BNT162b2 mRNA Covid-19 Vaccine

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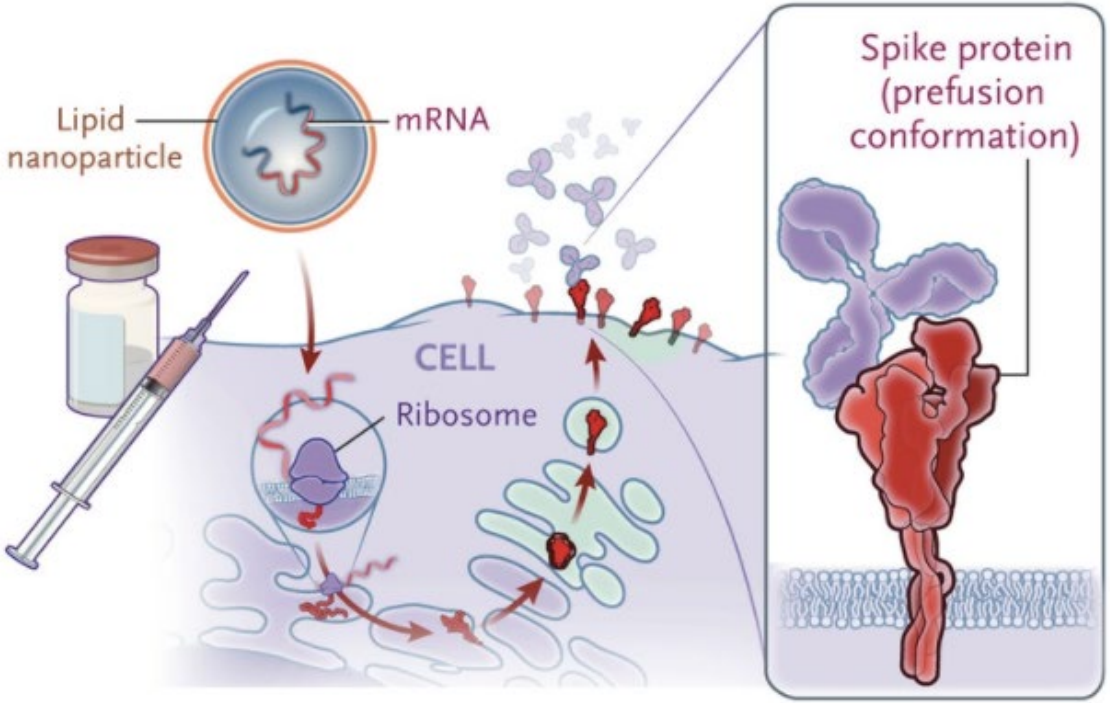
Worldwide Pandemic 2019: SARS- CoV-2

- ★ Covid-19 has affected tens of millions of individuals worldwide since it was declared a pandemic by the World Health Organization on March 11, 2020.
- ★ Covid-19
  - Severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) infection
  - Who is at the highest risk for COVID-19 and its complications:
    - Older adults
    - Persons with certain coexisting conditions
    - Front-line workers
- ★ This global outbreak has led to devastating medical, economic, and social consequences.
- ★ Safe and effective vaccines are needed **urgently**.

