Interim Utilization Results from a Post-Approval Safety Study of Pfizer-BioNTech Monovalent COVID-19 Vaccine in the United States

Conflict of Interest: *This study was funded by Pfizer, Inc. Some co-authors on this abstract are employed at organizations which conduct work for government and private organizations, including Pfizer, Inc. and other pharmaceutical companies.*

Sophie E. Mayer[*1], Alison Kawai[*2], Candace C. Fuller[1], Anna A. Agan[1], Sapna Rao[2], Nana Koram[3], Brian Calingaert[2], James Marshall[1], John G. Connolly[1], Erick Moyneur[4], Aziza Jamal-Allial[5], Jeffrey Brown[1,6], Jillian Burk[1], Andrea Chomistek[7], Kimberly Daniels[5], Katherine Dea[4], Terese DeFor[8], Brandon Diessner[7], Djeneba Audrey Djibo[9], Stephen Ezzy[7], Rebecca Hawrusik[1], Catherine B. Johannes[2], Katie Kendrick[3], J. Bradley Layton[2], Qianli Ma[10], Xiaodan (Melody) Mai[1], Michael Mack[5], Pamala A. Pawloski[8], Juliane S. Reynolds[1], Mano Selvan[10], Vaibhav Sharma[9], Joy Vetter[7], Cheryl N. McMahill-Walraven[9], Richard Platt[†1], Alicia Gilsenan[†2] [*]Co-lead authors [†]Co-senior authors

Introduction

- A comparative safety study of Pfizer-BioNTech original monovalent COVID-19 vaccine (BNT162b2) is being conducted in the United States (US)
- This interim analysis evaluated COVID-19 vaccine utilization using data from 5 commercial insurers participating in the Sentinel System supplemented with immunization information system (IIS) registry data, where available

Objectives

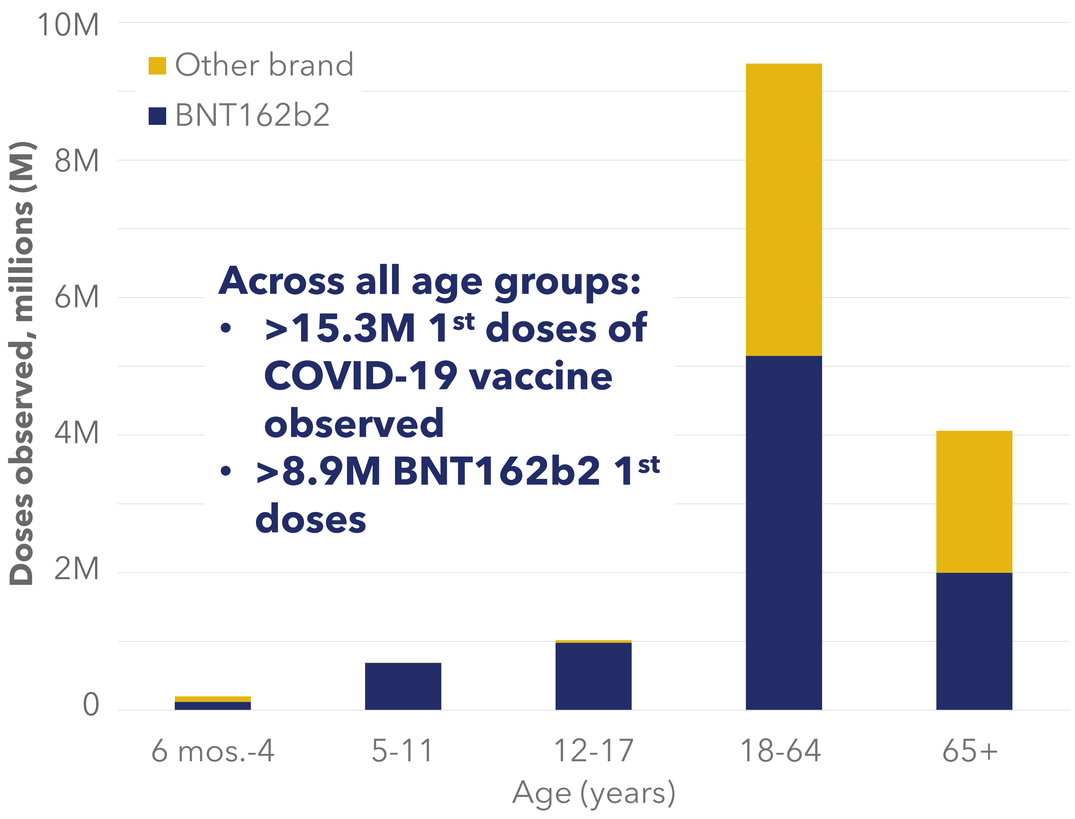
- To assess receipt of at least 1 (≥1) COVID-19 vaccine (any brand; excludes bivalent mRNA vaccines) and of ≥1 BNT162b2 dose
- To describe subsequent doses and their timing among BNT162b2 vaccinees

