

Is this worth a **Shot?**

Considering questions & concerns about COVID vaccinations

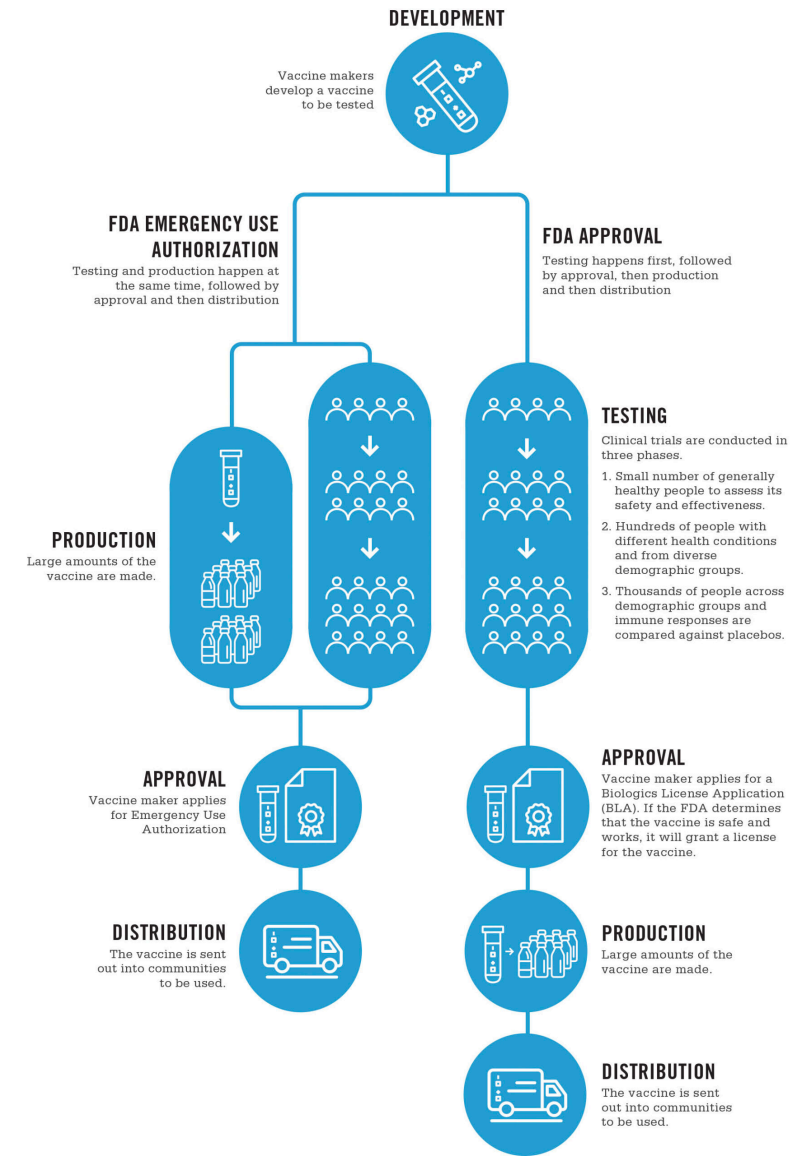


Extras

More useful information

FDA Emergency vs Full Approval

- All top CDC/FDA leadership and scientists agree on the final safety and efficacy of vaccines
- Unfortunately, still complying with the bureaucracy of paperwork and timelines for usual full approval process



Rumored Alternative Treatments

- Hydroxychloroquine
 - Studies revealed “no benefit for decreasing the likelihood of death or speeding recovery”, “unlikely to kill or inhibit the virus that causes COVID-19”
 - Serious side effects including heart rhythm problems, blood and lymph system disorders, kidney injuries, and liver problems and failure
- Zinc
 - No evidence to recommend use as treatment of COVID-19
 - Excessive zinc supplementation can cause hematologic defects and irreversible neurologic disorders
- Ivermectin
 - Used for treatment of parasitic worms, not an anti-viral drug
 - Extremely dangerous in high doses needed to even be possibly useful

Vaccine Mandate Effectiveness

DISEASE	TWENTIETH CENTURY ANNUAL MORBIDITY	2000†	PERCENTAGE DECREASE
Smallpox	48,164	0	100
Diphtheria	175,885	4	99.99
Measles	503,282	81	99.98
Mumps	152,209	323	99.80
Pertussis	147,271	6755	95.40
Polio (paralytic)	16,316	0	100
Rubella	47,745	152	99.70
Congenital rubella syndrome	823	7	99.10
Tetanus	1314	26	98.00
Haemophilus influenzae type b and unknown (<5 years)	20,000	167	99.10

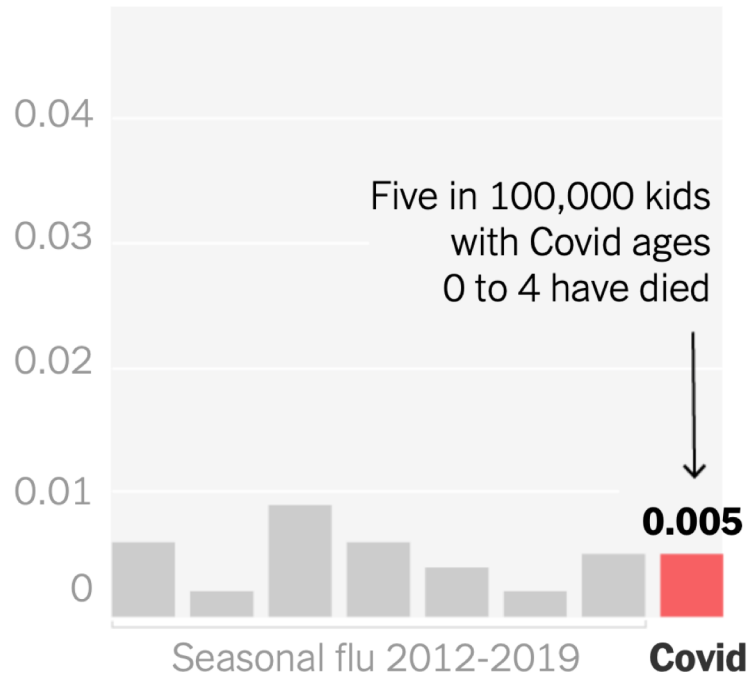
Annual Flu Comparison

Covid death rates among kids are similar to those for the seasonal flu.

