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COVID Vaccination among Medicare Beneficiaries: Findings from an IMPACT Supplement

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University of Delaware

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Assistant Professor,
Brown University

Housekeeping

- All participants will be muted
- Enter **all questions** in the Zoom **Q&A/chat box** and send to Everyone
- Moderator will review questions from chat box and ask them at the end
- Visit impactcollaboratory.org

Disclosures

- This work was supported by U54AG063546, which funds the NIA IMPACT Collaboratory. Supplemental funding was provided under grant numbers U54AG063546-S07 and U54AG063546-S08.
  - The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

- KH: investigator-initiated grant funding paid directly to Brown University for investigator-initiated research from Sanofi, Genentech, and GlaxoSmithKline unrelated to this work.
- DH: investigator-initiated grant funding paid directly to the University of Delaware from GSK for research related to the shingles vaccine. Consulting fees from Sanofi paid directly to DH for consulting fees related to the influenza vaccine and epidemiologic research methods.

Agenda

1. Provide an overview of the process to construct the COVVAXAGE database

2. Walk through five exemplar papers from the IMPACT COVID-19 projects

3. Discuss lessons learned from working with industry partners

Learning Objectives

Upon completion of this presentation, you should be able to:

- Be familiar with the NIA Linkage program and COVVAXAGE linked database of Medicare claims.
- Understand the benefits of data linkages to Medicare data for studying COVID-19 vaccines and clinical outcomes.
- Discuss findings from real-world COVID-19 vaccine studies examining use, safety, and effectiveness among older adults in the US.

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Part I: Project Launch and COVVAXAGE Database

International Journal of Population Data Science (2023) 8:6:02

International Journal of Population Data Science

Journal Website: www.ijpds.org

Data resource profile: COVid VAXines effects on the aged (COVVAXAGE)

Kaleen N. Hayes[1,*], Daniel A. Harris[1], Andrew R. Zullo[1,2,3], Djeneba Audrey Djibo[4], Renae L. Smith-Ray[5], Michael S. Taitel[5], Tanya G. Singh[5], Cheryl McMahill-Walraven[4], Preeti Chachlani[1], Katherine J. Wen[1,6], Ellen P. McCarthy[7,8], Stefan Gravenstein[1,3,9], Sean McCurdy[10], Kristina E. Baird[10], Daniel Moran[10], Derek Fenson[10], Yalin Deng[1], and Vincent Mor[1,3]

Let's go back to 2021…

- Need for comprehensive, real-time data to answer questions related to COVID-19 vaccines
  - Two IMPACT administrative supplemental awards to (S7, S8)
- **Objectives:**
  1. Data: Match the records of CVS Health and Walgreens pharmacy customers to Medicare data
  2. Utilization: Examine factors associated with vaccine uptake
  3. Safety and Effectiveness: Estimate the rate of adverse events attributable to the vaccine and estimate breakthrough COVID illness among vaccinated Medicare beneficiaries

Exemplar papers

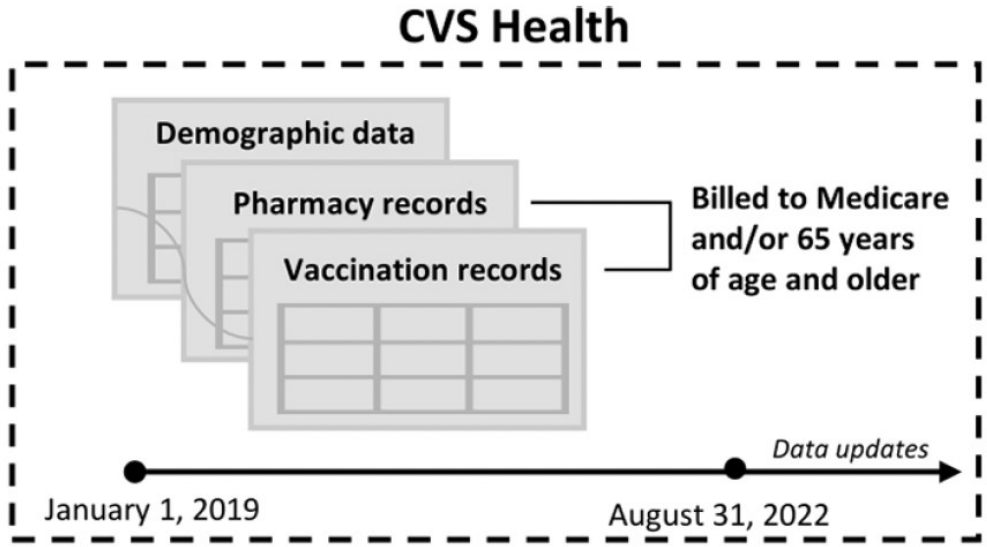
- Data
  - Paper 1: Creation of COVVAXAGE (Kaley)
- Utilization
  - Paper 2: Geographic variation in mRNA vaccines (Kaley)
  - Paper 3: Disparities in booster vaccine uptake (Kaley)
  - Paper 4: Coadministration of vaccines (Dan)
- Safety and Effectiveness
  - Paper 5: Comparative effects of mRNA vaccines (Dan)

Data Linkage: the work before the work

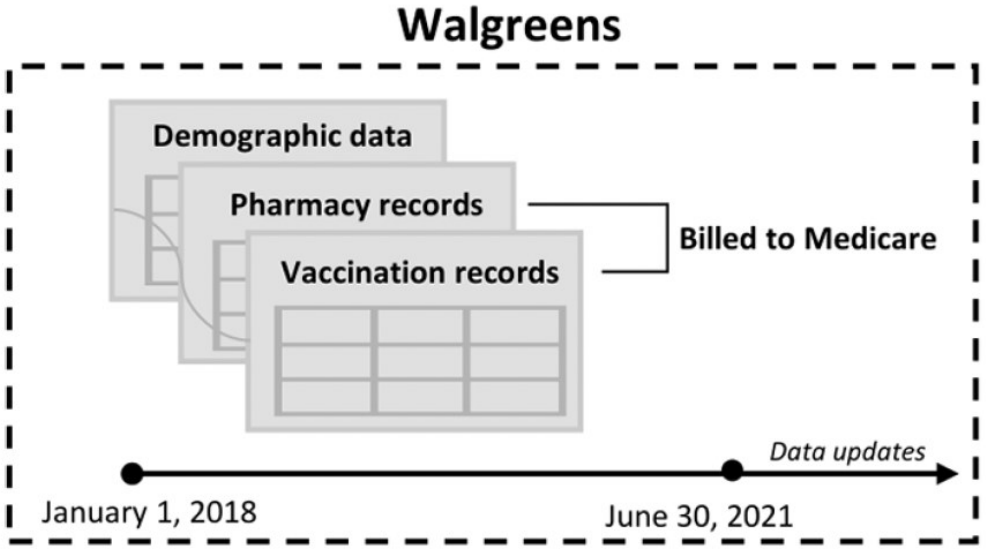
- The first project in the NIA LINKAGE program (external data linkage to CMS data in NIA-funded projects)
  - Worked directly with Acumen
  - *Happy to answer questions about our experience with LINKAGE!*

