IIS Supplement Health Insurance Claims for Vaccine Safety & Effectiveness

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Disclosure Statement

The views expressed here are those of the authors and not necessarily those of the U.S. Food and Drug Administration.

I have no personal or financial relationships relevant to this presentation to disclose.

Outline

CBER Active Surveillance Program

IIS-Claims Data Linkage

Regulatory and Public Health Impact

Conclusion

FDA CBER Active Surveillance Program

Through multiple contracts and partnerships, CBER works with a diverse group of epidemiologists, clinicians and data scientists to conduct active surveillance studies.

BEST: Biologics Effectiveness and Safety

Federal Partner and BEST Initiative Data Sources

Data Source*	Database Type	Number of Patients Covered (Millions)	Time Period Covered
CMS - Medicare	Claims	105	2005 - present
Blue Health Intelligence	Claims	46	2012 - present
Optum - Adjudicated	Claims	66	1993 - present
Optum - Pre adjudicated	Claims	30	2017 – present
Carelon Research	Claims	69	2010 – present
CVS Health	Claims	37	2018 – present
Optum EHR	EHR	102	2007 - 2020
Optum Integrated Claims - EHR	Linked EHR Claims	25	2007 - 2020

*Data lag varies for different databases.

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IIS Partnership with FDA: Flow of Data

IIS

Data Partners

FDA/CBER BEST System

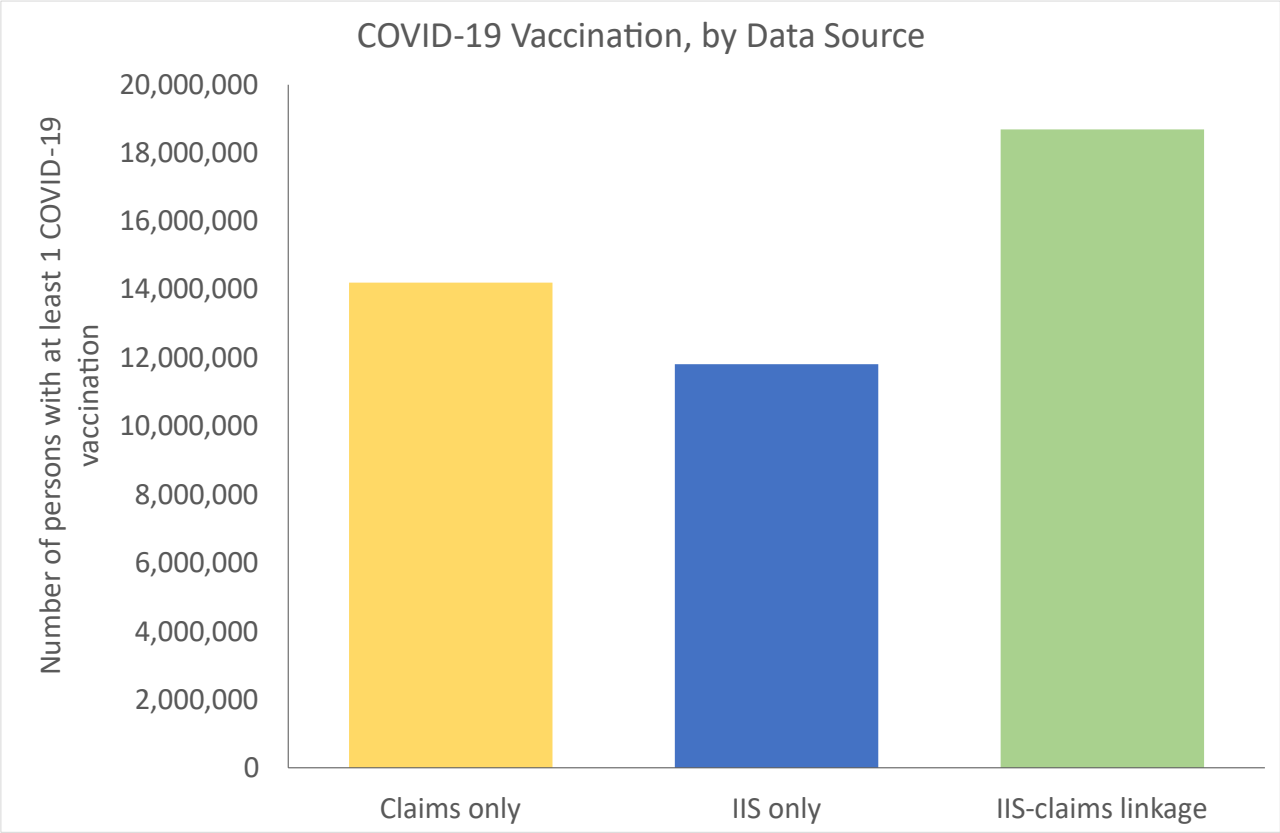
IIS share vaccination data on health plan members with **BEST health plan data partners**

