Immunization Evaluation and Forecasting during COVID-19

American Immunization Registry Association (AIRA)
National Meeting
April 2022

Agenda

- Background: Evaluations and Forecasts
- Immunization Calculation Engine (ICE)
- COVID-19 ACIP Timeline
- Challenges
- Lessons Learned

Background: Evaluations and Forecasts

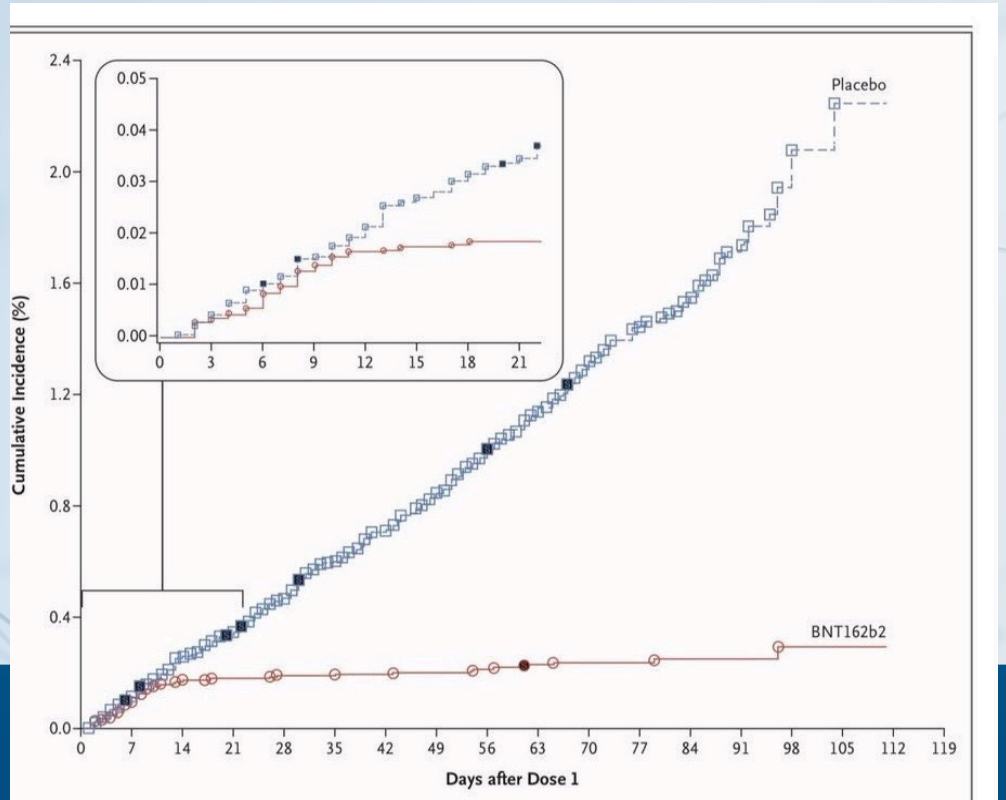
- Evaluation: Was a dose valid or not? If not, why not?
  - Minimum interval from prior dose violated
  - Minimum age violated
  - Live virus interval violated
  - Grace periods
- Forecast: What is recommended next?
  - Repeat doses after invalid doses
  - Completing primary series
  - Booster doses