- Termed the **The COVid VAXines Effects on the Aged (COVVAXAGE) database**

Data Linkage Overview



N=27,086,723



N=23,510,025

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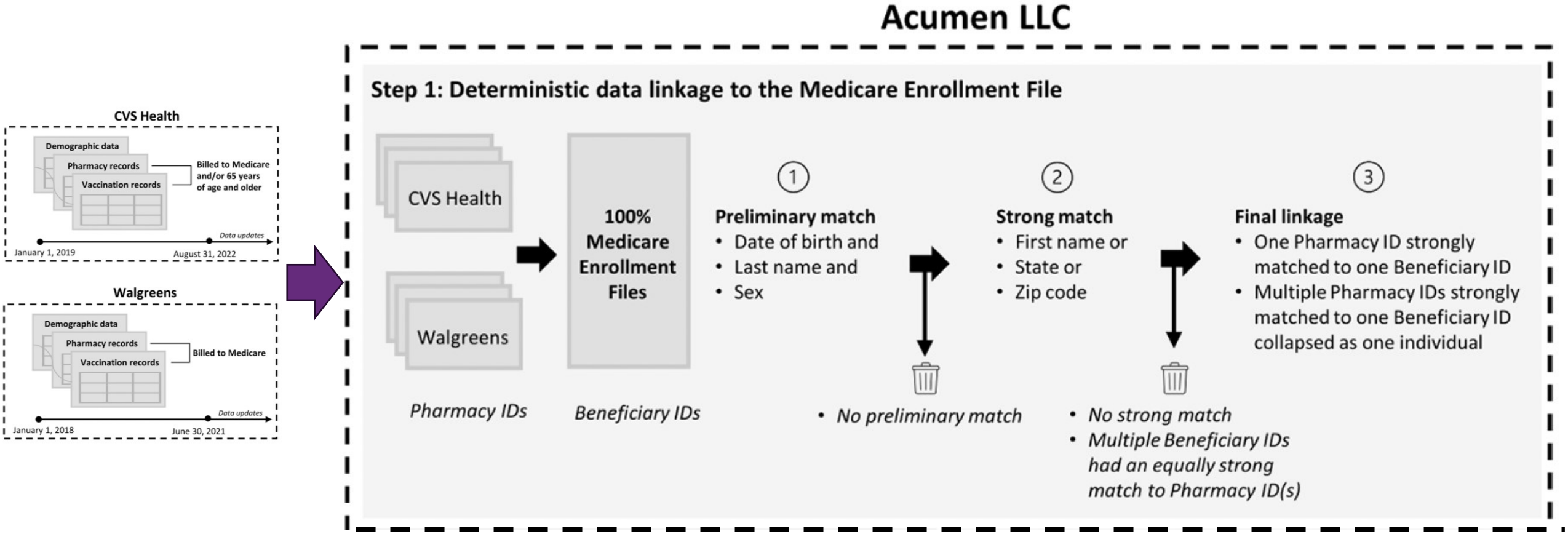
Data Linkage Overview

94.3% of CVS Health
96.0% of Walgreens IDs (age 65+) matched



Who's in the database?!

- 38,250,873 unique beneficiaries (~60% Medicare population)
  - Aged 65+ represents >70% of the older adult Medicare population

	% at first week of Medicare enrollment (Jan 2018- Aug 2022)
Age in years, Mean (SD)	70.47 (9.53)
Female	56.7%
Fee-for-Service	54.4%
Medicare Advantage	33.0%
Full Dual Medicaid Eligible	11.0%
White Race	74.2%
Black Race	10.7%

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Part II: Which vaccines went where?

By Katherine Wen, Daniel A. Harris, Preeti Chachlani, Kaleen N. Hayes, Ellen McCarthy, Andrew R. Zullo, Renae L. Smith-Ray, Tanya Singh, Djeneba Audrey Djibo, Cheryl N. McMahill-Walraven, Jeffrey Hiris, Rena M. Conti, Jonathan Gruber, and Vincent Mor

DATAWATCH

COVID-19 Vaccines: Moderna And Pfizer-BioNTech Use Varied By Urban, Rural Counties

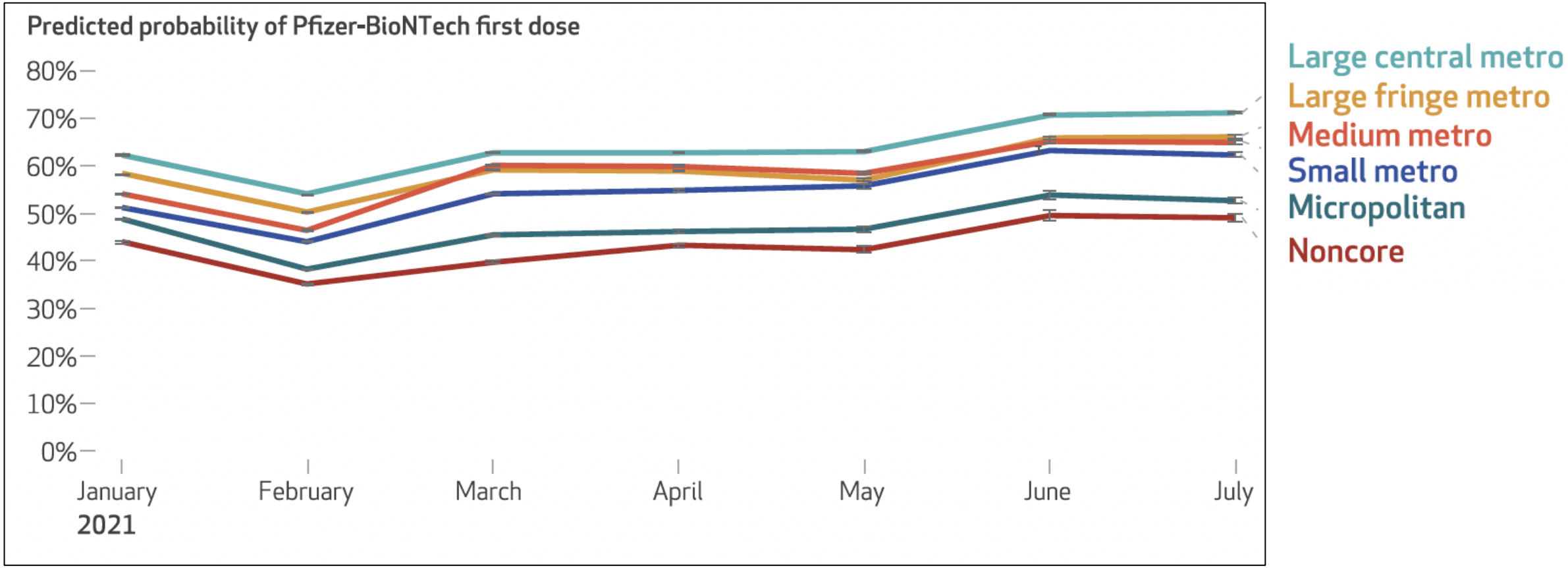
Wen KJ, Harris DA, Chachlani P, Hayes KN, et al. COVID-19 Vaccines: Moderna And Pfizer-BioNTech Use Varied By Urban, Rural Counties. Health Affairs. 2024;43(5):659-665. PMID: 38709973. PMCID: PMC11148879

Leveraging the COVVAXAGE database

- Little known about how specific mRNA vaccine products were distributed in the US

- **Objective:** To explore geographic variation at the county-level in the use of Pfizer-BioNTech and Moderna mRNA vaccines for the primary and booster vaccine seasons

