Year 2 of a PCORnet-CDC Partnership on COVID-19 Surveillance



Tom Carton, PhD Jason Block, MD

PCORnet[®], the National Patient-Centered Clinical Research Network is funded by the Patient-Centered Outcomes Research Institute (PCORI)

Objectives

- Describe the development of a PCORnet CDC partnership on COVID-19 surveillance
- Highlight 2 studies that showcase both the COVID-related research facilitated by the PCORnet infrastructure
- Describe the challenges and strengths of using electronic health record data for surveillance



PCORnet Networks



What Patient Data are Represented?

Encounters with 66 million people result in data available throughout the nation in all types of communities. Over 30 million encounters in 2021.

Number of Participants





PCORnet Data Assets

Ready for Research						Available, But Still Evolving								
De Da	Death Data		Diagnoses		Medication Orders		Geocodes		Social Determinants of Health		Tumor Registry		Biosamples	
Claims Labs		ıbs	Demo- graphics		Procedures		Patient-F Outc	eported mes Genom		c Results	Natural L Proce Derived (anguage essing Concepts	Pat Genera	ient- ted Data



Needs Articulated

- O Urgent need
- O Rapid pulls/analyses of EHR-derived data, informally sharing
- O Focused on comorbidities
- O No funds and "very informal"
- O Could transition to funded, formal model later. Need to start now!



Lots of fundamental changes required

O Needed mechanism for changing standard processes

- Quarterly refresh of data, 2 weeks to respond to queries
- Updates to our modular programs, which generate descriptive data, necessary to provided data requested
 - Cohorts defined by laboratory results
 - Examination of trends over time
 - Capabilities for distributed analytics such as regression
 - Efficiencies to allow for sites to respond quickly



Re-engineering the CDM for COVID-19 Surveillance





CDC PCORnet COVID Project

- O Started April 2020 with first query; funded by CDC in October 2020
- 43 participating institutions update data monthly; frequently distributed data queries returning aggregate data only (to date)
- Population includes all patients with SARS-CoV-2 testing, viral illness diagnostic codes, and COVID-19 vaccination
- O March 2020 Jan 2022:
 - Adults: 16 million overall, 1.3 million with SARS-CoV-2 13% hospitalized, 2% mortality
 - Children: 5.6 million overall, 400k with SARS-CoV-2 3% hospitalized



Scope of Queries ~ 40 Completed to Date

- Descriptive trends of infections by care setting and demographics
- Post-acute sequalae of COVID among those SARS-CoV-2 positive and negative
- Vaccinations, including demographics, breakthrough infections and adverse events
- Admission and readmissions from COVID
- Chronic disease control/severity and severe COVID
- Treatment trends, including emerging therapeutics and disparities
- Comparative risk of cardiac complications after SARS-CoV-2 infection and mRNA COVID-19 vaccination



Tools updated to accommodate rapidly changing needs

- O Define cohorts based on nearly all data available, with new capabilities based on lab results, vital measures, mortality, and immunizations
- Examine trends by race, ethnicity, age, and care setting; dashboard to visualize
- O Mechanism to pull and deidentify patient-level datasets
- O Distributed analytics to accommodate controlled analyses



Now... Let's See Some Results

- O Cumulative query
 - COVID+ geography
 - Adult trends by race across care settings
 - CDC COVID Data Tracker
- **O** Treatment disparities Monoclonal antibodies
- O Cardiac complications from SARS-CoV-2 infection vs. vaccination





Adults with SARS-CoV-2, by Race

Proportions by Race - Inpatient

Relative Risks of Testing Positive - Inpatient



30-Day Mortality, By Month and Race





CDC COVID Data Tracker

Invasive Mechanical Ventilation (IMV) among Hospitalized COVID-19 Patients, by Month and Data Source



Treatment disparities - Monoclonal antibodies

- O Assessed ~6m patients tested for SARS-CoV-2 from November 2020 to August 2021
- O Calculated how treatment differed systematically over time by race or ethnicity
- Relative monthly treatment disparities = difference in % of patients treated between racial/ ethnic minority (Black, Asian, Other for race; Hispanic ethnicity) and majority (White; non-Hispanic) groups divided by the % in majority groups



Treatment disparities - Monoclonal antibodies



Monthly percentage of COVID-19 patients (n = 805,276) receiving monoclonal antibody treatment,⁺ by race[§] and ethnicity[¶] — 41 health care systems in the National Patient-Centered Clinical Research Network — United States, November 2020–August 2021

SARS-CoV-2 vs. Post-Vaccination Cardiac Complications

- Assessed myocarditis & myocarditis or pericarditis after SARS-CoV-2 infection and vaccination
 - Further assessed these diagnoses with MIS after infection
- Calculated 7-, 21-, and 42- day incidence and risk ratios of complications after SARS-CoV-2 to after vaccination
- Examined 1st, 2nd, unspecific, and any doses of vaccines
- O Study included 40 of the participating sites
- O Stratified by age and sex



Comparisons and Risk Ratio Calculations

- Incidence of myocarditis after SARS-CoV-2 infection DIVIDED BY incidence of myocarditis after 1st, 2nd, unspecified and any doses of mRNA COVID-19 vaccine
- O Same for myocarditis or pericarditis
- Last comparison was for incidence of myocarditis, pericarditis, or MIS after infections DIVIDED by incidence of myocarditis or pericarditis after vaccination



Risk Ratios for Cardiac Complications after SARS-CoV-2 vs. Vaccination, 21- and 42-day

Males aged 12-17 years Myocarditis (21 days, 1st dose) Myocarditis or Pericarditis (21 days, 1st dose) Myocarditis or Pericarditis or MIS-C/A (42 days, 1st dose) Myocarditis (21 days, 2nd dose) Myocarditis or Pericarditis (21 days, 2nd dose) Myocarditis or Pericarditis or MIS-C/A (42 days, 2nd dose) Males aged 18-29 years Myocarditis (21 days, 1st dose) Myocarditis or Pericarditis (21 days, 1st dose) Myocarditis or Pericarditis or MIS-C/A (42 days, 1st dose) Myocarditis (21 days, 2nd dose) Myocarditis or Pericarditis (21 days, 2nd dose) Myocarditis or Pericarditis or MIS-C/A (42 days, 2nd dose)





A Word about Denominators

- Missing data on vaccinated and infected individuals only 28% of 5+ year olds with vax; unknown % of infected
- O Inaccurate risk ratios only if differential ascertainment
- Possible that our post-vax risks inflated and post-COVID risks underestimated
 - Is vaccination more likely to be documented if experience outcome?
 - What if we counted all MIS cases MIS typically occurs without a positive SARS-CoV-2 test antigen or PCR test?
 - Are mild cardiac complications from COVID more likely to be dismissed as acute COVID or MI? Different from mild post-vage pcornet

Evolution of PCORnet Surveillance Work

- True collaboration between federal public health and PCORnet investigators – hoping to expand this further; seeding and supporting other initiatives
- Moving to advanced analytics with capture of patient-level data, supported distributed analytics
- Seeking efficiencies at both site level and in processing of data
- Need to improve capture of vaccination, through systematic linkage with registries and claims long-term goal
- Also true for therapeutics missing monoclonals in community centers and possibly oral antivirals through test and treat in pharmacies
- Moving back to broader surveillance, beyond COVID-19