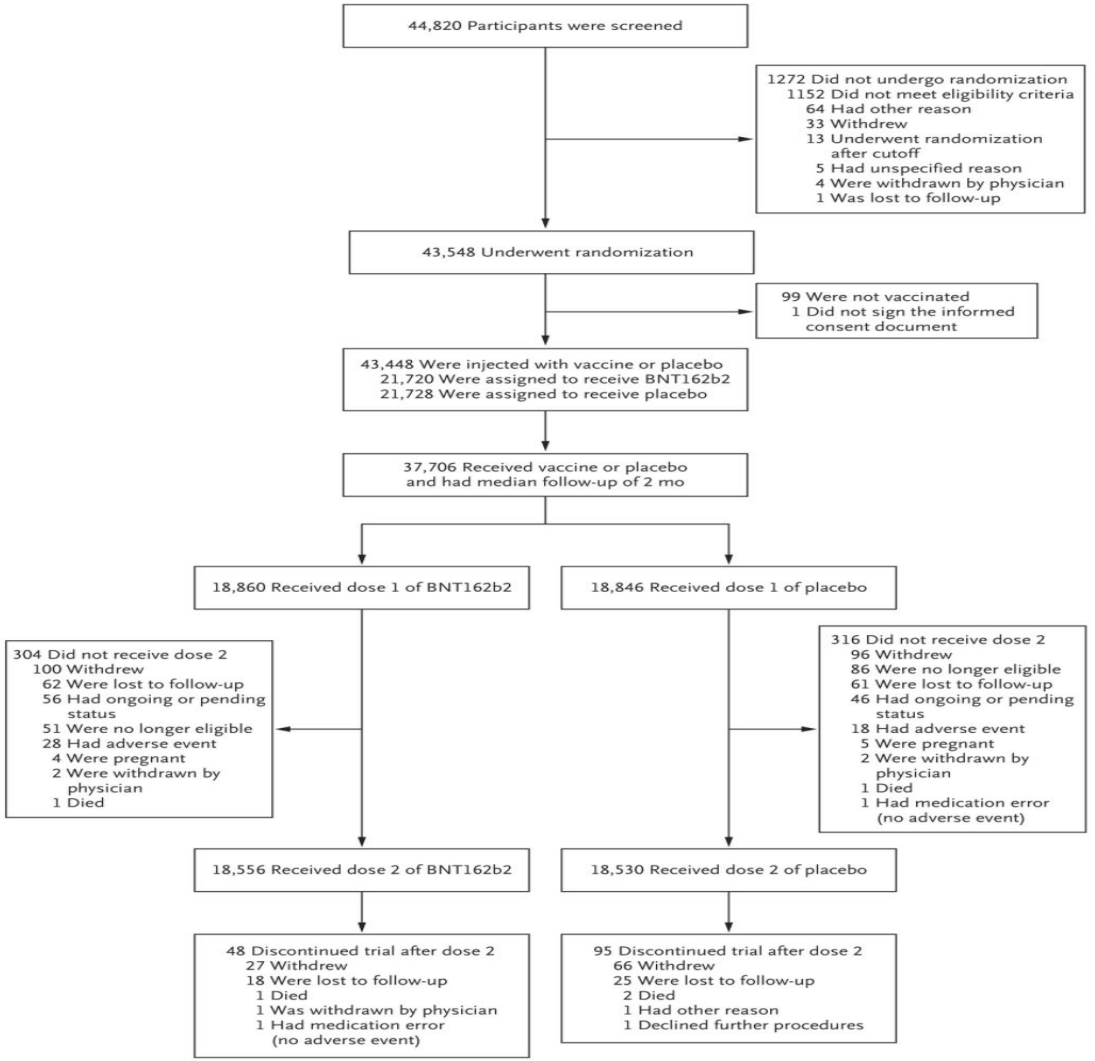
Pfizer & BioNTech



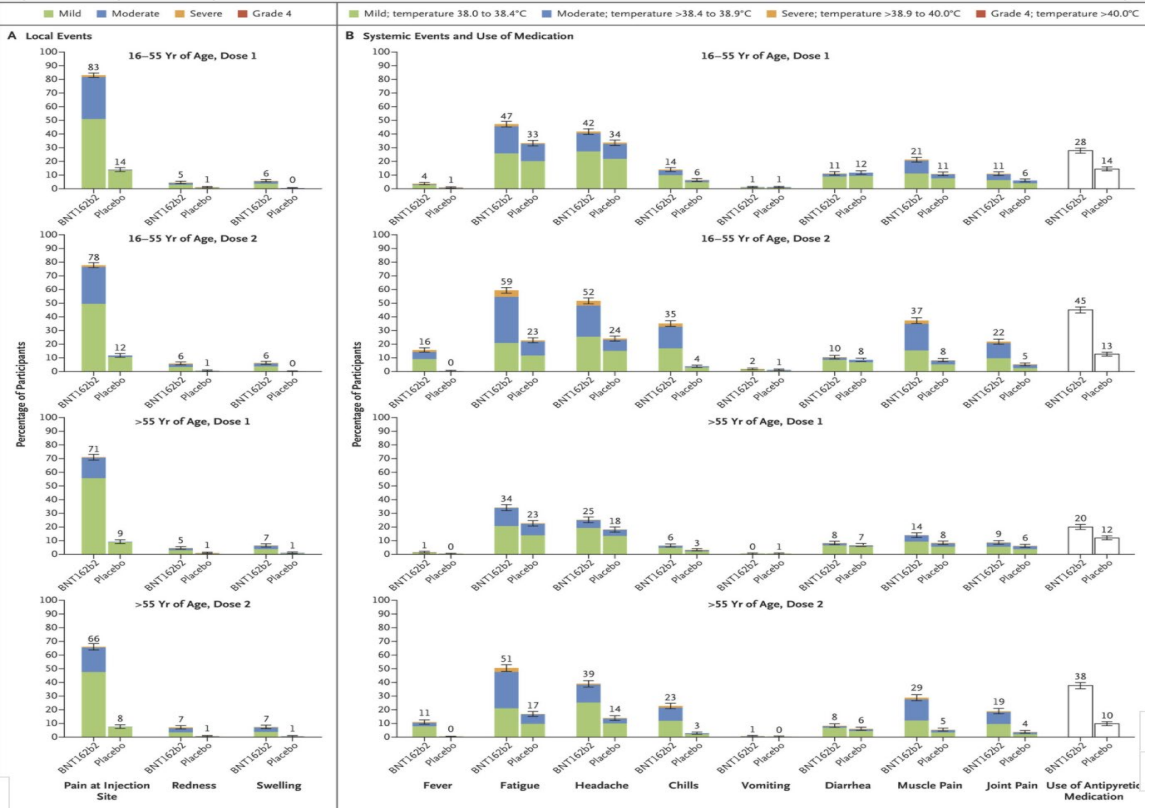
★ BNT162b2
- Lipid nanoparticle-formulated, nucleoside-modified RNA vaccine.
- Encodes a prefusion stabilized, membrane-anchored SARS-CoV-2 full-length spike protein.
- This two dose (30-µg) regimen is given by intramuscular injection approximately two weeks apart (~21 days)

