

Clinical Decision Support for COVID-19 Immunizations: State and Local Challenges

2022 NACCHO360 Conference
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Agenda

- Background: Immunization Evaluation and Forecasting
- Immunization Calculation Engine (ICE)
- COVID-19 Vaccines and Clinical Rules
- Challenges
- Lessons Learned



Background: Evaluations and Forecasts

- ❑ Evaluation: Was a dose valid or not?
If not, why not?
 - Minimum interval 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

Table 1

Recommended Child and Adolescent Immunization Schedule

These recommendations must be read with the notes that follow. For those who fall below the recommended age, see the catch-up schedule (Table 2).

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos
Hepatitis B (HepB)	1 st dose	← 2 nd dose →			← 3 rd dose →
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)			1 st dose	2 nd dose	See Notes
Diphtheria, tetanus, acellular pertussis (DTaP <7 yrs)			1 st dose	2 nd dose	3 rd dose
<i>Haemophilus influenzae</i> type b (Hib)			1 st dose	2 nd dose	See Notes
Pneumococcal conjugate (PCV13)			1 st dose	2 nd dose	3 rd dose



ICE: Immunization Calculation Engine

- ❑ Open Source Clinical Decision Support System – anyone can download and contribute at <https://www.hln.com/ice>
- ❑ Built on OpenCDS platform for Integration with Health Information Systems – IIS, EHR, PHR
- ❑ Original ICE collaborators: New York City Citywide Immunization Registry, HLN Consulting, LLC, Alabama Department of Public Health, OpenCDS Team



OpenCDS

- ❑ Software platform and toolkit for developers implementing CDS services
- ❑ Open source
- ❑ Standards-based
- ❑ Web Service interface
- ❑ Collaborative project, led by Dr. Kensaku Kawamoto at University of Utah



Inputs to ICE

- ❑ Patient parameters
 - Date of birth
 - Gender
 - Immunization history (vaccine and admin date)
 - Disease immunity
- ❑ Situational parameters
 - Immunization schedule identifier
 - Evaluate-as-of Date



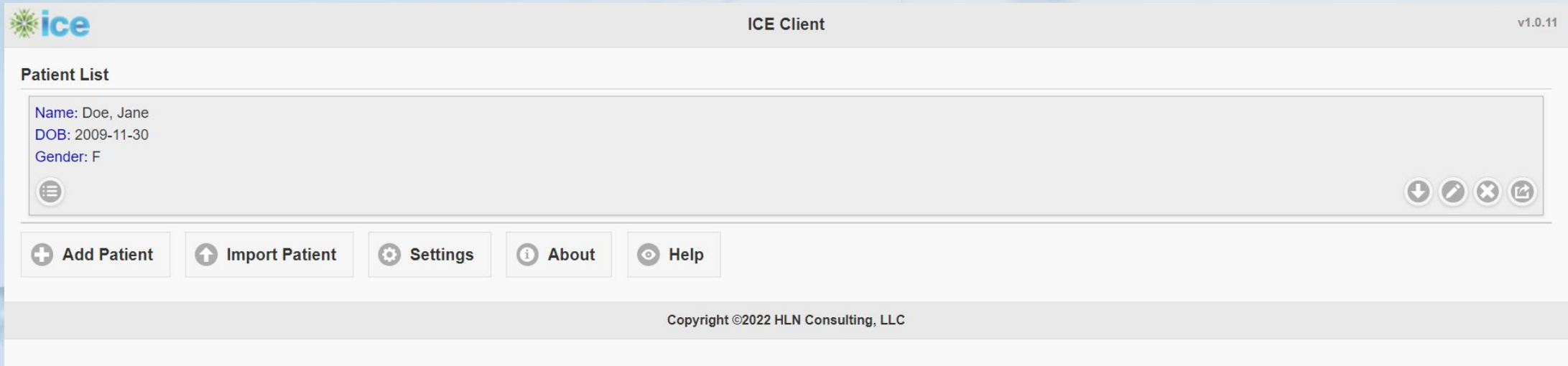
Outputs from ICE

- ❑ Evaluation of each dose
 - Evaluation = Valid, Invalid, or Accepted
 - Invalid Reason(s), for each Invalid dose
- ❑ Recommendation for each vaccine group
 - Recommendation = Recommended, Future recommended, Conditional, or Not recommended
 - Earliest recommended due date
 - Reason



