

Preventing COVID-19 in High-Risk Patients

Are pre-exposure monoclonal antibodies an option for Patients unlikely to respond to vaccines?

Speaker Disclosure

- **Presenter's Name: Dr. Brian Conway**
- **I have the Relationships with commercial interests:**
 - Advisory Board/Speakers Bureau, honorarium, grant support: AbbVie Corporation, AstraZeneca, Gilead Sciences Inc., Indivior Canada Ltd., Merck & Co., Moderna, Sanofi Pasteur, and ViiV Healthcare
- **Speaking Fees for current program:**
 - I have received a speaker's fee from Astra Zeneca for this learning activity

Speaker Disclosure

- **Presenter's Name: Michael Boivin**
- **I have the Relationships with commercial interests:**
 - Advisory Board/Speakers Bureau: Novo-Nordisk, Emergent BioSolutions, Pfizer
 - Speaker/Consulting Fees: Teva, Pfizer, Novo Nordisk, Khiron, Tilray, mdBriefcase, J & J, Abbvie, Ascensia, Astra Zeneca, Biosynt, Boehringer Ingelheim, Moderna

Speaking Fees for current program:

- I have received a speaker's fee from Astra Zeneca for this learning activity

Disclosure

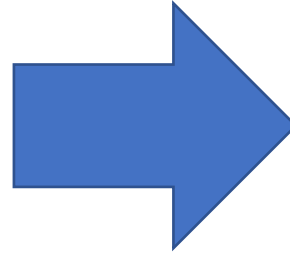
- The opinions expressed in this presentation do not necessarily reflect those of AstraZeneca.

Learning Objectives

1. Discuss the indications and recommendations for Tixagevimab/Cilgavimab in preventing COVID-19 in high-risk patients
2. Determine potential candidates for Tixagevimab/Cilgavimab to prevent COVID-19 infections and severe outcomes
3. Discuss the potential adverse effects and administration of Tixagevimab/Cilgavimab
4. List potential roles for pharmacists in recommending Tixagevimab/Cilgavimab

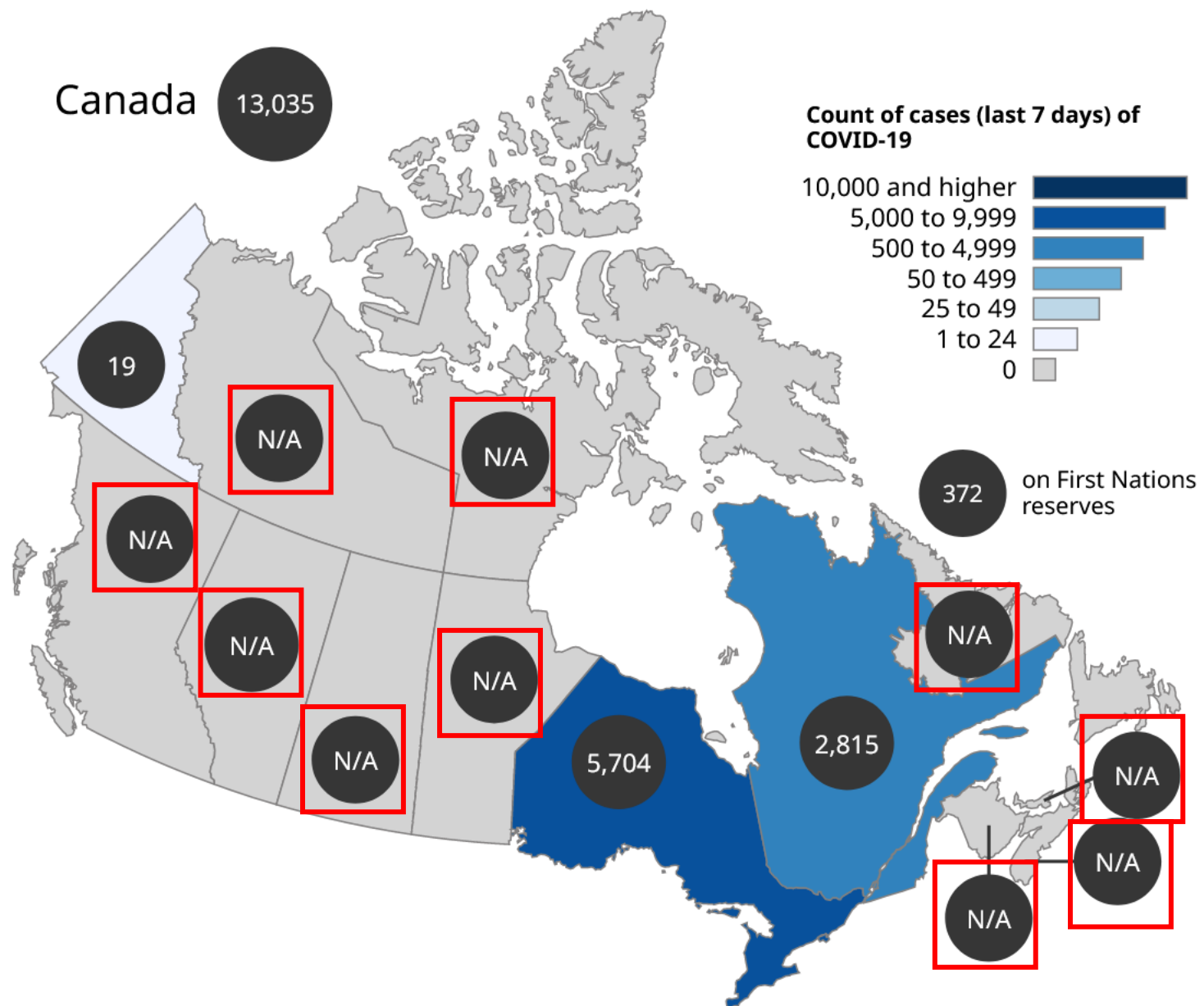
What a Difference a Year Makes

The Masking Changes

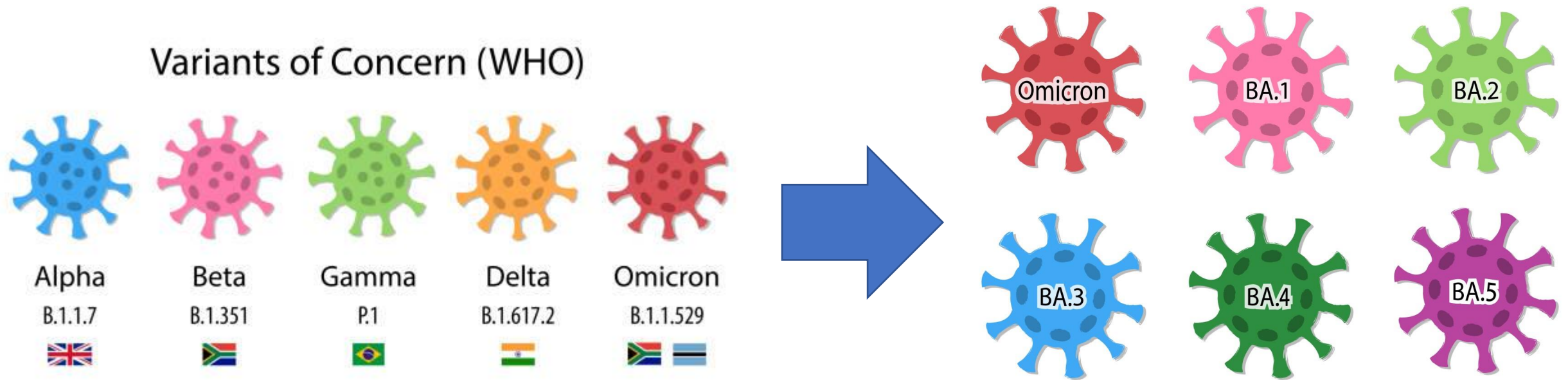


From

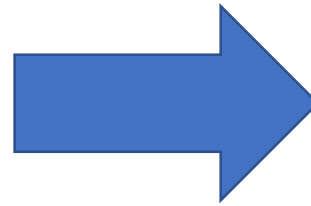




From Variants to Omicron Subvariants



From a Primary Focus to an Afterthought

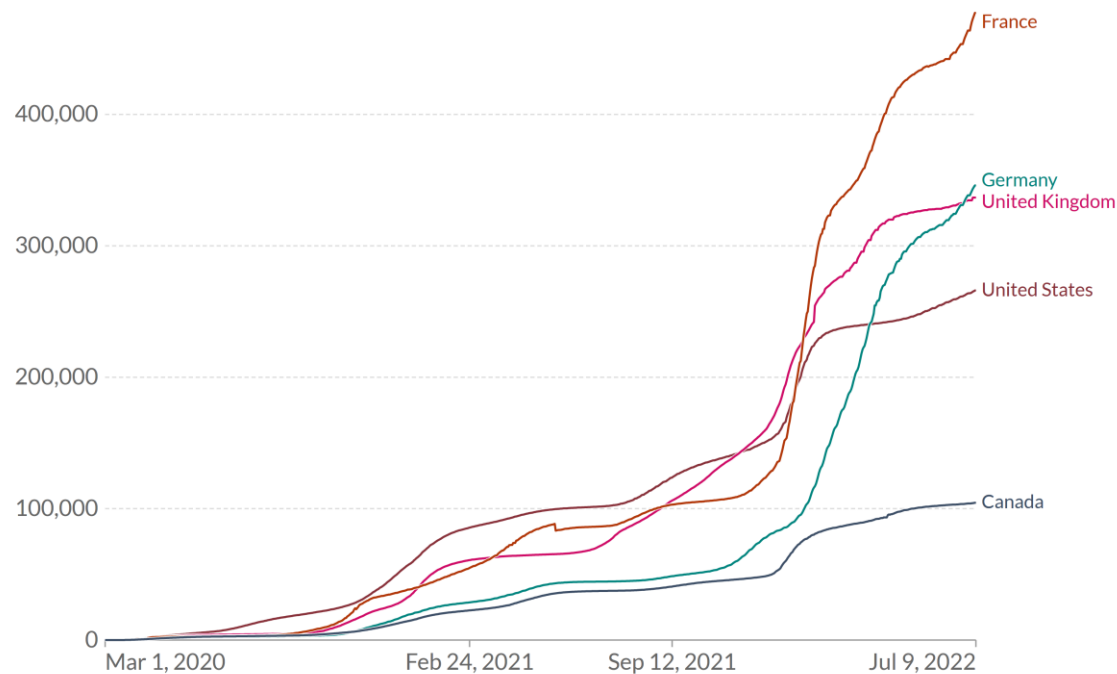


Overall, Canada has Done Well
Compared to Many Other
Nations

Our World in Data Canada

Cumulative confirmed COVID-19 cases per million people

Due to limited testing, the number of confirmed cases is lower than the true number of infections.



