Overview of Lab Meeting #32

During the 32nd Therapeutics Evidence Accelerator Lab Meeting on May 6th we heard from insurers and payors about the challenges of accessing and analyzing COVID-19 vaccine information. In the first segment, we heard two presentations, one from Dr. Edward McEachern of Pacific Source Health Plans, and then from Dr. Natalie Sheils of OptumLabs, on experiences and challenges using multiple sources of vaccination data to gain insights into vaccination uptake. Lastly, Dr. Anne-Marie Meyer of Roche and Dr. Andrew Weckstein of Aetion presented on the “complex and context-specific” factors associated with vaccine hesitancy drawing on historical data around MMR vaccination uptake and non-medical exemptions.

COVID-19 Vaccination Response

Dr. Edward McEachern, Pacific Source

Role of the Health Plan/Mission: To support and facilitate the equitable administration of vaccination to each of our regional populations in pursuit of herd immunity.

Challenges

- Vaccinations are not billed or submitted in claims
- There are multiple sources for vaccination data and many of these are in unstructured data formats such as spreadsheets
- Inconsistent models for identification of priority populations
- Achieving equity is challenging due to technological and transportation barriers, as well as vaccine confidence
- Some don’t believe health plans need or should have vaccine data
- Lack of clarity around health plans’ role in our health ecosystem

Goals

- Monitoring vaccination administration
- Develop a vaccination registry to support iterative response and tracking efforts including 1st and 2nd dose and booster vaccinations
- Participate in regional/state strategic development and bring valid, reliable, accurate and predictive data to our environments
- Participate in care coordination and member outreach where deemed valuable
- Contribute data to systems where deemed valuable
Data Strategy

- Vaccination dashboard that shows the percent of the population that is vaccinated broken down by REAL-D slicers to assist in monitoring for equity.
- Consolidated vaccine data sources of all vaccination information we have to date to inform vaccination registry and metrics.
- Member/patient registry with a detailed list of prioritized populations to assist in responding efficiently to provider partner requests. (includes contact information, rate code, residential setting indicators, REAL-D where available, provider assignment/attribution, etc.).

Use Cases for Vaccine Data

1. Provider requests for prioritized lists (received vaccination, dose)
2. Prioritization of populations for outreach to members
3. Optimization of vaccine delivery
4. Tracking second and subsequent immunizations
5. “What gets measured gets done” – dashboard helps show what is measured and what needs to be done
6. Make sure work is addressed in an equitable way

Vaccine Data Sources: Claims (medical and pharmacy), state immunization data bases, health information exchange (Collective and Reliance), Federal “data lake”, other supplemental data and spreadsheets. States provide data in various formats/pipelines.

Collaborative Strategy: Working collaboratively with state/regional entities, supporting providers and social services, educating and informing (internally and externally) to increase vaccine confidence, monitoring for equity and developing antidote strategies, and developing strategies for supporting members with “COVID wrap around services”, social determinants of health (SDOH), leveraging Community Information Exchange (CIE).

Assistance Needed

- Access to data – allowing health plans to access state vaccine registry databases for the duration of the public health emergency solely for accessing COVID vaccine data on the plan’s members.
  o This is also a policy problem across the country – restrictions on how data accessed from state registries can be utilized for research.
- Clarifying the role of the Health Plan as a facilitator and stakeholder in vaccination efforts
- Identifying best practices models for vaccine administration, addressing SDOH, COVID wrap around services (housing, food).

OptumLabs Insights: COVID-19 Vaccination Data

Dr. Natalie Sheils and Megan Jarvis, Optum Labs

Data Sources

- Linked across three data sources – medical claims & EMRs, pharmacies, and state registries.
- Medical claims & EMRs – Available weekly, 50+ million individuals over 5 years
- Pharmacies – Available weekly, 30+ million individuals over 6 years
- State registries – Historically used for childhood vaccinations, updated weekly, currently only from 3 states (MD, MA, and RI)
State registries are challenging because people are getting vaccinated across state lines, makes it difficult to make connections.
Also need more states’ data.

OptumLabs Information: COVID-19 Vaccine Records

- 20.5+ million adults (16+ y/o) enrolled from 12/2020 through 4/2021
- 2.4+ million (11.9%) adults with record of at least one dose
- 1.2+ million (6.3%) adults with record of full vaccination
  - ~12% of total population have been partially vaccinated – we believe this number is less than actual number given other sources
- Of those who are not yet fully vaccinated (those who are receiving the two-dose vaccines), 848,462 (73.3%) are within five weeks of their 1st dose. This indicates that many are on track and will get their second dose.
  - Given the incompleteness of our data, we need to do more work to figure out why if and why individuals do not go back to get their second dose.
- Varying vaccination rates across states. Massachusetts, which provides state registry data, has the highest rate of vaccination at 33.3%. States not providing data likely have higher rates than we are observing.
- 80% of individuals who got Moderna’s two-dose vaccine received their second dose within one day of the recommended 28-day timeframe.
- 73% who got Pfizer’s two-dose vaccine received their second dose within one day of the recommended 21 day timeframe. 8.7% received their second vaccine at 28-days (some places scheduling all two-dose vaccines at 28-days apart).
- 109 (0.008% of all fully vaccinated individuals) had positive PCR test results occurring 14-days after final dose.
- 209 COVID-related hospitalizations after first dose (0.018% of people with first-dose), 0 deaths in hospital, avg. admission was 12-days after first dose.
- 650 COVID-related hospitalizations after second dose (0.050% of fully vaccinated people), 21 deaths in hospital, avg. admission 27-days after dose 2.
  - Unclear what final cause of death is.