Using ICE

- ❑ Web Service API
- ❑ FHIR/CDS Hooks
- ❑ Interactive Web client at <https://cds.hln.com/iceweb>



COVID-19 ACIP Timeline (continued)

- ☐ December 12, 2020: Pfizer
- ☐ December 19, 2020: Moderna
- ☐ 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
- ☐ April 2022: Booster updates
- ☐ May 2022: Booster for 5-11 year olds
- ☐ June 2022: Moderna and Pfizer for 6 months to 5 years; Moderna for 6-17 year-olds
- ☐ Clinical considerations updated throughout



COVID-19 Immunization Rules

COVID-19 Vaccine Group Evaluation and Forecasting Rules

General Rules for COVID-19

General rules are not series-specific; general rules apply to the entire vaccine group.

Rules for Recommending at the CVX Code vs. Vaccine Group Level

- If the patient has no shots on record,
 - and is < 5 years old, recommend CVX 218 at 5 years old.
 - and is > = 5 years old and < 12 years old, recommend CVX 218 at today's date.
 - and is > = 12 years old, recommend at the vaccine group level at today's date.
- If the patient has shots on record and the series is not complete,
 - and is < 5 years old, recommend CVX 218 at 5 years old.
 - and is > = 5 years old and < 12 years old (or will be < 12 years old at the recommended due date), recommend CVX 218 for the next target dose.
 - and is > = 12 years old (or will be > = 12 years old at the recommended due date) and < 18 years old, recommend at the vaccine group level for the next target dose.
 - and is > = 18 years old and is in the following series:
 - Pfizer COVID-19 2-dose Series, recommend at the vaccine group level for the next target dose.
 - Moderna COVID-19 2-dose Series, recommend at the vaccine group level for the next target dose.
 - Janssen COVID-19 1-dose Series, recommend at the vaccine group level for the next target dose.

Series Completion Special Rule

- Once a patient completes:
 - the Pfizer COVID-19 2-dose series, Moderna COVID-19 2-dose series, a COVID-19 vaccine series not authorized by the FDA, but authorized by the WHO, or a COVID-19 vaccine series not authorized by the FDA or WHO, but is an active COVID-19 vaccine candidate as part of a U.S.-based clinical trial of a COVID-19 vaccine,
 - recommend a booster dose of COVID-19 (at vaccine group level) at recommended interval (5 months) or at recommended age (12 years), whichever date is later, along with recommendation reason code BOOSTER_DOSE.
 - and receives an additional dose¹, the Recommendation is Conditional and the reason code is COMPLETE_HIGH_RISK.
 - and receives a booster dose², the Recommendation is Not Recommended and the reason code is COMPLETE.
 - the Pfizer COVID-19 (5-17) 2-dose series,
 - and is > = 12 years old, recommend a booster dose of COVID-19 (at vaccine group level) at recommended interval (5 months) or at recommended age (12 years), whichever date is later, along with recommendation reason code BOOSTER_DOSE