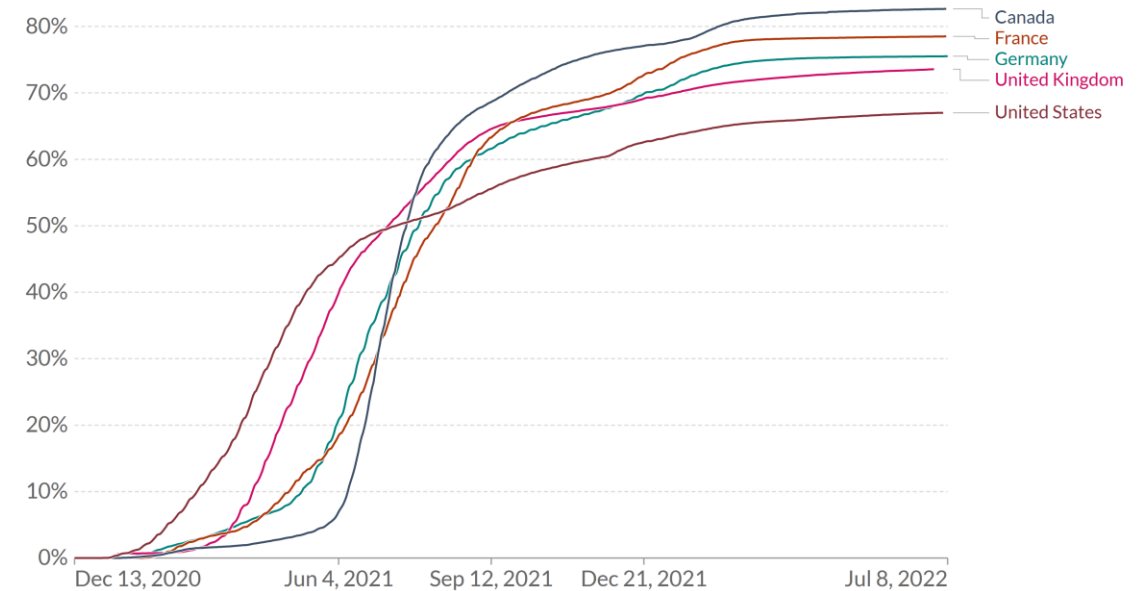
Source: Johns Hopkins University CSSE COVID-19 Data

Our World
in Data

CC BY

Share of people who completed the initial COVID-19 vaccination protocol

Total number of people who received all doses prescribed by the initial vaccination protocol, divided by the total population of the country.



Source: Official data collated by Our World in Data

Note: Alternative definitions of a full vaccination, e.g. having been infected with SARS-CoV-2 and having 1 dose of a 2-dose protocol, are ignored to maximize comparability between countries.

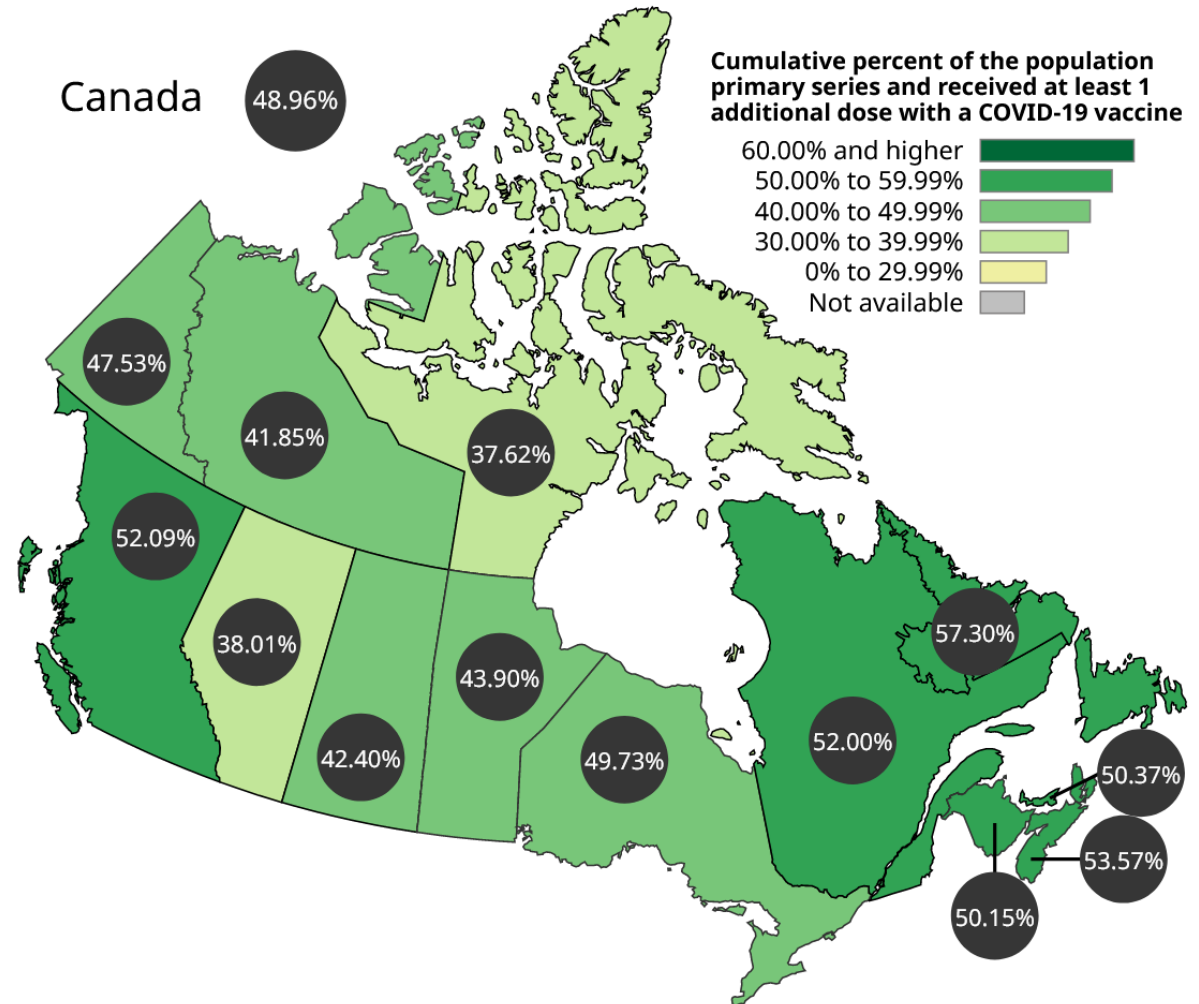
Our World
in Data

CC BY

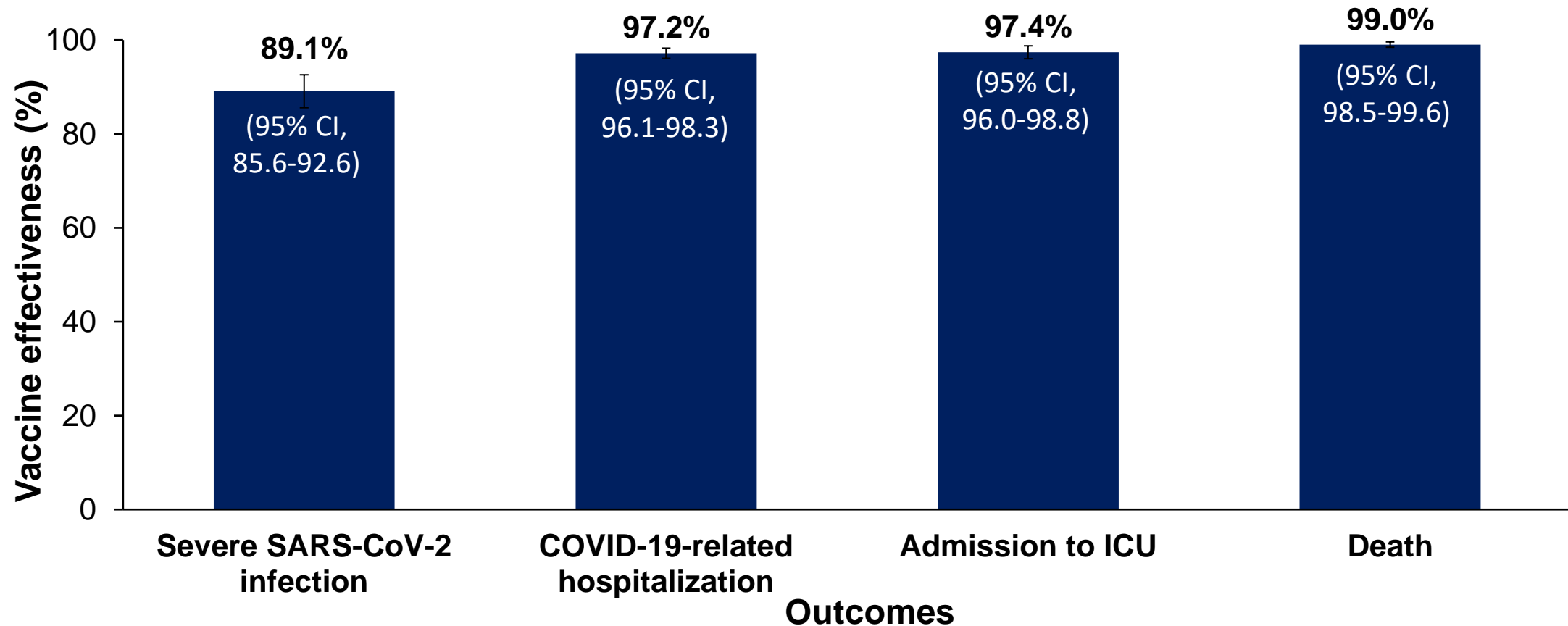
<https://ourworldindata.org/covid-cases>

We Have Good Vaccine Uptake – Although Booster Data is Far from Optimal

Primary series and
received at least 1
additional doses



COVID-19 vaccines have proven to be an effective prophylaxis strategy for the majority of the population



^aThe included studies investigated five brands of COVID-19 vaccine: Pfizer-BioNTech, Moderna, Oxford-AstraZeneca, CoronaVac and Janssen.