Data partners clean, validate, aggregate and analyze linked vaccination and claims data per FDA protocols

Data Partners provide aggregated summary data to **FDA/CBER**, to monitor vaccine safety and effectiveness.

Pandemic Era IIS COVID-19 Vaccination Data Linkage (All DPs)

- Vaccinated rates
  - Claims data alone: 13.5–46.4%
  - IIS—claims linkage: 22.5–65.5%
- Some linkages contributed to as much as 50% increase in immunization data.
- Linkage to IIS decreases COVID-19 vaccine misclassification in studies that rely on claims.



NOTE: Data current as of September 30, 2022
Vaccine totals represent at least 1 COVID-19 vaccination in IIS jurisdictions exchanging data with any BEST DP

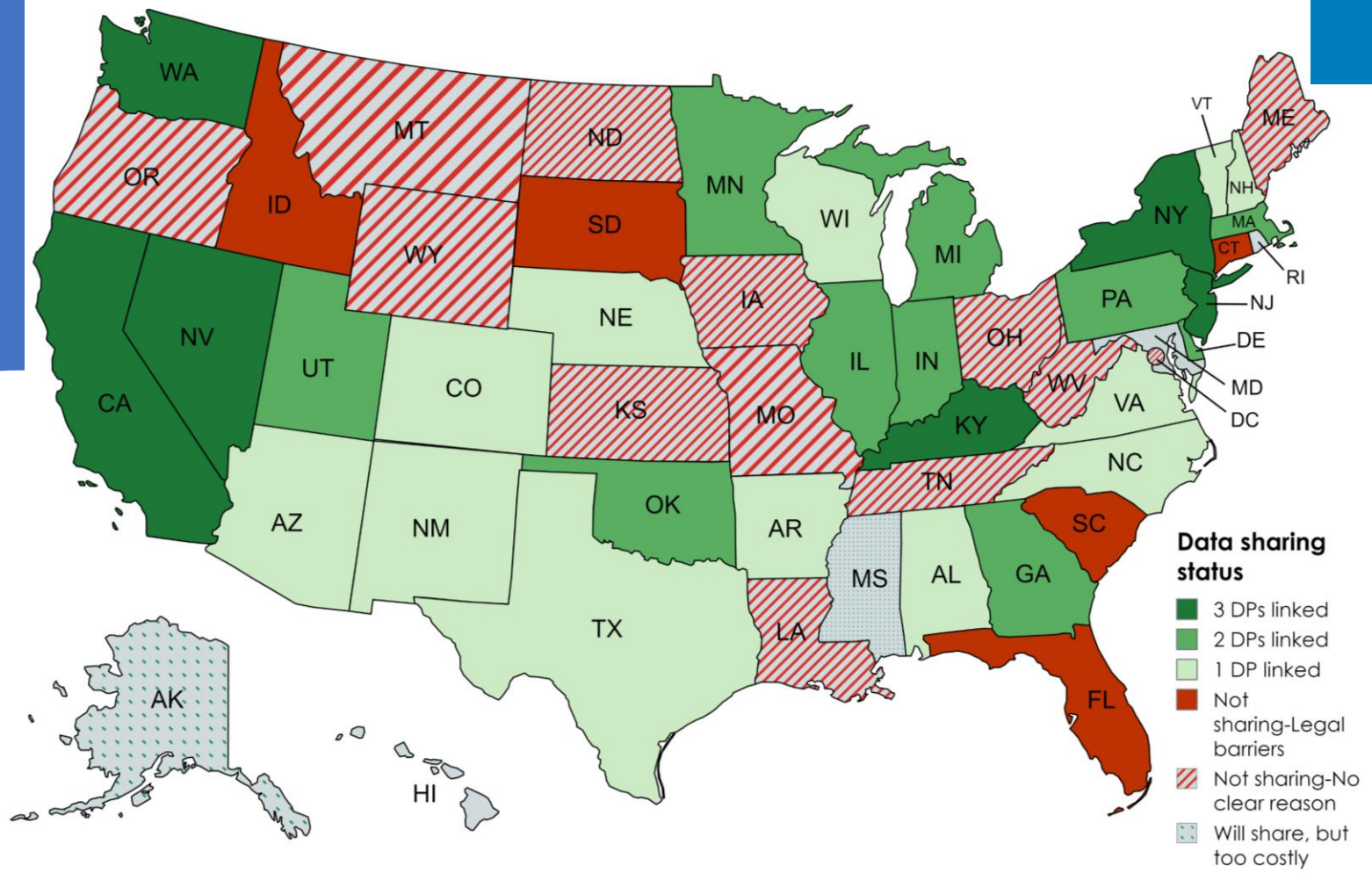
Current IIS Contributions to claims data linkage for vaccination studies (All DPs)