Methods

- **Period:** December 2020 - July 2023
- **Exposures:** Dispensing, procedure, or CDC vaccine administered (CVX) codes
- **Population:** Individuals were enrolled with medical and drug coverage for at least 1 day during the study period. For analyses of subsequent BNT162b2 doses and cumulative incidence, individuals were also required to be 1) eligible to receive COVID-19 vaccination based on age per emergency use authorization (EUA) and 2) enrolled since earliest eligibility to be vaccinated
- **Analyses:**
  - We assessed BNT162b2 vaccines received prior to EUA during the study period for those aged <16 years
  - We described COVID-19 vaccines observed ≥4 days apart after 1 or 2 BNT162b2 doses (results reported separately) and timing of 2nd and 3rd doses in these populations
  - We estimated cumulative incidence of ≥1 COVID-19 vaccine and of ≥1 BNT162b2 dose using the Aalen-Johansen estimator. Competing events were mortality, receipt of bivalent vaccines, and—for BNT162b2 analyses—receipt of other/unknown brand COVID-19 vaccines or of BNT162b2 >4 days before recommended minimum dose spacing. Estimates were compared to those from a prior monitoring query (MQ) without IIS data

Results

Figure 1. BNT162b2 and other brand COVID-19 vaccines as an individual's 1st COVID-19 vaccine, by age group



Dose receipt, brands and timing

- <0.1% of BNT162b2 doses were received outside EUA-authorized age groups over the study period
- 83% of 1st dose BNT162b2 vaccinees received a 2nd dose of COVID-19 vaccine
  - 99% of 2nd doses were BNT162b2
  - <1% were too early (4-16 days after dose 1)
- 49% of 2-dose BNT162b2 vaccinees received a 3rd dose of COVID-19 vaccine
  - 91% of 3rd doses were BNT162b2

