yearly symposium with scientific presentations covering present-day vaccination topics:

Vaccins en vaccinaties zijn sowieso altijd belangrijk, maar dit jaar halen beide termen al maandenlang dagelijks de pers, en dat zal ook de komende tijd nog zo zijn. ***"Het is dan ook vrij logisch dat de focus van ons symposium dit jaar zal liggen op COVID-19"****, vertelt prof. Pierre Van Damme (UAntwerpen).* ***"We bekijken het thema vaccins vanuit heel verschillende, multidisciplinaire invalshoeken."***

www.uantwerpen.be/valentijn

19de VALENTIJN VACCINATIESYMPOSIUM

COVID-19 vaccins: waar staan we?

Introductie over COVID-19 vaccins
Prof. Pierre Van Damme
(UAntwerpen)

De rol van sociale media en desinformatie:
Prof. Karolien Poels
(UAntwerpen)

Modellering van de infectie:
Prof. Niel Hens
(UAntwerpen/UHasselt)

Vaccingedrag:
Prof. Philippe Beutels (UAntwerpen)

Veiligheidsbewaking:
Dr. Elena Prokofyeva &
Dr. Françoise Wuillaume
(FAGG)

Perspectief van de producent:
Dr. Johan Van Hoof (Janssen)

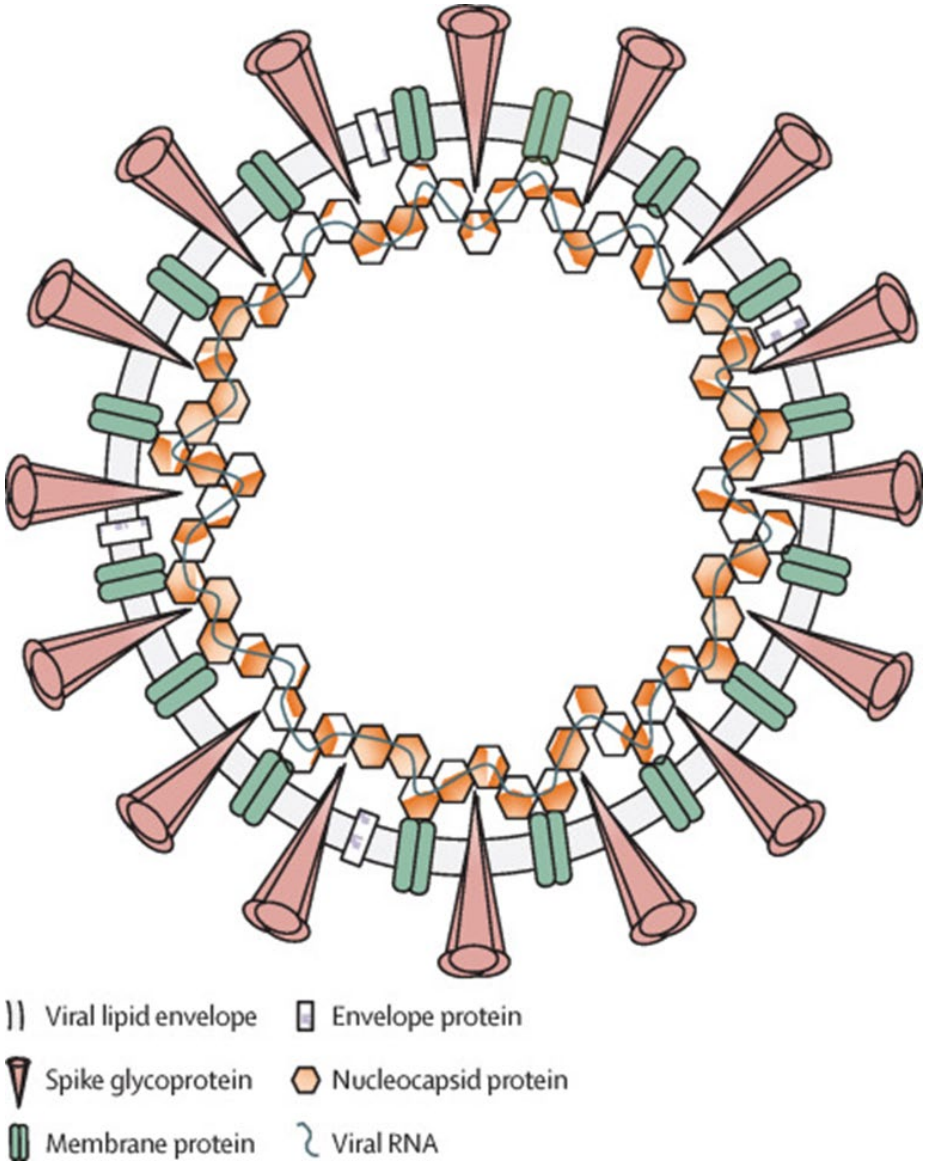
Praktisch uitrollen van een vaccinatieprogramma:
Dr. Geert Top (Vlaams Agentschap Zorg en Gezondheid)

Centrum voor de Evaluatie van Vaccinaties
Vaccin & Infectieziekten Instituut
Universiteit Antwerpen