2022–2023 vaccines used to prevent mpox, and 2023–2024 Formula COVID-19 and Influenza vaccines:

Across all DPs with linked IIS jurisdictions

Vaccine	Number of IIS jurisdictions linked to claims	Vaccinations Records Observed in IIS Only	
		%	Range (Min, Max) %
COVID-19 (2023-2024 formulations)	~31	30.4	(5.9, 54.7)
Influenza (2023-2024 formulations)	~20	25.9	(2.4, 47.6)
Mpox	~18	82.3	(48.2, 98.2)

Status of CBER-BEST and Data Partners IIS Jurisdiction Outreach



Note: Sharing data means made at least 1 data linkage/exchange with an FDA DP.

Last updated April 2024

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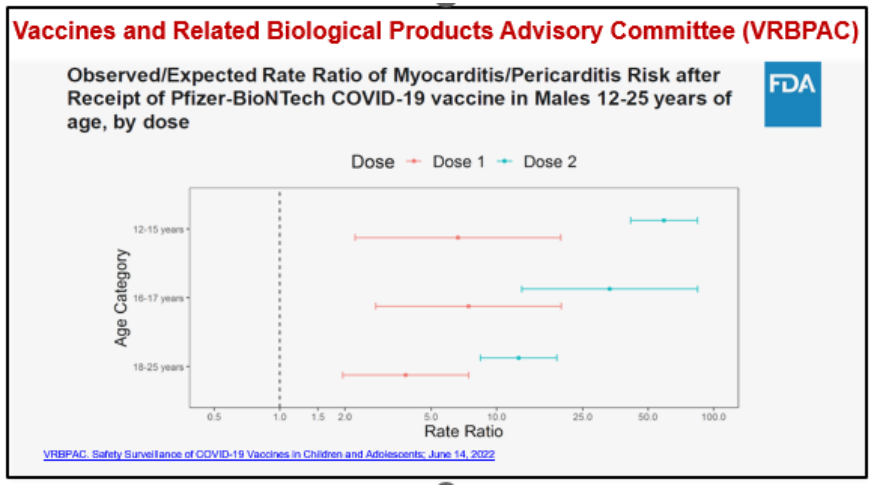
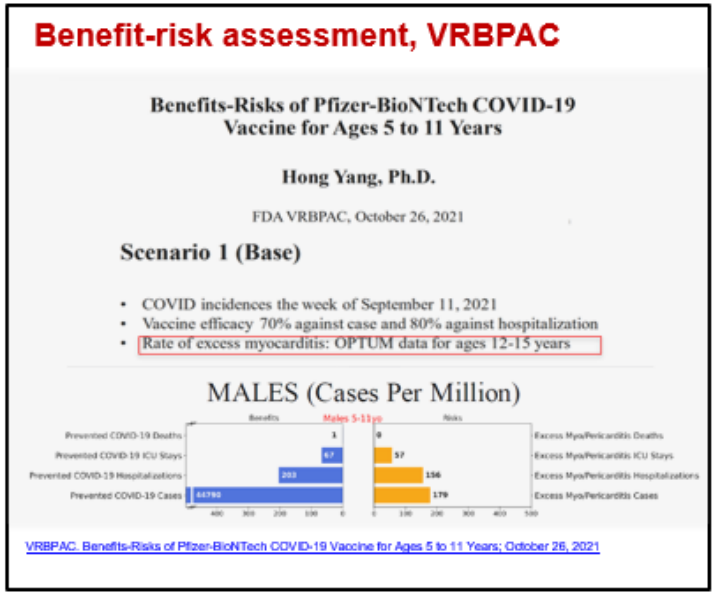
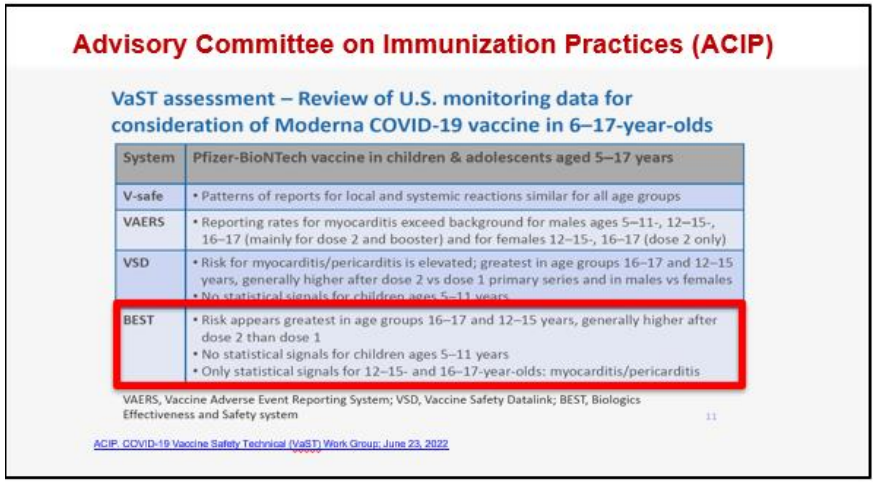
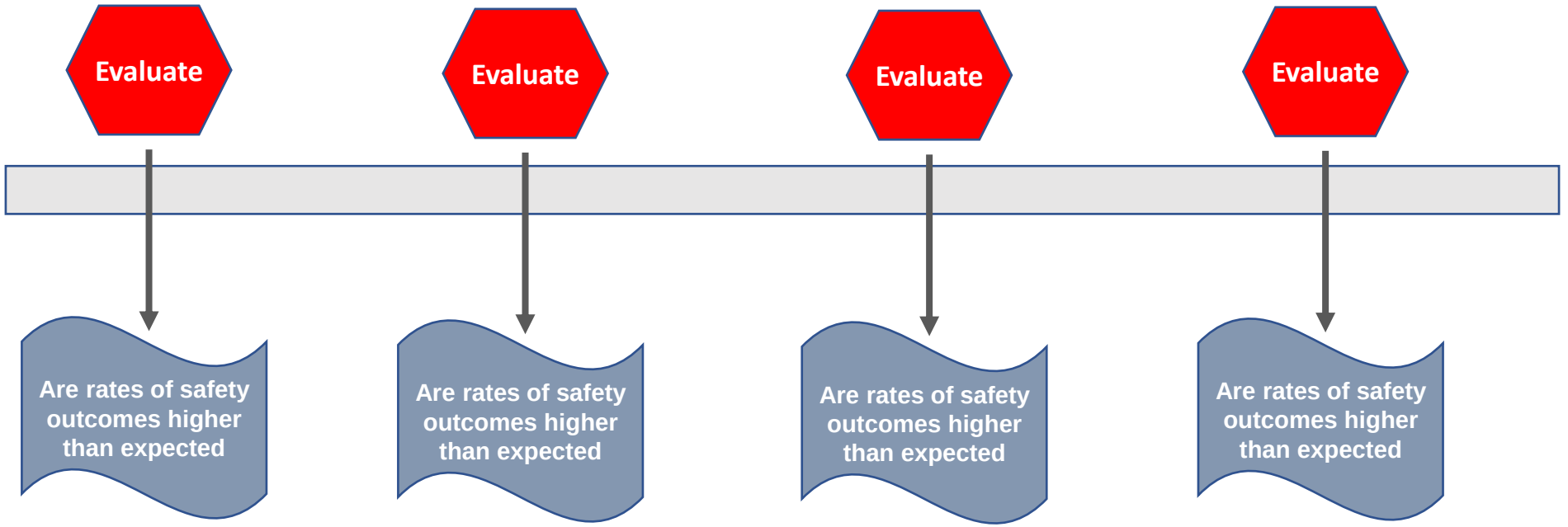