Estimated share of patients who died

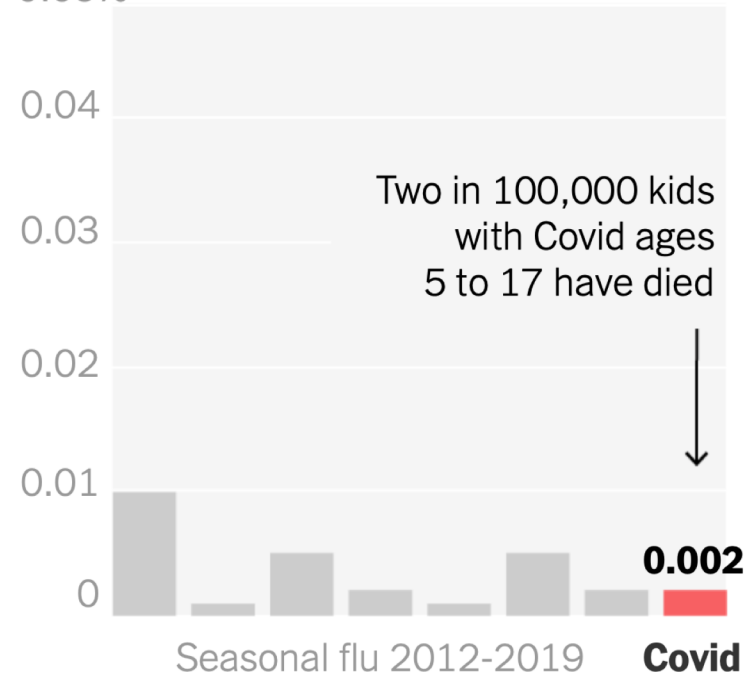
0-4 years

0.05%



5-17 years

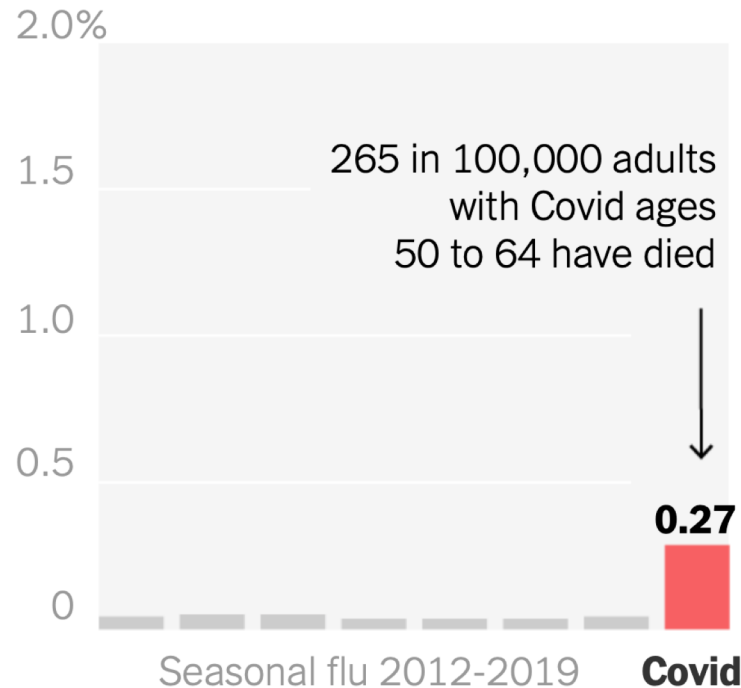
0.05%



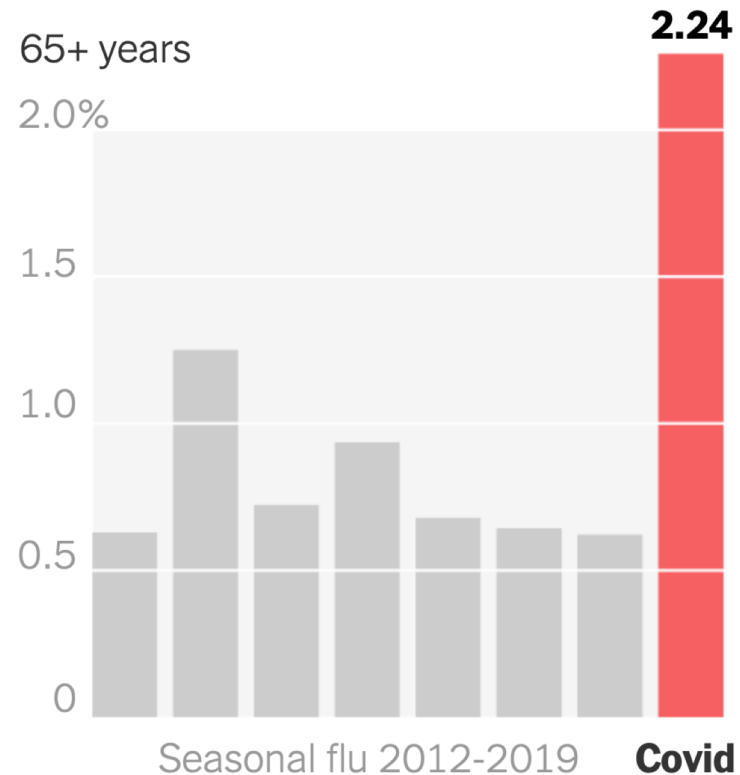
Annual Flu Comparison

For adults, however, Covid-19 is far deadlier. Among people 65 and over, the disease has killed more than 2 percent of those who contracted it.

50-64 years



65+ years



Vaccine Ingredients

- mRNA or inactivated adenovirus expressing spike protein
- Lipids: protect the mRNA
- Acids and stabilizers: stabilize the vaccine
- Salts: balance acidity in body
- Sugars: help withstand freezing

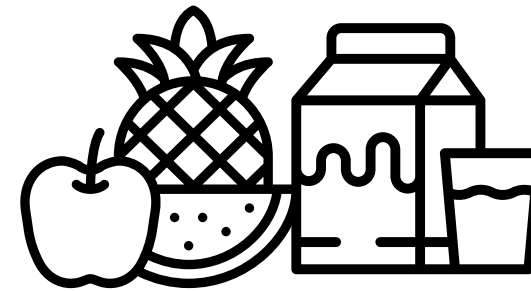
**What is in
Pfizer's
COVID-19
vaccine?**

What is in **Pfizer's** COVID-19 vaccine?



Potassium chloride

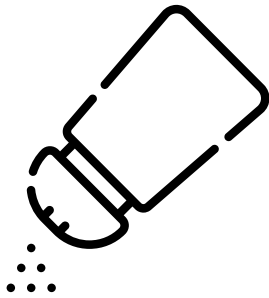
Which is also in...
baby formulas, cereals, frozen entrees,
meats, snack foods (such as chips or
crisps), sports/electrolyte drinks, soups,
sauces, snack/meal bars



Monobasic potassium phosphate

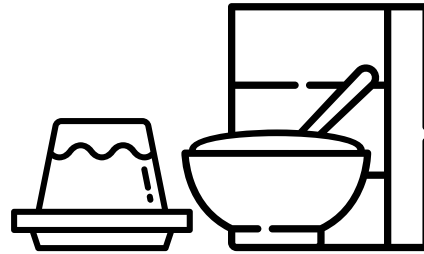
Which is also in...
dairy products, frozen meats, fruits,
vegetables, & cereals

What is in **Pfizer's** COVID-19 vaccine?



Sodium chloride

Basic table salt



Dibasic sodium phosphate dihydrate

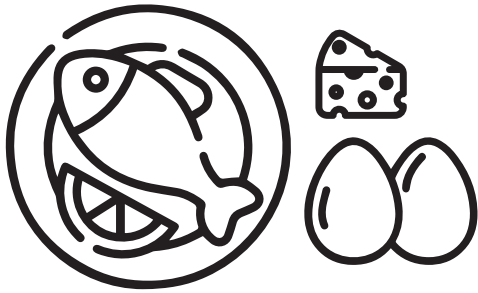
Which is in...
Various desserts, puddings,
cream of wheat, & jell-o



Sucrose

Which is **table sugar**,
naturally found in fruits
and vegetables, and added
to almost everything sweet
(chocolate, cookies,
cakes...)

What is in **Pfizer's COVID-19 vaccine**?



Cholesterol

Fat-like substance found in all animal cells (ours included).

High content found in eggs, cheese, meat, & fish



1,2-Distearoyl-sn-glycero-3-phosphocholine

Which is a phospholipid that contains both a lipid and phosphate group

Lecithin is a very common example found in red meat, eggs, seafood, soybeans, & black beans

What is in **Pfizer's** COVID-19 vaccine?



2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide

Polyethylene glycol found in numerous medications and laxatives

N,N-ditetradecylacetamide is a lipid complex for delivering nucleic acid

Basically used as a vehicle to deliver the other dissolved components



((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)

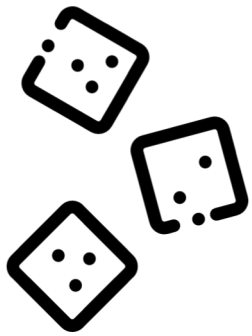
Hexyldecanoate used as food additive in flavorings.

Hexane-6,1-diyl is a fatty alcohol, similar to waxy skin naturally found on fruits.

It promotes uptake of nucleic acids.

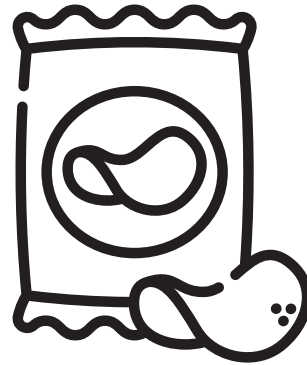
**What is in
Moderna's
COVID-19
vaccine?**

What is in Moderna's COVID-19 vaccine?



Sucrose

Which is **table sugar**, naturally found in fruits and vegetables, and added to almost everything sweet (chocolate, cookies, cakes...)



Sodium acetate

Primary flavoring in **salt and vinegar potato chips**

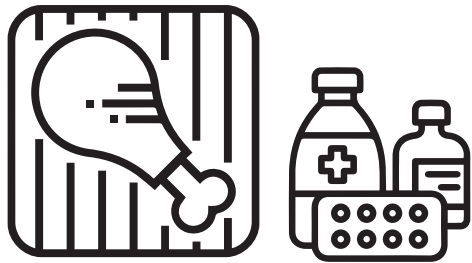
Add to foods to prevent bacterial growth



Acetic acid

Souring agent used in vinegar, **pickled vegetables**, and **sauces**

What is in Moderna's COVID-19 vaccine?