AGENTSCHAP ZORG & GEZONDHEID

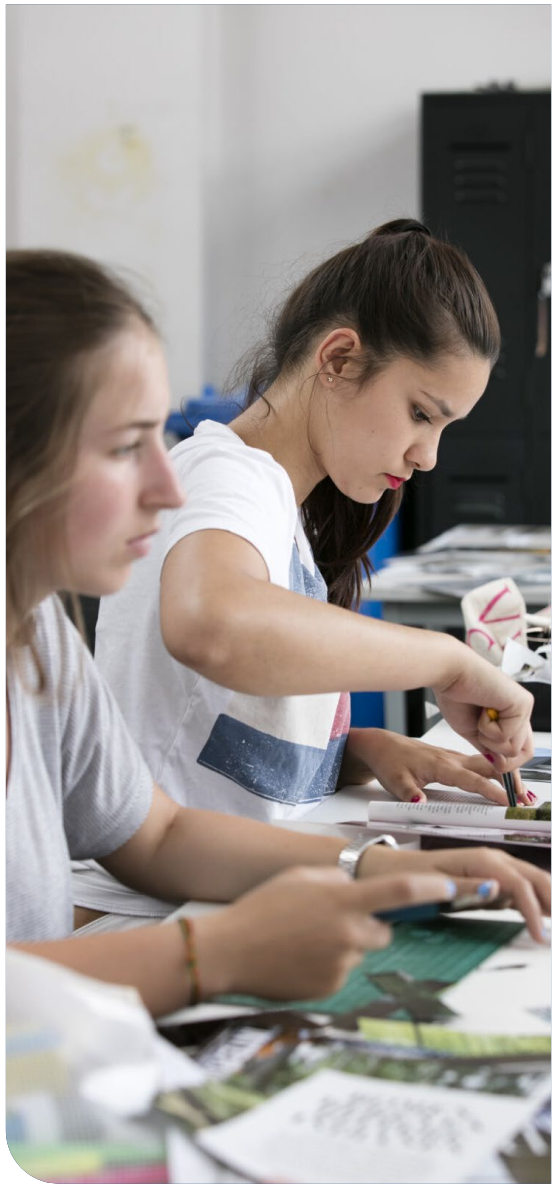
Vlaanderen is zorg

For researchers and vaccinators (doctors and nurses) in the healthcare sector.
Helping with practical vaccine-related questions through questions & answer sessions.



Het COVID-19 virus

- Het virus bevat op zijn oppervlak een eiwit, dat zich kan vastbinden op bepaalde slijmvliezen in ons lichaam, het S-eiwit.
- Het S-eiwit bindt zich vast op de ACE-2 receptoren en dringt zo menselijke cellen binnen om zich te vermenigvuldigen
- Zo kan het virus ons ziek maken en voor verwikkelingen zorgen



COVID-19 vaccins? (29/1/2021)

- Meer dan 237 vaccins zijn in ontwikkeling, waarvan enkele in een laatste fase, en waarvan 4 hun goedkeuringsdossiers hebben ingediend, en 3 al goedgekeurd:
  - Pfizer (goedgekeurd), Moderna (goedgekeurd) en Oxford/Astra Zeneca vaccins (29 jan 2021)
- Vaccins worden beoordeeld op **kwaliteit, veiligheid en werkzaamheid** alvorens op de markt te komen

A29 | Platform

World Health Organization

R&DBluep
Powering research to prevent epidemics

COVID-19 - Landscape of novel coronavirus candidate vaccine development worldwide

vrijdag

DISCLAIMER: *These landscape documents have been prepared by the World Health Organization (WHO) for information purposes only concerning the 2019-2020 pandemic of the novel coronavirus. Inclusion of any parti*
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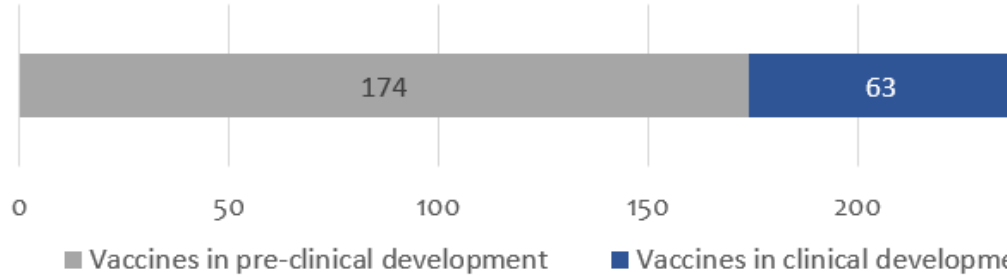
Summary Information on Vaccine Products in Clinical Development

1. - Number of vaccines in clinical development 63

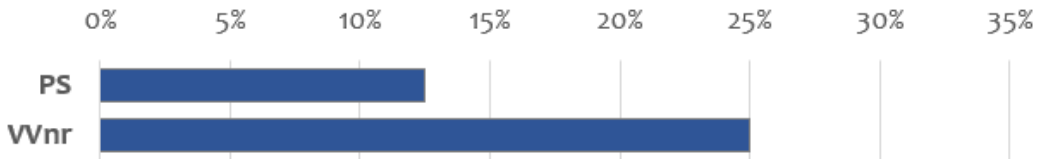
2. - Number of vaccines in pre-clinical development 174



3. - Candidates in clinical phase

Filter	Phase 3	Select phase of development (default is all)

Platform	Candidate vaccines (no. and %)