COVID-19=coronavirus disease 2019; ICU=intensive care unit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Zheng C, et al. *Int J Infect Dis.* 2022;114:252–260.

As We Move On, We Are Leaving Some Behind



There are Many Immunocompromised Patients in Practice

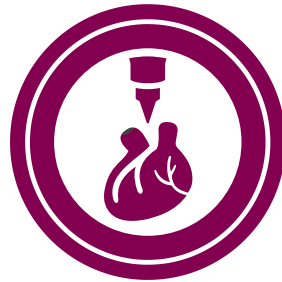
In the US of the adult population is moderately to severely immunocompromised, leading to increased vulnerability to COVID-19¹⁻³
about 3%



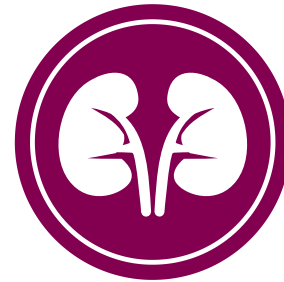
Blood cancers³



Active chemotherapy³



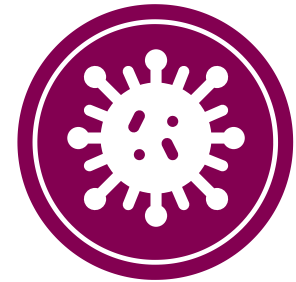
Transplant³



Dialysis⁴



Taking immunosuppressants^a



Primary immune deficiency

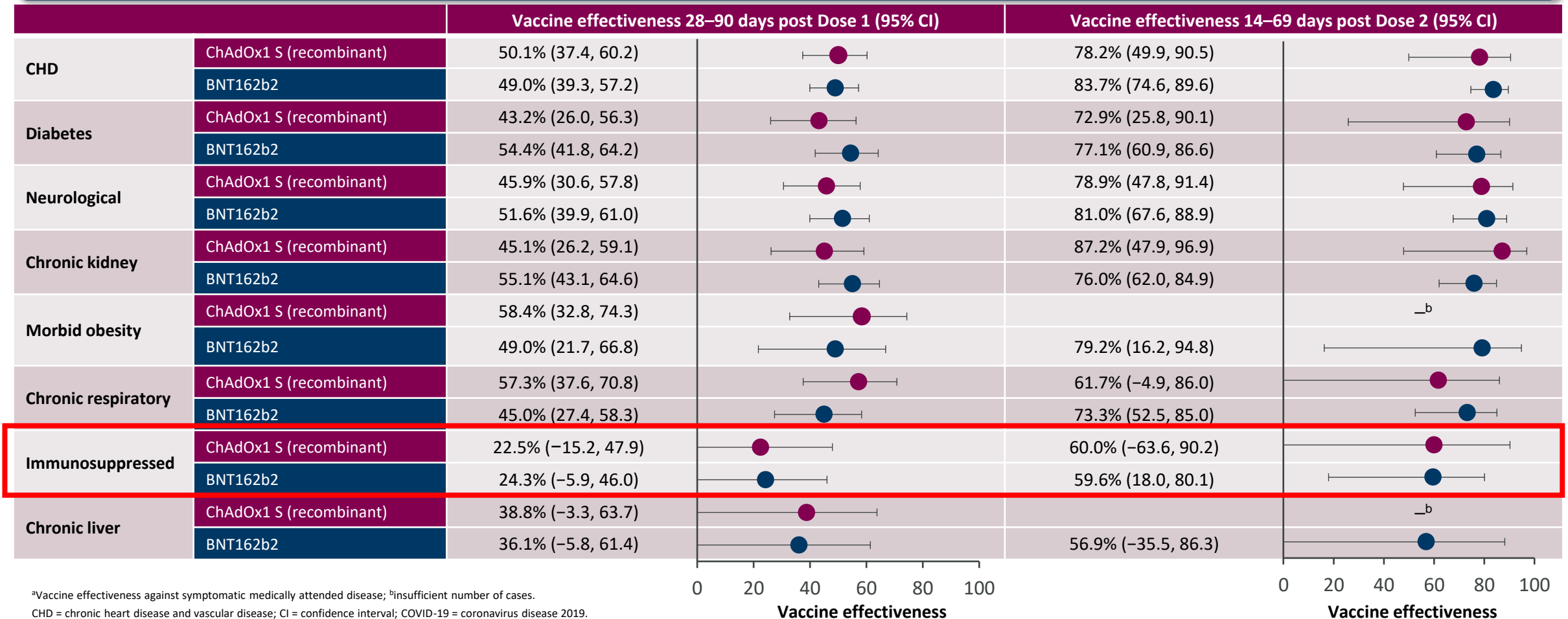
^aImmunosuppressants could include medicines for non-Hodgkin's lymphoma, lupus, multiple sclerosis, rheumatoid arthritis.^{3,5}

COVID-19 = coronavirus disease 2019; US = United States.

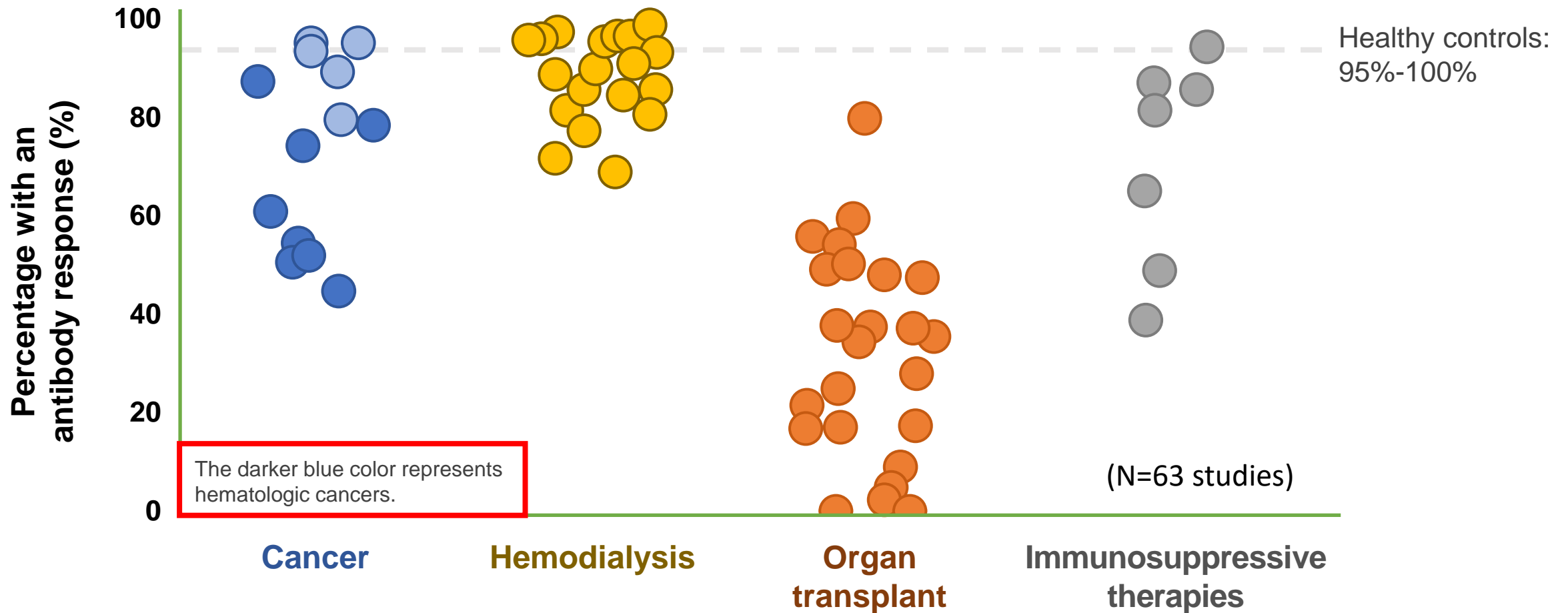
1. Harpaz R et al. *JAMA*. 2016;316:2547-2448; 2. COVID-19 Vaccines for Moderately to Severely Immunocompromised People. Centers for Disease Control and Prevention. Updated September 2, 2021. Accessed October 1, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html>; 3. Abbasi J. *JAMA*. 2021;325:2033-2035; 4. Rincon-Arevalo H et al. *Sci Immunol*. 2021;6:eabj1031. <https://dx.doi.org/10.1126/sciimmunol.abj1031>. Accessed September 24, 2021; 5. Richard-Eaglin A et al. *Nurs Clin N Am*. 2018;53:319-334.

COVID Vaccine Effectiveness and Comorbidities

Cohort and nested test-negative case-control vaccine efficacy^a analyses were conducted in the UK
(n=5,591,142; 1,533,879 belonged to a risk group)



Antibody Response Varies Based on Patient and Condition (2 doses mRNA vaccine)



- Studies that compared the response after the first and second dose demonstrated a poor response to dose 1
- Antibody measurement and threshold levels varied by study protocol

COVID-19 = coronavirus disease 2019; mRNA = messenger ribonucleic acid.

Evidence to recommendation framework: an additional dose of mRNA COVID-19 vaccine following a primary series in immunocompromised people. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-13/02-COVID-Dooling-508.pdf>. Accessed April 8, 2022.

What if we Give These Patients a Third Dose?