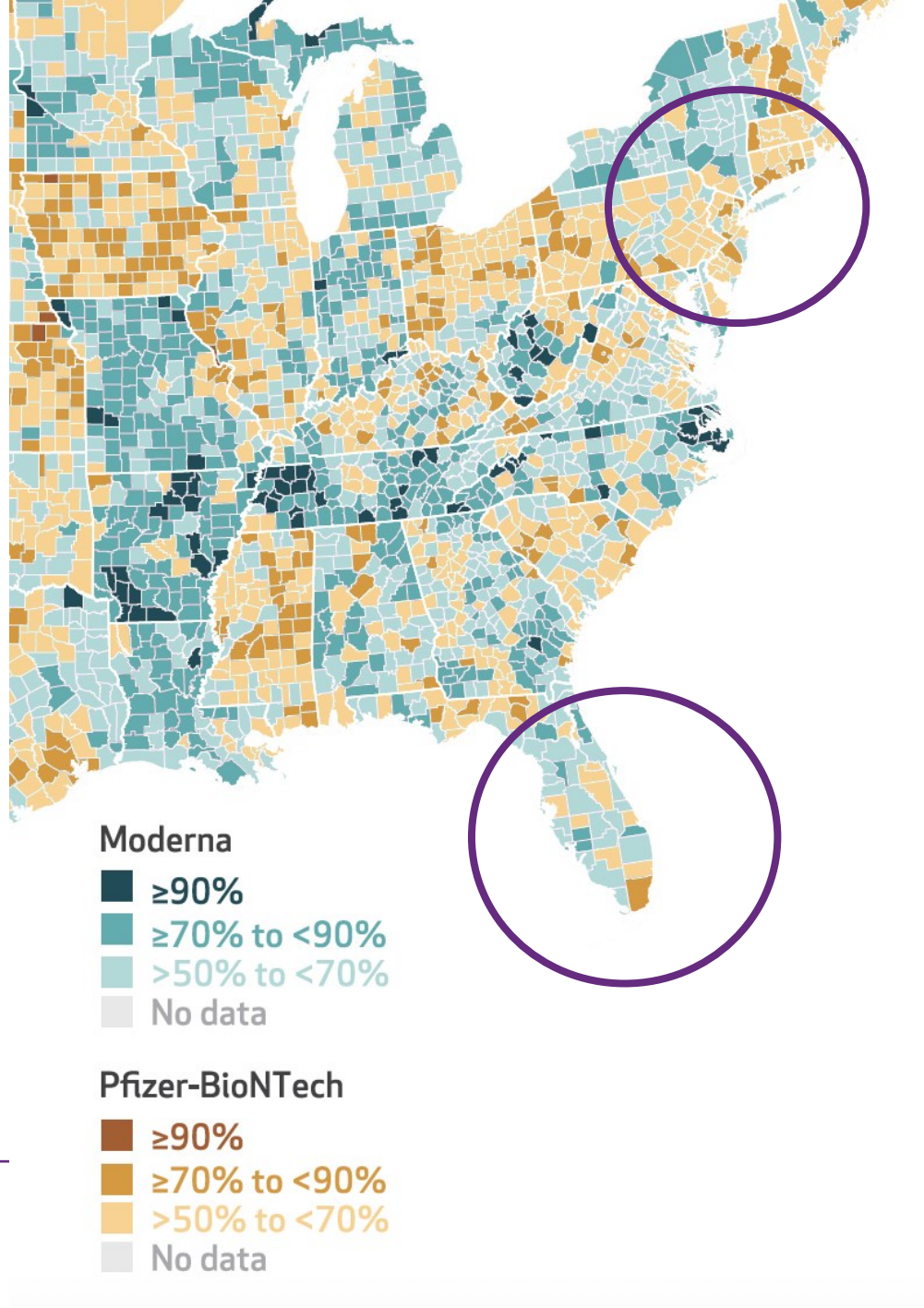
Urbanicity directly predicted which vaccine was received



First dose

n=14,448,485

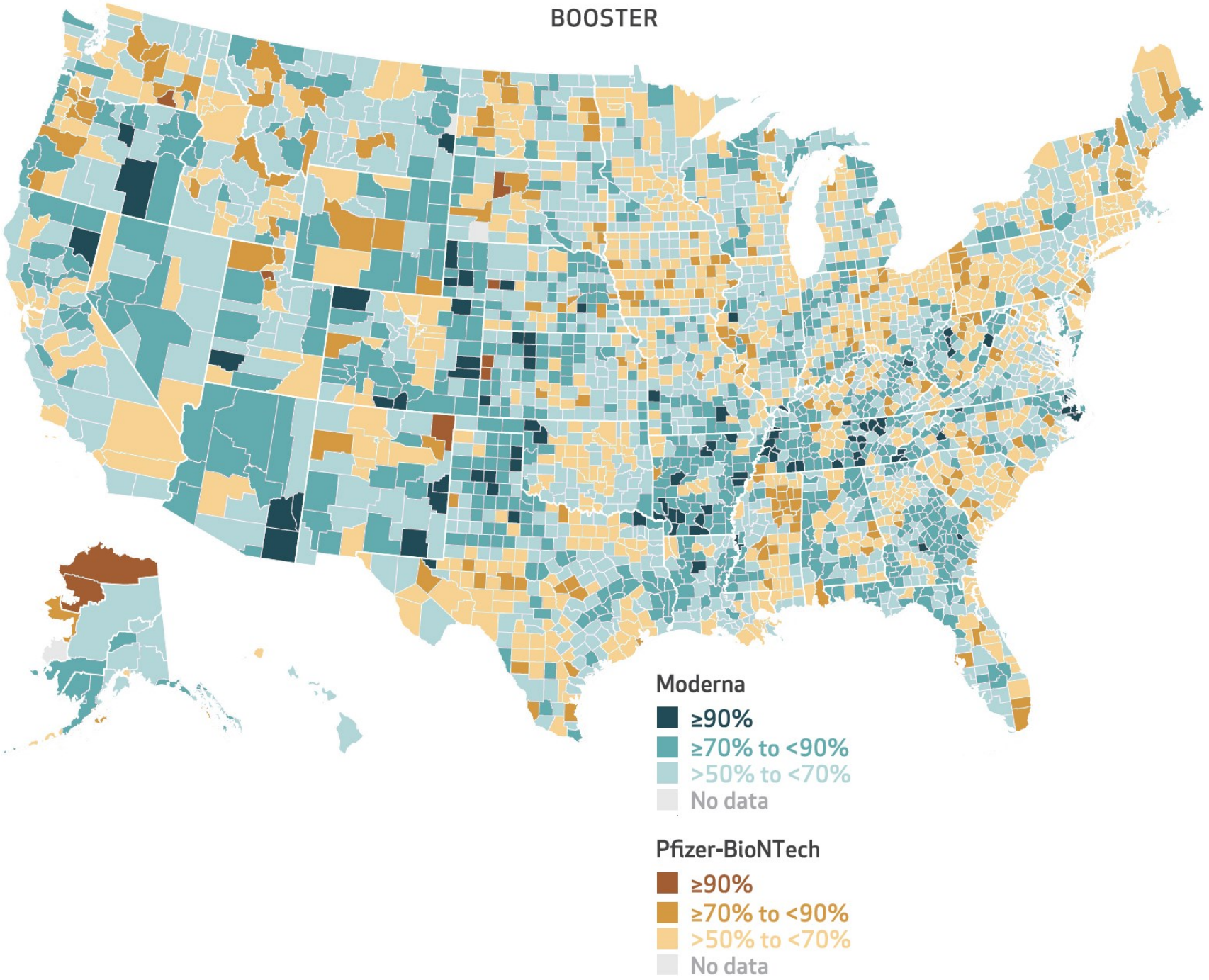
Jan-Jul 2021



Booster dose

n=19,151,132,

Aug 2021 – Apr 2022



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Bottom line

- Rural counties more likely to receive Moderna
  - Moderna did not require a cold-chain transportation network (earlier)
  - Moderna distributed in smaller batches (later)

- There are some differences in the effectiveness between the two mRNA vaccines (more in a bit)
  - Studies on vaccine effectiveness and safety should consider geography in analysis, as it is associated with both exposure (vaccines) and outcomes

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Part III: Disparities in booster vaccinations

frontiers | Frontiers in Public Health

TYPE Brief Research Report
PUBLISHED 10 August 2023
DOI 10.3389/fpubh.2023.1243958

Racial and ethnic disparities in COVID-19 booster vaccination among U.S. older adults differ by geographic region and Medicare enrollment

Kaleen N. Hayes[1,2]*, Daniel A. Harris[1,2], Andrew R. Zullo[1,2,3,4], Preeti Chachlani[1,2], Katherine J. Wen[1,2,5], Renae L. Smith-Ray[6], Djeneba Audrey Djibo[7], Ellen P. McCarthy[8,9], Alexander Pralea[1], Tanya G. Singh[6], Cheryl McMahill-Walraven[7], Michael S. Taitel[6], Yalin Deng[2], Stefan Gravenstein[1,2,4,10] and Vincent Mor[1,2,4]

Hayes KN, Harris DA, Zullo AR, Chachlani P, Wen KJ, Smith-Ray RL, Djibo DA, McCarthy EP, Pralea A, Singh TG, McMahill-Walraven CN, Taitel MS, Deng Y, Gravenstein S, Mor V. Racial and ethnic disparities in COVID-19 booster vaccination among U.S. older adults differ by geographic region and Medicare enrollment. Front Public Health. 2023;11:1243958. PMID: 37637796. PMCID: PMC10456997.