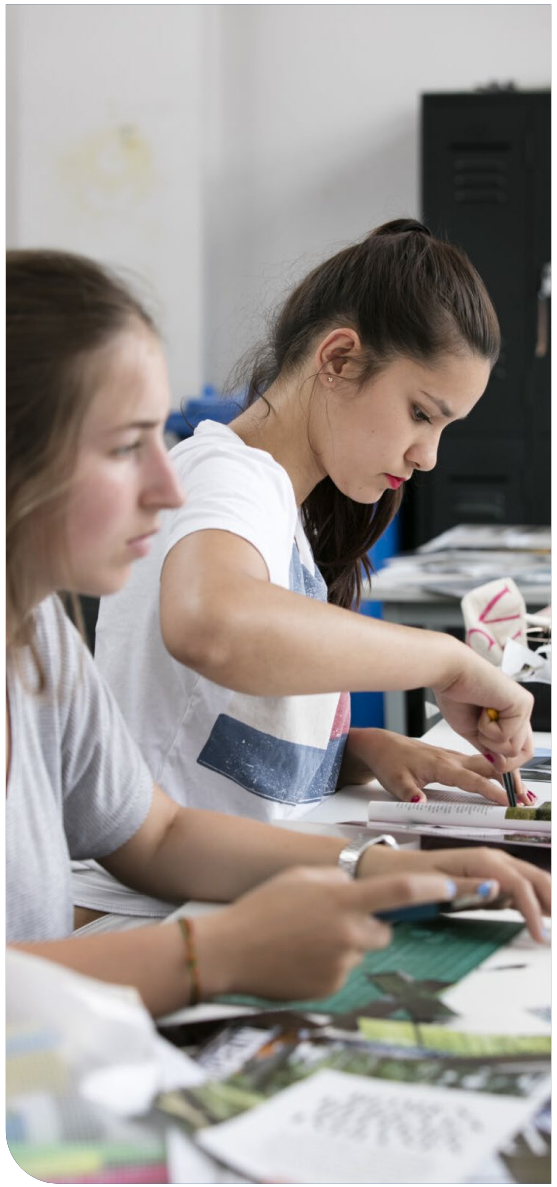


Summary | Clinical | Pre-Clinical

16 vaccin-kandidaten in fase 3

Platform		Candidate vaccines (no. and %)	
PS	Protein subunit	2	13%
VVnr	Viral Vector (non-replicating)	4	25%
DNA	DNA	1	6%
IV	Inactivated Virus	6	38%
RNA	RNA	3	19%
VVr	Viral Vector (replicating)	0	0%
VLP	Virus Like Particle	0	0%
VVr + APC	VVr + Antigen Presenting Cell	0	0%
LAV	Live Attenuated Virus	0	0%
VVnr + APC	VVnr + Antigen Presenting Cell	0	0%
		16	

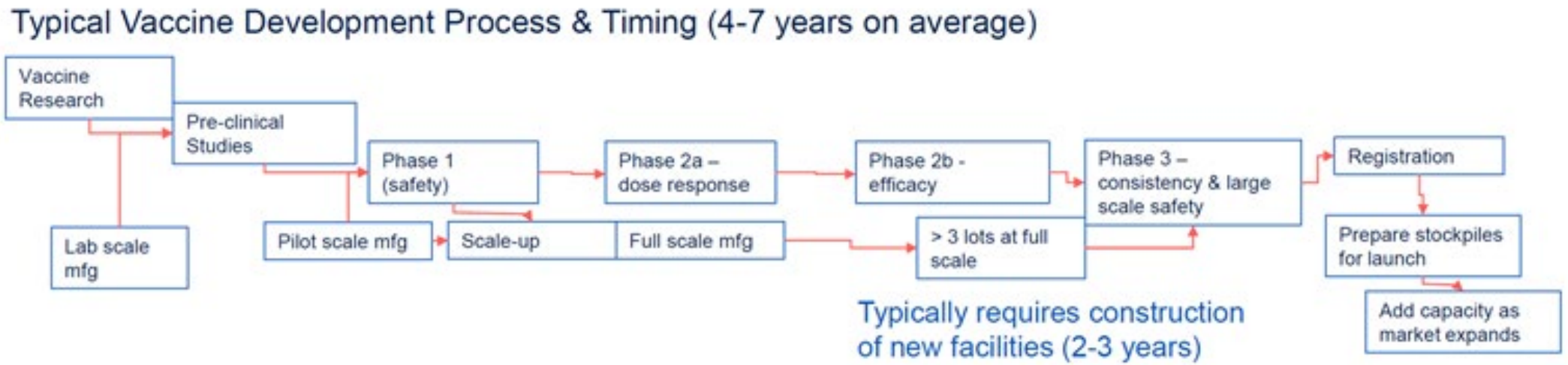
https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

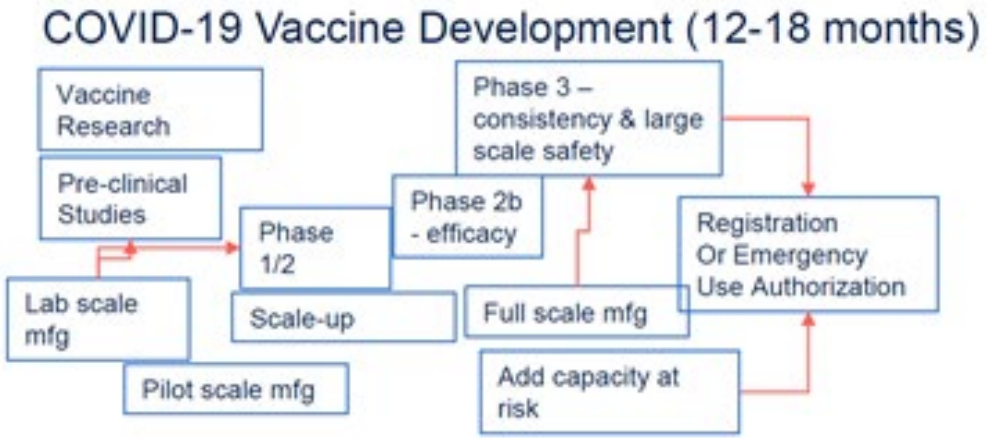


Hoe kon het COVID-19 vaccin zo snel ontwikkeld worden?