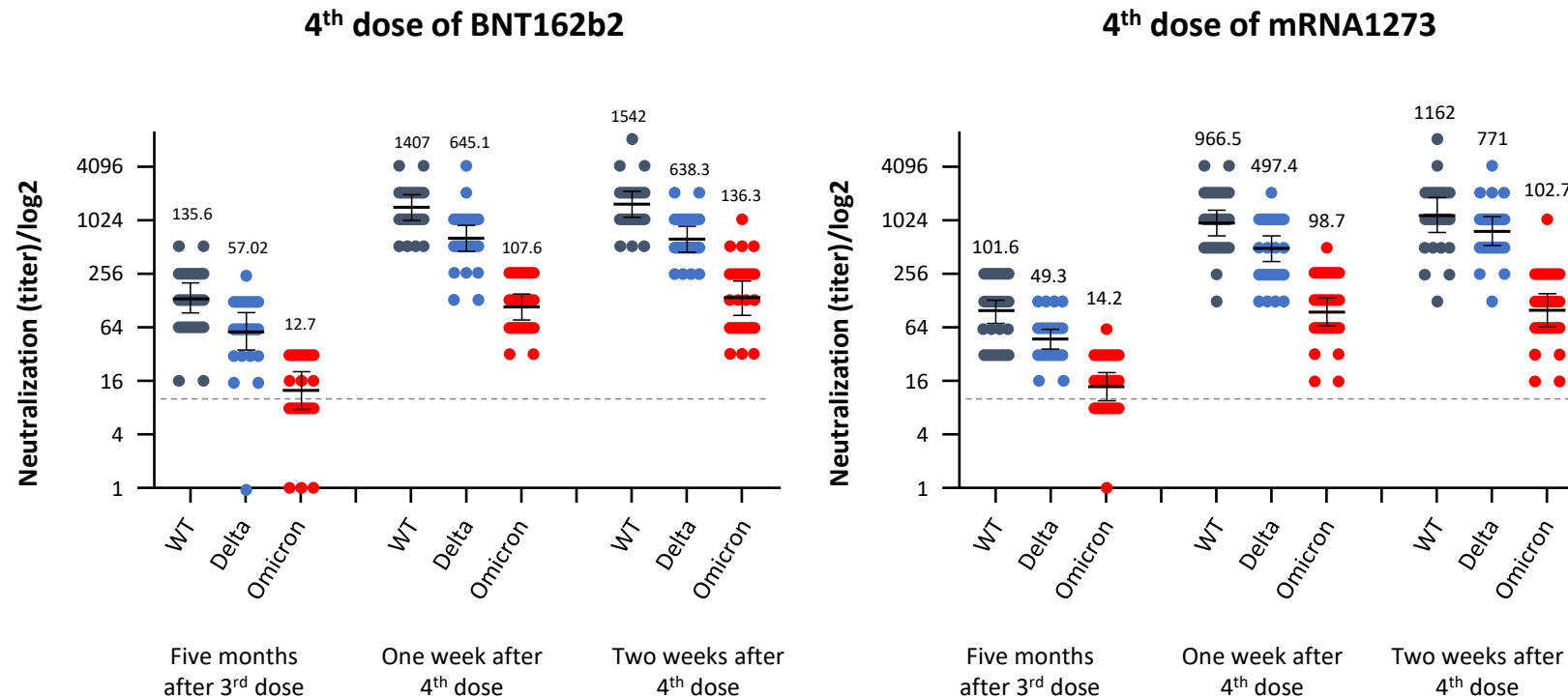
Response to a second and third dose of COVID-19 vaccine in 245 KTRs
and 51 patients treated for CLL

Response to COVID-19 vaccine	Kidney transplant				Chronic lymphocytic leukemia			
	After Dose 2 (n=97)		After Dose 3 (n=160)		After Dose 2 (n=51)		After Dose 3 (n=20)	
	No	Yes	No	Yes	No	Yes	No	Yes
n	55	42	85	75	22	29	10	10
%	57%	43%	53%	47%	43%	57%	50%	50%

- Prevalence of positive anti-spike IgG in KTRs tested either after the second or third vaccine dose was not significantly different
- There was no increase in prevalence of positive anti-spike IgG in patients treated for CLL between the second and third vaccine doses

Does Omicron make a Difference?... YES!

Live virus neutralization efficiency of fourth vaccine dose against WT, Delta and Omicron (n=25)



Patients at high risk of COVID-19 were determined by pre-defined antibody threshold (≤ 700 BAU/mL)^a

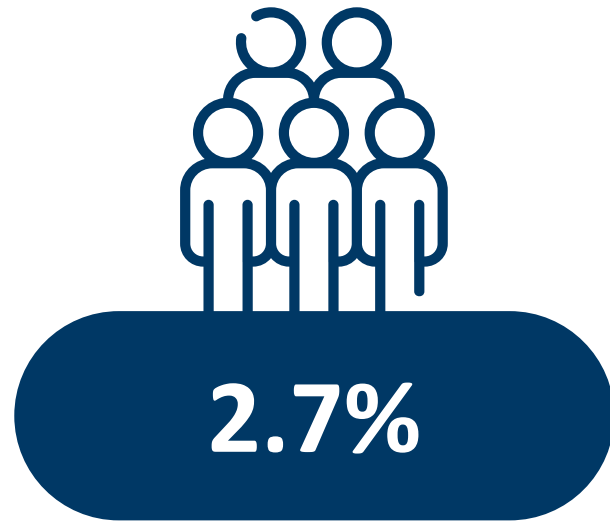
The fourth COVID-19 vaccine dose restores antibody titers to peak post third dose titers; however, neutralization remains lower for Omicron vs Delta (4-7-fold) and WT (10-fold)

^aIn order to enroll persons at expected higher risk of infection, the trial population was selected among participants of the serology study cohort who had IgG titers below the 40% percentile at that time of ≤ 700 BAU/mL. GMT with 95% CI are depicted; dotted line depicts lower limit of detection.

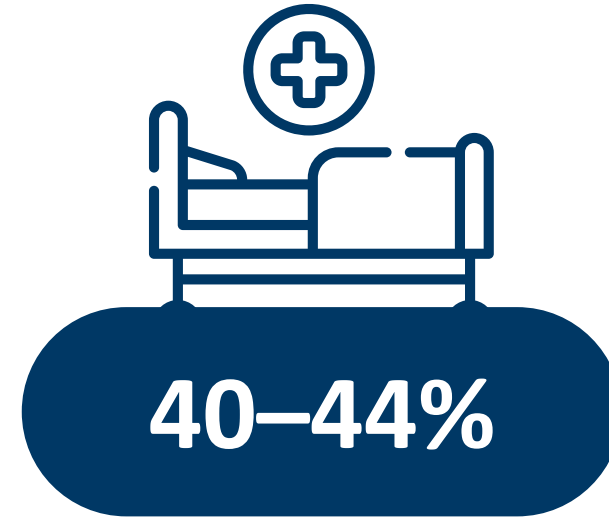
BAU = binding antibody units; CI = confidence interval; COVID-19 = coronavirus disease 2019; GMT = geometric mean titer; Ig = immunoglobulin; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; WT = wildtype.

Regev-Yochay G et al. Preprint published online. *medRxiv*. 2022.

Despite the Vaccines, These Patients Remain at risk



of the vaccinated population is considered at increased risk of an inadequate immune response to a COVID-19 vaccine^{1,2,a}



of patients hospitalised with breakthrough cases are immunocompromised^{3,4,b,c}

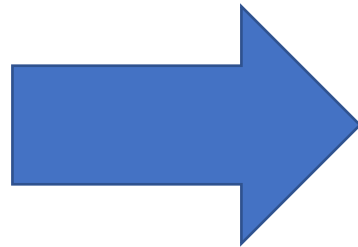
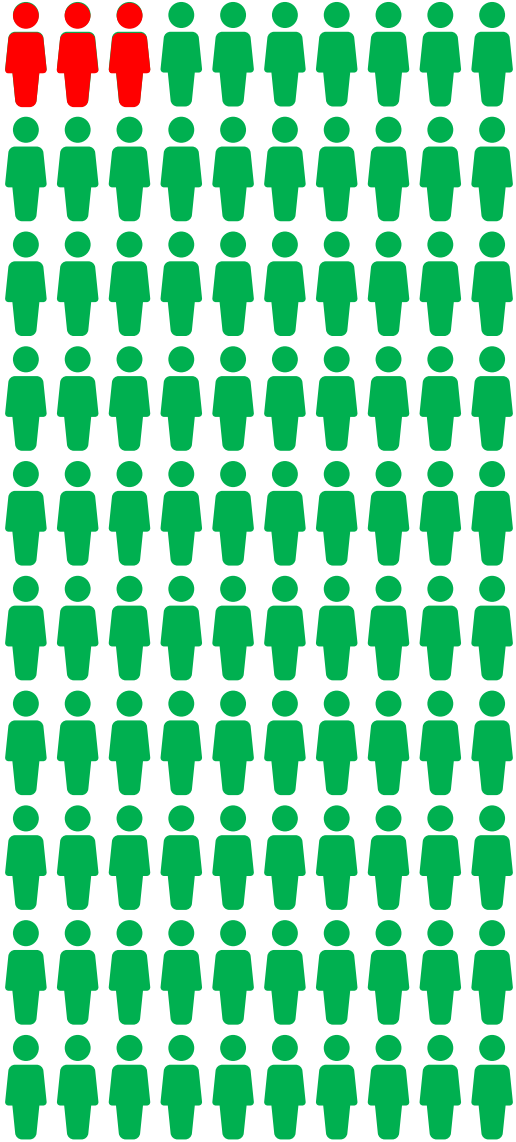
^aCross-sectional analysis from the USA (N=34,426); ^bin a real-world evidence study in the USA, 45 of 1212 patients were hospitalized with vaccine breakthrough infections after receiving an mRNA vaccine; ^cin a retrospective multicenter cohort study of 152 patients from 17 general hospitals across Israel who had received 2 doses of BNT162b2, had a PCR-confirmed diagnosis of SARS-CoV-2 infections, and were hospitalized in a COVID-19 dedicated unit.

COVID-19 = coronavirus disease 2019; mRNA = messenger RNA; PCR = polymerase chain reaction; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

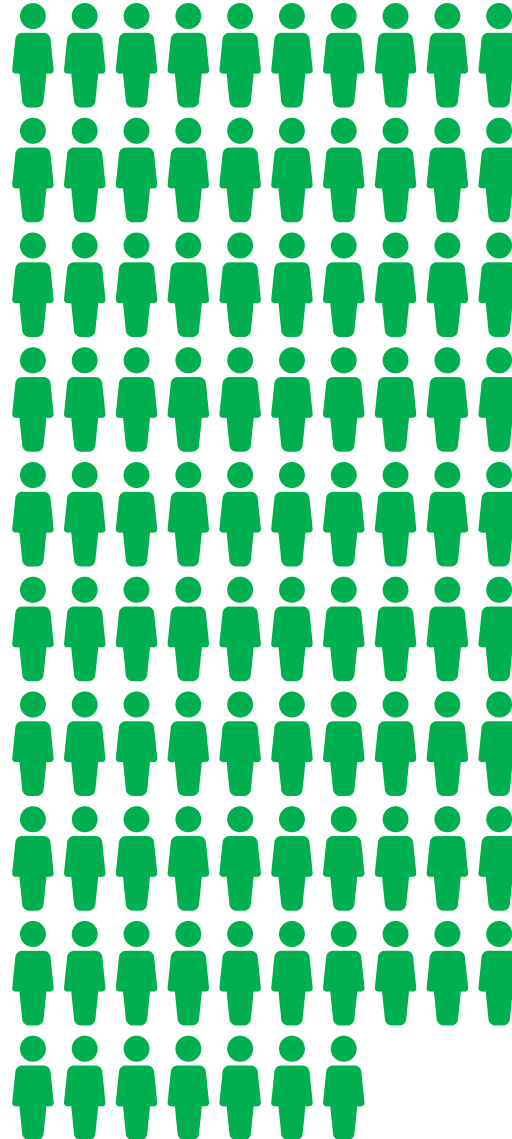
¹. Harpaz R et al. *JAMA*. 2016;316:2547–2548; 2. Centers for Disease Control and Prevention (CDC). COVID-19 Vaccines for Moderately to Severely Immunocompromised People. 2021.