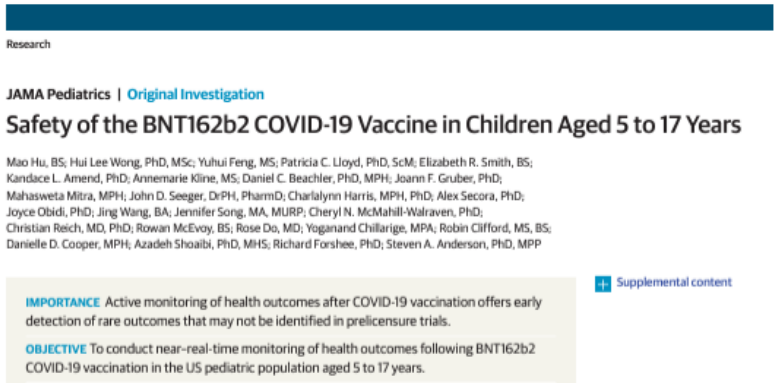




- BEST studies have contributed to EUA and approvals during numerous FDA advisory panels.
- BEST studies provided risk estimates for input in benefit–risk assessment for regulatory decision making.
- As part of the both passive and active US surveillance system, BEST studies contribute to the advisory committee that determines the public health policies regarding vaccines in the US.

COVID-19 Vaccine Safety Surveillance





Research

JAMA Pediatrics | Original Investigation

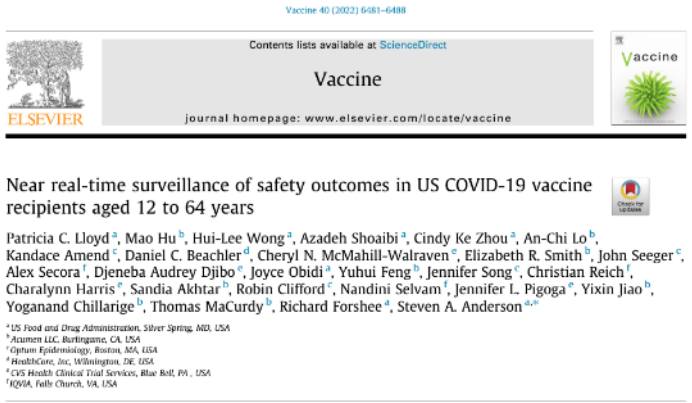
Safety of the BNT162b2 COVID-19 Vaccine in Children Aged 5 to 17 Years

Mao Hu, BS; Hui Lee Wong, PhD, MSc; Yuhui Feng, MS; Patricia C. Lloyd, PhD, ScM; Elizabeth R. Smith, BS; Kandace L. Amend, PhD; Annemarie Kline, MS; Daniel C. Beachler, PhD, MPH; Joann F. Gruber, PhD; Mahasweta Mitra, MPH; John D. Seeger, DrPH, PharmD; Charlalynn Harris, MPH, PhD; Alex Secora, PhD; Joyce Obidi, PhD; Jing Wang, BA; Jennifer Song, MA, MURP; Cheryl N. McMahill-Walraven, PhD; Christian Reich, MD, PhD; Rowan McEvoy, BS; Rose Do, MD; Yoganand Chillarige, MPA; Robin Clifford, MS, BS; Danielle D. Cooper, MPH; Azadeh Shoaibi, PhD, MHS; Richard Forshee, PhD; Steven A. Anderson, PhD, MPP

Supplemental content

IMPORTANCE Active monitoring of health outcomes after COVID-19 vaccination offers early detection of rare outcomes that may not be identified in prelicensure trials.