- 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
- “rolling review”

COVID-19 Manufacturing in Fast Forward





VIRUS VACCINES

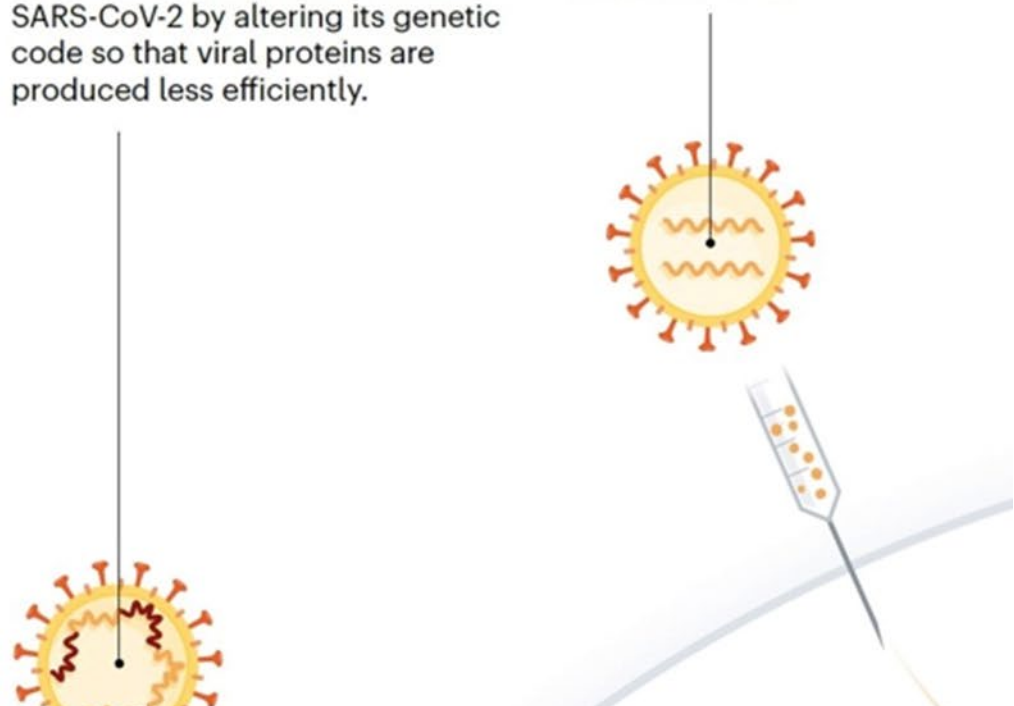
At least seven teams are developing vaccines using the virus itself, in a weakened or inactivated form. Many existing vaccines are made in this way, such as those against measles and polio, but they require extensive safety testing. Sinovac Biotech in Beijing has started to test an inactivated version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



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)

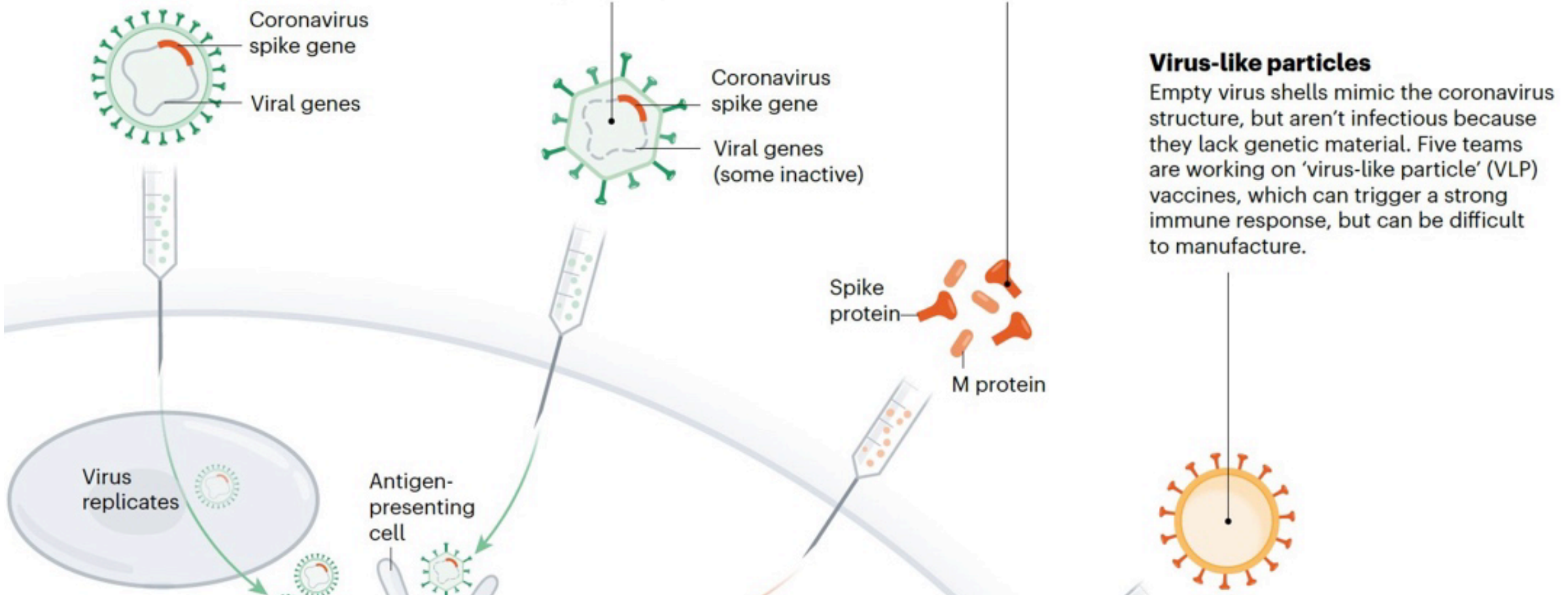
No licensed vaccines use this method, but they have a long history in gene therapy. Booster shots can be needed to induce long-lasting immunity. US-based drug giant Johnson & Johnson is working on this approach.