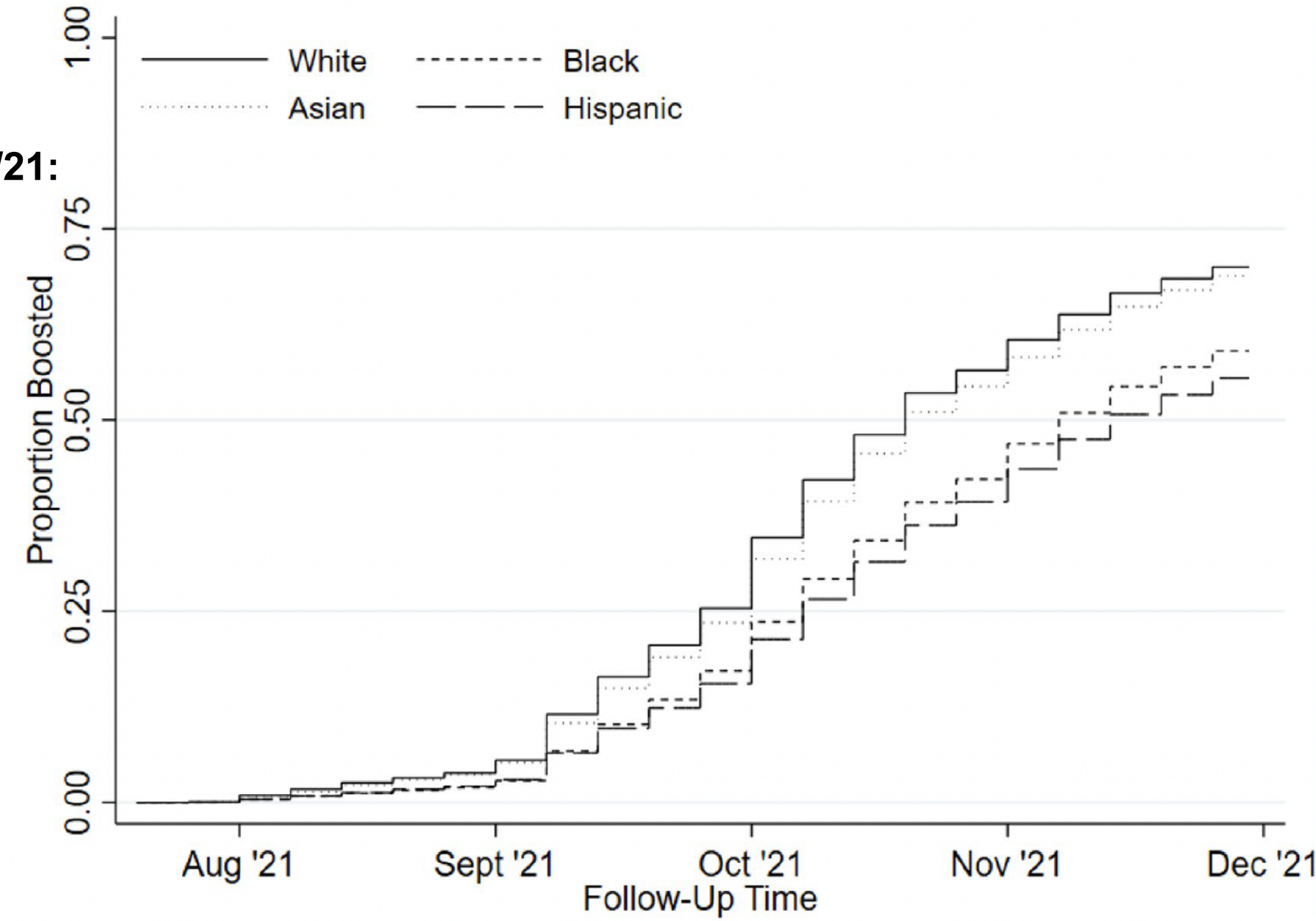
Disparities in COVID-19 boosters

- Racial and ethnic disparities for COVID-19 booster vaccines are known, but estimates had limitations:
  - Did not examine longitudinally among those eligible for booster vaccines
  - Did not examine how these disparities vary by other factors, e.g., geography
- **Objective:** Estimate absolute incidence and the relative rate of COVID-19 booster vaccine receipt in 2021 between race and ethnicity groups among Medicare beneficiaries who completed the primary vaccine series
  - Also explore variation by patient characteristics and geography

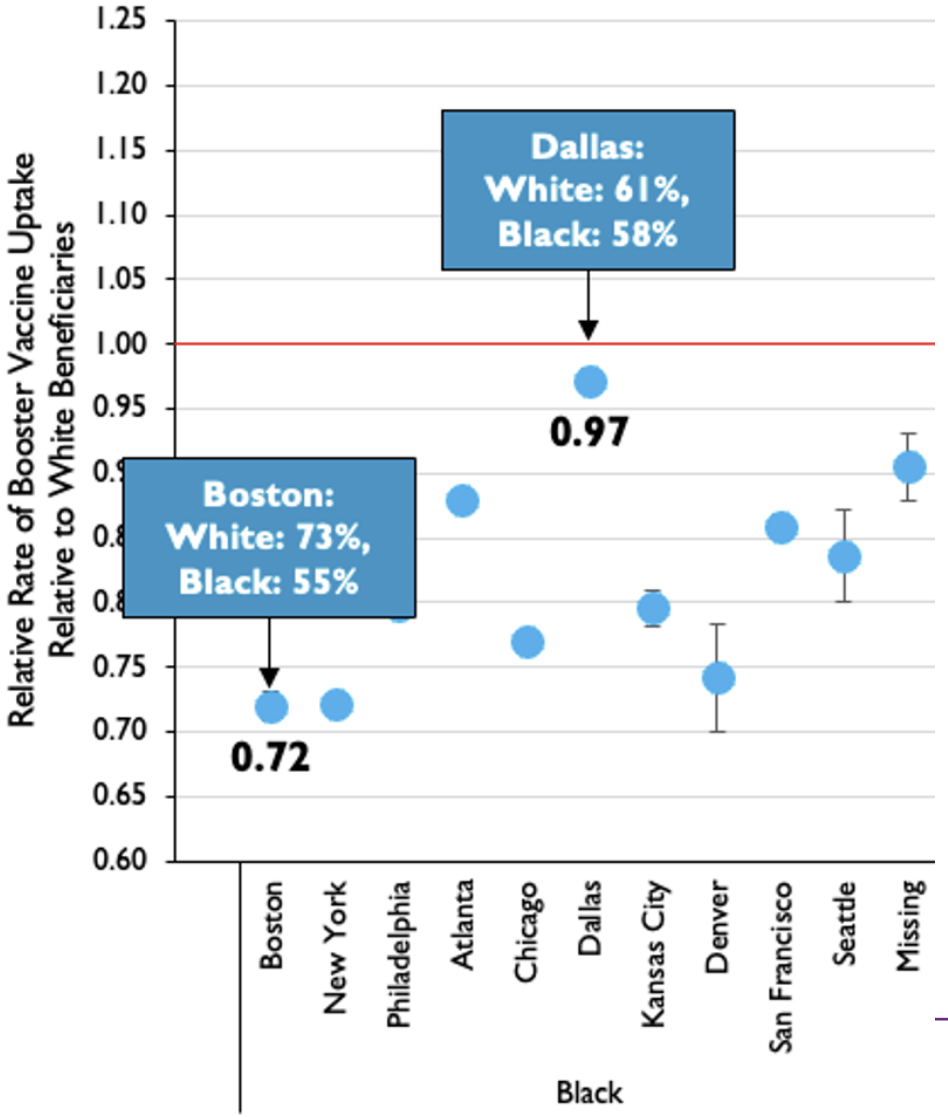
Overall disparities in booster vaccination confirmed

Proportion boosted by 12/31/21:

- White = 68.5%
- Asian = 67.0%
- Black = 57.0%
- Hispanic = 53.3%



Variation found by geographic region



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Bottom line

- Major racial and ethnicity disparities in COVID-19 booster vaccination exist
- Disparities varied by geographic region, urbanicity, and Medicare/Medicaid coverage
  - But not age or sex

Bottom line

- Magnitude of disparities depended on vaccination among White beneficiaries
  - From the most rural to most urban counties, proportion of White individuals boosted increased monotonically from 61 to 70%
    - But the proportion of vaccinated Black individuals across rural–urban levels varied less (55-59%)

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Part IV: COVID-19 meets influenza

› Am J Prev Med. 2024 Jul;67(1):67-78. doi: 10.1016/j.amepre.2024.02.013. Epub 2024 Feb 23.