³. Brosh-Nissimov T et al. *Clin Microbiol Infect*. 2021;27:1652–1657; 4. Tenforde MW et al. *Clin Infect Dis*. 2021;ciab687.

“We are ALL in This Together!”



“See you Later”



“What about Us?”



These are many times people limited by their condition. There is no foreseeable end to the pandemic as they remain at high risk

What Does This Mean for your Patients?

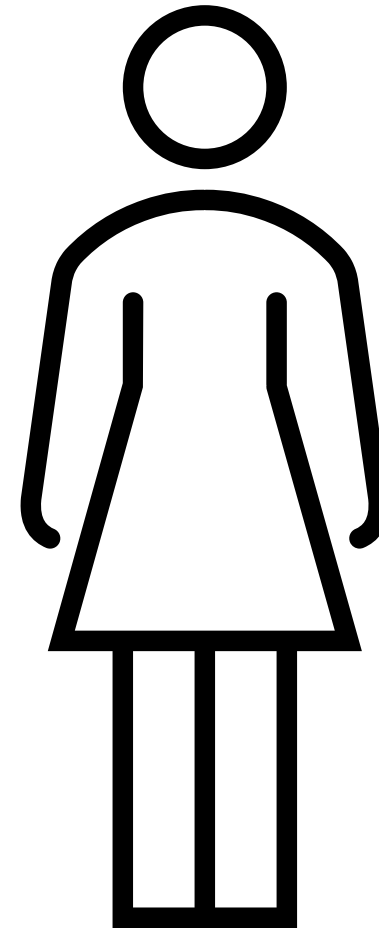
- Vaccines have reduced the risk of severe COVID-19, but a portion of patients don't respond well to them
- Transplant patients, those with hematological cancers and some immunosuppressive therapy causes a poor response to COVID-19 vaccines
- Even additional doses of COVID-19 vaccine, may not protect the patient
- For these vulnerable patients, they will feel left behind as we move on
- We must do more to protect these patients

Discussing Options with Patients

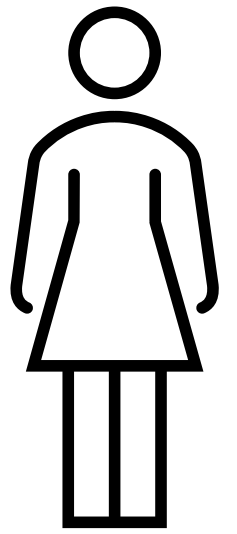
Strategies beyond vaccines

Meet Our Patient – Renata

- Background
 - 61-year-old
 - Renal transplant (5 months ago)
- Medications
 - MMF
 - Tacrolimus
 - Prednisone
- Discussion
 - History of mild depression (no therapy)
 - Delayed 3rd dose of vaccine
 - Presents today for 3rd dose of vaccine



Interactive Question

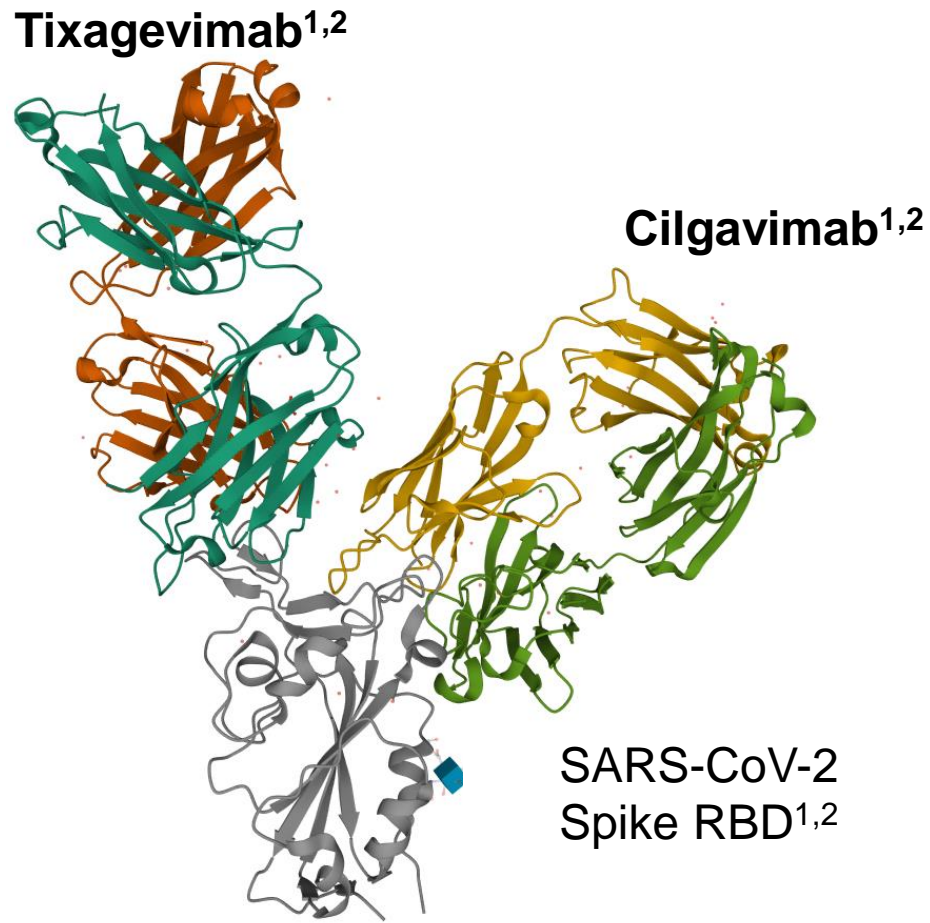


If Renata was your patient, what would be your course of action? (check all that apply)

- a) Ensure the patient has 3rd vaccine dose and discuss booster
- b) Discuss how she is at high risk of COVID-19
- c) Review public health protections (e.g. mask, distance)
- d) Discuss other options to enhance protection
- e) Book patient for medication review

- Background
 - 61-year-old
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What is Tixagevimab/Cilgavimab?



- 2 human mAbs binding 2 distinct epitopes³
- Highly potent⁴
- Retained neutralizing activity against variants of concern³
- Extended half-life⁵
- Favourable safety profile⁶
- Efficacy was shown for pre-exposure prophylaxis in high-risk populations⁵

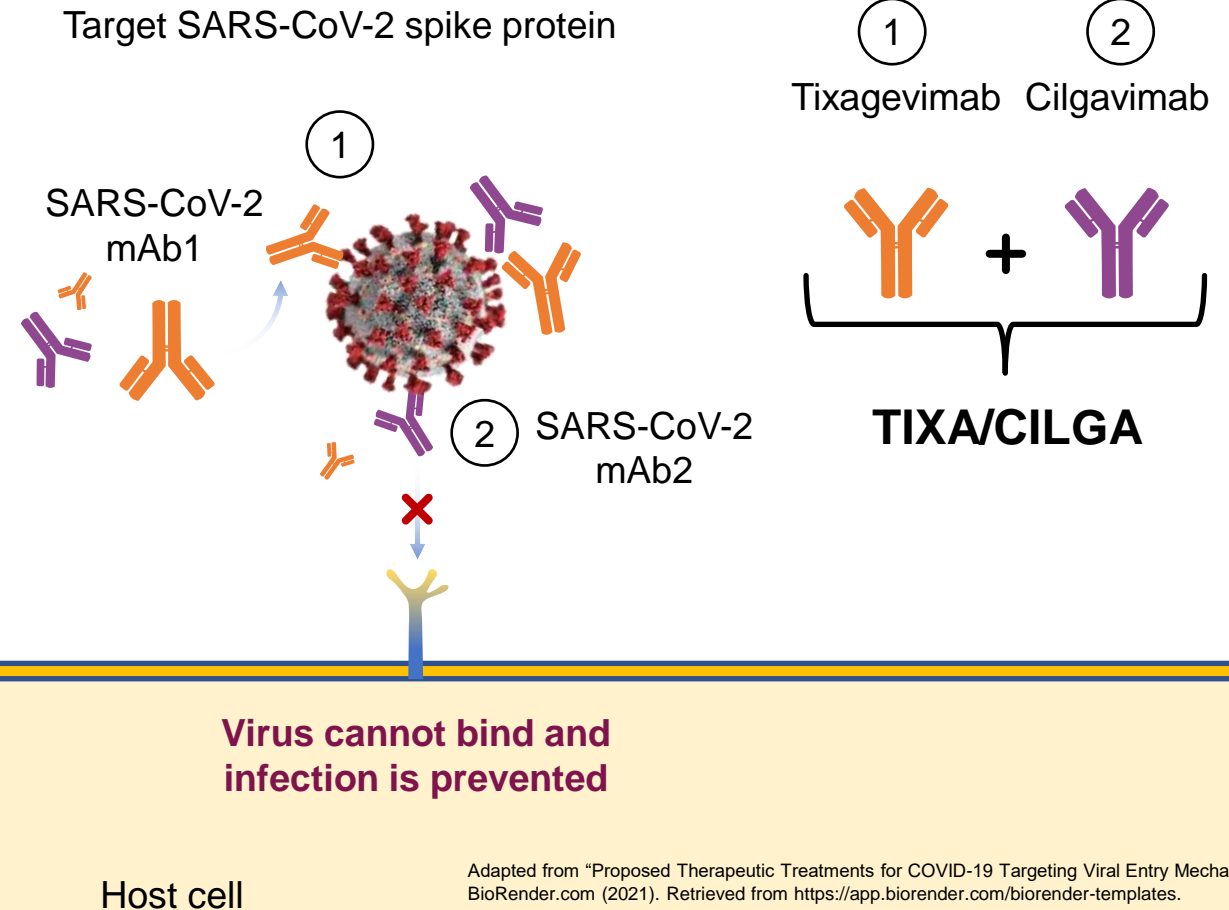
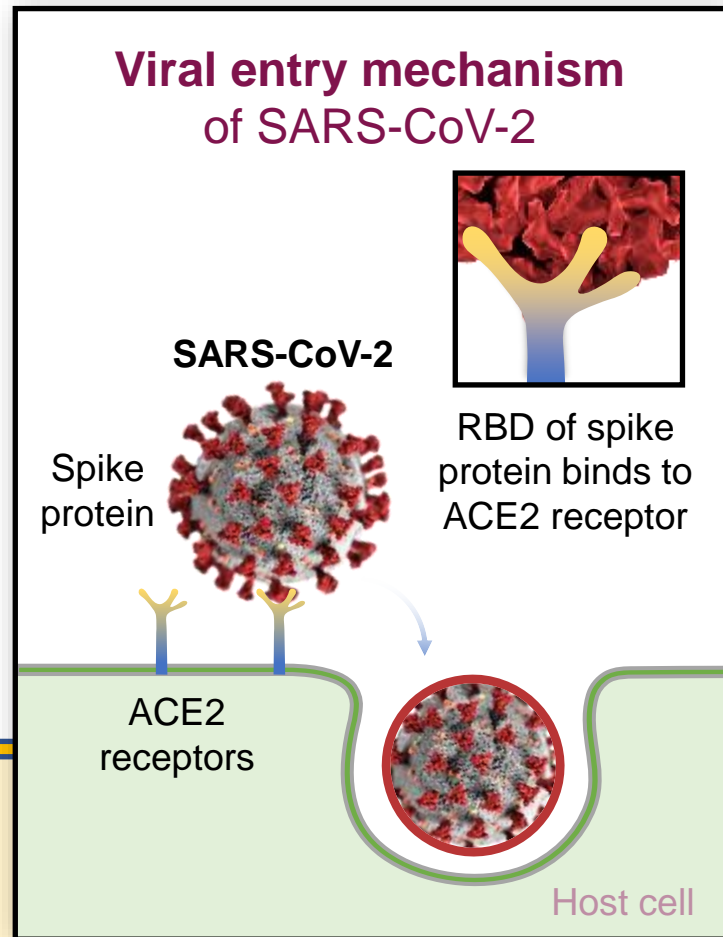
Some of the information provided is based off a preprint research paper that has not been peer reviewed.