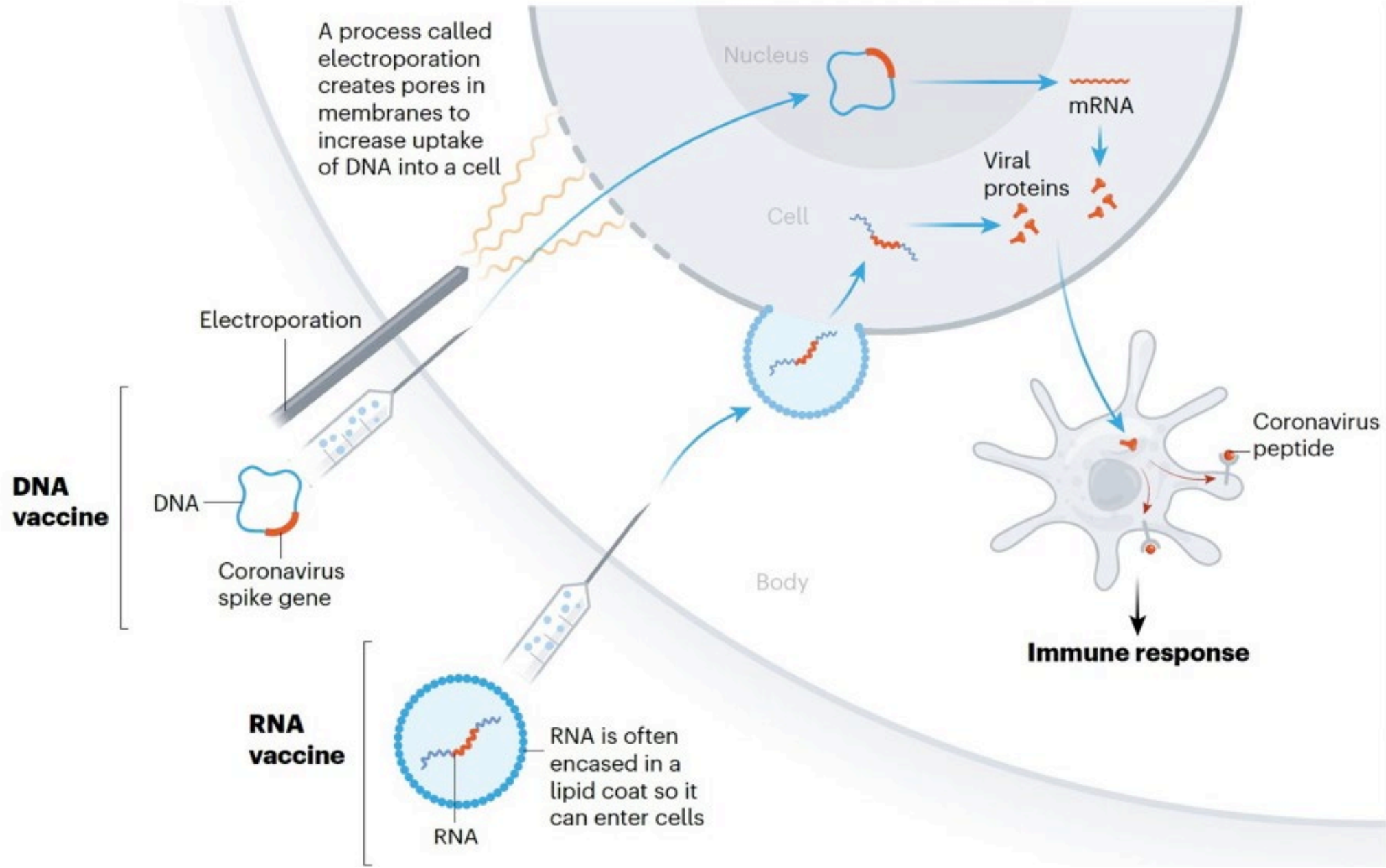
Protein subunits

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.

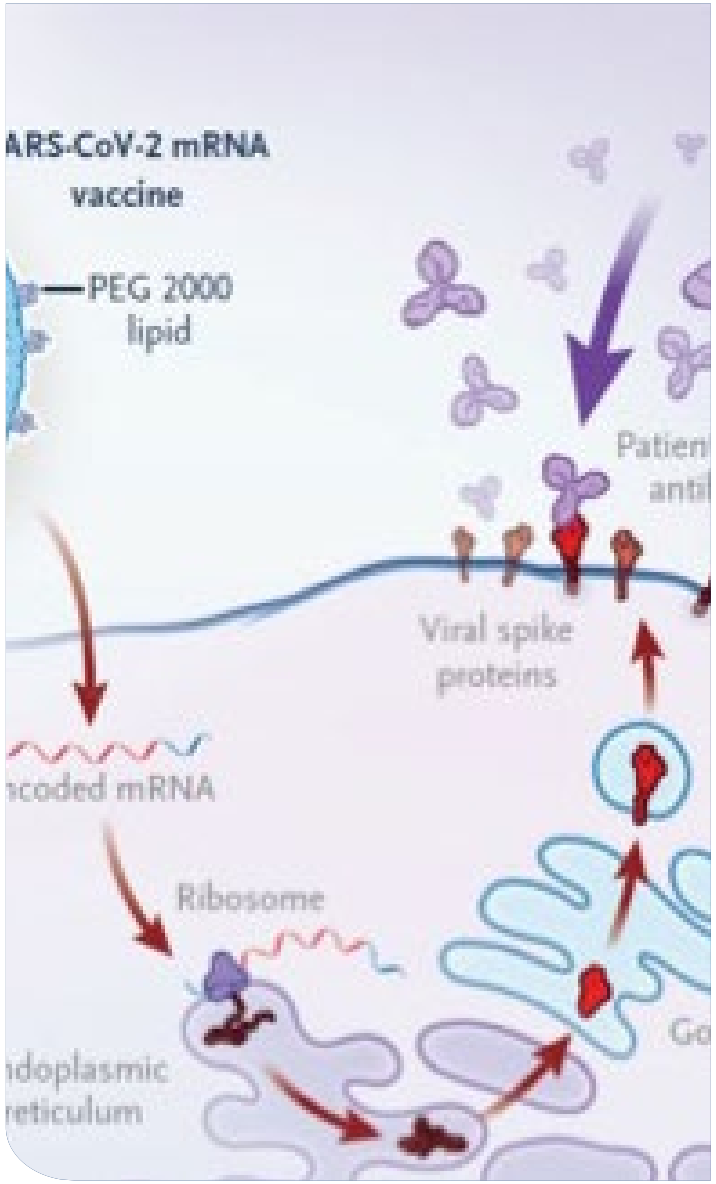
Virus-like particles

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.