Tromethamine hydrochloride

Amine compound for pH control, amines are commonly found in fermented and grilled foods

Used in medication to maintain the pH of body fluids



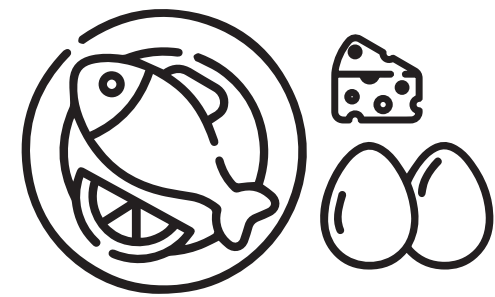
DSPC

1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE

Form of glycerophospholipid, cellular membranes of all cells and organelles

Common inactive ingredient in pharmaceuticals

Used to form liposomes, spherical lipid for drug delivery



Cholesterol

Fat-like substance found in all animal cells (ours included).

High content found in eggs, cheese, meat, & fish.

What is in Moderna's COVID-19 vaccine?



SM-102

HEPTADECAN-9-YL 8-((2-HYDROXYETHYL)
(6-OXO-6-(UNDECYLOXY)HEXYL)AMINO)OCTANOATE)

A novel lipid delivery system developed by Moderna prior to 2018

Heptadecane, found in **lemon balm**, **coconuts**, and **orange bell peppers**

Hydroxyethyl, naturally occurring compound derived from **plant cellulose**

Octanoate, a metabolite of *Saccharomyces cerevisiae* (the yeast used to make **sourdough**, **wine**, and **beer**)



PEG2000-DMG

POLYETHYLENE GLYCOL [PEG] 2000 DIMYRISTOYL GLYCEROL [DMG]

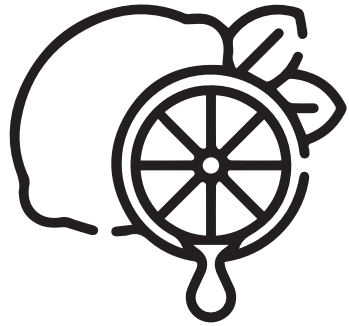
Prepares lipid nanoparticles, common in anticancer drugs

PEG common food additive in **drink mixes**, **dressings**, **food coloring**

DMG is a glycerolipid that helps form the structure of **plant and animal membranes**

**What is in
J&J's
COVID-19
vaccine?**

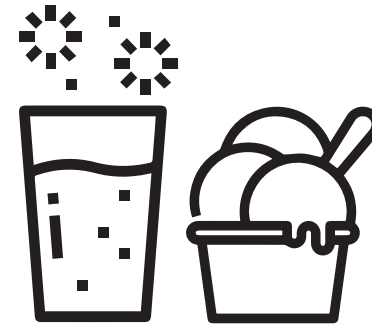
What is in J&J's COVID-19 vaccine?



Citric acid monohydrate

Found in all citrus fruits

Used in pharmaceuticals for antioxidant properties (prevents cell damage)



Trisodium citrate dihydrate

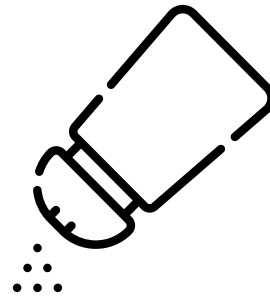
Anticoagulant, used in food preservatives and flavorings in drink mixes, yogurt, ice cream

What is in J&J's COVID-19 vaccine?



Ethanol

Found in all
alcoholic beverages



Sodium Chloride

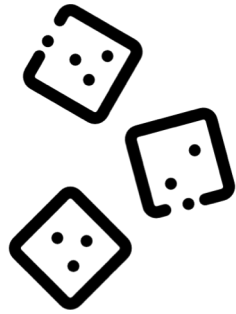
Basic table salt



Polysorbate 80

An emulsifier that stabilizes
liquid mixtures in foods such as
ice cream, custard, sherbert,
whipped cream

What is in J&J's COVID-19 vaccine?



2-hydroxypropyl- β -cyclodextrin (HBCD)

A cyclic oligosaccharide (cyclodextrin),
mix of simple sugars, found in food additives
to stabilize flavors

Improves solubility in liquid



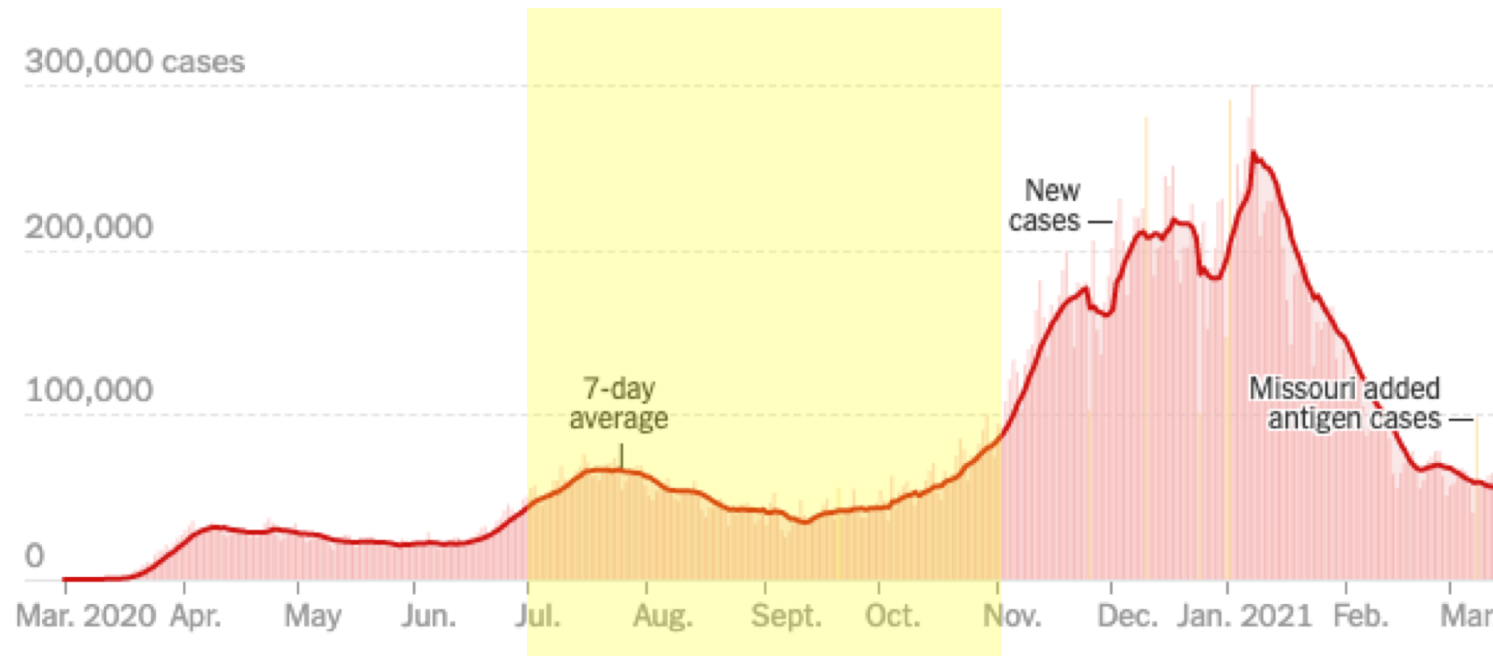
Sodium hydroxide & hydrochloric acid

Used as acidity regulators, they react together to form
water and harmless salts

Sodium hydroxide is an ingredient
in many food preservatives (often
in canned foods)