C1q = complement component 1q; mAb = monoclonal antibody; FcR = fragment crystallizable region; LAAB = long-acting antibody; RBD = receptor-binding domain; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; TM = triple modification; YTE = M252Y/S254T/T256E.

1. Sehna D et al. *Nucleic Acids Res.* 2021;49:W431-W437; 2. Protein Data Bank. <https://www.rcsb.org/>. 7L7E. Accessed November 10, 2021; 3. Y.-M. Loo et al., *Sci. Transl. Med.*10.1126/scitranslmed.abl8124 (2022);

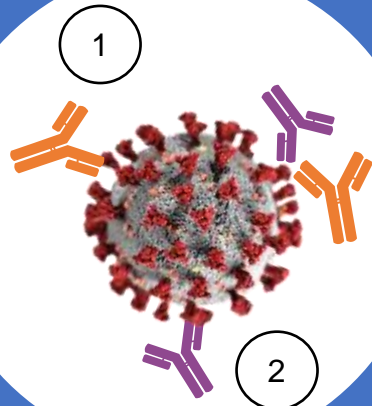
4. Zost SJ et al. *Nature.* 2020;584:443-4493. 5. Fact sheet for healthcare providers. Emergency Use Authorization (EUA) of EVUSHELD™ (tixagevimab co-packaged with cilgavimab). 2021; 6. Levin M et al. Presentation at: IDWeek 2021; September 29-October 3, 2021; virtual conference.

What is the MOA of Tixagevimab/Cilgavimab?



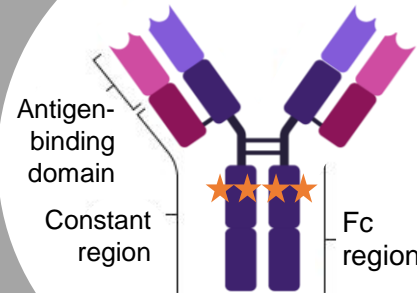
Adapted from "Proposed Therapeutic Treatments for COVID-19 Targeting Viral Entry Mechanism," by BioRender.com (2021). Retrieved from <https://app.biorender.com/biorender-templates>.

Key Properties of Tixagevimab/Cilgavimab



Synergy and potency^{1,2}

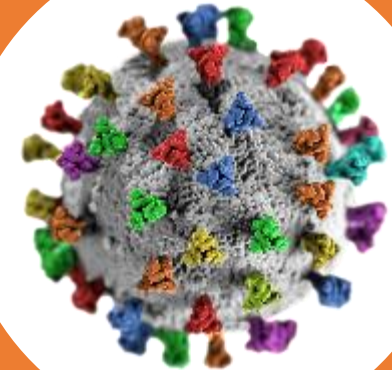
- 2 antibodies that simultaneously bind distinct, noncompeting sites on spike RBD with
 - Synergy
 - High potency



Created with BioRender.com.

Optimization with Fc modifications^{3,4} (★)

- Half-life extension (20 vs 70-100 days)
 - Maximizes antibody localization to mucosa
- Triple modification minimizes risk of antibody-dependent enhancement



Potential to protect against variants⁵

- In vitro neutralization of variants of concern and variants of interest

Antibody image created with BioRender.com.

Fc = fragment crystallizable region; IgG = immunoglobulin G; RBD = receptor-binding domain; YTE = M253Y/S254T/T256E.

1. Zost SJ et al. *Nature*. 2020;584:443-449; 2. Dong J et al. *Nat Microbiol*. 2021;6:1233-1244; 3. Robbie GJ et al. *Antimicrob Agents Chemother*. 2013;57:6147-6153;

4. Oganessian V et al. *Acta Crystallogr D Biol Crystallogr*. 2008;64:700-704; 5. Wang L et al. *Science*. 2021;373:eabh1766. <https://dx.doi.org/10.1126/science.abh1766>. Accessed September 28, 2021.

How Well Does it Work? (PROVENT Study)



Selection Criteria:

Key inclusion criteria:

- Adults age ≥ 18 years at increased risk for inadequate response to vaccination or SARS-CoV-2 infection
- Negative point-of-care SARS-CoV-2 serology test and unvaccinated at screening
- Negative RT-PCR at dosing



Key exclusion criteria:

- History of laboratory-confirmed COVID-19 infection, SARS, MERS
- Prior vaccine or mAb/biologic for COVID-19

TIXA/CILGA

300 mg single dose ($\times 2$ IM injections of 1.5 mL each)^{a,3}
n=3460

Randomization
2:1
N=5197

Placebo (normal saline)

Single dose ($\times 2$ IM injections of 1.5 mL each)³
n=1737

Primary endpoints:



Efficacy endpoint:
SARS-CoV-2 RT-PCR-positive symptomatic illness within 183 days post-single dose



Safety Endpoint:
Adverse events through 457 days (15 mo) post-dose

Conducted in the UK, US, Spain, Belgium, and France

^aGiven by intra-muscular injection.

COVID-19 = coronavirus disease 2019; IM = intramuscular; mAb = monoclonal antibody; MERS = Middle East respiratory syndrome; mo = month; RT-PCR = reverse transcription polymerase chain reaction; SARS = severe acute respiratory syndrome; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; TIXA/CILGA = tixagevimab/cilgavimab; UK = United Kingdom; US = United States.

1. AstraZeneca Pharmaceuticals LP press release. Published August 20, 2021; 2. Study NCT04625725. ClinicalTrials.gov website; 3. Levin M et al. Presentation at: IDWeek 2021; September 29-October 3, 2021; virtual conference.

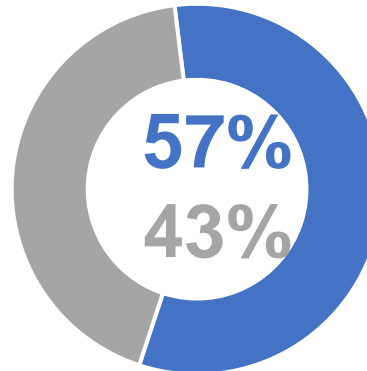
What Patients were Included in PROVENT?

≥75% of participants had baseline comorbidities^a such as:

- Immunosuppressive disease or taking immunosuppressive medications
- Diabetes
- Severe obesity
- CVD
- COPD
- CKD
- CLD

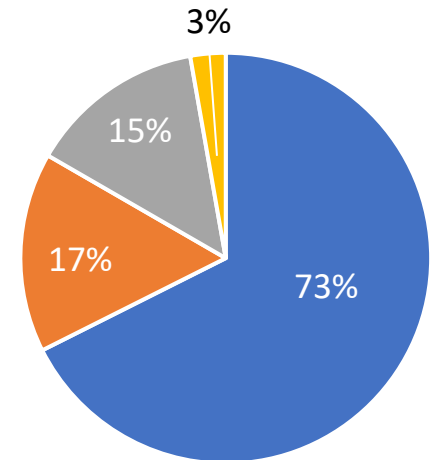
Age of participants

- <60 years
- ≥60 years



Ethnicity

- White
- Black
- Hispanic
- Asian



^aAssociated with an increased risk for severe COVID-19.

CKD = chronic kidney disease; CLD = chronic liver disease; COPD = chronic obstructive pulmonary disease; COVID-19 = coronavirus disease 2019; CVD = cardiovascular disease.

1. AstraZeneca Pharmaceuticals LP press release. Published August 20, 2021; 2. Study NCT04625725. ClinicalTrials.gov website.