A process called electroporation creates pores in membranes to increase uptake of DNA into a cell
Nucleus
mRNA
Viral proteins
Cell
Electroporation
DNA vaccine
DNA
Coronavirus spike gene
Body
Coronavirus peptide
Immune response
RNA vaccine
RNA is often encased in a lipid coat so it can enter cells
RNA

COVID-19 RNA-vaccins



- **RNA-vaccin:**
  - Een stukje genetisch materiaal (=afleescode) dat zorgt voor het S-eiwit wordt toegediend zodat we zelf dat S-eiwit aanmaken, waartegen we dan antilichamen gaan vormen
  - Het RNA = stukje genetisch materiaal komt niet in de celkern, en kan dus onmogelijk ons menselijk DNA of genetisch materiaal beïnvloeden!
  - mRNA blijft enkele uren in ons lichaam.
  - We hebben al jaren ervaring met RNA-vaccins ontwikkeld o.a. voor hondsdolheidsvaccins of zelfs ter bestrijding van kanker (=kankervaccins).

COVID-19 RNA-vaccins

Vlaanderen

Vaccine Safety Net Member

CEBAM

a Factcheck vaccinatie Patiëntenrichtlijnen Eerste hulp Ons project Factcheck corona

Hoe werkt het mRNA-coronavaccin? En is het veilig?

- Gezondheid in de media -

Marleen Finoulst Verschenen op 10/12/2020

Gerelateerde richtlijnen

Coronavirusinfecties: covid-19

Gerelateerde nieuwsberichten

Zijn er diverse beloftevolle coronavaccins in aantocht? 20 nov 2020

Zit er DNA in sommige vaccins? 15 jan 2020

Is het onvoorzichtig om massaal mRNA-coronavaccins toe te dienen?

- Gezondheid in de media -

Marleen Finoulst Verschenen op 13/01/2021

Gerelateerde richtlijnen

Coronavirusinfecties: covid-19

Gerelateerde nieuwsberichten

Hoe werkt het mRNA-coronavaccin? En is het veilig? 10 dec 2020

Kan vaccinatie auto-immuunziekten veroorzaken? 04 mei 2020

COVID-19 vaccins in België

- België heeft ondertussen 5 merken van vaccins aangekocht (info dec 2020):
  - Pfizer: 5 miljoen dosissen + 7.5 miljoen
  - Moderna: 2 miljoen + 3.7 miljoen
  - Astra-Zeneca: 7.5 miljoen
  - Janssen Pharmaceutica: 5 miljoen
  - Curevac: 2.9 miljoen dosissen
- Goedgekeurd: Pfizer op 21/12/2020 – Moderna op 6/1/2021
- We starten met vaccinatie met het Pfizer-vaccin op 28/12/2020 (pilootmatig) en met het hele programma op 5 jan 2021
- Het Pfizer-vaccin en het Moderna-vaccin zijn RNA-vaccins

Het Pfizer RNA-COVID-19 vaccin: wat weten we?

- Goedgekeurd door het Verenigd Koninkrijk, Canada, de Verenigde Staten, en de EU
- Goedkeuringsprocedure werd afgerond voor de EU op 21 december 2020
- Kwaliteit, veiligheid en werkzaamheid zijn uitvoerig onderzocht (fase 3)
- Kan toegediend worden vanaf 16 jaar (Moderna: 18 jaar) (Astra Zeneca: 18 jaar)
- 2 dosissen schema met 21d (19-23d) tussentijd (Moderna 28d.) (AZ: 4-12 wkn)
    - https://www.bmj.com/content/372/bmj.n226 (21-42d)
- Vaccins bevat geen bewaarstoffen of kwik of hulpstoffen
- Toe te dienen in de bovenarm spier, intramusculair
- zoals bij andere intramusculaire vaccin-toedieningen is ontsmetting van de plaats van injectie niet meer nodig; ook de ‘aspiratieproef’ is al een aantal jaren niet meer nodig.

Het Pfizer RNA-COVID-19 vaccin: wat weten we?

- **Fase 3**: **21 823 vaccin, 21 828 placebo**
- **Studie-opzet:** gerandomiseerd, placebo-gecontroleerd, geblindeerd voor de onderzoekers
- **Deelnemers:**
- Gezonde mannen en vrouwen > 16 j: **21% > 65 j – 4% > 75j (N=1712)**
- Gezondheidswerkers
- Deelnemers met stabiele chronische ziekten **(46%)**
    - Overgewicht (35%) en obesitas (35%)
    - Hypertensie (25%)
    - Astma
    - Diabetes (8%)
    - Chronisch longlijden (8%)
    - COVID-19 positief (3%: N= 1125)

Het Pfizer RNA-COVID-19 vaccin: wat weten we?