Challenge: 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

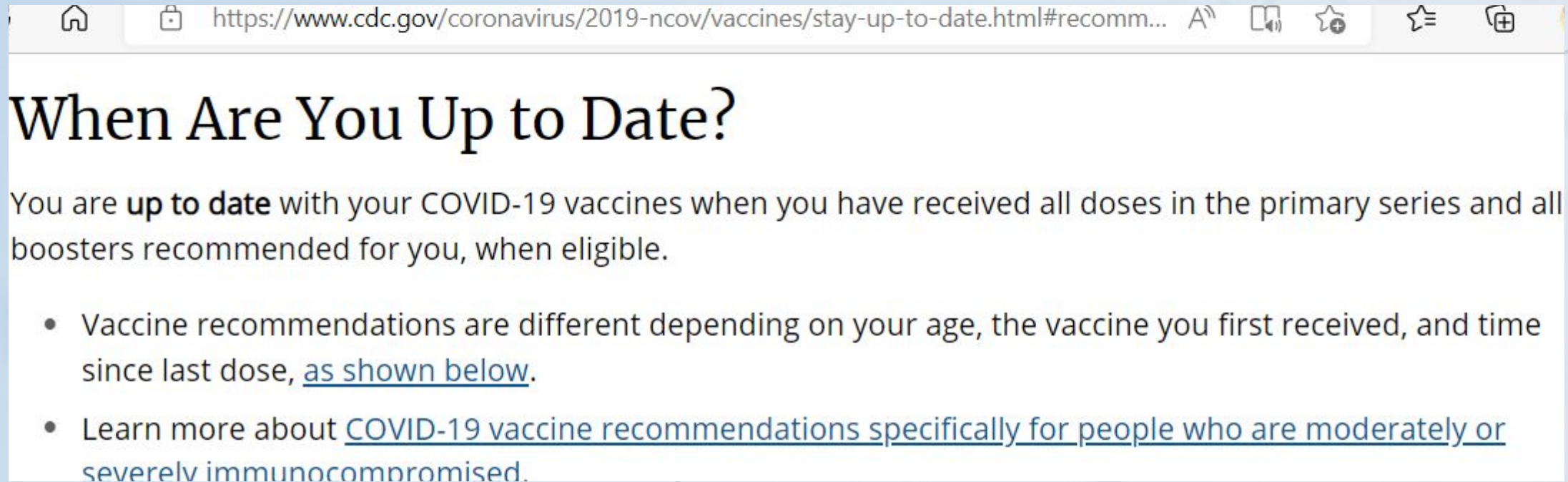


Clinical vs. “Administrative” Status

- ❑ Fully vaccinated vs. Up to date
- ❑ Desire to recommend booster doses but also convey “series complete”
- ❑ School vs. work vs. venue entry rules



Up to Date



The screenshot shows a web browser window with the URL <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html#recomm...>. The page title is "When Are You Up to Date?". The main text states: "You are **up to date** with your COVID-19 vaccines when you have received all doses in the primary series and all boosters recommended for you, when eligible." Below this, there are two bullet points:

- Vaccine recommendations are different depending on your age, the vaccine you first received, and time since last dose, [as shown below](#).
- Learn more about [COVID-19 vaccine recommendations specifically for people who are moderately or severely immunocompromised](#).



47 year-old with 3 mRNA doses

Recommendation Date: N/A

Overdue Date: N/A

Earliest Date: N/A

Status: CONDITIONAL

Message: COMPLETE_HIGH_RISK

Vaccine Group: COVID-19



Date: 2021-04-01

Age: 46y 3m 30d

Valid: true

Vaccine: COVID-19, mRNA LNP-S, PF, Pfizer (208)



Date: 2021-05-01

Age: 46y 4m 29d

Valid: true

Vaccine: COVID-19, mRNA LNP-S, PF, Pfizer (208)



Date: 2021-11-01

Age: 46y 10m 30d

Valid: true

Vaccine: COVID-19, mRNA LNP-S, PF, Pfizer (208)



50 year-old with 3 mRNA doses

Recommendation Date: 2022-03-01
Overdue Date: N/A
Earliest Date: 2022-03-01
Status: RECOMMENDED
Message: DUE_NOW,BOOSTER_DOSE
Vaccine Group: COVID-19



Date: 2021-04-01
Age: 50y 3m 30d
Valid: true
Vaccine: COVID-19, mRNA LNP-S, PF, Pfizer (208)



Date: 2021-05-01
Age: 50y 4m 29d
Valid: true
Vaccine: COVID-19, mRNA LNP-S, PF, Pfizer (208)



Date: 2021-11-01
Age: 50y 10m 30d
Valid: true
Vaccine: COVID-19, mRNA LNP-S, PF, Pfizer (208)



46 year-old with J&J and mRNA

Recommendation Date: N/A
Overdue Date: N/A
Earliest Date: N/A
Status: CONDITIONAL
Message: COMPLETE_HIGH_RISK
Vaccine Group: COVID-19