COVID-19 and Influenza Vaccine Coadministration Among Older U.S. Adults

Daniel A Harris [1], Preeti Chachlani [2], Kaleen N Hayes [2], Ellen P McCarthy [3], Katherine J Wen [4], Yalin Deng [2], Andrew R Zullo [5], Djeneba Audrey Djibo [6], Cheryl N McMahill-Walraven [6], Renae L Smith-Ray [7], Stefan Gravenstein [8], Vincent Mor [9]

Affiliations + expand

PMID: 38401746 PMCID: PMC11193626 DOI: 10.1016/j.amepre.2024.02.013

Abstract

Introduction: Coadministering COVID-19 and influenza vaccines is recommended by public health authorities and intended to improve uptake and convenience; however, the extent of vaccine coadministration is largely unknown. Investigations into COVID-19 and influenza vaccine coadministration are needed to describe compliance with newer recommendations and to identify potential gaps in the implementation of coadministration.

Methods: A descriptive, repeated cross-sectional study between September 1, 2021 to November 30, 2021 (Period 1) and September 1, 2022 to November 30, 2022 (Period 2) was conducted. This study included community-dwelling Medicare beneficiaries ≥ 66 years who received an mRNA COVID-19 booster vaccine in Periods 1 and 2. The outcome was an influenza vaccine administered on the same day as the COVID-19 vaccine. Adjusted ORs and 99% CIs were estimated using logistic regression to describe the association between beneficiaries' characteristics and vaccine coadministration. Statistical analysis was performed in 2023.

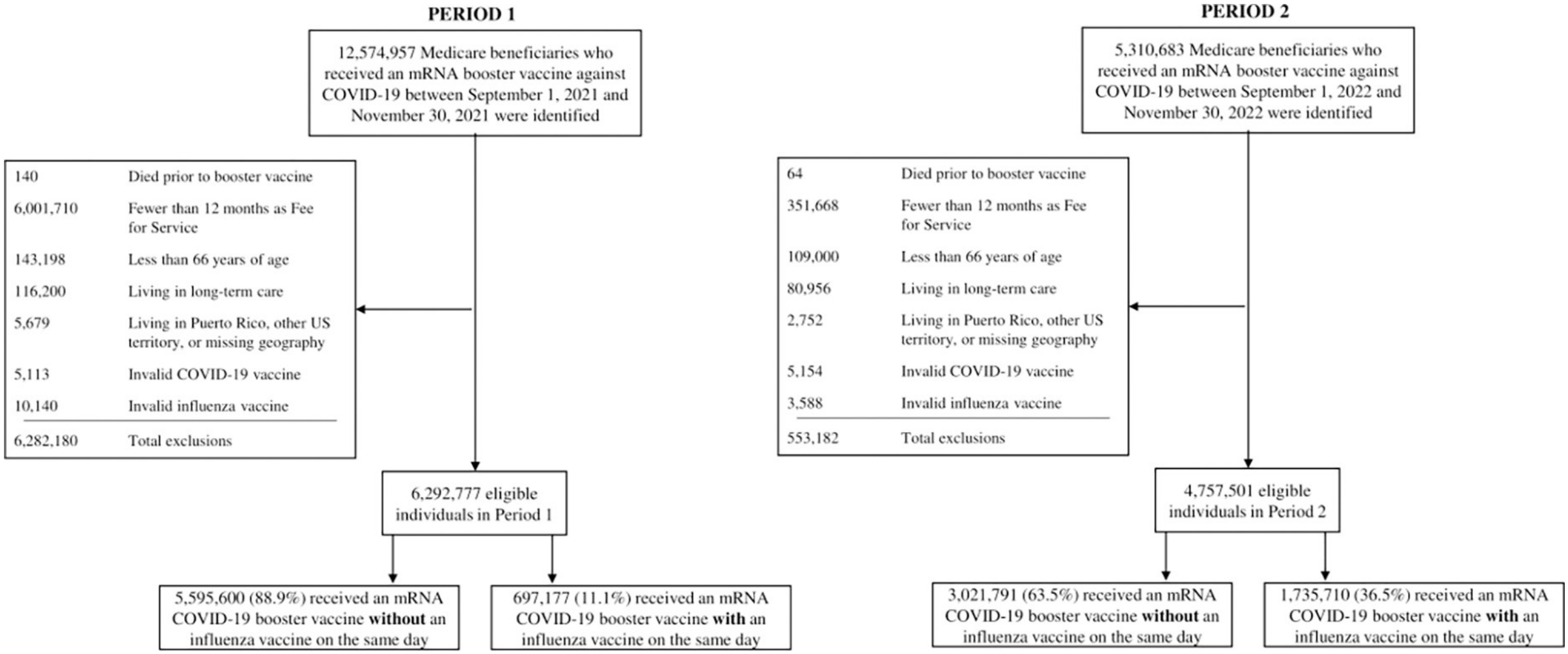
Harris DA, Chachlani P, Hayes KN, McCarthy EP, Wen KJ, Deng Y, Zullo AR, Djibo DA, McMahill-Walraven CN, Smith-Ray RL, Gravenstein S, Mor V. COVID-19 and Influenza Vaccine Coadministration Among Older U.S. Adults. Am J Prev Med. 2024 Jul;67(1):67-78. doi: 10.1016/j.amepre.2024.02.013. Epub 2024 Feb 23. PMID: 38401746; PMCID: PMC11193626.

CDC recommends COVID-19 and influenza vaccine coadministration

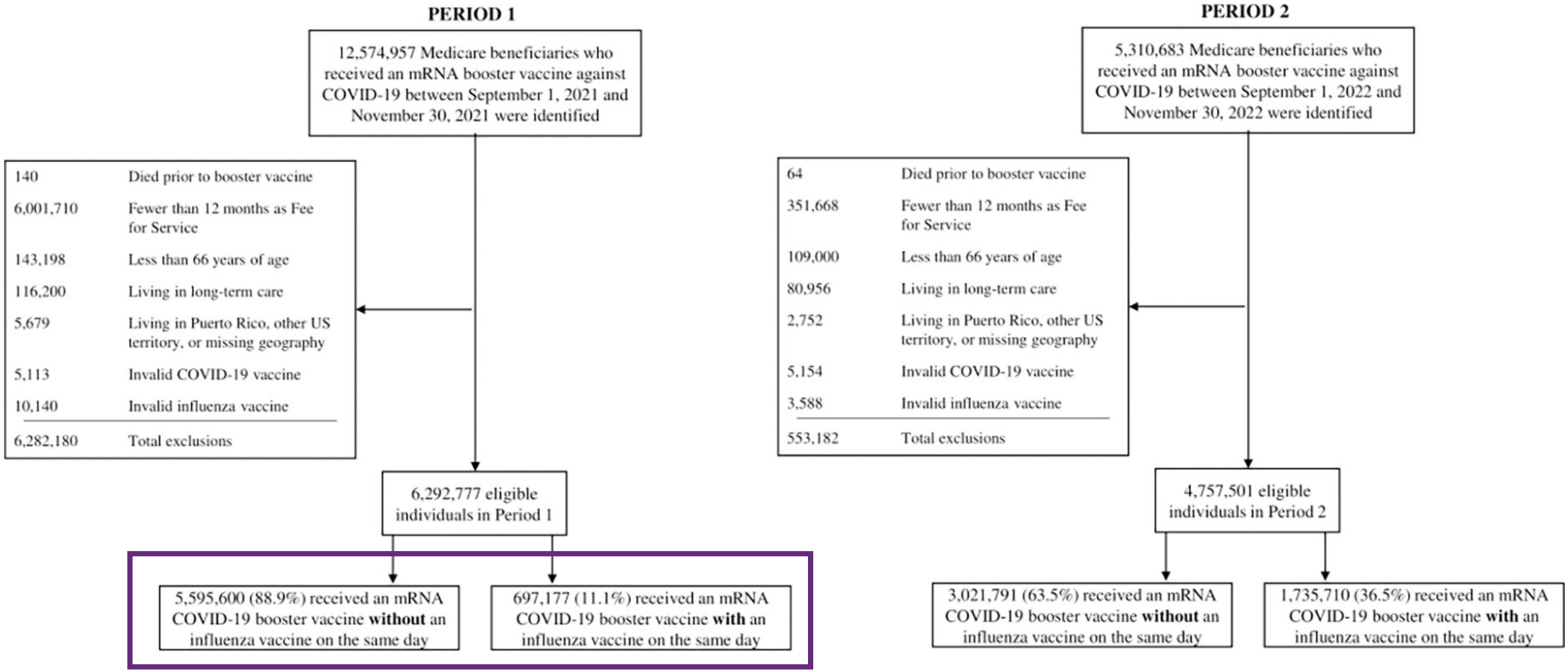
- Annual influenza season provides an opportunity to boost COVID-19 immunity through vaccine co-administration.
- In 2021 and 2022, COVID-19 booster vaccines were available in the fall – aligning with the influenza season in the Northern hemisphere.
- **Research Questions:**

    1. Among older adults receiving a COVID-19 booster vaccine in 2021 and 2022, how many also received an influenza vaccine?
    2. How do those receiving coadministered vaccines differ across clinical, geographic, and demographic characteristics?