Clinical Trial: A Randomized, Double-Blind Study

- ★ 43,448 participants received injections:
  - 21,720 with BNT162b2
  - 21,728 with placebo
- ★ Adults 16 yrs. Of age or older who were healthy or had stable chronic medical conditions, including but not limited to HIV, Hepatitis B Virus, Hepatitis C infection were eligible for participation.
- ★ Key exclusion criteria included a medical history of Covid-19, treatment with immunosuppresive therapy, or diagnosis with an immunocompromised condition



Local & Systemic Reactogenicity



- ★ Systemic Reactogenicity
  - Solicited 1,803 participants.
  - More BNT162b2 recipients reported local reactions than placebo recipients
  - BNT162b2
    - 0.9% or less
  - 2nd Dose
    - after injection)
    - Except redness (3.8%)
  - Local reactions were mild-to-moderate in severity and resolved within 1-2 days.

Efficacy & Results

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 (17,411)	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

- ★ Participants who had no evidence of existing or prior SARS-CoV-2 infection:
  - 8 cases of Covid-19 among vaccine recipients
  - 162 among placebo recipients
  - This case corresponds to 95.0% vaccine efficacy!
- ★ Participants with and those without evidence of prior SARS CoV-2 infection:
  - 9 cases of Covid-19 among vaccine recipients
  - 169 among placebo recipients
  - This corresponds to a 94.6% vaccine efficacy!

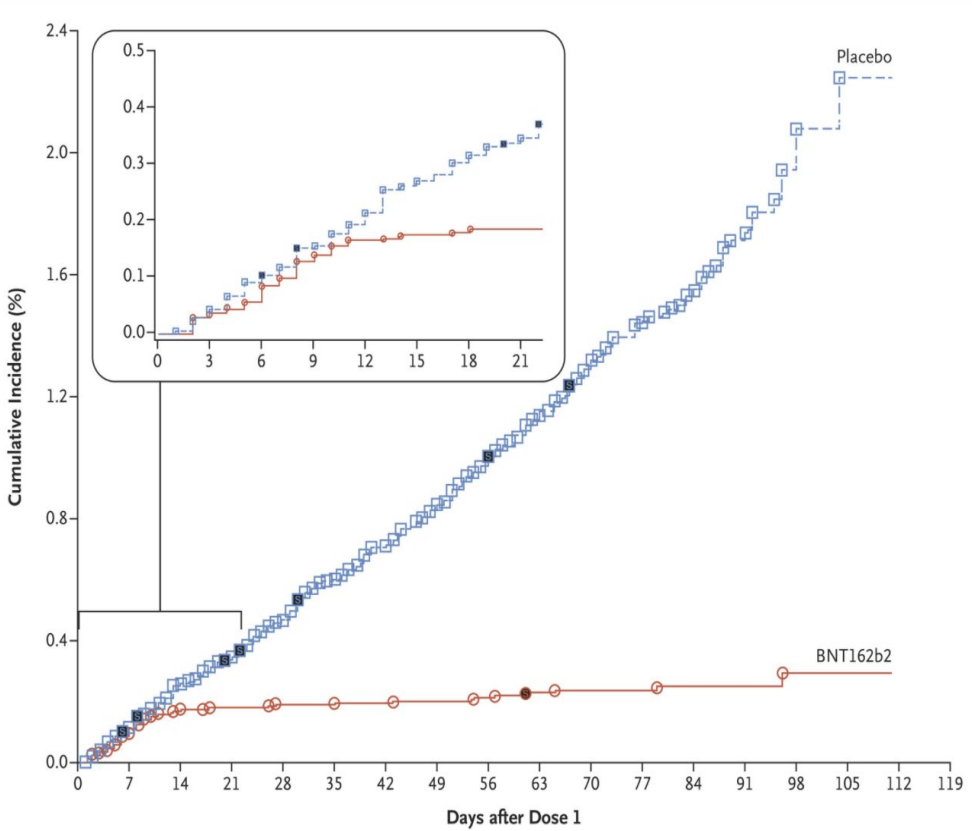
Conclusions

Safety:

- Vaccine recipients had local and systemic reactions at higher rates than placebo recipients, with more reactions following the second dose.
- Most were mild-to-moderate and resolved rapidly

Efficacy:

- The vaccine showed protection 7 days after the second dose; 95% efficacy was observed.



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)

Resources:

[1] Polack, F., Al., E., For the C4591001 Clinical Trial Group*, Author Affiliations

From Fundacion INFANT (F.P.P.) and iTrials-Hospital Militar Central (G.P.M.), Longo, E., Others, J., . . . F. P. Polack and Others. (2020, December 31). Safety and efficacy of the BNT162b2 Mrna Covid-19 Vaccine: NEJM. Retrieved March 31, 2021, from https://www.nejm.org/doi/10.1056/NEJMoa2034577?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub++0pubmed