Date: 2021-04-01
Age: 46y 3m 30d
Valid: true
Vaccine: COVID-19, vector-nr, Janssen (212)

Date: 2021-11-01
Age: 46y 10m 30d
Valid: true
Vaccine: COVID-19, mRNA LNP-S, PF, Pfizer (208)



47 year-old with 2 mRNA

Recommendation Date: 2022-04-01
Overdue Date: N/A
Earliest Date: 2022-04-01
Status: RECOMMENDED
Message: DUE_NOW,BOOSTER_DOSE
Vaccine Group: COVID-19



Date: 2021-04-01
Age: 46y 3m 30d
Valid: true
Vaccine: COVID-19, mRNA LNP-S, PF, Pfizer (208)



Date: 2021-11-01
Age: 46y 10m 30d
Valid: true
Vaccine: COVID-19, mRNA LNP-S, PF, Pfizer (208)



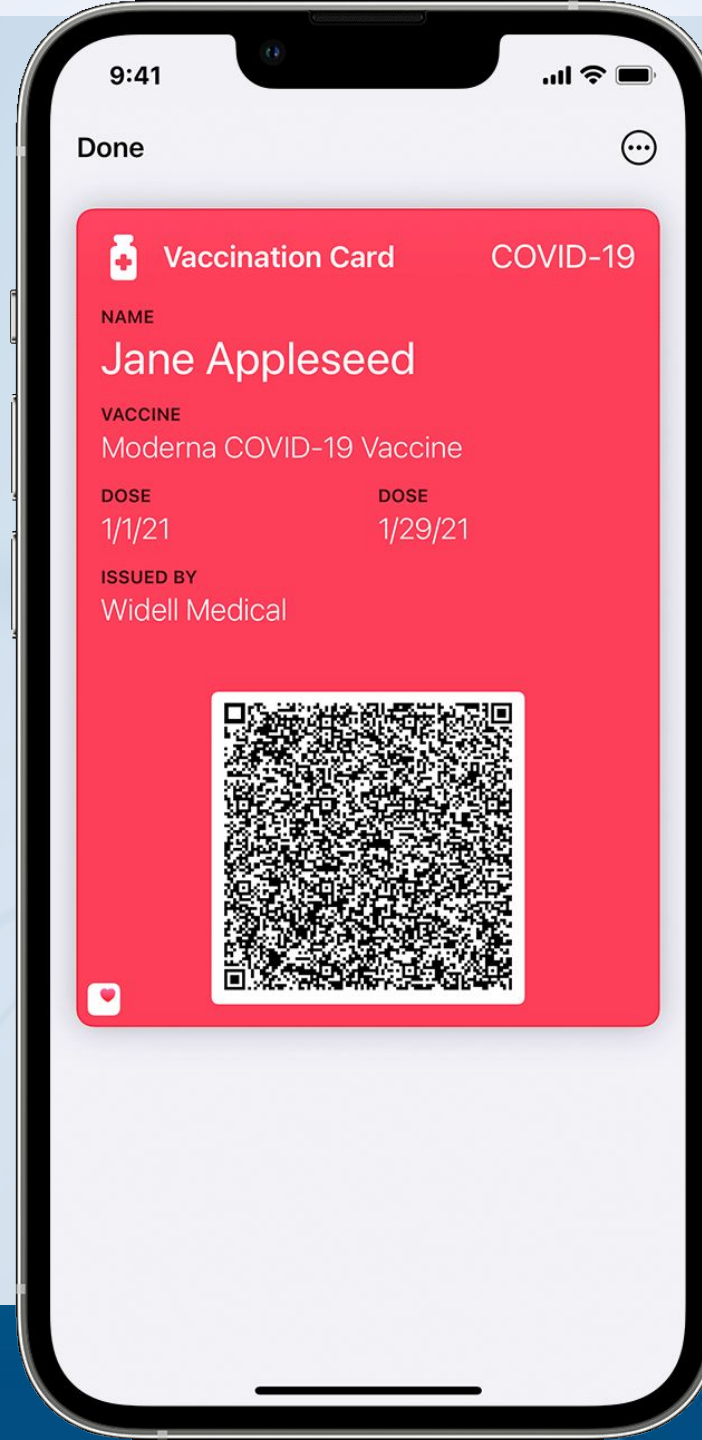
Sending Evaluations & Recommendations Downstream