Methods


PERIOD 1
12,574,957 Medicare beneficiaries who received an mRNA booster vaccine against COVID-19 between September 1, 2021 and November 30, 2021 were identified
140 Died prior to booster vaccine
6,001,710 Fewer than 12 months as Fee for Service
143,198 Less than 66 years of age
116,200 Living in long-term care
5,679 Living in Puerto Rico, other US territory, or missing geography
5,113 Invalid COVID-19 vaccine
10,140 Invalid influenza vaccine
6,282,180 Total exclusions
6,292,777 eligible individuals in Period 1
5,595,600 (88.9%) received an mRNA COVID-19 booster vaccine without an influenza vaccine on the same day
697,177 (11.1%) received an mRNA COVID-19 booster vaccine with an influenza vaccine on the same day
PERIOD 2
5,310,683 Medicare beneficiaries who received an mRNA booster vaccine against COVID-19 between September 1, 2022 and November 30, 2022 were identified
64 Died prior to booster vaccine
351,668 Fewer than 12 months as Fee for Service
109,000 Less than 66 years of age
80,956 Living in long-term care
2,752 Living in Puerto Rico, other US territory, or missing geography
5,154 Invalid COVID-19 vaccine
3,588 Invalid influenza vaccine
553,182 Total exclusions
4,757,501 eligible individuals in Period 2
3,021,791 (63.5%) received an mRNA COVID-19 booster vaccine without an influenza vaccine on the same day
1,735,710 (36.5%) received an mRNA COVID-19 booster vaccine with an influenza vaccine on the same day

Methods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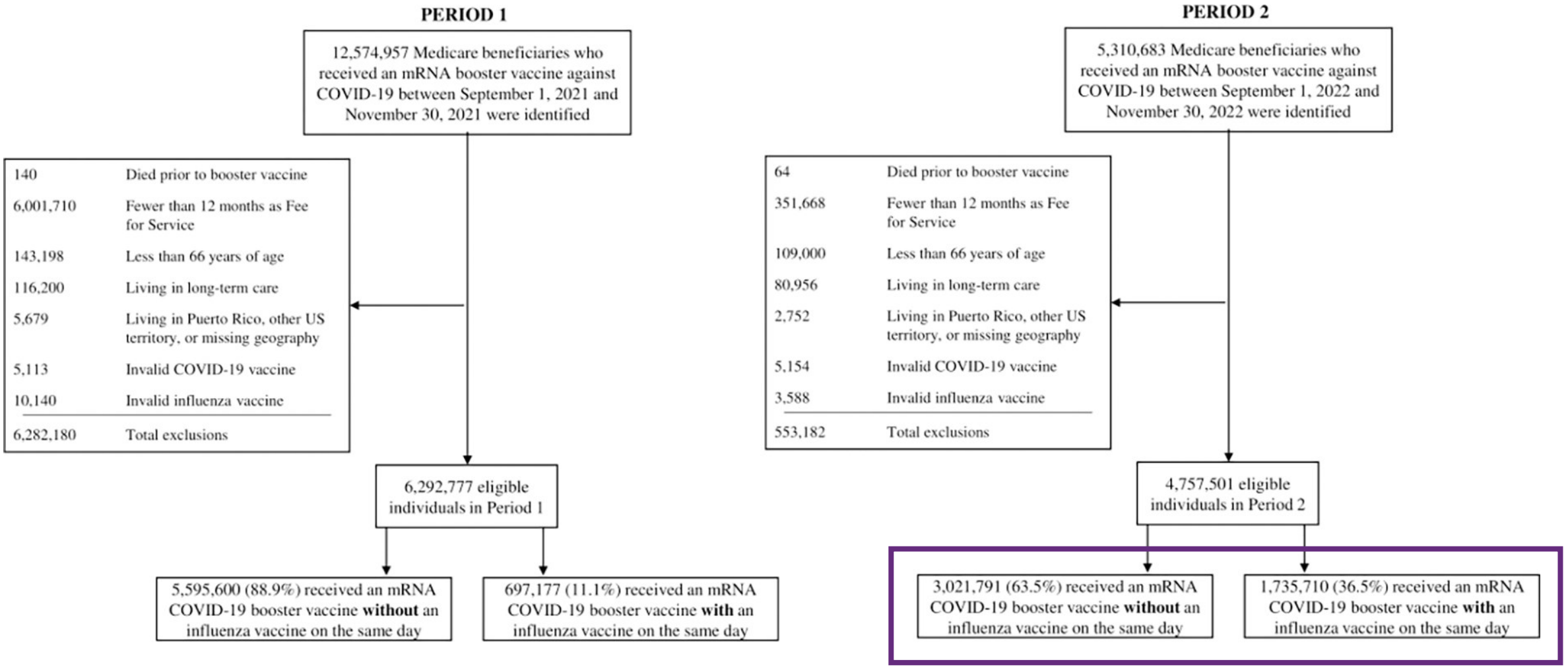
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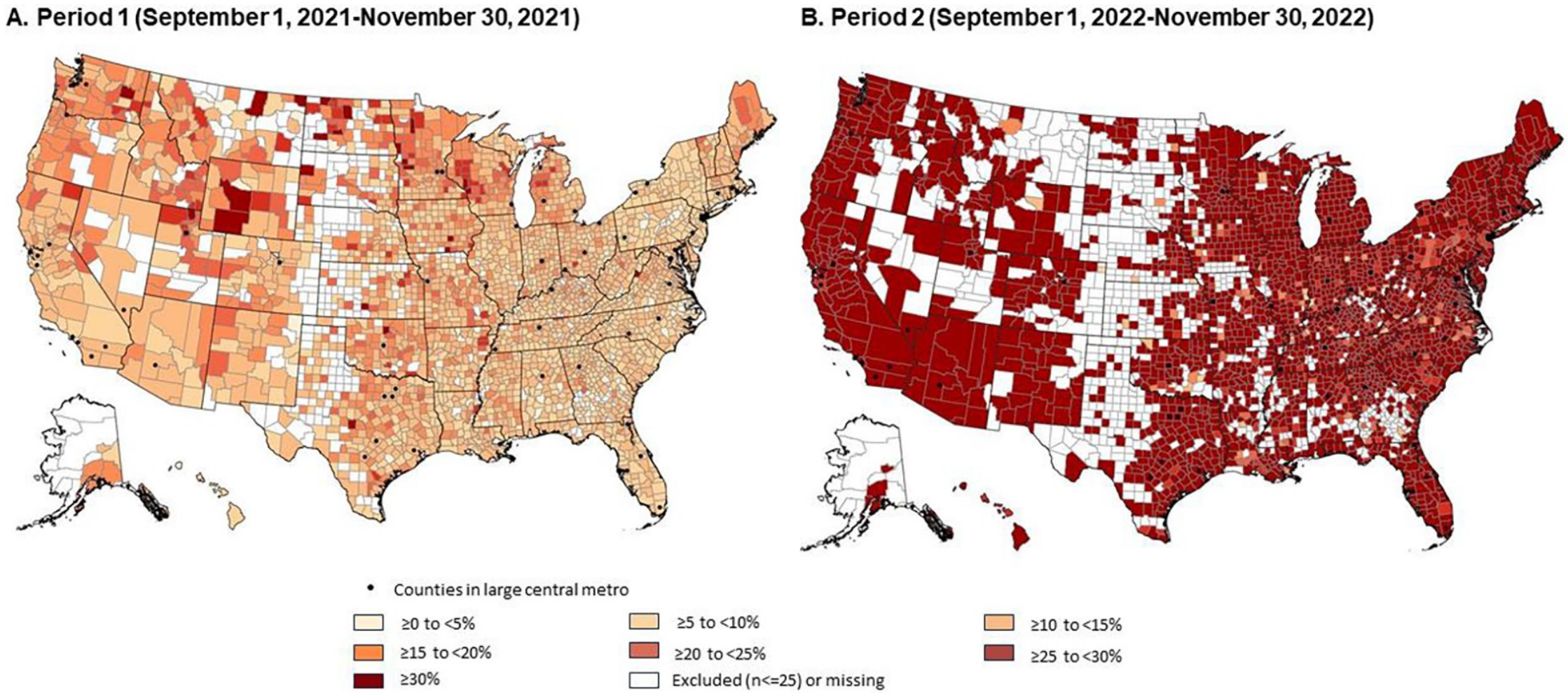
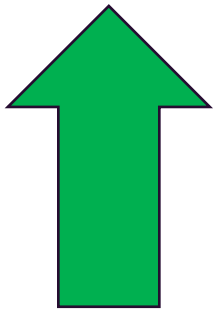
Geographic Findings