Hydrochloric acid is found
in vegetable juices,
canned goods, and corn
syrup

Pfizer Trial



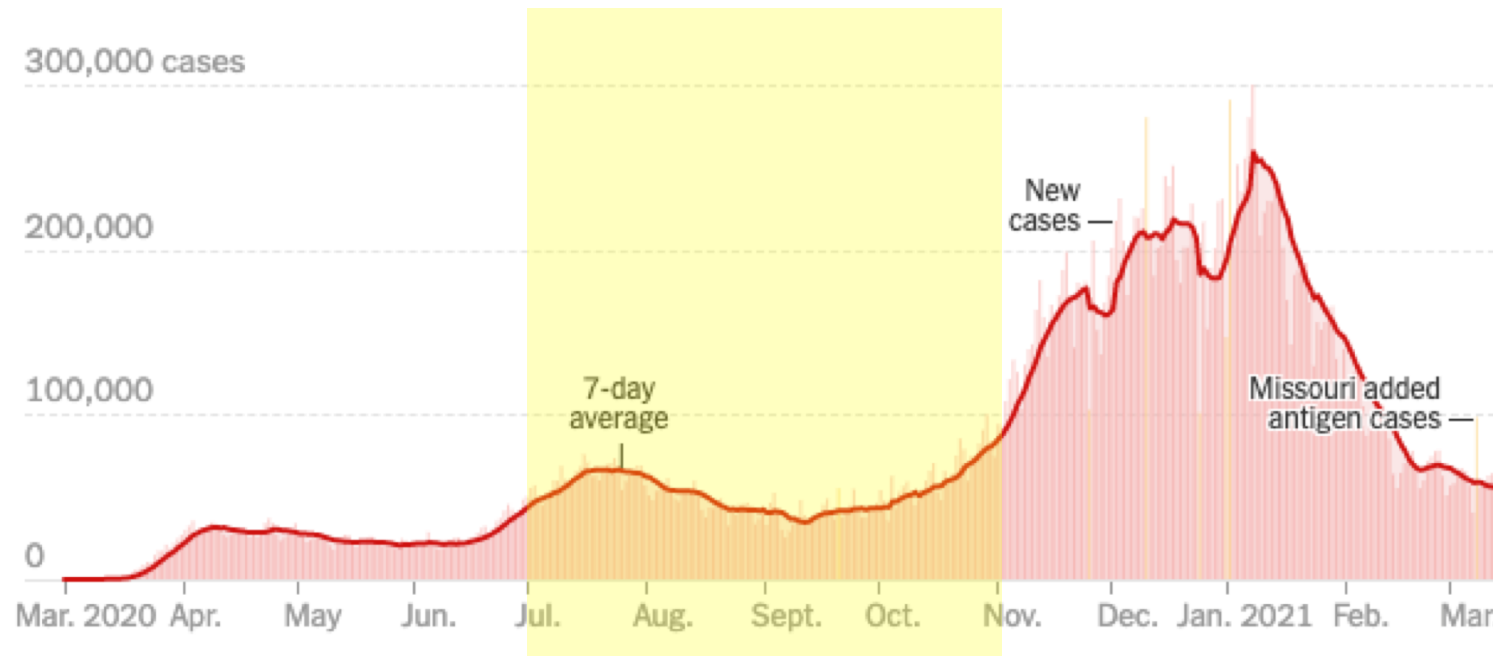
43,448 participants, age 16+
21,720 vaccine, 9 cases (.00041436)
21,728 placebo, 169 cases (.00777798)

$$\frac{.00041436}{.00777798} = .053$$

= 94.7% efficacy

Phases 3 July-Nov 2020

Moderna Trial



28,207 participants, age 18+

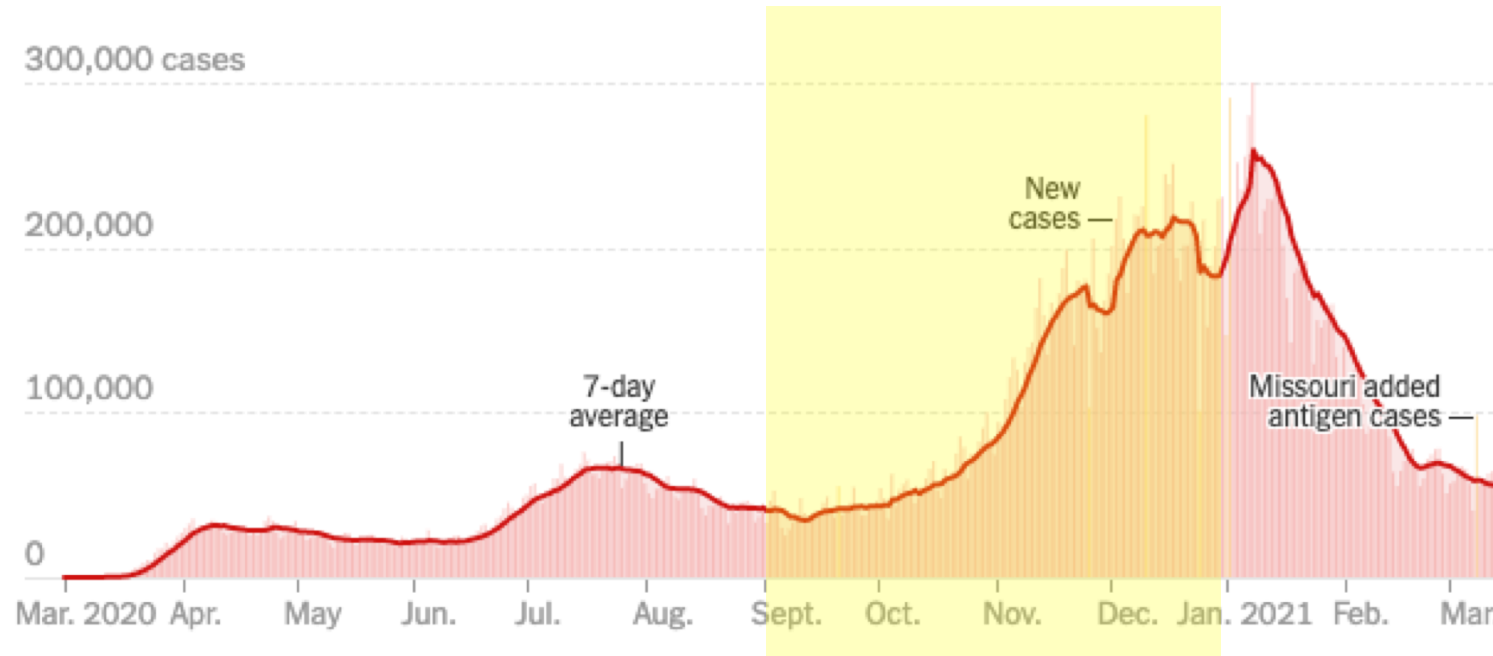
14,134 vaccine, 11 cases (.00077827)

14,073 placebo, 185 cases (.01314574)

$$\begin{aligned} &.00077827 / .01314574 = .059 \\ &= 94.1\% \text{ efficacy} \end{aligned}$$

Phases 3 July-Nov 2020

J&J Trial



38,484 participants, age 18+

19,306 vaccine, 65 cases (.00336683)