- ❑ 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



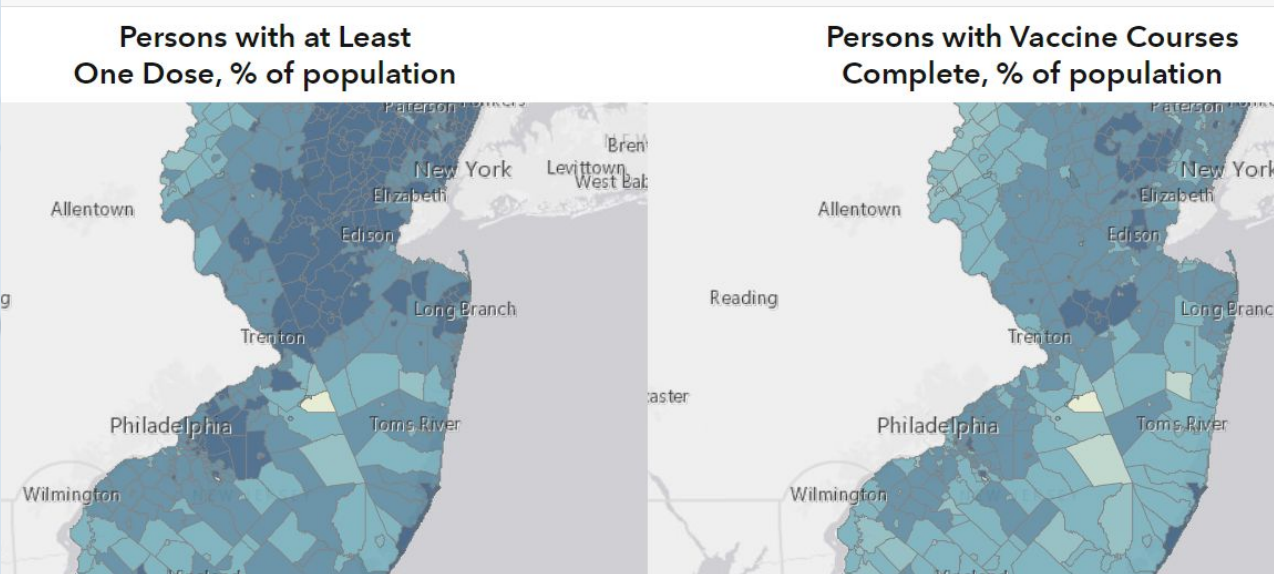
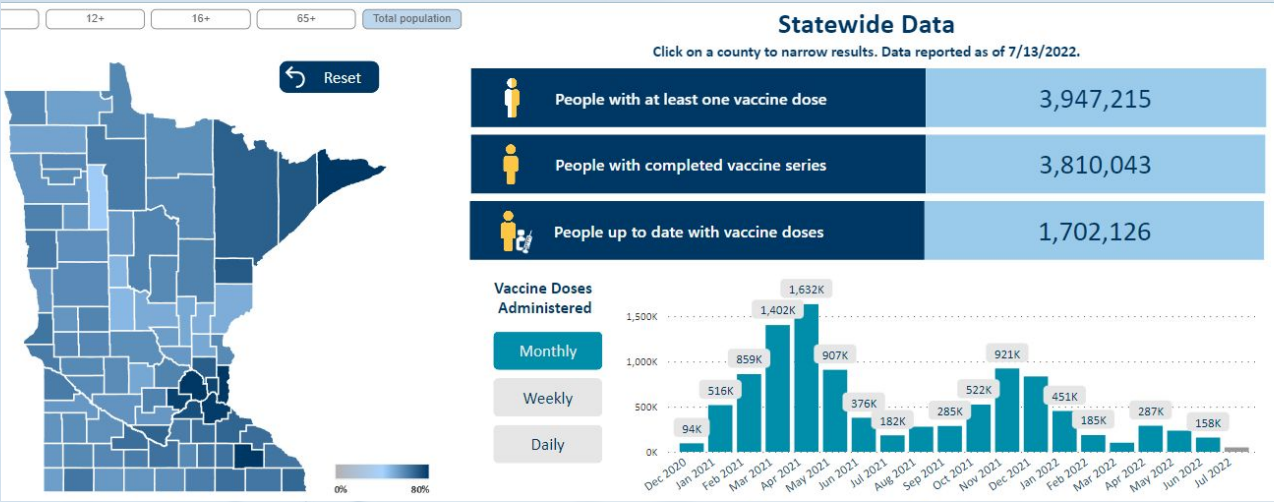
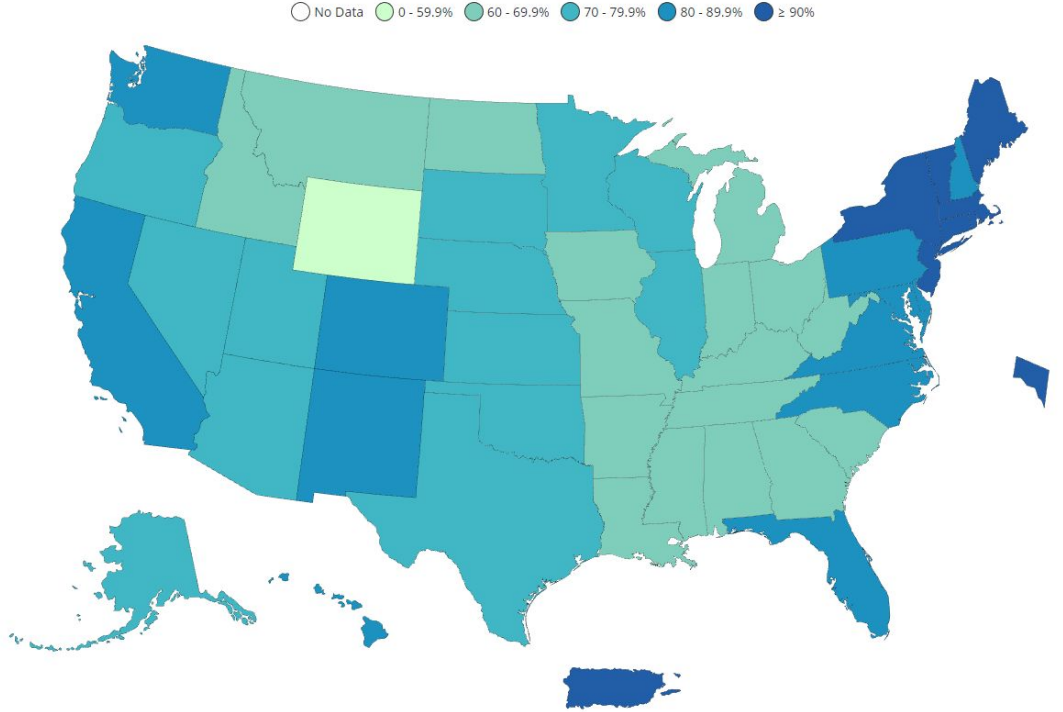
Vaccine

Credentials



Dashboards

Percent of People Receiving at Least One Dose Reported to the CDC by State/Territory and for Select Federal Entities for the Total Population



State and Local Dashboard Measures

- ❑ People with **at least one** vaccine dose
- ❑ People with **completed** vaccine (primary) series
- ❑ People with **first booster**
- ❑ People with **second booster**
- ❑ People with **up to date** vaccine doses

Amount of CDS needed



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.
- ❑ In many jurisdictions the “raw” vaccination data from IIS is transferred to external systems that are used both to populate public dashboards and often provide digital credentials.
- ❑ The clinical decision support available from the IIS is often not conveyed along with the vaccination dose data, leading to misinterpretations of the validity of current doses and the absence of reliable prediction of future doses.
- ❑ Explaining the nuance behind CDS for immunizations, and ensuring that systems relying on IIS data interpret that data properly, will continue to be a challenge for public health agencies.



For More Information or Questions

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