Figure 2. Receipt of ≥1 COVID-19 vaccine & ≥1, ≥2 or ≥3 dose(s) of BNT162b2

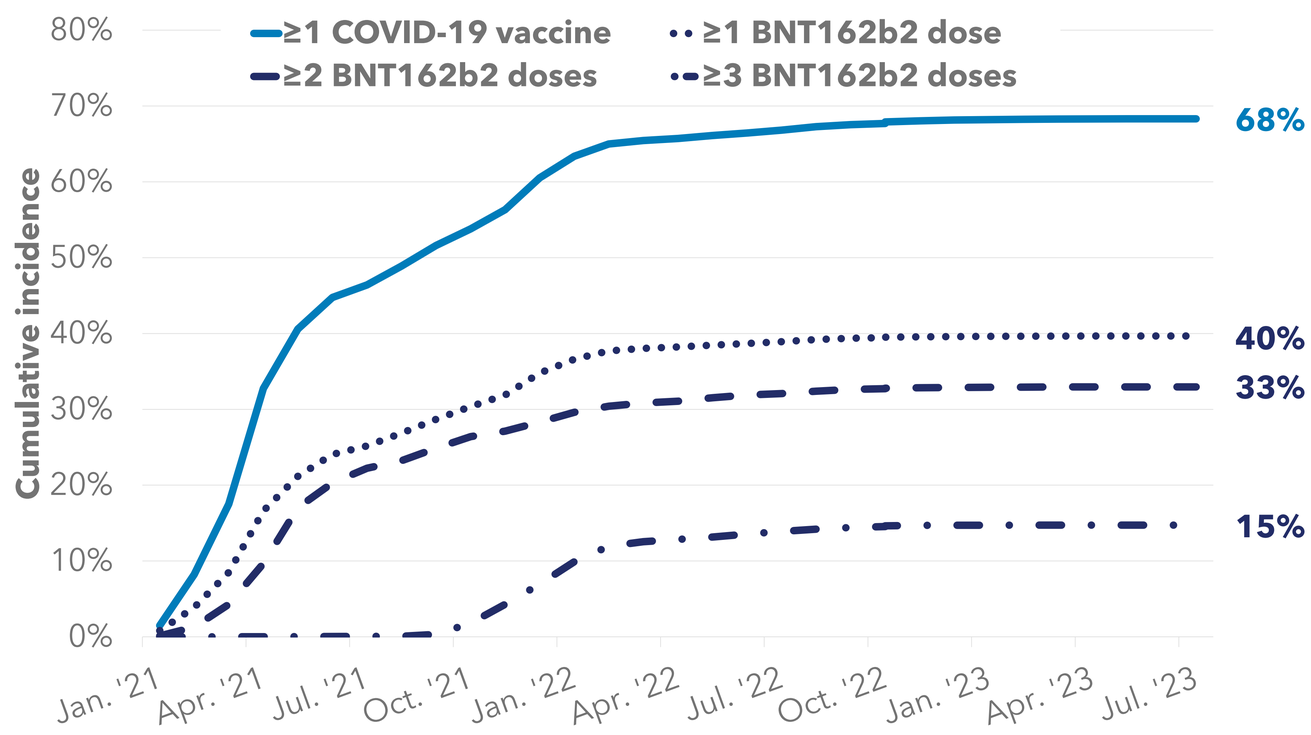
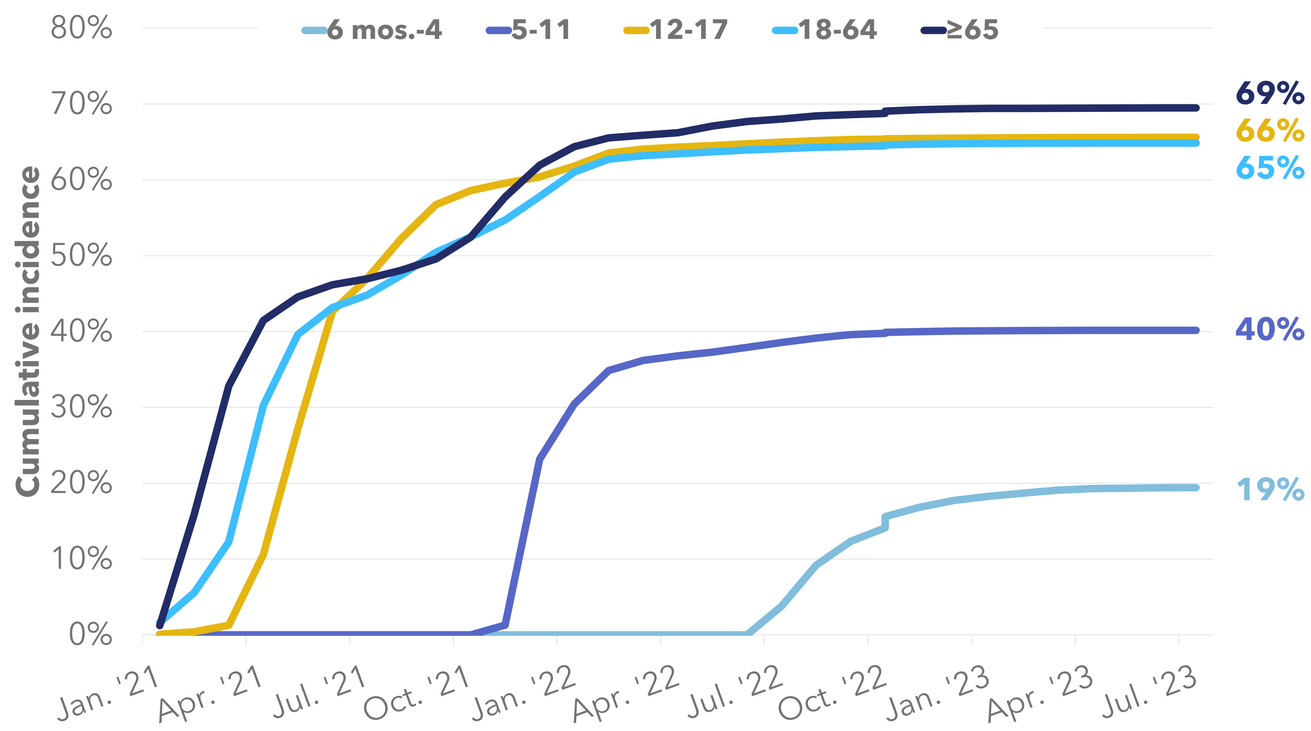


Figure 3. Receipt of ≥1 COVID-19 vaccine dose, by age group (years)



Cumulative incidence statistics

- ≥1 COVID-19 vaccine dose (any brand): 68%
- ≥1, ≥2, and ≥3 BNT162b2 dose(s): 40%; 33%; 15%
- Incorporating IIS data resulted in 1.7x higher vaccine coverage (≥1 dose) through Oct. 2021 than in the MQ without IIS data

Conclusions

- Interim analysis achieved BNT162b2-exposed sample sizes needed to support final comparative safety analyses
- COVID-19 vaccine coverage was improved through incorporation of available IIS registry data. The moderate vaccine coverage supports the use of unvaccinated comparators for the final cohort safety analyses
- Most BNT162b2 vaccines were received according to age-based authorization and dose spacing recommendations

Author affiliations

[1]Harvard Pilgrim Health Care Institute
[2]RTI Health Solutions
[3]Pfizer, Inc.
[4]Statlog
[5]Carelon Research, Inc.
[6]TriNetX
[7]Optum Epidemiology
[8]HealthPartners
[9]CVS Health
[10]Humana Healthcare Research, Inc.

Acknowledgements

- For study support: Kim Wideman[2], Annemarie Kline[9], Carla M. Brannan[9], Ana M. Martinez-Baquero[9]
- Many thanks are due to the Research Partners who provided data used in the analysis