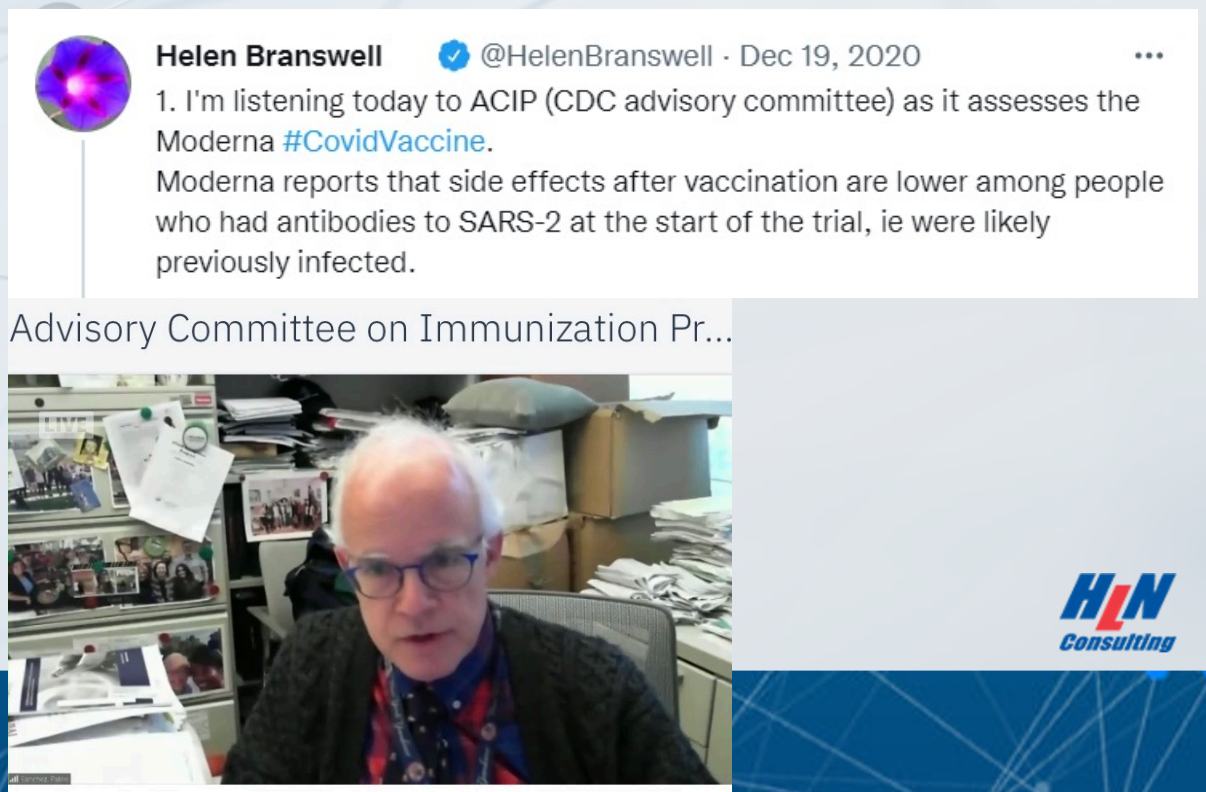
ICE: Immunization Calculation Engine

- Open Source Clinical Decision Support System
- Built on OpenCDS platform for Integration with Health Information Systems – IIS, EHR, PHR
  - Current IIS users include NJ, NYC, MI, RI, VT
- Original ICE collaborators: New York City Citywide Immunization Registry, HLN Consulting, LLC, Alabama Department of Public Health, OpenCDS Team
- Web service interface

COVID-19 ACIP Timeline

- December 12, 2020: Pfizer
- December 19, 2020: Moderna





Coadministration with other vaccines

- Pfizer-BioNTech COVID-19 vaccine should be administered alone with a minimum interval of 14 days before or after administration with any other vaccines
  - Due to lack of data on safety and efficacy of the vaccine administered simultaneously with other vaccines
- If Pfizer-BioNTech COVID-19 vaccine is inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine

Interchangeability with other COVID-19 vaccine products

- Pfizer-BioNTech COVID-19 vaccine not interchangeable with other COVID-19 vaccine products
  - Safety and efficacy of a mixed series has not been evaluated
- Persons initiating series with Pfizer-BioNTech COVID-19 vaccine should complete series with same product
- If two doses of different mRNA COVID-19 vaccine products inadvertently administered, no additional doses of either vaccine recommended at this time
  - Recommendations may be updated as further information becomes available or additional vaccine types authorized

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AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

Hello,

As part of our ongoing commitment to share important decisions and recommendations with you, below is a summary of today's Advisory Committee on Immunization Practices (ACIP) meeting and subsequent vote.

The ACIP met today, December 19, to discuss and vote on recommendations for the Moderna COVID-19 vaccine. The ACIP members received an update on the safety and efficacy data for the Moderna COVID-19 vaccine. The members then used the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach to develop recommendations.

Recommendations

The committee members voted to recommend that "The Moderna COVID-19 vaccine is recommended for persons 18 years of age and older in the U.S. population under the FDA's Emergency Use Authorization."

The recommendation should be implemented in the context of current CDC allocation recommendations.

Impact on IIS

The Clinical Decision Support for Immunization (CDSi) rules are currently being developed and reviewed. The draft version will be released soon, and the official version will become available shortly after publication of the *Morbidity and Mortality Weekly Report*.

The next scheduled ACIP meeting is tomorrow, **December 20 from 11 a.m. to 4:30 p.m. ET**.

HLN Consulting

COVID-19 ACIP Timeline (continued)

- February 2021: Janssen
- April 2021: Janssen pause; Janssen resumption
- May 2021: Pfizer for 12-15 year olds
- August 2021: mRNA additional dose; Pfizer FDA full approval
- September 2021: Pfizer booster
- October 2021: Booster dose expansion
- November 2021: Pfizer for 5-11 year olds; booster expansion
- December 2021: mRNA over Janssen
- January 2022: Booster for 12-15 year olds
- February 2022: Moderna full approval
- Clinical considerations updated throughout

Lack of Guidelines During Early Phases

- Absolute minimum intervals
- Overdue intervals
- Repeat doses
- Mixed vaccines & unspecified vaccines
- Age cutoffs
- Emergency Use Authorization vs. CDC clinical guidance

Adoption of New Guidelines Over Time

- Absolute minimum intervals
- Age groups
- Pause / resumption
- Risk groups
- Retroactive application of new guidelines
- Non-US / WHO approved

Clinical vs. "Administrative" Status

- Fully vaccinated
- Up-to-date
- How could one be fully vaccinated if 2nd dose was given prior to the grace period and ACIP did not recommend any further doses?
- Are school entry rules similar to COVID work/school/venue entry rules?
- Desire to recommend booster doses but also convey "series complete"

Sending Evaluations & Recommendations Downstream

- During COVID-19, more downstream consumers of IIS data than ever before:
  - CDC Data Clearinghouse
  - Dept. of Health epidemiologists
  - State COVID portals and dashboards
  - Providers
  - Payers
  - Patients
  - Other IIS
- Not all downstream consumers accept or interpret clinical evaluations and recommendations
- Same challenge of recommending booster doses while conveying "series complete"

Data Quality and Demands for Timeliness

- Common data quality issues
  - Duplicate doses
  - Incorrect vaccine codes
  - Incorrect dates
  - Unspecified vaccine codes
- A need for data as soon as possible
  - CDC Data Clearinghouse – next day
  - State COVID dashboards
  - Patient access
- Without absolute minimum intervals, duplicate doses cannot be invalidated

Summary and Lessons Learned

- Rapid development, approval, and recommendation of the COVID-19 vaccines led to new challenges for immunization evaluation and forecasting.
- Sometimes rules must be made with incomplete guidance; AIRA & CDC CDSi are very helpful resources
- Without absolute minimum intervals, cannot rely on dose invalidation for data quality improvement
- Downstream providers don’t always use or know how to use evaluations and forecasts

For More Information or Questions

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