PCORnet CDC COVID 19 Project, June Webinar

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June 28, 2021
Agenda

- Update on queries and manuscripts
- Coming distributed regression queries
- Year 2 scope
- Vaccine adverse event query
Query updates

- 12th query distributed last week – repeat of query on admissions/readmissions post index encounter for SARS-CoV-2
- 3 more queries planned before end of project period for a total of 15 in 10-month contract period
- Final queries will be distributed regression on predictors of long COVID (conditions and symptoms) and chronic disease control/severity and COVID outcomes
Manuscript updates

- Have several manuscripts in process/planned
- Some manuscripts have collaborative author lists with representation per site and others have only writing groups
- Manuscripts with collaborative authors
  - Pediatric trends manuscript – writing group reviewing; collab authors to receive soon
  - Adult trends manuscript – collab authors already reviewed; manuscript nearly completed updated with final version to be circulated for approval
- Other manuscripts on Long COVID, vaccine adverse events, chronic disease and COVID
Year 2 updates, scope

- Hope to hear whether funded by end of June/early July
- Scope of year 2
  - Queries 1-2 per month; refreshes monthly
  - Submission of patient-level dataset for more efficient, predefined regression analyses
  - Linkage of procedure codes and immunization data with loading of immunization data in PCORnet CDM
- Coordinating Center will continue activities and revise tools to account for varied data for cohort formation (e.g., immunization codes)
Vaccine Adverse Event Query

- Initiated in discussions with PEDSnet after initial reports of myocarditis in young adults
- CDC wanted to proceed, understanding that our approach was slightly different than the typical methodology used by CDC for detecting vaccine adverse events
- Preliminary report below – sensitive and please do not distribute
ACIP reviewed evidence; new package warning

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: June 25, 2021

For Immediate Release: June 25, 2021

The U.S. Food and Drug Administration (FDA) continued to take action in the ongoing response to the COVID-19 pandemic:

- Today, the FDA is announcing revisions to the patient and provider fact sheets for the Moderna and Pfizer-BioNTech COVID-19 vaccines regarding the suggested increased risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue surrounding the heart) following vaccination. For each vaccine, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) has been revised to include a warning about myocarditis and pericarditis...
Vaccine Adverse Event Query Parameters

- Identified cohorts based on SARS-CoV-2 test, vaccine or viral illness diagnostic codes
- 42 healthcare systems, 1 HPRN
- Assessed diagnostic codes for designated potential co-occurring conditions or adverse events at
  - 0+, 0-30, and 31+ days post index for several conditions
Qualifying cohorts

- SARS-CoV-2 + or –
- Any other patient in COVID CDM, which primarily includes patients with viral illness diagnostic codes
- Pfizer, Moderna, and J&J vaccines identified by procedure codes; only assessed 1\textsuperscript{st} appearance of procedure code for a vaccine

- Separated by 8-11 years, 12-15 years, 15-24 years, 25-34 years and 35+ years
Population Size, Vaccines
March 1, 2020 – May 24, 2020

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Pfizer</th>
<th>Moderna</th>
<th>Janssen</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-to-15 years</td>
<td>21,835</td>
<td>1-5 Patients</td>
<td>0</td>
</tr>
<tr>
<td>16-to-24 years</td>
<td>101,313</td>
<td>15,768</td>
<td>6,555</td>
</tr>
<tr>
<td>25-to-34 years</td>
<td>134,453</td>
<td>32,850</td>
<td>10,643</td>
</tr>
<tr>
<td>35+ years</td>
<td>705,301</td>
<td>252,319</td>
<td>61,083</td>
</tr>
</tbody>
</table>
## Population Size, “Controls”

<table>
<thead>
<tr>
<th>Age Group</th>
<th>SARS-CoV-2 +</th>
<th>SARS-CoV-2 -</th>
<th>Viral Illness Dx</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-to-15 years</td>
<td>38,625</td>
<td>237,035</td>
<td>362,739</td>
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<tr>
<td>16-to-24 years</td>
<td>131,908</td>
<td>679,011</td>
<td>733,307</td>
</tr>
<tr>
<td>25-to-34 years</td>
<td>141,257</td>
<td>892,784</td>
<td>793,384</td>
</tr>
<tr>
<td>35+ years</td>
<td>516,325</td>
<td>3,609,499</td>
<td>3,740,169</td>
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</tbody>
</table>
Conditions Assessed: ICD-10-CM Codes

- Myocarditis
- Pericarditis
- DVT
- PE
- Other VTE
- Anaphylaxis
- Syncope

- Heparin induced thrombocytopenia
- Multi-inflammatory Syndrome
- Arterial embolism
- Stroke (hem & ischemic)
- TIA
- MI
Summary of Project to Date

- Mix of standard queries, urgent responses, and new priority areas
- Expect to complete 15 queries by end of project period in 1 month
- Year 2 updates coming soon – nothing finalized but hopeful
- Regression queries coming – first time these have been completed in network
- Vaccine focused query has provided CDC with important information, helping put myocarditis/pericarditis risk in context