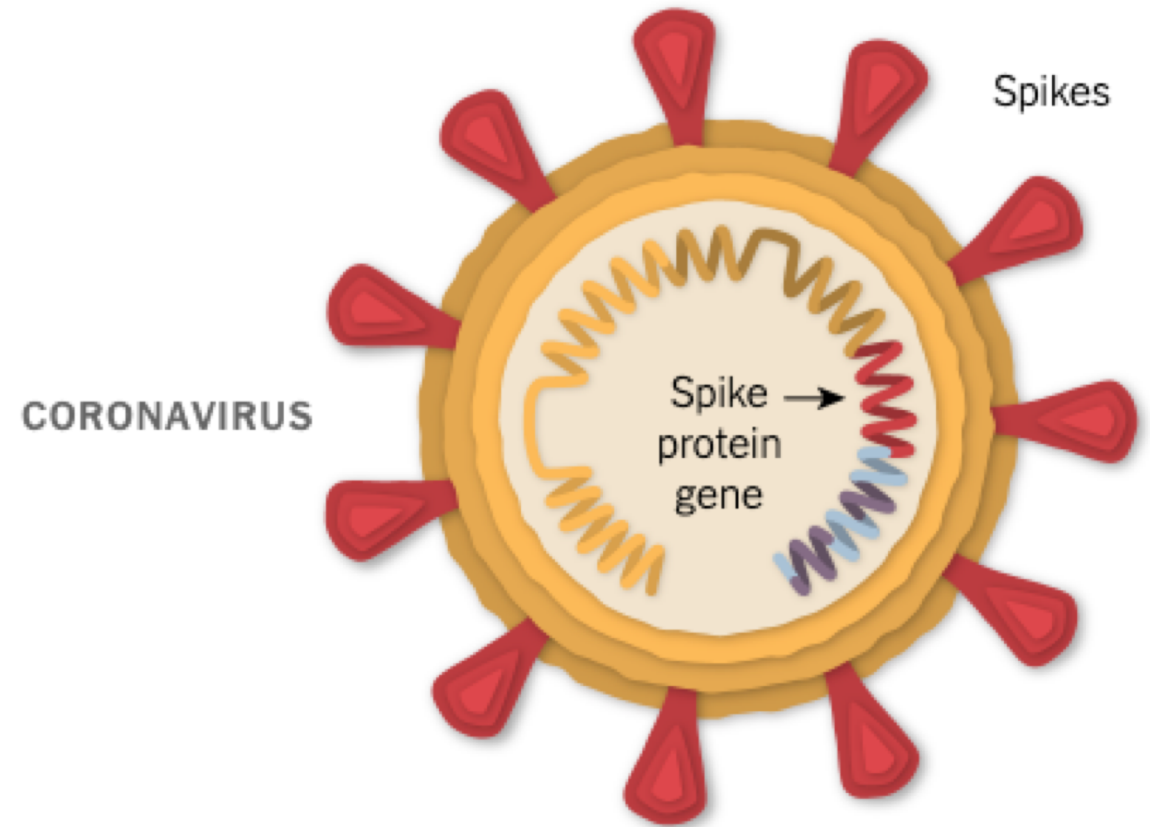
19,178 placebo, 193 cases (.01006361)

$$\begin{aligned} &.00336683 / .01006361 = .3345 \\ &= 66.55\% \text{ efficacy} \end{aligned}$$

Phases 3 Sep-Jan

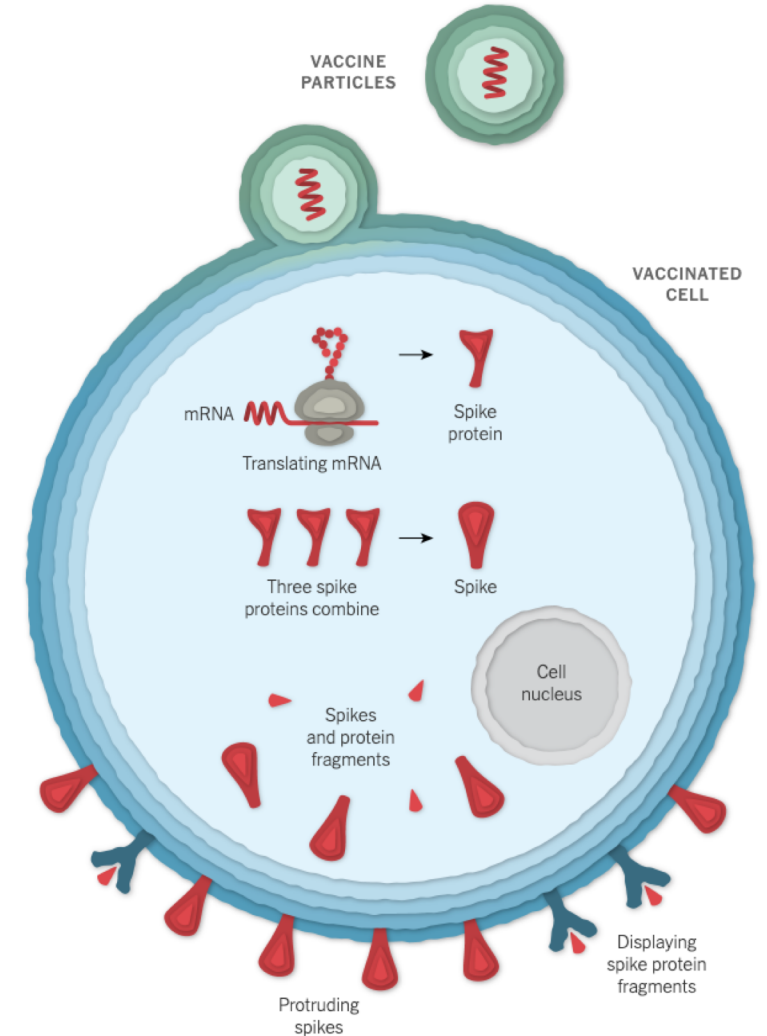
How COVID-19 Vaccines Work

- All of the vaccines aim to build spike proteins, like those surrounding the coronavirus.
- Predominant vaccine types either deliver the spike protein genetic code via messenger RNA (mRNA) or DNA embedded within an inactive virus.
- This trains the body's natural immune system to recognize the spikes and either block or destroy them.