Areas for Future Research

- Comparative efficacy of vaccines
- Investigating the completeness of state registries compared to claims/EMRs
- Understanding the effect of vaccines on long-haulers
- Reducing vaccine hesitancy

Drivers of Vaccine Hesitancy

Dr. Anne-Marie Meyer, Roche
Dr. Andrew Weckstein, Aetion

Barriers to Vaccine Uptake

- Known Barriers: Access, belief, distrust, ethical/political, etc.
- Unknowns: the degree to which these barriers or influences impact uptake varies across subgroups.
• Barriers make vaccine rollouts and tailoring interventions challenging. There is not a “one-size-fits-all” solution.
• Several “hotspots” across the US where vaccine uptake is lower for vaccine preventable diseases (e.g., Measles, MMR).

Pre-COVID Vaccine Hesitancy & Uptake

• Vaccine hesitancy is “complex and context-specific – varying across time, place, and vaccines.”
• Multi-dimensional and socio-ecological factors at play:
  o Individual perceptions and beliefs, socio-economic status (SES) and SDOH, accessibility, cost
  o Government austerity measures associated with downturns in vaccination
  o Ideological, “civil liberty” and political divides are newer but growing
  o Localized outreach, tailored messaging and using community advocates or “lay health advisors” can be effective.
• Unique to COVID is the perceived “maturity” of mRNA technology, speed of approvals, representation in clinical trials, and lack of trust in gov’t processes

RWD at the Population Level: Help quantifying the known, knows

• Fast, aggregated, wide lens on the population
• Can use spatial epidemiological approaches to quantify complex, correlated relationships
• Requires systematically reported and localized vaccine data – don’t have yet for COVID, but we do for MMR
  o Reliable county-level data on MMR vaccination rates and non-medical exemptions provide a proxy exploring factors related to COVID vaccination uptake and hesitation.

Example: MMR Vaccination in Michigan

• Lake County, MI and Livingston County, MI
• 6.9% and 5.3% of kindergartners, respectively, had documented non-medical exemptions (NMEs) for MMR vaccination in 2016-17 (among the highest NME rates in Michigan and nationally)
• Very different counties when looking at key variables that impact vaccine uptake:
  o Lake County – lower income and education, more rural, higher relative proportion of minorities
Livingston County – higher median income and college education, less rural, lower proportion of minorities

- These data show there is no dominant “vaccine hesitant” archetype for MMR. Likely a different set of factors driving the perception of MMR vaccines.

COVID Vaccination Learnings

- No one distinct set of factors contributing to COVID vaccine hesitancy.
- Access, independent of hesitancy, remains a barrier to vaccine uptake.
- Success is predicated on systematically reported localized vaccine data – unlike MMR we don’t yet have this for COVID.

Using RWD to ‘think globally, act locally’

- RWD and historical vaccine hesitancy in spatial models can help understand existing heterogeneity in the “archetypes” of vaccine hesitancy.
- We can leverage what is known from public health and health behavior on vaccine uptake to inform evidence-based interventions
  - At the policy/community, interpersonal, and individual level
  - Localized outreach that engages faith-based organizations, lay health advisors, and trusted community leaders
  - Address access-related issues and identify meaningful incentives for participation
- Build bridges between “actors” in the ecosystem and improve data/information sharing (public health, healthcare, regulators, life sciences/pharma)
- Enable more systematic and evidence-based research on vaccination rates (e.g. VACCINES Act, H.R. 2862)
Data Visualization of the Week

This infographic provides an overview of how the development of vaccinations typically occurs and how these processes were adjusted to facilitate rapid development of vaccinations for COVID-19.

**HOW WAS TIME SAVED?**

1. **RESEARCH**
   The SARS-CoV-2 genetic sequence was identified and tested right away thanks to past research.

2. **MANUFACTURE**
   Private companies and the U.S. government are investing in manufacturing. FDA is inspecting facilities earlier (while clinical trials are ongoing), which allows products to be manufactured for rapid distribution upon authorization/approval instead of during FDA review, in normal circumstances.

3. **CLINICAL TRIALS**
   Clinical trials were carefully designed to test for safety, dosage, and effectiveness in phases that partially overlapped instead of running consecutively. Because COVID-19 is so widespread, finding people to participate in clinical trials and assessing the vaccine’s performance have been faster than normal.

4. **LICENSE/AUTHORIZATION**
   An Emergency Use Authorization can be requested by vaccine developers for the FDA to review preliminary data from clinical trials to determine if the benefit outweighs the risks for use in a public health emergency. The vaccine data must show safety and efficacy to earn an emergency use authorization.

5. **DISTRIBUTE**
   Substantial U.S. government resources are being used to coordinate distribution to the public.

*During the pandemic, COVID-19 vaccines may be authorized by FDA for public use under an emergency use authorization process or via full licensure.*