Tixagevimab/Cilgavimab Reduced the Risk of Symptomatic COVID-19 – 6 Month Data

6-month (median) follow-up: Reduction in the incidence of symptomatic COVID-19 with TIXA/CILGA compared with placebo^{1,2}

Case severity	Number of cases	
	TIXA/CILGA	Placebo
Severe COVID-19	0 ↓	5 ↓
Death from COVID-19	0	2
Symptomatic cases, relative risk reduction (%)	RRR: 83%	

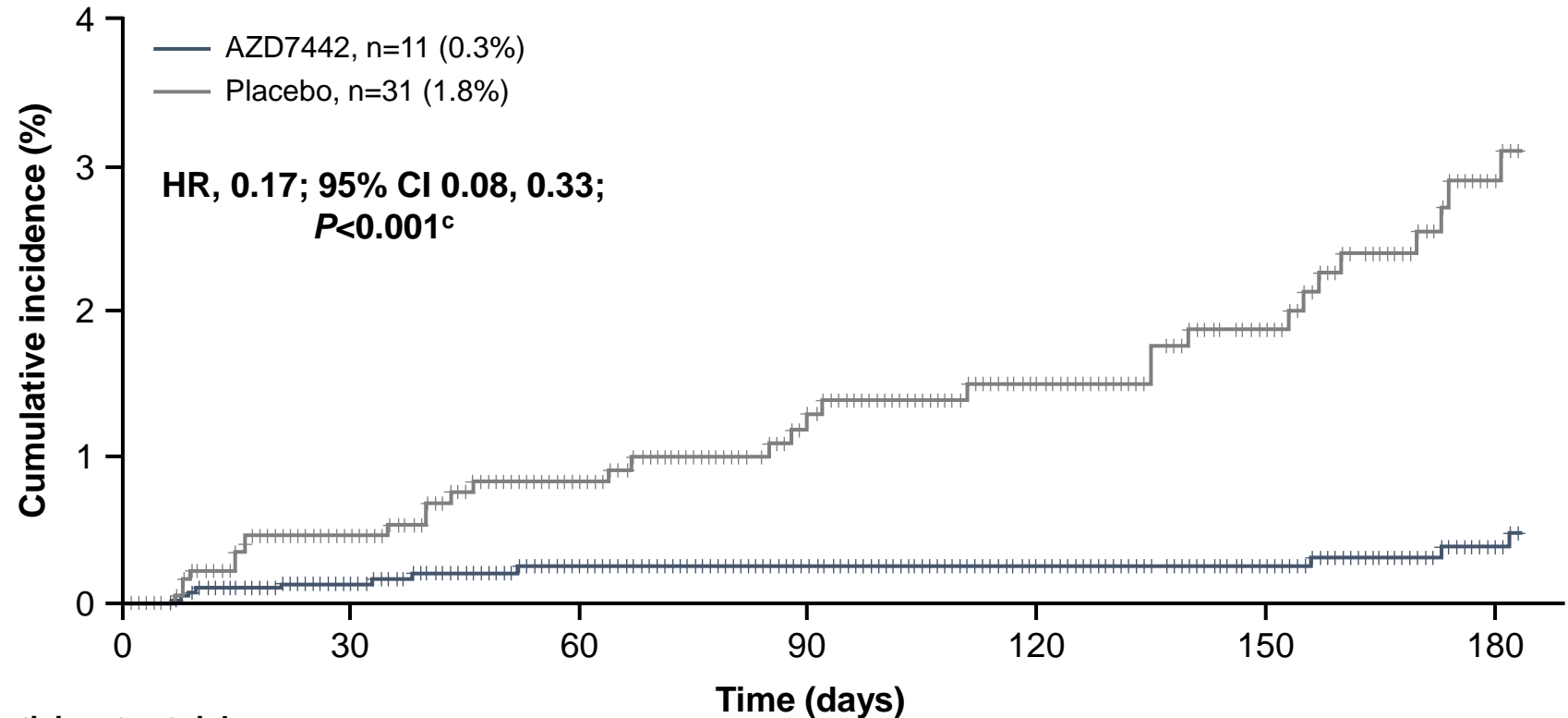
TIXA/CILGA reduced the risk of symptomatic disease by 83% through 6-month (median) follow-up¹

COVID-19 = coronavirus disease 2019; LAAB = long-acting antibody; RRR = relative risk reduction; TIXA/CILGA = tixagevimab/cilgavimab.

1. AstraZeneca Pharmaceuticals LP press release. Published November 18, 2021; 2. Study NCT04625725. ClinicalTrials.gov website.

Incidence of Symptomatic COVID-19

- Primary efficacy endpoint was met: 77% (95% CI 46, 90) reduction in symptomatic COVID-19 with AZD7442 vs placebo ($P < 0.001$)^a
- Efficacy maintained at median 6-months follow-up: 83% (95% CI 66, 91) reduction in symptomatic COVID-19 with AZD7442 vs placebo^b



No. of participants at risk:

AZD7442	3441	2957	2393	2054	1815	1667	1044
Placebo	1731	1483	1177	991	856	774	472

What are the Adverse Effects of Tixagevimab/Cilgavimab?

No. (%) of participants with:	TIXA/CILGA (n=3461)	Placebo (n=1736)
≥1 AE	1221 (35.3)	593 (34.2)
≥1 SAE	50 (1.4)	23 (1.3)
≥1 Treatment-related SAE	1 (<0.1) ^a	0
≥1 AE leading to study withdrawal	1 (<0.1) ^b	0
≥1 AESI	93 (2.7)	37 (2.1)
Injection site reaction	82 (2.4)	36 (2.1)
Anaphylaxis	1 (<0.1)	0
Immune complex disease	1 (<0.1)	0
Other	9 (0.3)	2 (0.1)

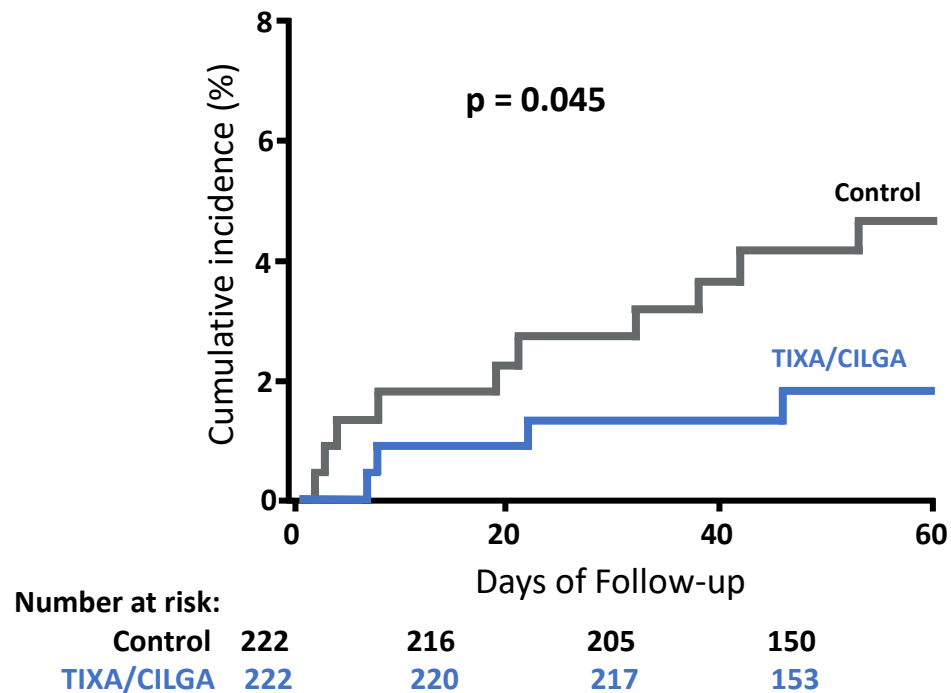
^aMesenteric artery thrombosis; ^bParticipant who died of end-stage renal disease; the investigator characterized the death as the AE leading to study discontinuation: this is not consistent with usual practice.

AE = adverse event; AESI = adverse event of special interest; MAAE = medically attended adverse event; RT-PCR = reverse transcriptase–polymerase chain reaction; SAE = severe adverse event; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; TIXA/CILGA = tixagevimab/cilgavimab.

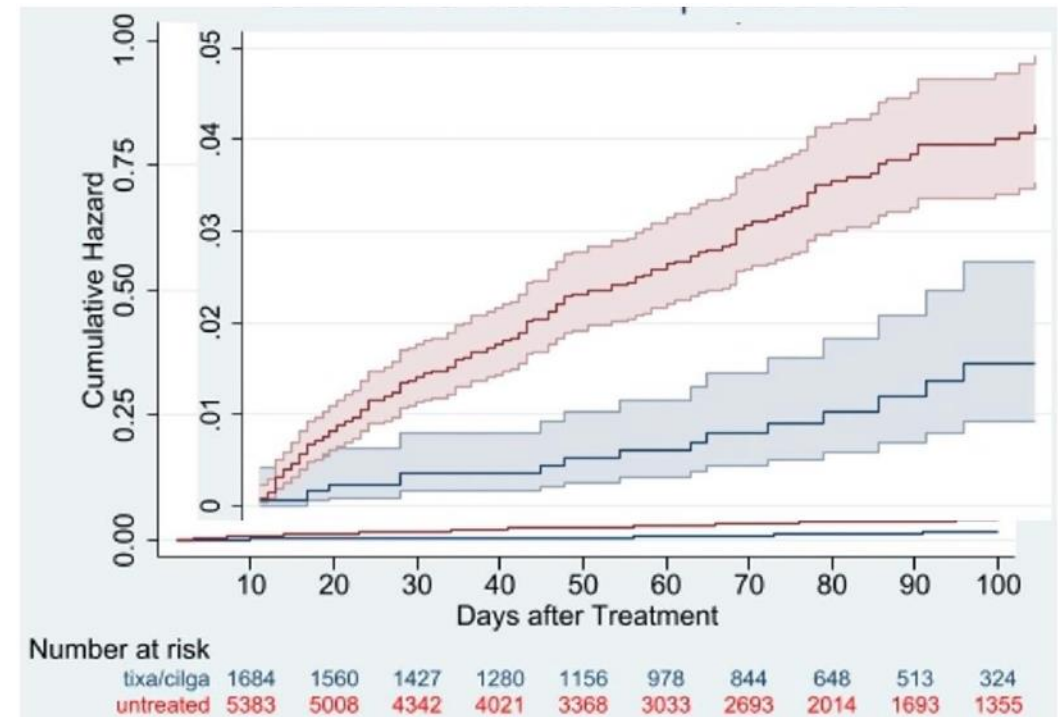
1. AstraZeneca Pharmaceuticals LP press release. Published August 20, 2021; 2. Study NCT04625725. ClinicalTrials.gov website; 3. Levin M et al. Presentation at: IDWeek 2021; September 29-October 3, 2021; virtual conference.