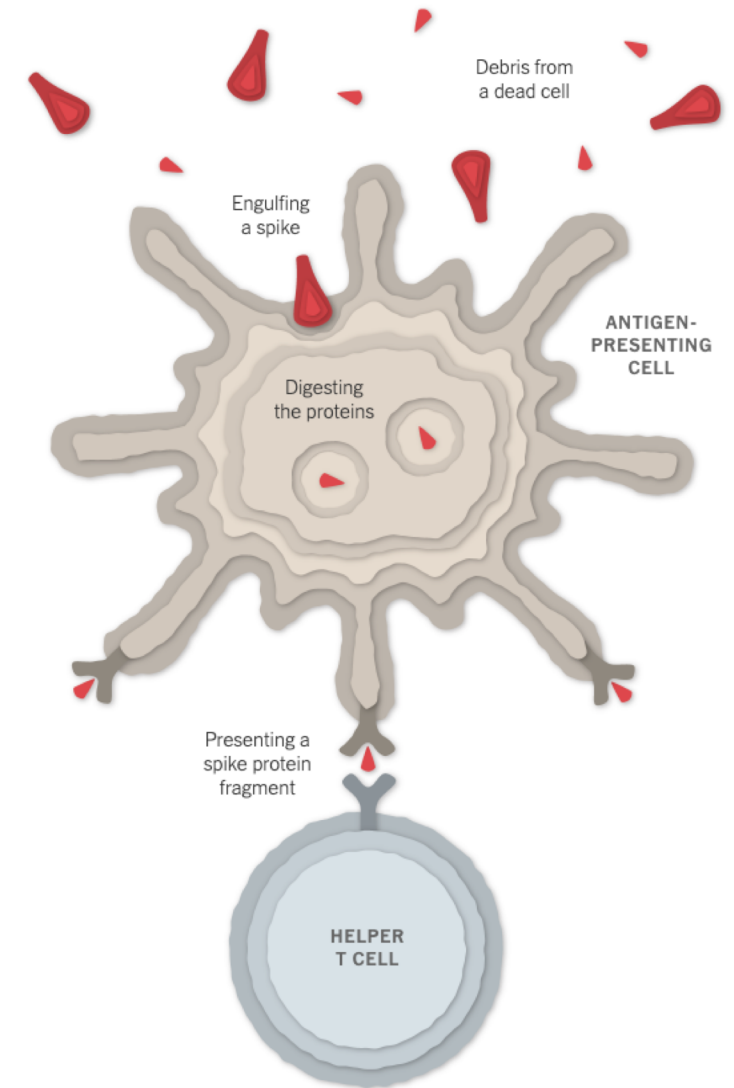
Cells contacting the vaccine

Read the code and build spikes



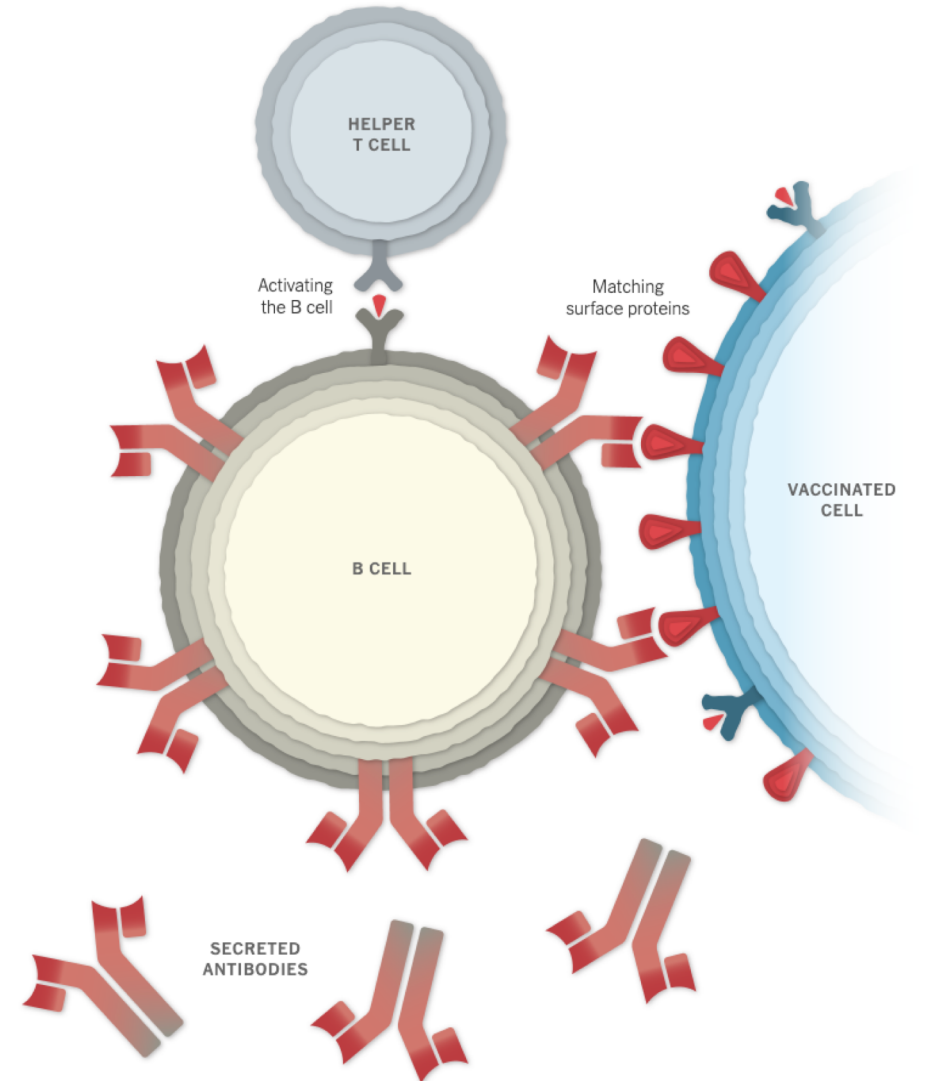
Helper T Cells

Detect spike fragments and raise the alarm



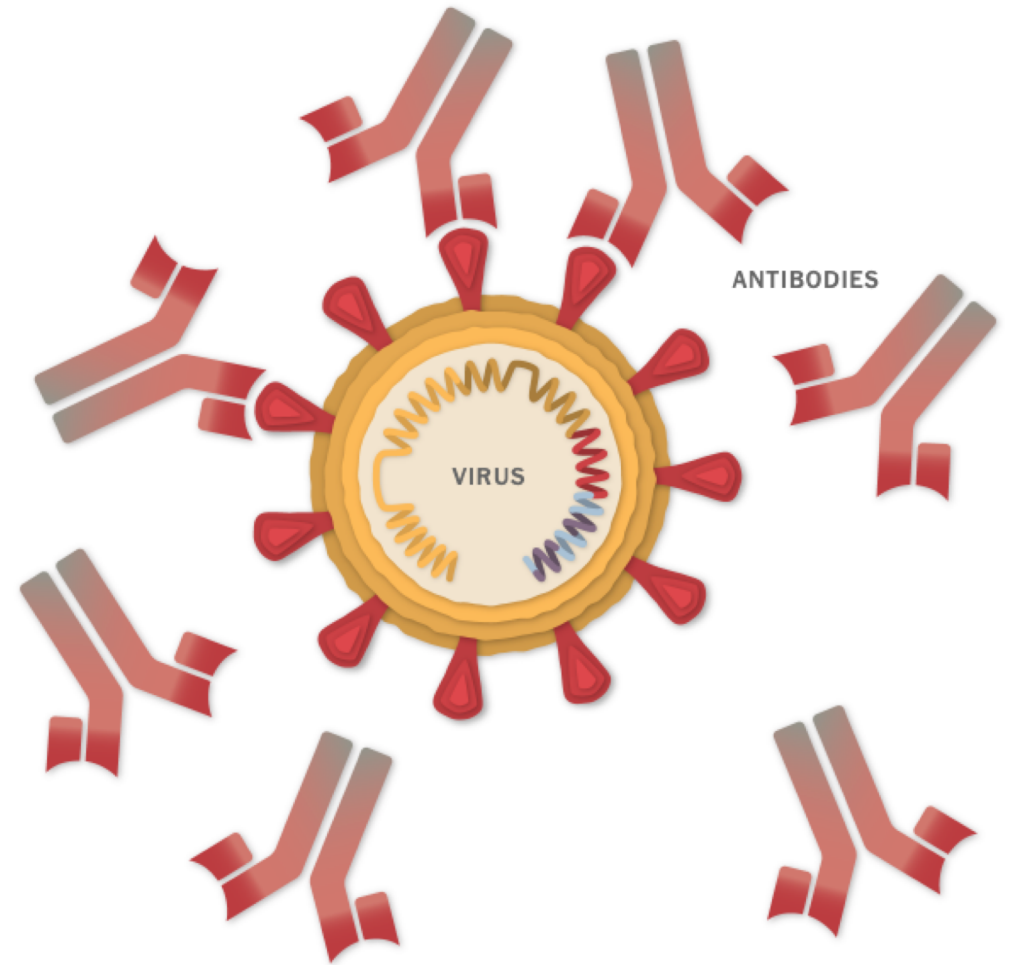
B Cells

Develop and secrete antibodies that bind to spike proteins and prevent them from attaching to other cells