OBJECTIVE To conduct near-real-time monitoring of health outcomes following BNT162b2 COVID-19 vaccination in the US pediatric population aged 5 to 17 years.



Vaccine 40 (2022) 6481–6488

Contents lists available at ScienceDirect

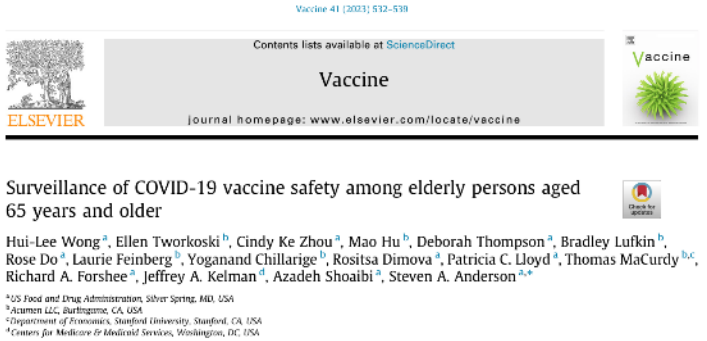
Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Near real-time surveillance of safety outcomes in US COVID-19 vaccine recipients aged 12 to 64 years

Patricia C. Lloyd [a], Mao Hu [b], Hui-Lee Wong [a], Azadeh Shoaibi [a], Cindy Ke Zhou [a], An-Chi Lo [b], Kandace Amend [c], Daniel C. Beachler [d], Cheryl N. McMahill-Walraven [e], Elizabeth R. Smith [b], John Seeger [c], Alex Secora [f], Djeneba Audrey Djibo [c], Joyce Obidi [a], Yuhui Feng [b], Jennifer Song [c], Christian Reich [f], Charalynn Harris [e], Sandia Akhtar [b], Robin Clifford [c], Nandini Selvam [f], Jennifer L. Pigoga [e], Yixin Jiao [b], Yoganand Chillarige [b], Thomas MaCurdy [b], Richard Forshee [a], Steven A. Anderson [a,*]

[a] US Food and Drug Administration, Silver Spring, MD, USA
[b] Acumen LLC, Burlingame, CA, USA
[c] Optum Epidemiology, Boston, MA, USA
[d] HealthCore, Inc, Wilmington, DE, USA
[e] CVS Health Clinical Trial Services, Blue Bell, PA, USA
[f] IQVIA, Falls Church, VA, USA



Vaccine 41 (2023) 532–539

Contents lists available at ScienceDirect

Vaccine

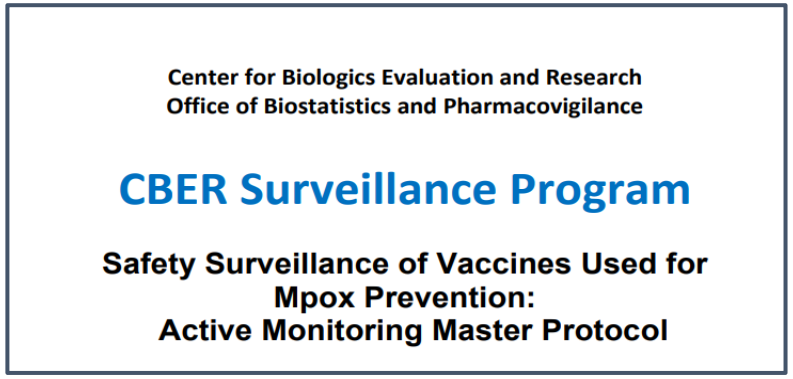
journal homepage: www.elsevier.com/locate/vaccine