- **Veiligheid**
  - Wordt zeer goed verdragen
  - Klassieke lokale nevenwerkingen ter hoogte van de plek van injectie: pijn, roodheid, zwelling
  - Iets meer aanwezig < 55 jaar dan > 55 jaar

Jan 27, 2021 – US news

47.2 million doses of COVID-19

reuters.com/article/idUSL4N2K24CO

REUTERS

World Business Markets Breakingviews Video More

RACE FOR A CURE JANUARY 27, 2021 / 10:00 PM / UPDATED 4 DAYS AGO

47.2 million doses of COVID-19 vaccines distributed, 24.6 million administered: U.S. CDC

By Reuters Staff

1 MIN READ

Reactogenicity reported to v-safe

Local and systemic reactions, day 0-7*,†	All vaccines %	Pfizer- BioNTech dose 1 %	Pfizer-BioNtech dose 2 %	Moderna dose 1 %
Pain	70.7	67.7	74.8	70.1
Fatigue	33.4	28.6	50.0	29.7
Headache	29.4	25.6	41.9	26.0
Myalgia	22.8	17.2	41.6	19.6
Chills	11.5	7.0	26.7	9.3
Fever	11.4	7.4	25.2	9.1
Swelling	11.0	6.8	26.7	13.4
Joint pain	10.4	7.1	21.2	8.6
Nausea	8.9	7.0	13.9	7.7

afe data lock point 1/14/2021, 5:00 AM ET
orted on at least one health check-in completed on days 0-7 after receipt of vaccine

Het Pfizer RNA-COVID-19 vaccin: veiligheid en werkzaamheid

- Pfizer COVID-19 vaccin wordt goed verdragen en is veilig
- Werkzaamheid tegen symptomatische covid-19: 95%
- Beschermend effect ook bij 65 en 75-plussers
- Beschermend effect bij mensen met co-morbiditeit
- Reeds partiële bescherming na eerste dosis
- Duur van het beschermend effect is (nog) niet gekend.

Moderna-vaccin

Table 9. Interim Analysis[a] for Primary Efficacy Endpoint, COVID-19 Starting 14 Days After the 2nd Dose, Per-Protocol Set

Primary Endpoint: COVID-19 (per adjudication committee assessment)	Vaccine Group N=13934 Cases n (%) (Incidence rate per 1,000 person-years)	Placebo Group N=13883 Cases n (%) (Incidence rate per 1,000 person-years)	Vaccine Efficacy (VE) % (95% CI)*	Met Predefined Success Criterion**
All participants	5 (<0.1) 1.840	90 (0.6) 33.365	94.5% (86.5%, 97.8%)	Yes
18 to <65	5 / 10407 (<0.1) 2.504	75 / 10384 (0.7) 37.788	93.4% (83.7%, 97.3%)	NA
65 and older	0 / 3527	15 / 3499 (0.4) 21.046	100%	NA

SMPC (p7) – Astra Zeneca -

Table 2 COVID-19 Vaccine AstraZeneca efficacy against COVID-19[a]

Population	COVID-19 Vaccine AstraZeneca		Control		Vaccine efficacy % (95% CI)[b]
	N	Number of COVID-19 cases, n (%)	N	Number of COVID-19 cases, n (%)	
Licensing regimen					
4 – 12 weeks (28 to 84 days)	5,258	64 (1.2)	5,210	154 (3.0)	59.5 (45.8, 69.7)

N = Number of subjects included in each group; n = Number of subjects having a confirmed event; CI = Confidence Interval;

[a] Efficacy endpoint was based on confirmed COVID-19 cases in subjects aged 18 years and over who were seronegative at baseline, who had received two doses and were on-study ≥15 days post second dose.

[b] CI not adjusted for multiplicity.

Vaccine efficacy was 62.6% (95% CI: 50.9; 71.5) in participants receiving two recommended doses with any dose interval (ranging from 3 to 23 weeks), in a pre-specified analysis.

mRNA-vaccins en mutaties/varianten

- In December 2020 werd een nieuwe variant, **B117** met 23 mutaties in de UK geidentificeerd, met 8 wijzigingen voor het S-eiwit glycoproteine, waaronder een verandering in de receptor binding domain (N501Y).
- In October 2020 werd een andere variant ontdekt in Z Afrika, **B1.351**, met 22 mutaties, waaronder 8 voor het S-eiwit, met 3 in de receptor binding domain.
- Beide kunnen dus implicaties hebben voor monoclonale antilichaamtherapie, convalescent plasma therapie en vaccins

mRNA-vaccins en mutaties/varianten (Xie et al, Wu et al, Wang et al, 2021)

Sera van 20 gevaccineerden (2 à 4 weken na 2° vaccindosis) toonden geen reductie van in neutralisatie van virussen die de Y501 spike mutatie vertoonden. De beperking hier is dat de virussen niet het ganse set aan spike mutaties vertoonden zoals bij de UK en ZA varianten. (Xie et al)