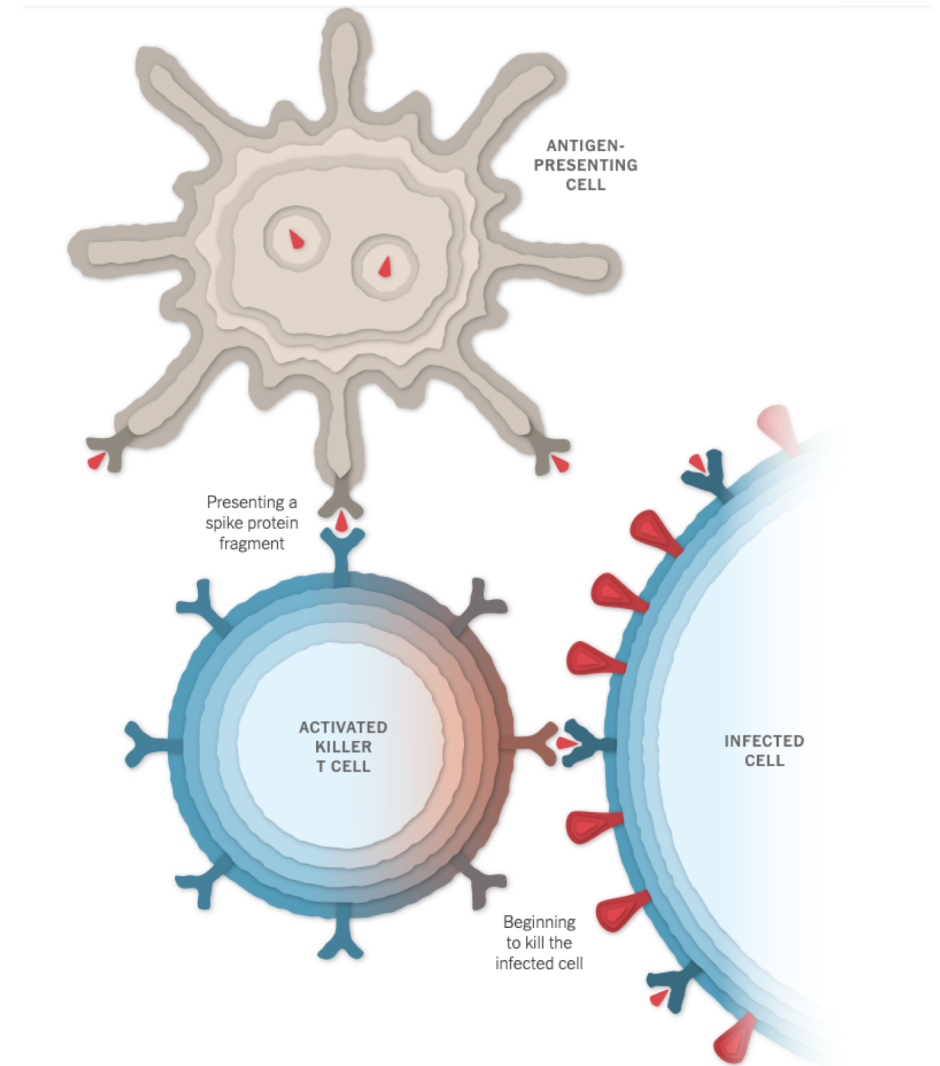
Antibodies

Latch onto spikes to prevent infection



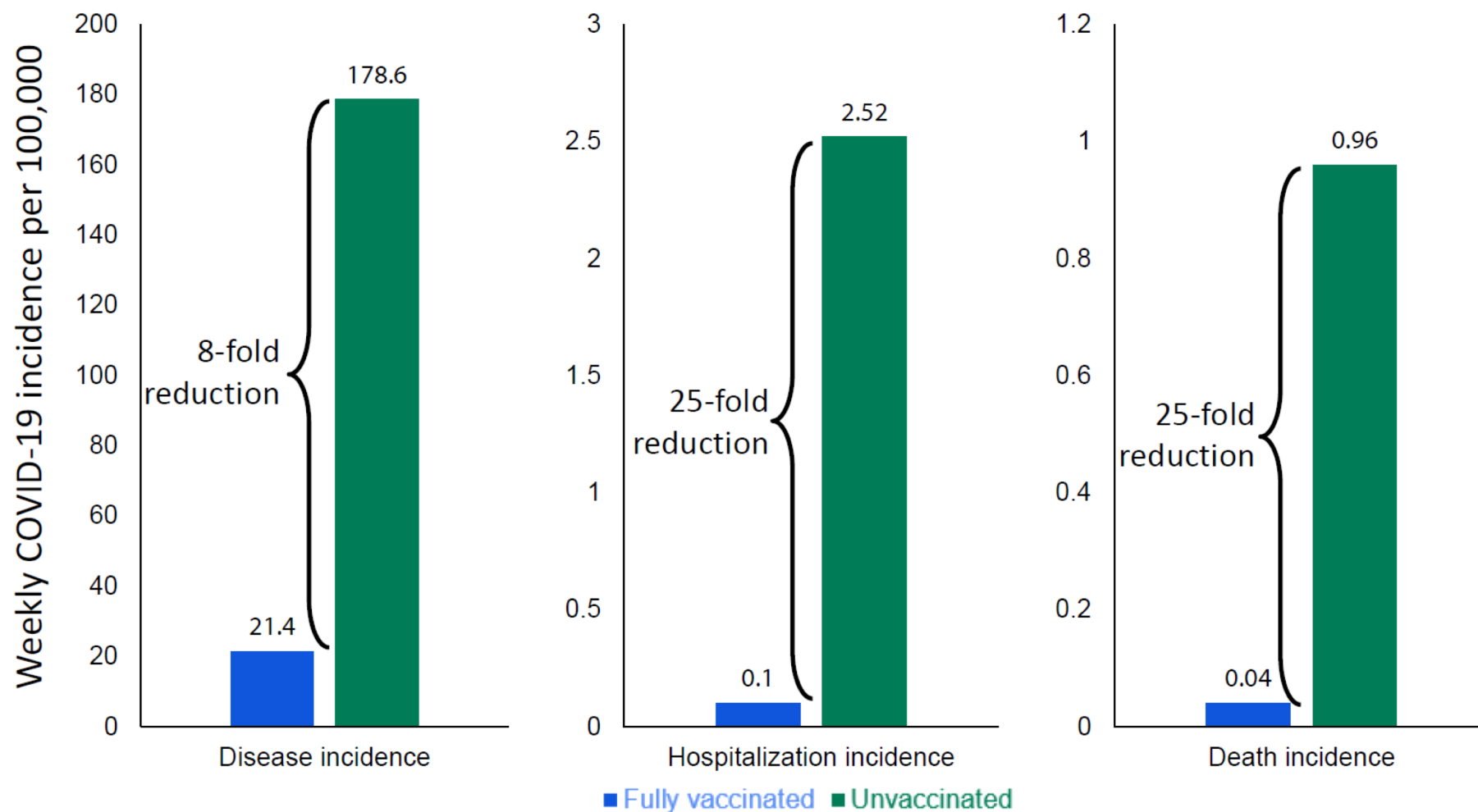
Killer T Cells

Destroy cells infected with coronavirus



CDC COVID-19 Presentation

Greater risk of disease, hospitalization and death among unvaccinated vs. vaccinated people: National estimates

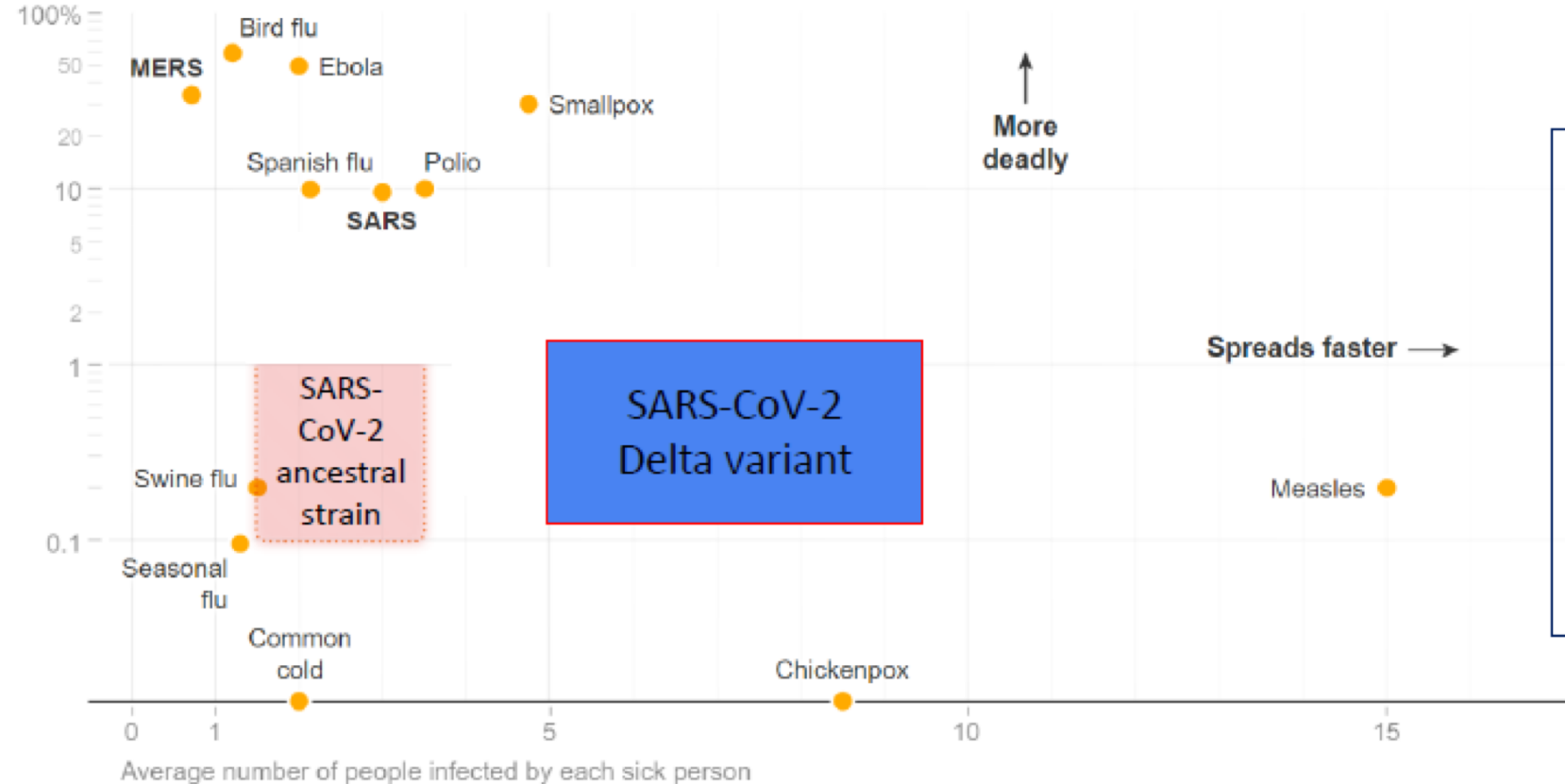


**At current incidence,
35,000 symptomatic
infections per week
among 162 million
vaccinated Americans**

Data from COVID Tracker as of July 24, 2021. Average incidence 100 cases per 100,000 persons per week. Vaccine effectiveness against symptomatic illness = 88% (Lopez Bernal et al. [NEJM 2021](#)), where risk is $[1 - VE]$ or 12%. Vaccine effectiveness hospitalization (or death) = 96% (Stowe et al. [PHE preprint](#)), where risk is $[1 - VE]$ or 4%. Rate in unvaccinated = Community rate / $((1 - \text{fully vaccinated coverage}) + (1 - VE) * \text{fully vaccinated coverage})$. Rate in fully vaccinated = $(1 - VE) * \text{Rate in unvaccinated}$. Fully vaccinated coverage proportions were from COVID Data Tracker as of July 24, 2021 (50% for US).