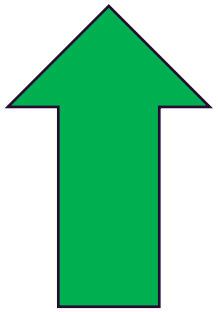
Clinical Findings

40% more likely to be co-administered



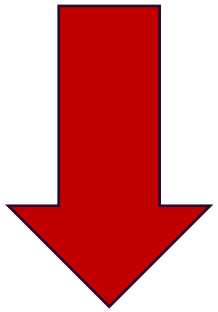
Alzheimer's disease and related dementias

28% more likely to be co-administered



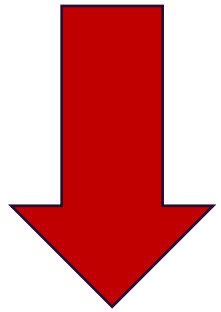
Mental health conditions

9% less likely to be co-administered



Cancer diagnosis

8% less likely to be co-administered



Immune disorder

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Part V: How do the mRNA vaccines compare in safety and effectiveness profile by frailty level?

JAMA Netw Open. 2023 Aug 1;6(8):e2326852. doi: 10.1001/jamanetworkopen.2023.26852.

Comparative Risks of Potential Adverse Events Following COVID-19 mRNA Vaccination Among Older US Adults

Daniel A Harris [1 2], Kaleen N Hayes [1 2], Andrew R Zullo [1 2 3], Vincent Mor [1 2 4], Preeti Chachlani [1 2], Yalin Deng [1 2], Ellen P McCarthy [5 6], Djeneba Audrey Djibo [7], Cheryl N McMahill-Walraven [7], Stefan Gravenstein [1 2 8]

Affiliations + expand

PMID: 37531110 PMCID: PMC10398407 DOI: 10.1001/jamanetworkopen.2023.26852

Abstract

Importance: Head-to-head safety comparisons of the mRNA vaccines for SARS-CoV-2 are needed for decision making; however, current evidence generalizes poorly to older adults, lacks sufficient adjustment, and inadequately captures events shortly after vaccination. Additionally, no studies to date have explored potential variation in comparative vaccine safety across subgroups with frailty or an increased risk of adverse events, information that would be useful for tailoring clinical decisions.

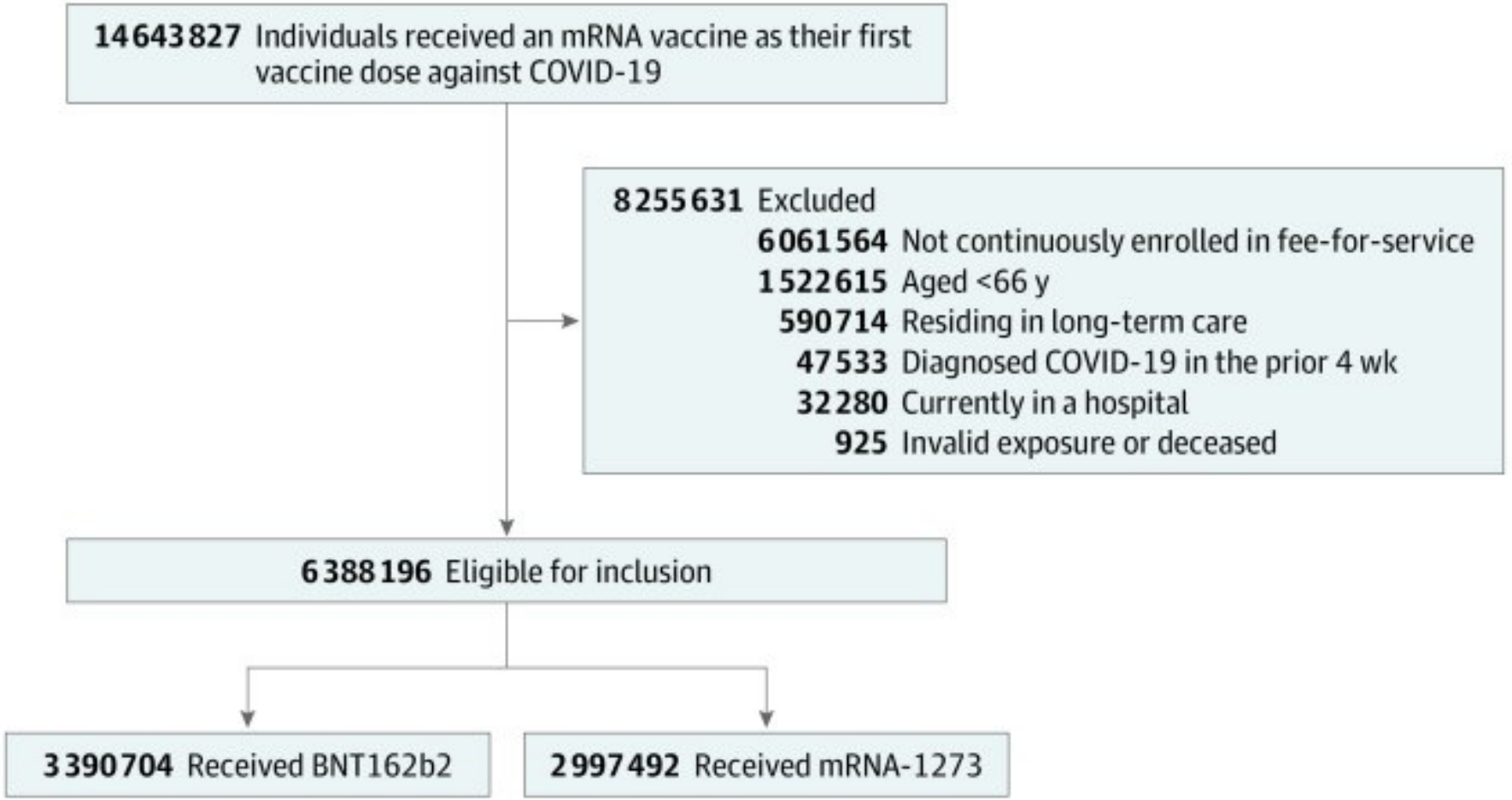
Objective: To compare the risk of adverse events between mRNA vaccines for COVID-19 (mRNA-1273 and BNT162b2) overall, by frailty level, and by prior history of the adverse events of interest.

Harris DA, Hayes KN, Zullo AR, Mor V, Chachlani P, Deng Y, McCarthy EP, Djibo DA, McMahill-Walraven CN, Gravenstein S. Comparative Risks of Potential Adverse Events Following COVID-19 mRNA Vaccination Among Older US Adults. JAMA Netw Open. 2023 Aug 1;6(8):e2326852. doi: 10.1001/jamanetworkopen.2023.26852. PMID: 37531110; PMCID: PMC10398407.

COVID-19 vaccines are safe and effective

- Greater frailty can modify vaccine response via immunosenence and other physiological mechanisms.
- mRNA vaccines are very similar but elicit slightly different immune cascades.
- Initial vaccine series differed in dose with Moderna > Pfizer.
- **Research questions:**
    1. What is the comparative safety and effectiveness of the mRNA vaccine primary series?
    2. Does frailty modify comparative safety/effectiveness profiles?