Surveillance of COVID-19 vaccine safety among elderly persons aged 65 years and older

Hui-Lee Wong [a], Ellen Tworkoski [b], Cindy Ke Zhou [a], Mao Hu [b], Deborah Thompson [a], Bradley Lufkin [b], Rose Do [a], Laurie Feinberg [b], Yoganand Chillarige [b], Rositsa Dimova [a], Patricia C. Lloyd [a], Thomas MaCurdy [b,c], Richard A. Forshee [a], Jeffrey A. Kelman [d], Azadeh Shoaibi [a], Steven A. Anderson [a,*]

[a] US Food and Drug Administration, Silver Spring, MD, USA
[b] Acumen LLC, Burlingame, CA, USA
[c] Department of Economics, Stanford University, Stanford, CA, USA
[d] Centers for Medicare & Medicaid Services, Washington, DC, USA

Safety Surveillance of Vaccines used to prevent Mpox



- IIS data were essential to measure exposure for JYNNEOS and ACAM2000.
- Vaccinated in Claims Only ~10% Vaccinated in IIS ~83%
- IIS data were critical to give us the ability to do monitoring.

- A total of 131,888 doses of JYNNEOS or ACAM2000 were administered during May 2022-April 2023, among adults aged 18–64 years
- Most doses administered across all data partners were JYNNEOS (131,513; 99.72% of all doses)
- Of those who received a first JYNNEOS dose (80,812), 62.38% received a second dose overall
- Across all data partners, the peak number of first and second JYNNEOS doses occurred in August and September 2022
- Most JYNNEOS doses were administered to males (94.26%), those aged 25–34 years old (35.20%), and those who lived in urban areas (98.80%)

Public Health Impact

The linkage of IIS data to commercial claims data allowed for a substantially increased capture of vaccines used to prevent mpox, which facilitated the characterization of the vaccinated population during the 2022 mpox outbreak in the US.

We were able to observe trends in doses and characteristics of the vaccinated population.

This work was part of the public health response to the mpox outbreak.

Data from this work provide further evidence of the importance of incorporating IIS data when vaccines are administered through local, state, and territorial health departments as part of an outbreak response.

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- BEST Initiative contributes to FDA CBER's mission to ensure biologic products safety and effectiveness through active surveillance.

- IIS data complements vaccination claims data adding up to 30% more immunization information for 2023-2024 COVID-19 vaccinations, ~26% for 2023-2024 flu vaccinations, and ~83% for vaccinations used to prevent mpox. IIS data contributes to timely, evidence-based regulatory decision making.

- Continued and expanded IIS data linkage is needed for BEST to continue generating rapid and comprehensive response to the COVID-19, seasonal influenza, and future outbreaks that require vaccine administration.

BEST Post-market Surveillance Activity

Biologics Effectiveness and Safety (BEST) Initiative

- **ABOUT**
  - BACKGROUND
  - COLLABORATORS
  - PRIVACY & SECURITY
- **DATA & SURVEILLANCE ACTIVITIES**
  - DISTRIBUTED NETWORK AND COMMON DATA MODEL
  - ARTIFICIAL INTELLIGENCE AND NATURAL LANGUAGE PROCESSING
- **COMMUNICATIONS & OUTREACH**
  - ENGAGING STAKEHOLDERS
  - EVENTS
  - PUBLICATIONS & PRESENTATIONS

Study Team

Tainya C. Clarke, PhD MPH MSc[1]; Patricia Lloyd, PhD[1]; Yixin Jiao, MPP[2]; Joann F. Gruber, PhD[1]; Lauren Peetluk, PhD[3]; Lauren Parlett, PhD[4]; Alex Secora, PhD[4]; Vaibhav Sharma, MS[5]; Yoganand Chillarige, MPA[2]; Megan Ketchell[3], Cheryl N. McMahill-Walraven, MSW, PhD[5]; Richard Forshee, PhD[1]; Steven A. Anderson, PhD, MPP[1].

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2. Acumen, LLC.
3. Optum Epidemiology
4. Carelon Research
5. CVS Health

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