Transmission of Delta variant vs. ancestral strain and other infectious diseases

Fatality rate
(log scale)



The New York Times

Original graph from 2/28/2020.

Delta variant is **more** transmissible than:

- MERS & SARS
- Ebola
- Common cold
- Seasonal flu & 1918 ("Spanish") flu
- Smallpox

Delta variant is **as** transmissible as:

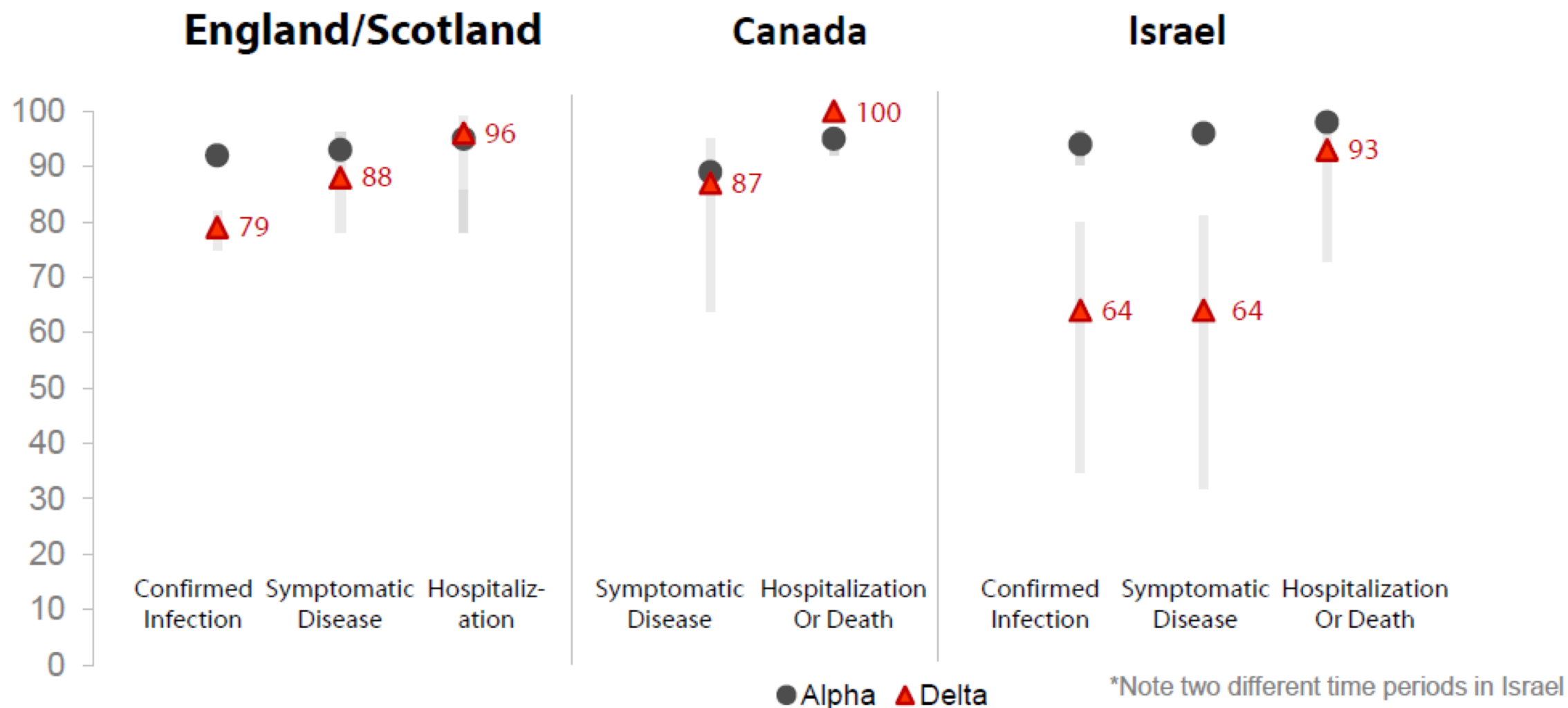
- Chicken Pox

Note: Average case-fatality rates and transmission numbers are shown. Estimates of case-fatality rates can vary, and numbers for the new coronavirus are preliminary estimates.

Delta variant vaccine breakthrough cases may be as transmissible as unvaccinated cases

- Breakthrough cases reported to national passive surveillance have lower Ct values by 3 cycles (**~10-fold increase in viral load**) for **Delta** (Ct=18, n=19) compared with Alpha (Ct=21, n=207) and other lineages (Ct=21, n=251)
- Barnstable County, MA, outbreak: **No difference in mean Ct values in vaccinated and unvaccinated** cases [median among vaccinated (n=80): 21.9; unvaccinated (n=65): 21.5]

Pfizer 2-Dose Vaccine Effectiveness for Alpha vs. Delta



Sheikh et al. Lancet (2021): [https://doi.org/10.1016/S0140-6736\(21\)01358-1](https://doi.org/10.1016/S0140-6736(21)01358-1); Lopez Bernal et al. medRxiv preprint; <https://doi.org/10.1101/2021.05.22.21257658>; Stowe et al. PHE preprint: https://khub.net/web/phe-national/public-library/-/document_library/v2WsRK3ZIEig/view/479607266; Nasreen et al. medRxiv preprint: <https://doi.org/10.1101/2021.06.28.21259420>; <https://www.gov.il/en/departments/news/06072021-04>

Delta infections associated with higher viral load and duration of shedding: Published evidence

- India report of lower cycle threshold (Ct) values in Delta breakthrough cases in HCW (n=47, mean Ct 16.5) compared to non-Delta breakthrough cases (n=22, mean Ct 19); also larger cluster size with Delta breakthrough
- Delta infection associated with longer duration of Ct values ≤ 30 [median 18 days vs. 13 days for ancestral strains]
- Risk of reinfection with Delta may be higher [aOR 1.46 (CI 1.03-2.05)] compared to Alpha variant, but only if prior infection ≥ 180 days earlier

Preliminary VE estimates assessing duration of protection for 2 doses of mRNA vaccines

- VISION (test negative design across 8 integrated healthcare systems), data through June 22, 2021
 - VE against hospitalization **88%** (CI 86-90)
 - No evidence of waning immunity to 16 weeks post-2nd dose
- IVY3 (test negative design across 21 hospitals), data through June 2021
 - VE against hospitalization **87%** (CI 85-97)
 - No evidence of waning immunity through 20 weeks post-2nd dose
- Healthcare personnel (test negative design across 33 sites), data to May 31, 2021
 - VE against symptomatic infection **90%**
 - No evidence of waning immunity through 14 weeks post-2nd dose

Vaccine breakthrough cases may reduce public confidence in vaccines

- Vaccine **breakthrough cases are expected** and increase as a proportion of total cases as vaccine coverage increases
- Vaccine breakthrough cases will occur more frequently in congregate settings, and in groups at risk of primary vaccine failure (i.e., immune compromised, elderly, etc.)
- Communication challenges have been associated with increasing proportions of cases vaccinated **even when vaccine effectiveness (VE) remains stable**
 - Concerns from local health departments about VE
 - Public convinced vaccines no longer work/booster doses needed
 - **Important to update communications describing breakthrough cases as “rare” or as a “small percentage” of cases**