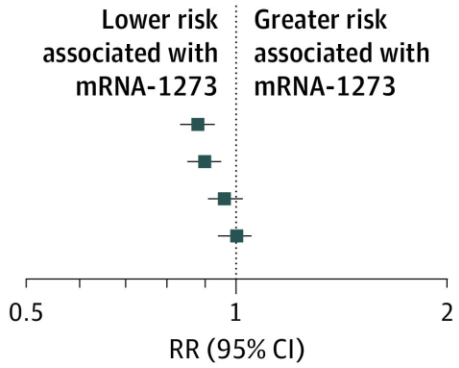
Methods


14643827 Individuals received an mRNA vaccine as their first vaccine dose against COVID-19
8255631 Excluded
6061564 Not continuously enrolled in fee-for-service
1522615 Aged <66 y
590714 Residing in long-term care
47533 Diagnosed COVID-19 in the prior 4 wk
32280 Currently in a hospital
925 Invalid exposure or deceased
6388196 Eligible for inclusion
3390704 Received BNT162b2
2997492 Received mRNA-1273

“Safety” findings

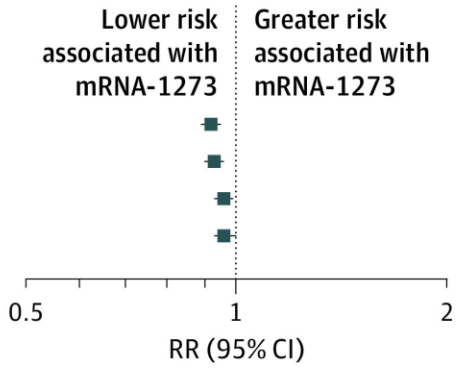
A Acute myocardial infarction

Model	RR (95% CI)
1	0.88 (0.83-0.93)
2	0.90 (0.85-0.95)
3	0.96 (0.91-1.02)
4	1.00 (0.94-1.05)



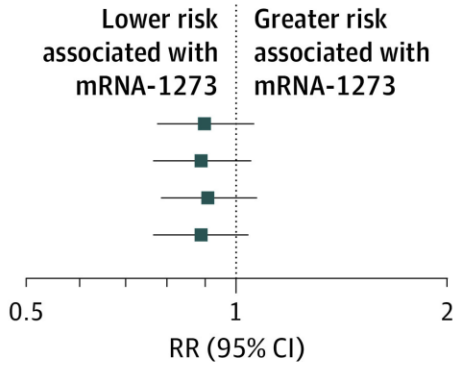
B Pulmonary embolism

Model	RR (95% CI)
1	0.92 (0.89-0.95)
2	0.93 (0.90-0.96)
3	0.96 (0.93-0.99)
4	0.96 (0.93-1.00)



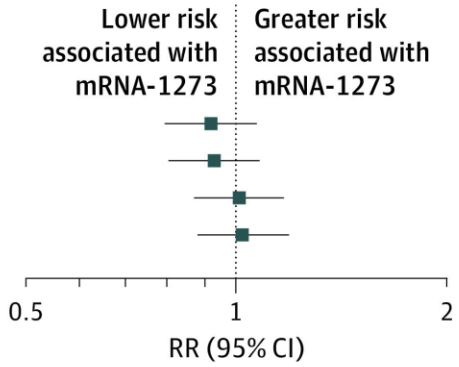
C Myocarditis or percarditis

Model	RR (95% CI)
1	0.90 (0.77-1.06)
2	0.89 (0.76-1.05)
3	0.91 (0.78-1.07)
4	0.89 (0.76-1.04)



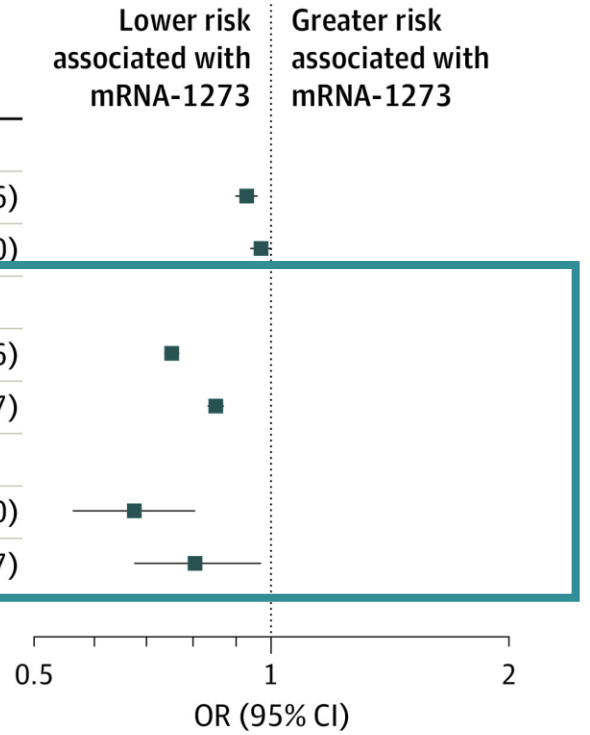
D Hemorrhagic stroke

Model	RR (95% CI)
1	0.92 (0.79-1.07)
2	0.93 (0.80-1.08)
3	1.01 (0.87-1.17)
4	1.02 (0.88-1.19)



Effectiveness findings

Diagnosis	No. of individuals BNT162b2	No. of individuals mRNA-1273	No. of events BNT162b2	No. of events mRNA-1273	OR (95% CI)
Pulmonary embolism alone	3 390 685	2 997 474	7849	6442	
Model 1 (unadjusted)					0.93 (0.90-0.96)
Model 4 (fully adjusted)					0.97 (0.94-1.00)
Diagnosed COVID-19 alone	3 390 685	2 997 474	20 208	13 376	
Model 1 (unadjusted)					0.75 (0.73-0.76)
Model 4 (fully adjusted)					0.85 (0.83-0.87)
Pulmonary embolism and diagnosed COVID-19	3 390 685	2 997 474	313	186	
Model 1 (unadjusted)					0.67 (0.56-0.80)
Model 4 (fully adjusted)					0.80 (0.67-0.97)



Effectiveness findings

Diagnosis	No. of individuals		No. of events		OR (95% CI)
	BNT162b2	mRNA-1273	BNT162b2	mRNA-1273	
Pulmonary embolism alone	3 390 685	2 997 474	7849	6442	
Model 1 (unadjusted)					0.93 (0.90-0.96)
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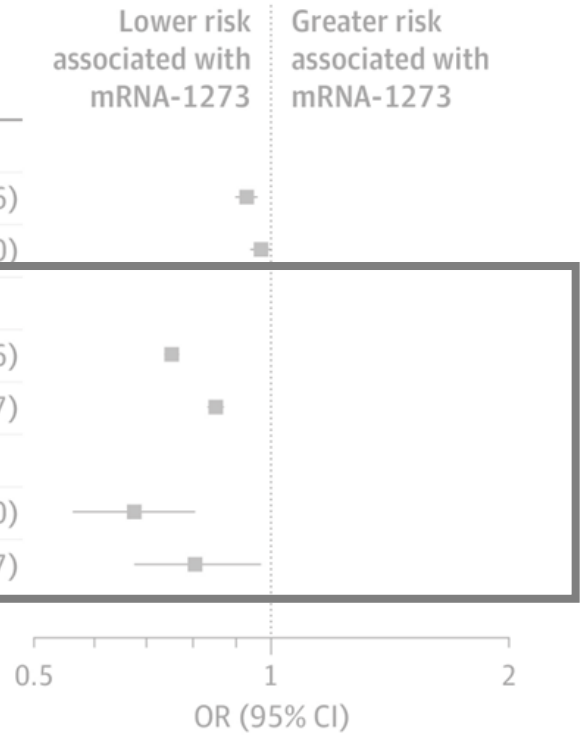

The mRNA-1273 vaccine was associated with a lower risk of COVID-19 after full adjustment (RR, 0.86 [95% CI, 0.83-0.87]); this association was attenuated in individuals categorized as frail (RR, 0.94 [95% CI, 0.89-0.99])

Lessons learned from working with industry partners

- Your partners will have many competing priorities
  - Studies that align with current priorities of the company are most likely to be seen through on their end
- Leadership and other roles change frequently
  - Documentation is imperative
  - Changing strategies can affect your research
    - A fast pace can help avoid sunk costs
- Every partner is different!

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Questions?

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