What about Tixagevimab/Cilgavimab in a Vaccinated Population during the Omicron Surge?

Cumulative incidence of breakthrough SARS-CoV-2 infections in a SOT population (Mass Gen)¹



Cumulative risk of composite COVID-19 General Immunocompromised population (VA)²



The information provided is based off a preprint research paper that has not been peer reviewed.

COVID-19 = coronavirus disease 2019; IQR = interquartile range; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SOT = solid organ transplant; TIXA/CILGA = tixagevimab/cilgavimab

1-Jurdi AA, et al. [medRxiv. 2022. <https://www.medrxiv.org/content/10.1101/2022.05.17.22274980v1>. 2-Young-Xu, et al. medRxiv. 2022. doi: <https://doi.org/10.1101/2022.05.28.22275716>.

Dosing, Administration, and Storage of Tixagevimab/Cilgavimab in Clinical Studies



Dosing^{1,3}

Single dose of TIXA/CILGA 300 mg (tixagevimab 150 mg and cilgavimab 150 mg) IM for prophylaxis or single dose of TIXA/CILGA 600 mg (tixagevimab 300 mg and cilgavimab 300 mg) IM for treatment

TIXA/CILGA was evaluated as IV in ACTIV-2/3 and DisCoVeRy



Storage^{1,2}

Vials stored at 2-8°C (36-46°F) for the duration of the product's shelf life



Supply^{1,3}

Supplied as separate vials of tixagevimab and cilgavimab



Administration^{1,2}

Use a separate disposable syringe each tixagevimab and cilgavimab injection

Given as separate, single IM injections, one for each mAb component, and administered sequentially with one 1.5 mL or 3 mL injection in each gluteal region¹⁻³



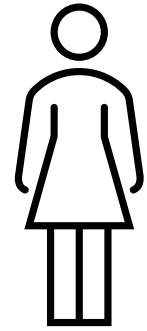
Contents^{1,2}

Does not contain preservatives

Information on the slide is representative of the clinical studies. Storage, supply, and handling of TIXA/CILGA are still under investigation and are subject to change.

IM = intramuscular; IV = intravenous; mAb = monoclonal antibody; TIXA/CILGA = tixagevimab/cilgavimab. 1. In House Data, AstraZeneca Pharmaceuticals LP. CSP D8850C00003; 2. In House Data, AstraZeneca Pharmaceuticals LP. CSP D8850C00002; 3. In House Data, AstraZeneca Pharmaceuticals LP. CSP D8851C00001.

Revisit – Renata



- Management

- Discuss the importance of keeping up to date with vaccines
- Discuss the importance of maintaining public health protections
- Review the potential role of Tixagevimab/Cilgavimab to lower her risk

- Action

- Patient wants protection, fax to transplant clinic
- Medication review and discussion of treatment options if she was to become ill

- Background

- 61-year-old
- Renal transplant (5 months ago)

- Medications

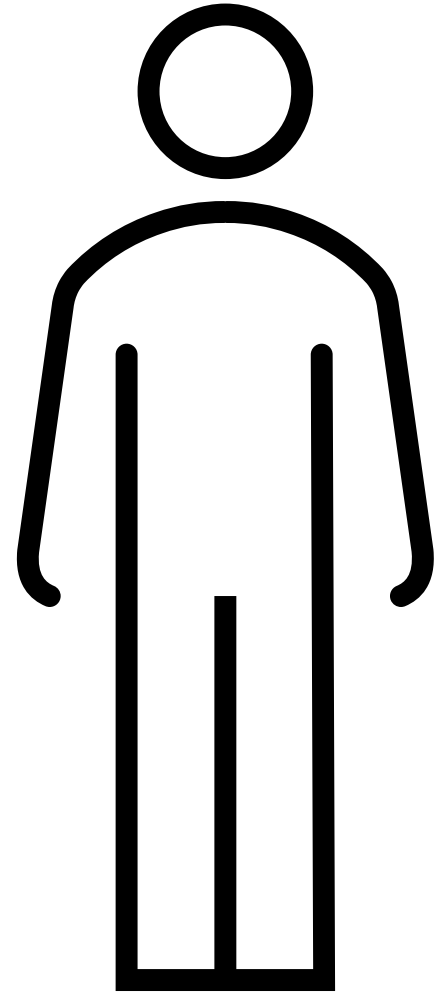
- MMF
- Tacrolimus
- Prednisone

- Discussion

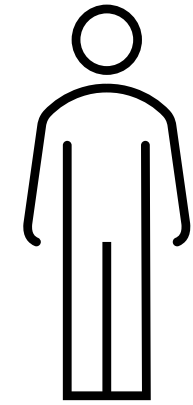
- History of mild depression (no therapy)
- Delayed 3rd dose of vaccine
 - Presents today for 3rd dose of vaccine

Meet Our Patient – Robert

- Background
 - 11-year-old
 - Relapsing remitting MS
- Medications
 - Ocrelizumab 600mg of every 6 months
 - Vitamin D 4000IU daily
- Discussion
 - Triple vaccinated and boosterd
 - Has long recovered from relapse/MS attack in December 2021
 - Fears returning to work as early childhood educator with level of SARS-CoV-2 circulation in the community



Interactive Question



If Robert was your patient, what would be your course of action? (Please check all that apply)

- a) Tell him to not worry as he is up to date with his COVID-19 vaccines
- b) Refer to clinic for Tixagevimab/Cilgavimab
- c) Review public health protections (e.g. mask, distance)
- d) Tell him to hold his ocrelizumab for an extra month while COVID-19 numbers are high
- e) Tell him the risk of SARS-CoV-2 transmission from children is low

- Background
 - 11-year-old
 - Relapsing remitting MS
- Medications
 - Ocrelizumab 600 mg of every 6 months
 - Vitamin D 4000 IU daily
- Discussion
 - Triple vaccinated and boosted
 - Has long recovered from relapse/MS attack in December 2021
 - Fears returning to work as early childhood educator with level of SARS-CoV-2 circulation in the community

What can Pharmacists Do?

- Learn the candidates in your province/territory
- Look for potential patients
- Approach the patient
- Collaborative approach with other healthcare professionals to ensure these patients are protected

The eligible patients can vary based on province/territory of practice. Please check the site where our video will be hosted for up to date links to provincial coverage information.

Approaching and Explaining this Treatment to your Patient

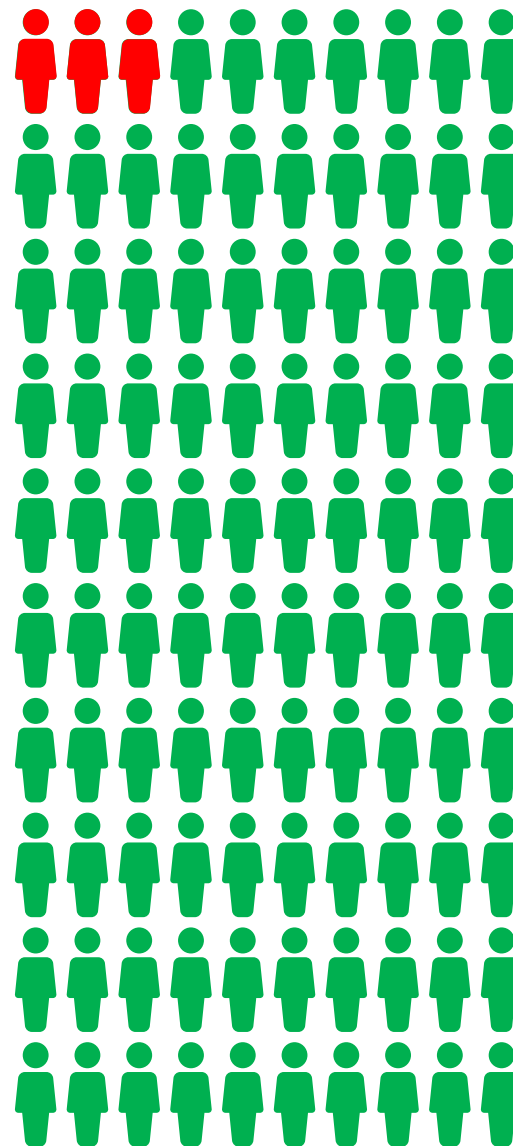
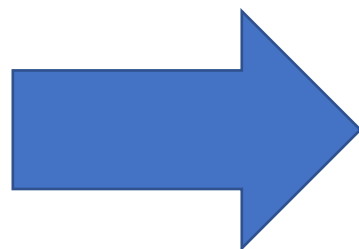
Mrs. Smith, you may know that your medication increases the risk of COVID-19. Your COVID-19 vaccine doses may not offer the same protection as it does for a person not taking your medication.

There is a new option that we have that can offer protection from severe COVID-19. It is a couple of injections and experts recommend that you should consider this injection. Would you like to hear more?

Patient Counselling Summary for Tixagevimab/Cilgavimab

- **Efficacy** – Shown to reduce the risk of COVID-19 by 77%
- **Side effects** – Well tolerated, with the most common side effect being soreness and irritation where it is injected
- **Administration:** 2 different injections
- **Vaccines:** Still important to staying up to date
- **How does the patient get it:** Depends on province/territory
- **Collaboration with other clinicians:** every HCP has a role to protect these patients

Many eligible patients will not know that this option is available. Consider actively approaching these patients to help reduce the risk.



Frequently Asked Questions

1. Does Tixagevimab/Cilgavimab replace the need for vaccines?

2. Will these patients still require additional COVID-19 vaccine boosters?

3. In an ideal world, when should this medication be considered?

4. What is the efficacy of Tixagevimab/Cilgavimab against omicron subvariants?

5. How fast does it protect these patients?

Key Learning Points

- COVID-19 vaccines have reduced the risk of severe COVID-19 outcomes
- Even with immunization, many immunocompromised patients are at high risk of severe COVID-19
- Tixagevimab/Cilgavimab is a long-acting monoclonal antibody combination that has been shown to reduce COVID-19 risk in these patients
- Tixagevimab/Cilgavimab can provide an additional layer of protection from COVID-19 to our most vulnerable patients