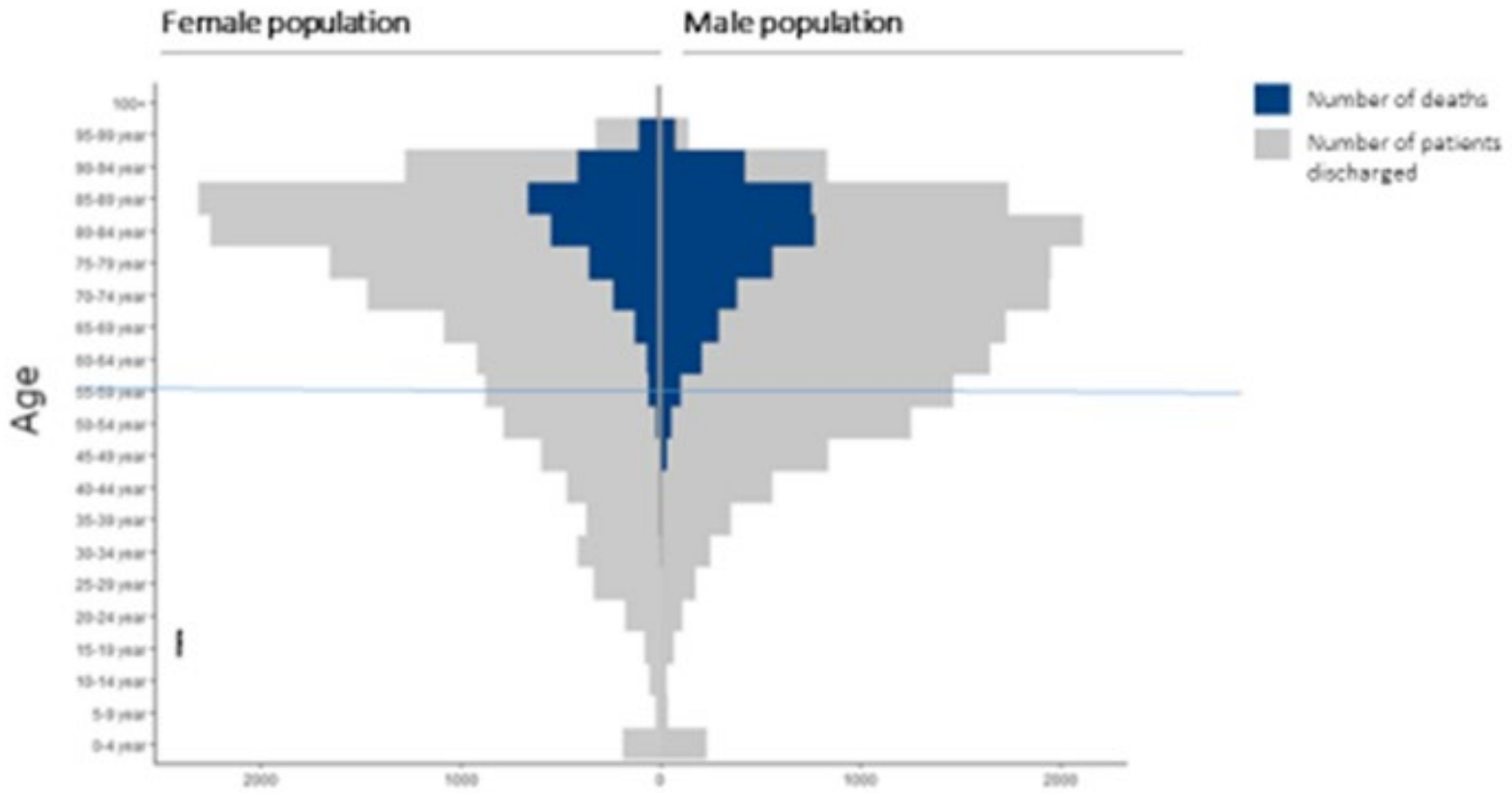
Sera van fase 1 Moderna vaccin deelnemers (7 dagen na dosis 2) werden getest voor neutralisatie van UK en ZA strains. Er werd geen vermindering van neutralisatie activiteit gezien voor de UK variant en licht verminderde neutralisatie van de ZA variant. (Wu et al).

Met de mRNA vaccin mogen we momenteel gerust zijn, wat ZA en UK variant betreft. Labo-onderzoek bevestigt de neutraliserende activiteit van de vaccin-geinduceerde AL tegen de 2 varianten. In 2 onderzoeken zien we een ‘modest lower potency’ voor de ZA variant wat kan te wijten zijn aan de concentratie aan antistoffen.

Company	Platform	Doses	Non-clinical results	Number of people who got vaccine	Protection from hospitalization/ death due to COVID-19	Protection from severe disease from COVID-19 (may not be hospital)	Efficacy against milder disease from COVID-19
moderna	mRNA-1273 mRNA in lipid nanoparticle	2	Neutralizing Abs; Strong Th1 response; protection from challenge	~15,000	100%	100% (30 cases in placebo arm; 0 in vaccine)	94.1%
Pfizer	BNT162b2 mRNA in lipid nanoparticle	2	Neutralizing Abs; Strong Th1 and Th2 response; protection from challenge	~18,600	100%	100% (9 cases in placebo arm; 0 in vaccine)	95%
AstraZeneca	AZD 1222 Non-replicating Chimp Adenovirus-DNA	2	Neutralizing Abs; Strong Th1 and Th2 response; protection from challenge	~5800	100%	100% (10 in placebo; 0 in vaccine)	82% 2 weeks after 0-12wk schedule
Johnson&Johnson	JNJ-78436725 Non-replicating human adenovirus/DNA	1	Neutralizing Abs; Strong Th1 and Th2 response; protection from challenge	~22,000	100%	85% (across South Africa, U.S., Latin America	72% US; 66% Latin America; 57% S. Africa
NOVAVAX Creating Tomorrow's Vaccines Today	NVX-CoV2373 Spike protein/RBD + Matrix M adjuvant	2	Neutralizing Abs; protection from challenge	~9700	100%		89.3% UK; 60% S. Africa
Sputnik V	Ad26 and Ad5 adenovirus/DNA	2	Neutralizing Abs; Strong Th1 and Th2	~11360	100%	100% (20 in placebo; 0 vaccine)	91.4%

mortaliteit en hospitalisaties bij COVID-19 (bron: Sciensano, steekproef: ong 60% van de gehospitaliseerden)

Outcome of hospitalized COVID patients based on COVID-19 Clinical Hospital surveillance (source: Sciensano)



Number of patients, out of 33157 in the sample
This Surveillance does not cover all hospitalised cases in Belgium

Israel 2/02/2021

Proximus 4G 13:39 53%

Collectie

Eran Segal
@segal_eran

Israel: We say with caution, the magic has started

Note blue lines, of 60+ years old (first to vaccinate), in the past 2 weeks:

~35% drop in cases
~30% drop in hospitalizations
~20% drop in critically ill

Stronger than in younger people & not seen in previous lockdown

>>>

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